

**OVERPRESCRIBED: THE HUMAN AND TAXPAYERS'
COSTS OF ANTIPSYCHOTICS IN NURSING HOMES**

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UNITED STATES SENATE
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OVERPRESCRIBED: THE HUMAN AND TAX-PAYERS' COSTS OF ANTIPSYCHOTICS IN NURSING HOMES

WEDNESDAY, NOVEMBER 30, 2011

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:03 p.m. in Room SD-G31, Dirksen Senate Office Building, Hon. Herb Kohl, Chairman of the Committee, presiding.

Present: Senators Kohl [presiding], Manchin, Blumenthal, and Grassley.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon to all of you. We appreciate your being here today, and we'll commence the hearing at this point.

Today we will be discussing the widespread, and costly, and often inappropriate use of antipsychotics in nursing homes, and efforts to find safe and effective alternatives. While antipsychotic drugs have been approved by the FDA to treat an array of psychiatric conditions, numerous studies have concluded that these medications can be harmful when used by frail elders with dementia who do not have a diagnosis of serious mental illness. In fact, the FDA issued a black box warning, citing increased risk of death when these drugs are used to treat elderly patients with dementia.

Despite these warnings, there has been little impact on antipsychotic prescription rates in long-term care facilities for dementia patients who do not have a diagnosis of psychosis. The most recent data indicates increasing usage of antipsychotics among nursing home residents with dementia, and that more than half of these patients have been prescribed these drugs.

Improper prescribing not only puts patients' health at risk, it also leads to higher health costs. Today, we'll hear testimony by the HHS Office of Inspector General that the use of antipsychotics in nursing homes for patients without a diagnosis of mental illness is costing taxpayers hundreds of millions of dollars every year.

Now, we know that we can do better. Our second panel features experts, including Tom Hlavacek, from my own State of Wisconsin, who'll be discussing safe and effective alternatives to using antipsychotics to deal with behavior issues in older dementia patients.

When properly prescribed, antipsychotics can offer beneficial treatment for individuals suffering from a mental illness; however,

we have a responsibility to patients and to their families to ensure that elderly nursing home residents are free from all types of unnecessary drugs. And we have a responsibility to taxpayers to be sure that they're not having to pay for drugs that are not needed. Toward that end, I'll continue working with my committee colleagues, as well as Senator Grassley, to address these issues.

So, we thank you all for being here, and we will turn to our first panel.

Our first witness today will be Daniel Levinson, the Inspector General of the U.S. Department of Health and Human Services. We thank you for being here.

Our next witness on the panel will be Dr. Patrick Conway, chief medical officer for the Centers of Medicare and Medicaid Services, and director of the Office of Clinical Standards and Quality. We thank you for being here.

Mr. Levinson.

**STATEMENT OF DANIEL R. LEVINSON, INSPECTOR GENERAL,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
WASHINGTON, DC**

Mr. LEVINSON. Good afternoon, Chairman Kohl. Thank you for the opportunity to testify about the use of atypical antipsychotic drugs in nursing homes. These drugs are powerful, and misuse poses a risk to the elderly.

Two recent OIG reports raise concerns about the use of antipsychotics by elderly nursing home residents, particularly those with dementia. We hired psychiatrists expert in treating elderly patients to review a sample of medical records. Their review revealed the following.

In 2007, 14 percent of nursing home residents, or nearly 305,000 patients, had Medicare claims for antipsychotic drugs. Half of these drug claims should not have been paid for by Medicare because the drugs were not used for medically accepted indications. For one in five drug claims, nursing homes dispensed these drugs in a way that violated the government standards for their use. For example, the prescribed dose was too high, or residents were on the medication for too long. Finally, prescription drug plan sponsors lack access to information necessary to ensure appropriate reimbursement of Part D drugs, including antipsychotics.

What do these findings mean? Too many institutions fail to comply with regulations designed to prevent over-medication, and Medicare pays for drugs that it shouldn't. Why should we be concerned? These powerful and, at times, dangerous drugs are too often prescribed for uses that are not approved by the FDA and do not qualify as medically accepted for Medicare coverage. The FDA has imposed a black box warning emphasizing an increased risk of death when used by elderly patients with dementia. Yet 88 percent of the time, antipsychotics were prescribed for elderly patients with dementia.

Physicians can use their medical judgment to prescribe drugs for uses not approved by the FDA, including to patients for whom the boxed warning applies. And most physicians in nursing homes dispensed antipsychotic drugs with the best interests of patients in mind. However, it is concerning that so many elderly nursing home

residents with dementia are prescribed antipsychotics. For instance, without a medical workup, one patient was given antipsychotics for agitation. A medical exam would have detected this patient's urinary tract infection, which may have been a source of the agitation.

How can we help protect this vulnerable population? CMS should, one, consider enhancing claims data to ensure accurate coverage determinations. For example, adding diagnosis codes to drug claims could help determine whether prescribing is appropriate and that the claim is payable. Two, hold nursing homes accountable for unnecessary drug use through the survey and certification process. And, three, explore other options, such as incentive programs and provider education, to promote compliance with quality and safety standards. For example, CMS could require nursing homes to reimburse the Part D program when claimed drugs violate these standards.

The government must also monitor the marketing of antipsychotics. There is ample evidence that some drug companies have illegally promoted these drugs for use by the elderly with dementia. Drug manufacturers have paid billions of dollars to settle allegations of off label marketing of these drugs. It is difficult to undo the influence of such marketing campaigns.

Doctors, nursing homes, and pharmacists can all help by carefully analyzing the patient's best interests when prescribing or dispensing antipsychotics. In partnership with medical professionals, families can support their loved ones by learning about appropriate use, proper dosages, and possible side effects.

My office continues to examine protections and quality of care for patients receiving antipsychotics. We are reviewing whether nursing homes are completing required patient assessments and care plans for these residents, and we have issued guidance to nursing homes about compliance risks related to the use of antipsychotics and other psychotropic drugs.

Over the next 18 years, 10,000 Americans will become newly eligible for Medicare each and every day. As the baby boomer population ages, it is imperative to address the overuse and misuse of antipsychotic drugs among nursing home patients.

Thank you for your interest in this issue, and I'm happy to take your questions. Thank you.

The CHAIRMAN. Thank you very much, Mr. Levinson.

Dr. Conway.

STATEMENT OF PATRICK CONWAY, DIRECTOR AND CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. CONWAY. Chairman Kohl, thank you for the opportunity to be here and discuss CMS' efforts to improve dementia care and ensure antipsychotics are used appropriately. CMS is committed to ensuring that every Medicare and Medicaid beneficiary receives appropriate and high-quality health care.

I left the private sector to take on my current career public servant role six months ago in order to improve the care delivered to all Americans. This topic is a significant opportunity for improve-

ment, and our Nation's seniors deserve our collective focus. I appreciate the committee's efforts to bring attention to the issue.

CMS is undertaking a multipronged approach, engaging with external stakeholders, to eliminate inappropriate use of antipsychotics in nursing homes. I will briefly summarize multiple steps that we've already taken and our plans in the future. I will highlight seven components to our approach: survey and certification, training and education, updating rules that govern nursing homes, research, quality measure development and transparency, partnering with States, and collaborative quality improvement.

First, to help ensure that nursing homes meet both Federal and State standards, CMS conducts inspections of all facilities participating in Medicare or Medicaid. CMS has implemented substantial improvements to help address concerns about over-utilization of medications. CMS provides guidelines for unnecessary medications, including requiring providers to use non-pharmacologic interventions to help manage behavioral issues, such as increasing exercise or time outdoors, monitoring or managing pain, or planned individualized activities.

CMS is working to enhance implementation of the guidance and utilize our quality assessment and performance improvement program better. The surveyors are armies of quality assurance staff in the field, so we need to focus this resource on appropriate behavioral interventions.

Second, CMS is working to improve training for both providers and surveyors to provide patient centered care that emphasizes non-pharmacologic interventions when appropriate. CMS added language to the state operations manual to make dementia care and abuse prevention issues a mandatory part of training. Additionally, CMS is producing educational DVDs that emphasize non-pharmacologic interventions. These will be distributed nationally to all nursing homes and State survey agencies. Finally, CMS updated the training curriculum to improve survey or skill at detecting unnecessary medication use.

Third, CMS is updating its rules regarding nursing homes and antipsychotic use. CMS proposed changes that will require long-term consultant pharmacists to be independent from LTC pharmacies, pharmaceutical manufacturers, and distributors. The goal is to assure that pharmacists' recommendations are made free from a possible financial influence. CMS is considering updates to other rules governing nursing homes.

Fourth, CMS is conducting research and leveraging research findings into practice. For example, CMS has awarded a contract to conduct a study in 20 to 25 nursing homes that will evaluate nursing home decision making and factors influencing prescribing practices for antipsychotic medications.

Fifth, CMS is seeking to encourage the development of quality measures addressing antipsychotic medication use. Once developed and validated, CMS would plan to publicly post the quality measures on first on Nursing Home Compare.

Sixth, CMS is interested in partnering with States to address this issue, and help identify and spread best practices. For example, CMS funded work with Illinois to use enhanced nursing home drug data to detect and monitor issues related to antipsychotic use.

Finally, and perhaps most importantly, we have recently engaged in a collaborative multi-stakeholder quality improvement initiative focused on reducing antipsychotic use in nursing homes by eliminating inappropriate use. I have personally led and participated in national quality improvement initiatives, and have seen their power to transform health care. These efforts are most successful when they engage a broad range of stakeholders, including front line clinicians, patients, and families.

Therefore, a few months ago we began proactively reaching out to stakeholders, including, but not limited to, the American Medical Directors Association, the American Society of Consultant Pharmacists, the American Health Care Association, LeadingAge, Consumer Voice, professional societies, government partners, and others to participate in a national collaboration. The response has been positive, and we are in the process of developing a national action plan. We are committed to working collaboratively to accomplish our shared goal.

I want to briefly share three of our guiding principles from the CMS Office of Clinical Standards and Quality that I led our organization in drafting.

First, constant focus on what is best for the patient; second, being a catalyst for health system transformation and improvement; third, collaboration across HHS and with our external stakeholders and partners. This is our approach going forward, both to dramatically improve the care of patients with dementia, as well as other issues we tackle.

CMS seeks to function as a major force and trustworthy partner for the continued improvement of health and health care for all Americans. As a practicing physician and son of a current and former Medicare beneficiary, I personally take this commitment very seriously. For nursing home residents suffering from dementia, this involves comprehensive behavioral health by an interdisciplinary team who are knowledgeable in the use of non-pharmacologic interventions and appropriate, judicious of medications when indicated.

We hope that members of the committee will serve as important partners in these efforts, and I look forward to hearing your suggestions and comments, and answering your questions.

As you noted, I have to mention my wife just gave birth to our third child, Alexa Diane Conway, so if I seem sleep deprived in my answering of questions, I apologize. Thank you for your time.

The CHAIRMAN. Thank you very much, Dr. Conway, for being here.

Mr. Levinson, your study found that about half of the 1.4 million atypical antipsychotic drug claims for nursing home residents did not comply with Medicare reimbursement criteria because they were not used for medically accepted indications. So, how can we increase Medicare's access to the information it needs to ensure appropriate reimbursement for drugs?

Mr. LEVINSON. Well, our report included several recommendations, and in my summary statement, I was including, you know, some of the options that I think CMS needs to explore.

But, first and foremost, you know, if we could have diagnosis information as part of the prescription, that would go a long way. It

wouldn't necessarily solve the entire problem, but having the diagnosis information available on the prescription could make potentially a significant difference in being able to ensure that the sponsors actually understand that, indeed, this is for a medically indicated application.

The CHAIRMAN. No, and almost every case, the prescription comes from a physician—correct?

Mr. LEVINSON. Yes.

The CHAIRMAN. Well, the physician understands how he is to prescribe for dementia and how he's to prescribe for mental illness. So, how is this mistake being made? After all, it's not just anybody that decides what to administer to a patient; it's a physician. So, how does this happen?

Mr. LEVINSON. Well, what we are focusing on is CMS' need to require the PDP sponsors to ensure that they have the diagnosis information available, because if you're reimbursing only half the time accurately, that is a problem that cries out for the need to ensure that CMS is saying, we need to ensure that we are only paying for those prescriptions in which we can support either FDA or off label, but medically indicated applications.

The CHAIRMAN. And I appreciate that, but I'm trying to somehow understand the medical part of this, because it's dangerous to prescribe inappropriately, right? I mean, we're talking about patients who are at risk from inappropriate prescription.

Mr. LEVINSON. Well, you know, on the medical expertise, I would defer, even if he's retired—

The CHAIRMAN. Dr. Conway—

Mr. LEVINSON [continuing]. The doctor at the table, but I would indicate that doctors are free to prescribe for any indication.

The CHAIRMAN. Sure. Dr. Conway, do you want to add, help us understand that?

Dr. CONWAY. So, we agree with the point that we have a shared goal of appropriate prescribing. I think our view of this, as I outlined, is a multi-faceted approach to appropriate prescribing. So, and we think about it in the course of all of our levers.

So, on one hand, it's education and training. So, I agree with you the decision should be between a physician and the patient. But there probably is an additional education and training for nursing home staff and physicians on this issue, especially around non-pharmacologic interventions.

I think, secondly, in terms of measurement and data, we agree with the OIG on the importance of data and on measurement. And as I alluded to, we're looking for additional measures so we can track this information. I won't recount everything I went through, but I think also in survey and certification, if there are outlier nursing homes with potential issues, you know, we are working through a process to make sure we have appropriate quality assurance in those settings for those nursing homes.

The CHAIRMAN. You regard this as a solvable problem, perhaps not easily, but a solvable problem.

Dr. CONWAY. I do.

The CHAIRMAN. Let me put it to you another way. Is there any reason, other than our inattention, for patients to be prescribed improperly?

Dr. CONWAY. So, I do believe it's a solvable problem. I think it is a complex problem, exactly as you said, Senator. I think addressing complex problems such as this, especially where the symptoms are sometimes difficult to distinguish as opposed to some other disease processes where it's more obvious, and I can talk more about that if you want me to.

I think here, it is a solvable problem, but it will mean collaborative quality improvement, as I alluded to, a collaborative focus. And I really think one of the major keys is this focus on non-pharmacologic treatments. So, we educate nursing homes and patients and families about the non-pharmacologic options to treat dementia and behavioral disturbances with patients with dementia.

The CHAIRMAN. Do you agree with that, Mr. Levinson?

Mr. LEVINSON. Yeah, I think that can be extremely, extremely helpful. That's very important. And, again, what is truly appropriate is a matter for the doctor to decide, perhaps in consultation with other medical professionals.

The concern from the Inspector General's standpoint is that CMS is reimbursing half the time where we just can't establish that there are actual medical indications that the CMS manual requires for there to be appropriate reimbursement.

The CHAIRMAN. Okay. Senator Manchin.

Senator MANCHIN. Thank you, Mr. Chairman.

Dr. Conway, and if you've gone over this and I missed it before I got here, I'm sorry. The Inspector General's report found that over half the antipsychotic claims—about 723,000 out of a million four—for the residents did not comply with the Medicare reimbursement criteria, which is, I think, what Mr. Levinson was just speaking about. And, I mean, that's an alarming rate. What authority do you need to create incentives, or improve data, or promote compliance within the rates of non-compliance you have now?

Dr. CONWAY. So, I agree that CMS should not be paying for medically inappropriate uses of medications. I think it is an inappropriate payment issue. It's also a quality of care issue. As I did allude to on the survey and certification, I do think quality measurement, which you touched on, is important, that we're measuring quality in this area, which historically we have not. We're working to be able to do that as early as this spring, so I think that's a critical factor. And then, transparently sharing that information with beneficiaries and their families on Nursing Home Compare.

I think, in addition, with our Part D colleagues, you know, we continue to work with PDP drug plan sponsors. We actually recently asked for more that we could do in this area in terms of input there.

So, I think it's a multi-faceted issue. We agree with you that we should not be paying inappropriately. I think our current authorities achieve that goal. Survey and certification now reports to me. I would reiterate, you know, the President put in the Fiscal Year '12 budget for survey and certification. We would support that budget. It allows us to do the important work of survey and certification in nursing homes. But I think we have the appropriate statutory authorities currently.

And as I outlined, we're going to take a multi-faceted approach to address this issue.

Senator MANCHIN. A lot of the States have basically their own controls, their oversights, their ombudsmen, things of this sort. Are you all exchanging your information freely? I mean, do you all—because I looked at just the figures of 2007—\$309 million was spent. Well, if half of it's spent or misspent, it's \$150 million. That was in 2007 dollars. I can only guess what it could be right now. But how do you all interact with States?

Dr. CONWAY. So, we work closely with States now, and we think we need to do more in the future. So, we're partnering with States. Illinois, for example, we're working with them on analyzing their data, identifying what may be inappropriate uses of antipsychotics. Massachusetts is convening a multi-stakeholder group to address this issue. So, we are closely working with States, including the State-based survey agencies in terms of addressing this issue.

Senator MANCHIN. Well, aren't the States doing more visitations than nursing homes than what you would say you are able to do?

Dr. CONWAY. Yes. So, it is the State survey agencies that will survey nursing homes—

Senator MANCHIN. Are they trained? Have they been trained properly to look for the types of so-called over prescriptions or abuse that might go on?

Dr. CONWAY. It's a great point. So, one of the aspects that we are trying to address is better training. So, we've started that through a series of, as an example, educational DVDs on this issue. Direct training with surveyors, so teaching surveyors and providers in nursing homes about non-pharmacologic treatments, and we think that's a critical point, exactly as you outlined. So, both the providers of care and the surveyors who are understanding that that care is present understand inappropriate use of antipsychotics, and also understand the non-pharmacologic interventions that are possible to treat these problems.

Senator MANCHIN. Here I was reading, it says, "These treatments are administered, despite FDA box warning concerning increased risk of mortality when drugs are used for the treatment of behavioral disorders in elderly patients with dementia, and no diagnosis of psychoses."

Is it kind of out of sight, out of mind, keep them calm, or what?

Dr. CONWAY. So, that would not be our goal.

Senator MANCHIN. I know it's not your goal. It looks like what the results have been.

Dr. CONWAY. So, on the FDA label, so, as you know, many medications are prescribed off label. However, we would always want appropriate use of antipsychotics. So, to give some tangible examples, if a patient with dementia has delusions, or hallucinations, or, you know, serious mental disturbances, then that can be appropriate use. But we would like to have the non-pharmacologic treatments be used more often.

Senator MANCHIN. Let me just say, sir, it's really a shame in this great country, as much money as we spend on nursing home care, not to get a better quality of care for the people that are in need. It just really is non-excusable.

Dr. CONWAY. I agree that it's a shame, and I agree that we need to do better.

Senator MANCHIN. Thank you.

The CHAIRMAN. Thank you, Senator Manchin.
Senator Grassley.

Senator GRASSLEY. Thank you, Mr. Chairman. I appreciate the opportunity and the invitation to come and participate in this hearing. Thank you.

I have just one question for each of you. I'll start with General Levinson. In your testimony, you highlighted the extensive evidence that drug companies have illegally marketed their atypical antipsychotics for off label use. You mentioned one company that used the slogan "Five at Five" to promote their powerful antipsychotic as a sleep aid for patients. Eli Lilly sales representatives told the doctors that giving five milligrams of their drug, Zyprexa, at 5:00 p.m. would help their patients sleep.

In 2009, this company pled guilty to illegal promotion and paid one and four-tenths billion dollars to settle a Federal lawsuit. Compared to the revenue this blockbuster drug generated, that large number becomes less significant, and unfortunately just the cost of doing business.

Now, as you described, it is a profitable investment because even after government action stops illegal marketing, their effect on prescribing patterns may be long lasting and difficult to undo.

So, my two-part question, General Levinson, is there a system currently in place to educate prescribers in response to this misleading promotion of drugs?

Mr. LEVINSON. Provider training is absolutely essential, Senator Grassley. And whatever is in place now needs to be far more robust. That is a key takeaway, I would hope, from what has been examined and what has been reported on, is that there needs to be far greater understanding of the potency of these drugs and their appropriate application, and how if you're going to use the backdoor as opposed to the front door of advancing this kind of drug regimen, it really needs to come with a really good understanding of what people are doing.

And it's hard to believe that in the past, that really has been effective, just given the record of litigation, because we've had not just that case, but nearly a half a dozen major settlements with drug companies over the past several years, totaling billions of dollars, that in one way or another involve these antipsychotic drugs.

So, it's a very important key part of the puzzle, if you will, that needs to be really made far—it really needs to be strengthened. And we're doing our part trying to advance the provider training initiatives. And we're going to continue on quality of care to do much the same by drilling down and understanding individual plans of care to see exactly how nursing homes are actually trying to implement a far more effective plan for patient safety.

Senator GRASSLEY. Okay. If there is such a system, it's inadequate, you just said, and needs to be improved or maybe even replaced. Do you have some idea how that system should be, and is it possible, if it needs more money, using a portion of the settlements of off labeled marketing?

Mr. LEVINSON. Well, we would certainly stand very ready, as we always have, to provide the kind of technical assistance that we do day in and day out to CMS, which really has the program responsi-

bility to design these kinds of efforts. We don't run the program; we evaluate it.

In terms of a kind of a counter design, my chief concern would be how we would oversee how the government would actively seek to provide some kind of counter balance to it. Wearing the oversight hat, that presents some challenging issues about how you, I take it, level the playing field, make sure people understand pros and cons comprehensively.

So, I mean, that would be a significant oversight challenge, and, therefore, it would be important to get the details of that kind of design right. And we would stand ready to certainly help.

Senator GRASSLEY. Okay. Dr. Conway, you mentioned proposed changes CMS is considering to require long-term care pharmacists to be independent from other pharmaceutical interests. Currently, about 80 percent of the consultant pharmacists at long-term care facilities are employed by long-term care pharmacies. There is then obviously a clear potential for conflict of interest.

However, one large long-term care pharmacy reported to me, and I won't give the name of that group, that all of the antipsychotic recommendations made by their consultant pharmacists, 99 and seven-tenths percent of those recommendations were to reduce or discontinue the antipsychotic dosage. One problem they presented was that these recommendations are often rejected by prescribing doctors who believe that high dosage is appropriate.

Does CMS keep data on recommendations made by consultant pharmacists on whether or not they're implemented?

Let me ask at the same time, does CMS require justification from a prescribing physician when they choose not to follow recommendations? So, two questions.

Dr. CONWAY. Yes, sir. So, on the first question, we are not currently capturing data on recommendations from the long-term care pharmacists to physicians because that's within the nursing home care setting. I think, as I alluded to earlier, I think the education component is not just in the pharmacy world; it's also to physicians. I'd also say it's to patients and their families, caregivers, nurses, CNAs, so the whole nursing home community, if you will, which we think will make it a much more receptive audience to recommendations.

On the long-term care pharmacy issue, you know, it is a proposed change. And as you alluded, the proposal was an attempt to ensure that financial arrangements weren't influencing the recommendations from the long-term care pharmacists.

Senator GRASSLEY. What about the—I hope you didn't answer this. If you did, I didn't get it. Does CMS require justification for the—from the prescribing physician when they choose not to follow recommendations?

Dr. CONWAY. I apologize, sir. I didn't answer the second part.

So, we currently do not require a written justification per se. It is similar to other prescribed medicines. The physician and the patient should have a discussion about the medication, the risks and benefits, or the patients' family in this case. And then, the prescription, either to increase or decrease in dose, or stopping a prescription would take place. But like other prescribed medicines, there's

not a justification—a written justification captured for the prescription.

Senator GRASSLEY. Thank you very much, Mr. Chairman. And thank you, witnesses.

Dr. CONWAY. Thank you, sir.

The CHAIRMAN. Thank you very much, Senator Grassley.

Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Mr. Chairman. And, first of all, my thanks to our chairman, Senator Kohl, for having this very important hearing, and for Senator Grassley's continuing investigation into this issue, which has been very, very important.

Over use of antipsychotics, as I don't need to tell the two witnesses and probably most of the people who are attending today, is a form of elder abuse, plain and simple. It's a form of abuse of people who often have no idea what is happening, and even their families may not have a clear or informed idea about how these drugs are prescribed and applied. And it occurs not just in occasional or isolated case, but as a routine pattern and practice, as some of the statistics show.

I don't know how many of them have been cited here, but 83 percent of claims for use of these antipsychotics to Medicare were associated with off label conditions like dementia. Fifty-one percent of Medicare claims for these drugs were erroneous. And, of course, millions of dollars wasted.

So, the question is, at the outset, if there is off label marketing, which is plainly a violation of current law as opposed to off label prescription which may not be, can you give me specific instances—both of you cited in your testimony of off label marketing occurring. What companies, what drugs?

Mr. LEVINSON. We've had a number of cases, and of the 18 settlements that we've had, Senator Blumenthal, I believe five in the past few years have involved antipsychotic drugs.

Senator BLUMENTHAL. I'm thinking more of going forward of what's occurring right now.

Mr. LEVINSON. Well, I can give you past cases, but in terms of current investigations, I certainly wouldn't be in a position. It would be in—it's something that wouldn't be proper to be talking about whatever current investigations might be ongoing with us as investigators in the Justice Department, as the prosecutors. But we have certainly a record of the kinds of cases you described that I think are a very important body of work that really underlay our evaluation work that we undertook to see further exactly how extensive the problem is in nursing homes with the percentages, and then to build on that work by looking at patient plans of care.

So, the litigation work that we have been involved with, in partnership with the Justice Department, lay the foundation for the report that's now before you, at least in part. And the report that's now before you will add further information and understanding to what is actually going on, if you will, on the ground, and will lead to a further investigation of plans of care in nursing homes to see how the mechanics of this actually is either operating or not operating appropriately.

Senator BLUMENTHAL. Are the penalties for off label marketing, in your view, sufficient to deter it in this area?

Mr. LEVINSON. Well, I mean, that's—you know, based on the record, it looks as if we're still facing a significant health issue. There's no question about that.

Senator BLUMENTHAL. Exactly, right. So, I think the answer probably is no.

Mr. LEVINSON. But that might be for others, you know, to answer. But I—

Senator BLUMENTHAL. Well, you're in charge of enforcement—

Mr. LEVINSON. Well, based on enforcement, we have quite an enforcement record at this point that we've built—

Senator BLUMENTHAL. Which is why I'm asking you the question. If anyone is expert on the issue of deterrence, it is you, and that's why I'm asking you the question.

Mr. LEVINSON. Well, we certainly view these kinds of returns, and we're talking about billions of dollars as a considerable amount of money. What happens with respect to the kind of cross-benefit evaluations that are undertaken by others, it's certainly very, very troubling that we have not just a case, but we do have a string of cases. And, therefore, you know, there's plainly a need to do more.

Senator BLUMENTHAL. In this area, would you suggest that there ought to be specific prohibitions applicable to the providers, in addition to the companies, for off label use in the area of use of antipsychotics for nursing home treatment?

Mr. LEVINSON. Well, I mean, I think in the context of anti-kick-back statute, and, you know, we've had some cases in which we have actually pursued at the provider level. I do think everybody needs to take ownership of the problem throughout the health care system, and it's not just a matter of the folks who are actually producing the drugs. I would agree with that.

Senator BLUMENTHAL. So, perhaps in the area of nursing care, the penalties for off label marketing should be also applicable to providers, or there's some institutional responsibility for off label use?

Mr. LEVINSON. Well, on the institutional responsibility, one of the chief concerns we have, as reflected in this report, is that more than 20 percent of the time, even when the drugs were used for medically accepted indications, they were being used for too long or improper dosages; that there's a lot of misapplication that's actually going on within the nursing home setting itself. And I think that we haven't really talked about that this afternoon, but that is equally concerning.

Senator BLUMENTHAL. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. In testimony that you've both made, and from what we've heard from other sources, it's been noted that rules to combat, which some refer to as chemical restraints, have been in place for many years now. So then, why are there still such high rates of over utilization of medications that appear in many cases to be used as a shortcut for proper care by well-trained staff? What's behind this all?

Mr. LEVINSON. Well, Chairman Kohl, I mean, I think that's what we need to further examine, and that's why I emphasized the follow-up reporting that we're going to be doing. And I certainly will defer to Dr. Conway to give his kind of medical perspective on it.

But we don't begin this kind of evaluation with any goal of what is the right number of dosages, or how many prescriptions should be allocated to this particular part of either the drug world or these kinds of issues. We look at what CMS requires in terms of what is reimbursable and what isn't, and that kind of gives us our road-map.

It obviously concerns a considerable percentage of elderly nursing home residents with a great deal of money involved. And as we've talked the last few minutes about the enormous investment of dollars from the pharmaceutical industry, there's a lot at stake here. And given how much is at stake here, both in terms of patient safety and financial investment, I think all of us as public officials need to do our part to make sure that there's a much better transparent and accountable understanding of exactly how these very powerful, important, and very positive drugs in the right setting need to be used and need to be paid for.

The CHAIRMAN. Are you of the opinion that in the year to come there's going to be significant improvement?

Mr. LEVINSON. I'm very careful in the inspector general's role not to predict so much as to evaluate what has happened, and certainly try to advance recommendations that will, you know, provide positive outcomes in the future. But in terms of what people will do either in response to this report, we hope that they'll take actions that indeed will fulfill, you know, that kind of positive prediction.

The CHAIRMAN. What about you, Dr. Conway? Do you think we're going to make some significant improvement in the next year?

Dr. CONWAY. I do think we have the right components in place to make significant improvements. So, specifically I think engaging in the multi-collaborative approach, as I outlined, you know, whether it's LeadingAge, ADMA, so many of the other folks in the room here, I think we've met a very receptive audience. I think behavioral change is complex, and we're asking for a behavioral change away from a medication based regimen in many cases to a non-pharmacologic treatment regimen.

But I think, as I outlined, if we align the levers of survey and certification, quality measurement and reporting, education and training, and a true quality improvement collaborative focused on this goal, which I think, you know, we have drafts of a national action plan, you know, working with these external stakeholders, I think that we have the potential for significant improvement.

The CHAIRMAN. Senator Manchin.

Senator MANCHIN. Thank you, Mr. Chairman.

And, if I could, just ask the question. This didn't happen overnight. This has been, I mean, you've seen the telltale signs for quite some time, the increased amount of reimbursements probably that you were making for these types of drugs, and how that's grown in pretty rapid succession. Didn't it raise anyone's alarm? Did anybody's alarm go off that something could be wrong?

Dr. CONWAY. I'll start to try to answer that question.

Senator MANCHIN. I'm just saying, when I look back at the years and the increases of reimbursements, that means increased usage. Is there other things like this that would be a telltale sign that there's abuses going on that basically haven't come to the forefront,

that you all can see the change in reimbursement that should've told us that something needed to be done much sooner than this? Go ahead. Either one.

Dr. CONWAY. I'll start, and then——

Senator MANCHIN. Sure.

Dr. CONWAY. So, I think certainly this is an issue, and in the interest of full disclosure, I'm interested, so I can't—I've been in this role for six months, so I can't speak to the history as specifically prior to that. But I think this is an issue that there was awareness of. I think that the awareness has grown. I think at CMS, we have some things already on this issue in terms of guidance, survey, and certification, et cetera. I think we have much more to do. So, I think——

And then, on this sort of coverage and reimbursement issues, I'd largely defer to my Medicare and reimbursement colleagues on the coverage and reimbursement issues.

Mr. LEVINSON. And the kind of reporting that we did does take time. I mean, we're looking at—in our report, we looked at the first half of 2007, and we asked medical experts to actually do the medical record review. And, therefore, we're looking at information that is now several years old. But we do, and we've been involved in the cases that resulted in significant settlements with pharmaceutical industries on these kinds of drugs for the last few years.

So, you know, we know that this is a—this has been a very large issue for us on that litigation front. As part of the settlements, there have been corporate integrity agreements——

Senator MANCHIN. Sure.

Mr. LEVINSON [continuing]. That these companies have had to sign with very robust compliance requirements that we in turn are in the process of monitoring.

Senator MANCHIN. Do you all have any litigation going on right now with any companies that you know of, or that you probably suspected any type of fraud whatsoever?

Mr. LEVINSON. Well, chances are my counsel in my Office of Investigations would advise me not to talk in public about ongoing investigations, and I try to adhere to their guidance.

Senator MANCHIN. That's a good policy to follow.

The only thing that bothers me more than anything is that—how much fraud, abuse, and waste that goes on in the whole system. If in anybody's budget, if we see a spike in reimbursements—requests for reimbursements, that should alarm that something's wrong. It's the easy way out, and it's the most profitable way, or you're sweeping it under the rug. I mean, I don't know why if someone's evaluating this, whether it be your medical staff or whatever, where does the flag go off or why—that's why I keep asking the same question, I know. But then, maybe you need to change your all's overview or oversight.

Mr. LEVINSON. I do think that there is considerable promise in the initiative of accountable care organizations, of coordinated or integrated care, to get health care professionals and different corners of the health care industry doing business with each other in a more integrated way than has existed in the past.

That does have promise to, in effect, serve as a very useful way of people being able to understand what kinds of therapies, wheth-

er it's pharmacological or otherwise, make the most sense for the patient. After all, we're dealing with a system in which the great majority of health care providers are honest. They are professional. They are trustworthy. They are people who we really count on to take care of us and our families. And the great majority of the time, they do so.

So, what we need to have is a system that really brings out those strengths and keeps the weaknesses, the marginal players out of the system entirely, or at least at bay, so that we don't have an issue that is as serious as this on both safety and financial grounds. And I think that that's a very good, positive development that I know CMS and other parts of HHS are now in the midst of unrolling, you know, this coming year and in the future. And I'm hopeful that it will have benefits on the health care fraud and abuse front as well.

The CHAIRMAN. We thank you both for being here today. You've added a lot to the discussion of this important issue. Thank you so much.

We'll now turn to our second panel. On the second panel, we'll have four distinguished witnesses.

First, we'll be hearing from Dr. Jonathan Evans, who's the incoming president of the American Medical Directors Association. Next, we'll be hearing from Tom Hlavacek. Mr. Hlavacek currently serves as executive director of the Alzheimer's Association of Southeastern Wisconsin. Our third witness will be Toby Edelman, senior policy attorney for the Center for Medicare Advocacy. And then, we'll be hearing from Dr. Cheryl Phillips, who's a senior vice president of advocacy at LeadingAge.

We thank you all for being here. And now, Dr. Evans, you may commence.

**STATEMENT OF DR. JONATHAN EVANS, VICE PRESIDENT,
AMERICAN MEDICAL DIRECTORS ASSOCIATION, COLUMBIA,
MD**

Dr. EVANS. Good afternoon, and thank you, Mr. Chairman, and members of the committee for allowing me the great privilege of appearing before you today.

Although my testimony today is quite personal, I also represent AMDA, the professional society for long-term care physicians, whose mission is to improve the quality of care for seniors.

My personal story is this. I'm a doctor who specializes in the care of frail elders. I practiced mostly in nursing homes and other long-term care settings, where physicians are frequently absent. I do use antipsychotic drugs to treat a small number of patients with long-standing schizophrenia or bipolar disorder. I do not prescribe antipsychotic job drugs for treatment of agitation or other behaviors in patients with dementia.

The entire leadership of AMDA acknowledges the use of these medicines in patients with dementia only as a last resort, and only when all else has been tried and failed, which is rare. I, and other like-minded doctors, face tremendous pressure and all care settings to prescribe medication to make confused patients behave. Most of the time, this equates to chemically restraining the patient. This pressure comes from frustrated caregivers and family members,

who are then led by other health care professionals to believe that these drugs are essential. A large number of patients that I see were started on antipsychotic drugs in the hospital for reasons that are entirely unknown. I routinely stop these and many other unnecessary or inappropriate drugs in patients admitted to my care. Nevertheless, my efforts to avoid or eliminate antipsychotic drugs often put me at odds with facility staff, patients and families, and other health care professionals.

The rate of off label antipsychotic drug use varies greatly between facilities and prescribers, and it's based upon their culture and attitudes, and not based upon medical diagnoses, severity of illness, or symptoms. Federal regulations regarding antipsychotic drugs, unnecessary medications, and chemical restraints only applies to nursing homes, but the problem of over prescribing antipsychotic drugs exists at all care settings. The majority of all off label antipsychotic drug prescribing occurs outside of nursing homes.

There is a firm fixed belief among many health care professionals that undesirable behavior is cause for medication, and that medication will be very likely to work. That firm fixed belief is false, but it's based in part on inadequate training to understand behavior and care for confused patients. Most doctors treat unwelcome behavior in all settings as a disease that requires medication. These drugs are used as chemical restraints. The real concern should be for improved dementia care in all settings that focuses on understanding behavior and its meaning in order to meet the patient's needs.

Most of the time, using drugs to stop behavior isn't doing the right thing; using drugs is instead of the right thing. Using drugs to try to make people behave creates unrealistic expectations and distracts caregivers from solving the underlying problems, resulting in these behaviors. Behavior is not a disease. Behavior is communication, and people who have lost the ability to communicate with words, the only way to communicate is through behavior. Good care demands that we figure out what they are telling us and help them.

Undesirable behavior and dementia is usually reactive and occurs in response to a perceived threat or other misunderstanding in patients who, by the very definition of their disease, have lost some ability to understand. These behaviors represent a conflict between a patient and their environment, us. Often we have to change our behavior in order to present an undesirable, but an entirely predictable, response.

AMDA believes in and promotes a multidisciplinary team approach to patient centered care, and is working with others to change the culture of health care in the United States. A minimum requirement of patient centered care is informed consent. Patients and their families must be afforded sufficient information and dialogue to make appropriate treatment decisions regarding potentially harmful medications. Likewise, we respect and strongly agree with existing Federal regulations regarding the avoidance of chemical restraints and unnecessary drugs.

We're developing core competencies for physicians in long-term care. We are raising the bar for dementia care, and helping dedi-

cated and caring individuals to leap over that bar. We're educating and empowering physicians, medical directors, and attending physicians and long-term care, and we believe that these efforts will lead to the kind of health care quality that we all want without increasing costs.

There's no substitute for good doctor spending time with their patients and families, time that they need to solve problems and relieve suffering. Doctors who are more often present and engaged in nursing facility care use fewer health care resources and fewer antipsychotic drugs. Physician training doesn't work to reduce antipsychotic drugs, and AMDA provides training on good dementia care and is working to provide more.

We acknowledge that virtually every dollar of health care spending at some point occurred as a result of the doctor's order.

Being a good physician requires being a good steward of scarce resources and focusing on what works. What the money is spent on should be a reflection of what we value most as a society. What my colleagues and I value most is loving care.

Thank you, Mr. Chairman, and members of the Committee.

The CHAIRMAN. Thank you very much, Dr. Evans.

Mr. Hlavacek.

STATEMENT OF TOM HLAVACEK, EXECUTIVE DIRECTOR, ALZHEIMER'S ASSOCIATION OF SOUTHEAST WISCONSIN, MILWAUKEE, WI

Mr. HLAVACEK. Good afternoon, Chairman Kohl and Senator Manchin. Thank you for the opportunity to discuss the very serious problems that overutilization of atypical antipsychotics present for people with Alzheimer's disease, particularly those who reside in long-term care.

Unfortunately, the Alzheimer's community in Wisconsin has seen firsthand what can happen when an individual with dementia is prescribed antipsychotics without proper precautions. At the time of his death, Richard "Stretch" Petersen, a friend of Senator Kohl's, was an 80-year-old gentleman with late stage dementia, who exhibited challenging behaviors in a long-term care facility.

After being at two hospitals in an effort to have his behaviors treated with antipsychotics, he was placed under emergency detention and was transferred by police in a squad car in handcuffs to the Milwaukee County Behavioral Health Psychiatric Crisis Unit. His family found him there, tied in a wheelchair with no jacket or shoes. In spite of his family's efforts to intervene and seek better care, he very quickly developed pneumonia, was transferred to a hospital, and died.

Richard Petersen worked hard all his life, raised his family, and contributed to his community in many ways. He did not deserve to die in the way that he did.

Mr. Petersen's death was not an isolated incident. It was the latest in a string of incidents in southeastern Wisconsin that involve tragic outcomes related to Alzheimer's behaviors and antipsychotic medications. In response to the growing problem, the Alzheimer's Association of Southeast Wisconsin and other concerned stakeholders created the Alzheimer's Challenging Behaviors Task Force. Our local task force eventually included 115 members from all per-

spectives on the issue, and published “Handcuff,” a report that provides a basic understanding of issues surrounding behaviors, and approaches to addressing the problem.

In Wisconsin, we found a reliance on atypical antipsychotics that were sometimes very poorly prescribed and administered. We found examples of untreated medical conditions, such as urinary tract infections, tooth decay, and arthritic pain, that led to agitated behaviors. And, of course, atypical antipsychotics will do nothing to treat those underlying medical conditions.

We also found negative outcomes from the revocation of individuals in and out of hospitals and long-term care facilities. Our experience indicates that these care transitions can exacerbate to say behaviors, and often lead to escalating drug treatments.

The task force is one local example of how the Alzheimer’s Association advocates for quality care and long-term care settings across the country, including the reduction of inappropriate use of antipsychotics. Recently, the National Alzheimer’s Association board of directors approved a position statement titled, “Challenging Behaviors,” which discusses the treatment of behavioral and psychotic symptoms of dementia, otherwise known as BPSD. The Association maintains the position that non-pharmacological approaches should be tried as first-line alternatives for the treatment of BPSD. I have included “Handcuffs” and the board’s statement with my written testimony.

The Alzheimer’s Association strongly believes one mechanism for reducing care transitions and improving overall care for residents in long-term care is to raise the level of expertise of facilities staff through training and education. The Alzheimer’s Association has developed two dementia care training programs specifically for staff—the classroom-based Foundations of Dementia Care, and the online CARES program. Both of these training programs have been identified by CMS as options for nursing facilities to satisfy the requirements of Section 6121 of the Affordable Care Act, which calls for dementia care training for certified nurse aides working in nursing homes.

The CARES program has a new module, dementia-related behavior, that focuses on non-pharmacological strategies for reducing or eliminating challenging behaviors. Local Alzheimer’s Association chapters across the country are excellent resources for these and other training programs to enhance care and support for persons with dementia and caregivers.

The Alzheimer’s Association also developed dementia care practice recommendations for assisted living residences and nursing homes. These are the basis for our campaign for quality residential care. The standards of care will improve quality of life for people with dementia.

The Alzheimer’s Association is committed to ensuring people with dementia have access to high-quality care and strongly believes that non-pharmacological approaches should be tried as the first line alternative for the treatment of behaviors.

Senator Kohl and Mr. Manchin, thank you for the opportunity to address this issue, and we look forward to the opportunity to work with the committee in the future.

The CHAIRMAN. Thank you very much, Mr. Hlavacek.

Ms. Edelman.

**STATEMENT OF TOBY EDELMAN, SENIOR POLICY ATTORNEY,
CENTER FOR MEDICARE ADVOCACY, WASHINGTON, DC**

Ms. EDELMAN. Thank you, Senator Kohl, and Senator Manchin.

Congressional attention to the misuse of antipsychotic drugs as chemical restraints is long standing. In 1975, this committee issued a report, "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks." Twenty years ago, this committee held a workshop on reducing the use of chemical restraints in nursing homes that identified many of the same issues we're discussing today—the misuse of drugs and the need for staff to see residents' behaviors as communication, not problems.

The Inspector General's very important May report actually understates the extent of the problem because it focused only on atypical antipsychotics, not conventional antipsychotics as well. Nursing facilities' self-reported data indicate that in the third quarter of 2010, 26.2 percent of residents had received antipsychotic drugs in the previous seven days. That's approximately 350,000 individuals. Facilities reported to CMA that they gave antipsychotic drugs to many residents who did not have a psychosis, including almost 40 percent of residents at high risk because of behavior issues.

I want to make just several brief points this afternoon. First, Federal law prohibits the antipsychotic drug practices we see in many facilities. Secondly, why are antipsychotic drugs so misused? Third, the high financial cost of these drugs, and, finally, some solutions.

The Federal Nursing Home Reform Law, since 1990, has limited the use of pharmacological drugs. Implementing regulations and CMS guidance to surveyors are very strong, but they are inadequately and ineffectively enforced.

Second, while there are many reasons why these drugs are inappropriately prescribed, the most significant cause is the serious understaffing in nursing facilities. Most facilities don't have enough staff or enough staff with specialized and professional training to meet the residents' needs. In addition, the enormous turnover in staff and the lack of consistent assignment of staff to residents, mean that staff don't know the residents they're caring for. They're less able to recognize and understand residents' non-verbal communications or changes in condition that could warrant an appropriate care intervention.

A second key reason for misuse of these drugs is the aggressive off label marketing of antipsychotic drugs, which we've talked about today. To give one example, in 2009 the Eli Lilly Company paid \$1.5 billion to settle civil and criminal charges for the off label promotion of Zyprexa as a treatment for dementia. Eli Lilly had trained its long-term care sales force to promote the drug as a treatment for dementia, depression, anxiety, and sleep problems.

A third concern is that many consultant pharmacists who are critical to implementing the Federal provisions about drug regimen review have not been independent. Another false claims act case against Johnson and Johnson charged that company with paying kickbacks to Omnicare, the largest nursing home pharmacy, so

that the pharmacists would recommend its drugs, including Risperdal, for use by residents. The consultant pharmacists were part of the sales force.

There are other reasons as well, of course. Drugs have replaced physical restraints, whose use has declined. And antipsychotic drugs are a protected class under Medicare Part D, and they're generally not subject to utilization control mechanisms.

I'd to discuss briefly the high cost of antipsychotic drugs. They're very expensive, the top selling drugs in the United States generating annual revenues of \$14.6 billion. But the costs, of course, extend far beyond the costs of the drugs themselves. Residents who are inappropriately given these drugs experience a number of bad outcomes that are expensive to try to correct. Falls, hip fractures, urinary incontinence, each with a high price tag, can be the result of the misuse of antipsychotic drugs.

Millions and billions of dollars that these poor outcomes cost were identified in the 20-year-old report by the Senate Labor and Human Resources Subcommittee on Aging, and by a report issued this past April by Consumer Voice. Links are in my testimony.

For solutions, what we recommend is implementing what virtually all commenters on all sides of this issue agree on, that non-pharmacological approaches should be tried first. To achieve that end, we recommend a number of approaches that would call prescribers' attention to the issue of antipsychotic drug use, slow down the process of prescribing these drugs, teach better non-drug alternatives, and create and impose stronger sanctions for inappropriate use.

Finally, I want to describe what eliminating antipsychotic drugs can mean for individual residents. A researcher working in New York to try to translate the research literature into practice at nursing homes sent me an e-mail about a small facility she had spoken with. She said that the director of nursing heard her speak, and although the nurse had originally been skeptical, she involved her medical director and consultant pharmacist. They were left with only two residents using antipsychotic drugs, both with a diagnosis of schizophrenia. And then this is what she said.

One man they found had severe back pain from spinal injury from a car accident years ago that was never addressed, but his dementia prevented his communicating the pain, and they had him in a deep seated Geri chair, which only exacerbated the pain, poor man. So, he had behavior issues and was on antipsychotic meds, couldn't communicate, or feed himself. He now eats lunch in the dining room and converses with his wife, participates in activities, et cetera. They have taken away the antipsychotics and replaced them with pain medication. One story makes it all worth it. I would add that this story could be replicated hundreds of thousands of times in nursing homes across the country.

Drastically reducing the use of antipsychotic drugs would improve the lives of residents—hundreds of thousands of residents—and save hundreds of millions, if not billions, of dollars. After 35 years of studies, reports, and hearings, it's time to eliminate the epidemic use of antipsychotic drugs. Thank you, sir

The CHAIRMAN. Thank you very much, Ms. Edelman.
Dr. Phillips.

**STATEMENT OF CHERYL PHILLIPS, SENIOR VICE PRESIDENT
OF ADVOCACY, LEADINGAGE, WASHINGTON, DC**

Dr. PHILLIPS. Thank you, Chairman Kohl. And thank you for addressing, one, this critical issue, and for involving all of us as witnesses, because there is an important story to be told here. And we appreciate it.

As way of background, my name is Cheryl Phillips, and I'm a fellowship trained geriatrician. And I, like my friends and colleagues, have spent several decades in clinical practice, predominantly in the long-term care setting. I now have the privilege of being the senior vice president of advocacy at LeadingAge, formally known as the American Association of Homes and Services for the Aging.

The 5,700 members of LeadingAge serve as many as two million people a day through their mission driven, not-for-profit organizations that offer a spectrum of services across a post-acute and long-term care continuum. And together we advance policies, promote practices, conduct research support, enable and empower people to live as fully as they can. So, not only do we embrace this issue as a critical, important platform, we're going to talk a lot about how both our members are participating, and how we are offering some solutions.

We've heard a lot about the demographics. It's worth noting that of seniors 80 years and older with a diagnosis of dementia, 75 percent will spend time in a long-term care setting. So, this is an important and relevant platform conversation. And even by CMS's own reports, 50 to 75 percent of long-stay nursing home residents have some degree of dementia.

But, as I say that, it's important to note that this is neither just a nursing home issue, nor just a U.S. issue. As part of my testimony, I included some materials that were shared from the United Kingdom, and Dr. Banerjee, who looked at the problem of both medication use and appropriate care of dementia across hospitals, outpatient, and nursing home settings, gave 11 recommendations that I think, despite the large pool of water between our two countries, has a lot of application that we can take and use in our thinking today.

So, I would start with the use, and we've mentioned it, but it's worth noting again, that the use of antipsychotics is related to a much larger challenge of how to best care for people with dementia. Medications are most often used as a first line of option because, quite frankly, families, caregivers, nurses, doctors across all settings of care, are not aware and don't even know of alternatives. They do believe that they are doing the right thing for the person that they love, or the person they're caring for.

It is I'll also add just a note of caution, if we merely target this as a one class of drug, in one setting, we may have some unintended consequences. For instance, if we look at just one narrow scope of drugs, what will happen is that prescribers will shift to other equally inappropriate drugs, such as Benzodiazepines, sedative hypnotics, and off label use of anti-seizure medicines, all of these which also carry a risk of falls, confusion, and death.

So, it's bigger than a drug problem, although the drug becomes the tip of the iceberg of what the underlying issue is.

We've also addressed that it's not just a nursing home problem, and if we focus just on the solutions in the nursing home, I do caution that we don't create inappropriate barriers to access for people who desperately need appropriate nursing home care.

So I think that the short-term solution is in fact not a short-term solution, but a twofold strategy that ties into a longer, sustained culture change. First is the application of non-pharmacologic interventions, and we've talked about behavior therapies. And second is when medications are used, there is the need for close monitoring of appropriate and limited use.

We've heard from the CMS that there are existing regulations. I won't go over them again. I will distill them, because when I worked with my own patients and with staff in nursing homes, we really narrowed it down to five simple questions. What is the specific indication, not why you want to use a drug, but for that person, what is the valid indication? If there was an appropriate indication, is it still appropriate now? Maybe the issue was a day ago, a week ago, the transition has happened, the agitation is resolved, the pain has been more appropriately addressed.

If the person is on an antipsychotic, is it actually working? Is what you're trying to address, have you documented its effectiveness? And I always use the standard, is the person that are able to function in their environment on the medicines, then off.

Fourthly, has the family or caregivers been involved in the choice? Are they aware of the indications, the risks, and potential benefits, and have they been engaged in that discussion? And is there a history of appropriate non-pharmacologic intervention, unless this was a short-term emergency?

So, if the answer to any of these five questions is no or unknown, then the meds should not be started or be discontinued.

The long-term answer, because we know that dealing with the meds alone isn't the solution, is much how we looked at physical restraint reduction that my colleague, Toby, referred to. It comes from a sustained campaign where caregivers focus on real person-centered care alternatives, including direct workforce training with evidence-based tools, dissemination of knowledge to nurses and physicians regarding true effectiveness of non-pharmacologic interventions, and an interdisciplinary team true monitoring when medications are used to ensure appropriate indication dose, duration, and response. This will all take a collaborative partnership. It includes CMS staff, physicians across the health care continuum, not just in the nursing homes, pharmacists, direct care workforce, and caregivers.

We need accurate data to look at timely information to feedback to prescribers. We need large-scale applied research to look at how these models can be disseminated widely. We certainly need enhanced survey or training as was mentioned. And we need investment in meaningful workforce.

We at Leading Age talk about some solutions. Again, as the not-for-profit difference we have convened a workgroup already looking at exciting models. A couple that I'll mention, Eliza Jennings in Cleveland and Ecumen in Minnesota, that are taking that same philosophy of medication free treatment to dementia, working through remarkable behavior interventions and alternatives.

And, lastly, I want to acknowledge that LeadingAge is a co-convenor of Advancing Excellence that represents truly a multi-stakeholder coalition that's committed to improving quality care for life for people in nursing homes.

So, in summary, yes, we have a significant problem with inappropriate use. The solution is how we better take care of persons with dementia, which includes focusing on dignity, compassion, having an across-the-board approach that involves direct caregivers, staff, prescribers, physicians, nurses, and families, and their loved ones, as all part of the caregiver team. And we set the challenge that actually nursing homes should not be the problem, but we believe they can be the centers of excellence for improving dementia care, and a learning laboratory for the rest of the health care setting.

Thank you very much.

The CHAIRMAN. Thank you very much, Dr. Phillips.

Dr. Evans.

Dr. EVANS. Sir?

The CHAIRMAN. You argue that using antipsychotics for patients with dementia should only occur as a last resort, and only when all other interventions have been tried and failed. How often in your experience do behavioral interventions fail? What is your estimate of how commonly antipsychotics would be used if health care professionals were trained in how to effectively and efficiently deploy a range of behavioral interventions?

Dr. EVANS. Well, as was mentioned earlier in so many words, if all you have is a hammer, everything looks like a nail. And that's the problem that we're dealing with now.

As I mentioned in my testimony, I don't use these drugs to treat behavior. These drugs, study after study has shown, are ineffective in treating behavior, and I believe that if appropriate steps were taken, or even if they weren't taken, that the use of these medications could be reduced to pretty close to zero in a variety of settings. That being said, because only a small proportion of the use of these medications happens in nursing homes, it may not have the huge impact that you're hoping for.

Eight billion dollars is spent on the off label use of these drugs currently per year, and based on the OIG's report, less than a fourth of that is in nursing homes.

The CHAIRMAN. So, what is your answer? Maybe you've given it, but I'd like to hear—

Dr. EVANS. My answer is close to zero.

The CHAIRMAN. Zero.

Dr. EVANS. Yes. In my personal practice it's zero. And other doctors will give you a different number. But there are so many other things that can be done that this really does not represent good dementia care.

The CHAIRMAN. Thank you.

Mr. Hlavacek, Mr. Petersen's tragic death seemed to a wakeup call for the need to find better ways to provide care for individuals with dementia. How's the Alzheimer's community in Wisconsin promoting education and training programs throughout our State so we can prevent others from suffering the same misfortune? And how can we here in Washington help to promote these training programs?

Mr. HLAVACEK. There are several answers to your question, Senator. We have two national programs, the Foundation of Dementia Care, which is the sort of classroom approach for direct care staff and supervisors, and we have the Online CARES program, which has a number of modules that are designed to train on a number of different facets of quality care. And the person from LeadingAge was absolutely correct. This is a problem that's in the middle of a bigger set of problems. It's nested within a number of other problems around quality care.

We certainly believe that staff training and education is critical. We think it should happen at all levels of the facility, certainly for the CNAs, as seen in the Affordable Care Act. But really oftentimes it's the janitor, it's someone else in the facility that picks up on behaviors earlier and says, something's wrong with that gentleman down in that hallway; we should check this out, and not wait for the problem to take place further. On our chapter level, we have a 16-hour dementia care specialist training, which is highly in demand across Wisconsin.

In many of these cases, we see, through the application of these training programs, that staff have a wakeup call, and they have new tools beyond just the hammer and the nail to address some of these difficult issues.

A further problem, though, just to complicate this a little bit, is staff turnover in these facilities, which is very, very rampant. You can go back to the same facility that you trained in a year later, and see a whole sea of fresh faces that weren't there before because of staff turnover. So, we don't really value these positions and these jobs too highly in our society. We need to perhaps look at that as why aren't we providing a better standard of living for the people working in the facilities.

The CHAIRMAN. Thank you very much, Mr. Hlavacek.

Ms. Edelman, what type of staff training would you recommend that CMS require to help curb the over utilization of antipsychotics in nursing homes? And should similar training be provided also in assisted living facilities, hospitals, as well as other health care settings?

Ms. EDELMAN. Training would be extremely important. We could use the model that we had with physical restraints when the Nursing Home Reform Law was first implemented in 1990. CMS did a lot of training about how to remove physical restraints. It was in-person surveyor training that I attended.

Now CMS does a lot of training with satellite broadcasts. It can do that. It can send out the word, train all kinds of people all over the country in better care practices.

One of the organizations that I've been working with very closely on the antipsychotic drug issue, the California Advocates for Nursing Home Reform, is conducting a series of trainings in the State. They had one a week or so ago, with several hundred nursing home staff members. And they are having people who have done what Dr. Evans described providing care to residents with dementia without chemical restraints, and having people who've done it teach other facilities how to do it. It's very effective. It definitely worked with physical restraints, and it should work with chemical restraints as well.

The CHAIRMAN. That's good. Thank you.

Dr. Phillips, are hospitals and nursing homes working together to reduce the rate of antipsychotic use? And if they're not, will LeadingAge commit to helping to make this happen?

Dr. PHILLIPS. The short answer is no, and that's unfortunate. There is a chasm between hospitals and nursing homes in a variety of problems, and I think the appropriate care of dementia is but one of them.

The opportunity, certainly through some of the new models of integrated care provisions, is an excellent starting point. It will take more than LeadingAge alone, and that's why we're working so closely with collaborators such as Advancing Excellence, because we recognize that as we provide that basis of both learned—let's learn from people who are doing it well and how to replicate it, but also to inform the clinicians across the continuum that there are valid and real alternatives.

Lastly, I want to put in an important issue. We talked about staff turnover with the Alzheimer's Association. One thing that Advancing Excellence has identified is when you have consistent staffing, so that the same person as often as possible taking care of that same resident. The behavior issues also tend to decline.

So, that's another area that with—we at LeadingAge, working with Advancing Excellence, are working on better understanding, both staff turnover, but also staff consistency, as probably a key quality measure. And that relates to falls and certainly to behavior management and persons with dementia.

The CHAIRMAN. Dr. Evans, you talked about informed consent.

Dr. EVANS. Yes, sir.

The CHAIRMAN. Do you believe that the family members of dementia patients understand that off label use of typical antipsychotic drugs can be quite harmful? And if not, what can we do to ensure that family members understand the risks of these drugs for their loved ones who cannot communicate their needs clearly, and who are thought to have behavior problems?

Dr. EVANS. Sir, the process of informed consent very seldom occurs in prescription and administration of these medications in any setting when treating behavior. Part of the reason for that is that the use of these medications very often represents a great deal of frustration and caregiver stress, whether it's in the hospital or nursing home or elsewhere.

And there's a sort of a fantasy really that if somehow there were just a magic pill that would make it go away, that all would be well. And so, oftentimes these drugs are initiated in kind of a crisis situation where it's considered by the people involved to be urgent, and, therefore, oftentimes family members aren't notified.

I think that in that particular situation, really what's going on is these medicines and others like them, other classes of drugs that Dr. Phillips talked about, are really being used as tranquilizers.

And, you know, there really aren't diseases that I know of that only occur on one shift, or on Saturdays only, or, you know, between—when they're giving report at the hospital or something like that. The pattern under which these crises develop often are related to other things going on in the environment.

And, frankly, I think of this problem that we're talking about the same way that I think about asbestos. It's been used everywhere based on what maybe at one time seemed like a good idea. But now we know it's harmful, and we have to get rid of it. And it's a rather expensive proposition.

But informed consent at least includes patients and families in the discussion. I mean, it's one of the fundamental basis, and certainly one of the most basic ethical principles about care in this country, and autonomy. And so, you know, I really can't defend not getting patients' permission to be provided treatment. Certainly we wouldn't stand for that if it was a surgery, but the risks that we're talking about are of comparable magnitude.

You know, having informed consent as part of the process in some ways allows for a little bit of a cooling off period as well in that those conversations should happen in the light of day. But, you know, I think that the reality is that what's easy and convenient is what gets done. And substantial and enduring change requires changing what's easy and convenient.

The CHAIRMAN. Thank you.

Dr. EVANS. Yes, sir.

The CHAIRMAN. Ms. Edelman, your testimony notes that 40 percent of nursing home residents are considered to be at high risk of receiving an atypical antipsychotic drug due to behavioral problems, which, of course, is an astonishingly high number. Is there evidence that behavior problems have somehow become worse over time?

Ms. EDELMAN. I don't know that we have any evidence that behavior problems have gotten worse. Residents have behavior issues, and there's not staff that know the residents and knows how to deal with them. There's general recognition that nursing homes are under staffed, and so they're not dealing with problems as well as they might.

Nursing homes maybe do have residents who are more seriously ill than before. We do have a whole new alternative of assisted living now where some people with lesser problems may be living, although they're beginning to look more and more like nursing home residents all the time, and I've seen some reports indicating that they take more drugs than nursing home residents. So, it's hard to say.

There are behavior issues that people have, and they're not being dealt with properly. That's probably the primary concern.

The CHAIRMAN. Dr. Phillips, you want to comment?

Dr. PHILLIPS. Well, I'll add that just from the clinical history of dementia, usually the behaviors, when they are problematic, are phasic. So, early on in the disease process, not so much. Somewhere in the middle phase, and not for everyone, and usually by outside—what I mean outside to the person triggering event, either too much noise, or fatigue, or pain, or other medical problems, something that creates an agitation.

But quite frequently, in fact, most commonly in advanced dementia, the behaviors fade away, if not disappear entirely. So, even if one argued that occasionally the medications are appropriate for short-term use, another piece to this problem is it's like barnacles. Once people are on these medicines, they don't come off. They tend

to just stay on, and they move from setting to setting with these medicines as part of their package, if you will.

So, when we think of dementia it's not just that behaviors get worse over time. In fact, they may be worse somewhere in the middle of the person's clinical course with dementia. But not everyone with dementia has difficult behaviors, and certainly the vast majority of difficult behaviors are triggered and, therefore, resolved by outside environmental issues that can be much better addressed through intervention rather than pills.

The CHAIRMAN. Dr. Phillips, are there safer medications than antipsychotics for individuals with dementia who are in pain? And if so, what are they?

Dr. PHILLIPS. Well, to address specifically pain, we have another issue in the nursing home that I know you're very familiar with, and that is the appropriate treatment of pain for nursing home residents. It has been noted by several studies that even the use of medications, like morphine, when people are in pain, their confusion gets better if their confusion was due to untreated pain.

What I'm cautious about and I had mentioned earlier in unintended consequences, is we don't substitute antipsychotics for other inappropriate drugs. But having said that, sometimes the very best management for a person who's acutely agitated who cannot give us their story through words is to look and see, is pain the underlying problem, and treat with pain.

In fact, some nursing homes have now routinely looked at low dose of medicines, like acetaminophen, to use in persons with dementia who have risk for pain to see if that doesn't, rather than waiting for their behaviors to escalate, if that doesn't modulate some of the agitation underline.

Now, I'm certainly not purporting that we just give medicines willy nilly to everybody without being very careful about what is the appropriate indication for any medicine, including pain medicines. But part of one piece to this problem is that when we don't appropriately treat pain, we see it resultant in increased agitation and what we label as difficult behaviors in persons with dementia.

The CHAIRMAN. Ms. Edelman.

Ms. EDELMAN. May I say something? The researcher that I talked about at the end of my testimony in New York has done work, and I will try to get a copy of this and submit it for the record. She's looked at residents who have dementia and whether they get as much pain medication as residents without dementia with the same physical diagnoses, the same medical problems. And she has found that they don't get as much pain medication as non-dementia residents get. So, that's a very strong indication that a lot of the problem is that people are in pain, and it's not being treated properly because it hasn't been identified.

Now, CMS is trying to fix that. The new assessment process, MDS 3.0, which has now been in place for about a year—a little over a year—has changed the way facilities assess residents' pain. In the past, the staff wrote down whether they thought residents were in pain. Now, the staff is asking residents if they're in pain.

And the numbers should really be considerably higher than we've seen before because most people think that maybe 50, 60 percent, 70 percent of residents have some pain problem. So, if that gets

identified and treated, there might be—yes, this could really be a very important way of getting around all this antipsychotic drug use, because the residents are in pain and it's not being identified and treated.

The CHAIRMAN. Yes, please submit it to us.

Mr. Hlavacek, any comments you wish to make to this panel?

Mr. HLAVACEK. Once again, thank you so much for holding this hearing. One of the things that was touched upon was the whole concept of care transitions, and I think that that's a very important piece for the committee to consider going into the future. We have definitely seen a breakdown in communications in our task force between the hospitals and the nursing homes and assisted living facilities. People get transferred out of a facility and into a hospital. The bed may close behind the hospital. The hospital may have a really difficult time getting the person placed back someplace in the community that's appropriate.

And the hospital, on the other hand, may say, you know, we send them back to the facility and they show up back here again in a few days, and we can't have that happen because of the Medicare readmission rules.

So, I think that looking at those care transitions in light of this particular issue, would be very informative because of the fact that our experience is that is one place where the use of those medications can truly escalate.

We've heard nursing homes say they come back from the hospital and they're on more medications than we know what to do with. And we've heard hospitals say when they come here, they're on 12 different medications; how does the nursing home allow that to happen?

So, it's a complex issue, but I think that there's a lot of room for both hospitals, and nursing homes, and long-term care facilities, and including assisted living, to have a strong vested self-interest in fixing that problem. It doesn't work for anybody. And so, I think that that would be a great idea for further development of policy, and collaborations, and best practice models.

The CHAIRMAN. That's a good comment. Thank you.

Anybody else like to add to this very informative discussion? Dr. Evans?

Dr. EVANS. If I could just add that, you know, we have a huge problem in this country with extraordinarily expensive care and significant concerns about health care quality such that we're not getting our money's worth. Doctors unfortunately, as this hearing has described, have a large share of responsibility for many of the problems that exist in health care, particularly with regard to prescribing medications. And I believe that doctors have a responsibility to be part of the solution. And my colleagues and I are very committed to solving this problem.

I also would just like to say that good care really shouldn't depend in this country on where you go to get it. People should have a reasonable expectation of good care anywhere and everywhere, whether it's a hospital, a nursing home, an office.

And so, it's my hope that in my lifetime that I will see the standard of care being applied really equally across all care settings, and

things that have been shown to be successful and effective in one setting apply to other settings.

The CHAIRMAN. Thank you, Dr. Evans.

Ms. Edelman.

Ms. EDELMAN. Yes. As important as training is, it is important for facilities to be trained and prescribers to be trained. It's also important that CMS strengthen a little bit the very excellent regulations that already has and the guidelines, but that it put some additional attention on the issue of antipsychotic drug use. If each survey made sure to include in the resident sample, resident with antipsychotic drugs, really focus attention on this issue, it would be very helpful.

And if the enforcement could be strengthened. I've read a couple of decisions from the administrative law judges where unnecessary drugs, antipsychotic drugs, have been cited, but the civil money penalty was \$300 a day. A \$3,900 penalty for over medicating a resident seems like a very inadequate penalty.

And, finally, I think there are a couple of laws and regulations that could help strengthen oversight of antipsychotic drug use. What we have is a very excellent base of law and regulation. Section 7 of the Prescription Drug Cost Reduction Act that you introduced last month would require physician certification that the off label prescription of an antipsychotic drug is for medically accepted indications. That would be very important. We would really hope that that would get enacted.

CMS recently proposed amending the consultant pharmacist regulations to make sure that they are independent. That's very important. Independent consultant pharmacists can make an enormous difference, and really call to the physician's attention that there's a problem with the prescribing of the drugs. And the physicians are required to respond to the irregularities. Not that they have to keep records, but they are required to respond.

And finally, in 1992, CMS proposed very comprehensive regulations on chemical restraints, which would strengthen the requirements on informed consent. Those regulations have never been issued in final form, and we would encourage CMS to do that as well.

The CHAIRMAN. Thank you.

Thank you all very much for being here. This is obviously a very important issue, and you did shine a lot of light as we move forward to improve. Thank you so much.

[Whereupon, at 3:39 p.m., the hearing was adjourned.]

APPENDIX



Testimony before the United States Senate
Special Committee on Aging

*“Overprescribed: The Human and Taxpayers’ Costs of
Antipsychotics in Nursing Homes”*

**Testimony of:
Daniel Levinson
Inspector General
Department of Health & Human Services**

**November 30, 2011
2:00PM
562 Dirksen Senate Office Building**



Testimony of:
 Daniel R. Levinson
 Inspector General
 U.S. Department of Health and Human Services

Good afternoon, Chairman Kohl, Ranking Member Corker, and other distinguished Members of the Committee. I am Daniel Levinson, Inspector General of the U.S. Department of Health and Human Services (HHS or the Department). Thank you for the opportunity to testify about the HHS Office of Inspector General's (OIG) work relating to the use of antipsychotic drugs in nursing homes.

Two recent OIG reports raise concerns about the use of atypical antipsychotic drugs¹ by elderly nursing home residents, particularly those with dementia.² We hired psychiatrists expert in treating elderly patients to review a sample of medical records. Their review revealed the following:

- 14 percent of nursing home residents, or nearly 305,000 patients, had Medicare claims for atypical antipsychotic drugs.
- Half of these drug claims should not have been paid for by Medicare because the drugs were not used for medically accepted indications.
- For one in five drug claims, nursing homes dispensed these drugs in a way that violated the Government's standards for their use. For example, the prescribed dose was too high, or residents were on the medication for too long.
- Part D prescription drug plan (PDP) sponsors lack access to the information necessary to ensure appropriate reimbursement of Part D drugs, including antipsychotics.

These findings indicate that Medicare is paying for drugs that it should not and Part D prescription drug plans are not able to adequately prevent inappropriate payments for drugs, including antipsychotics, for uses that do not meet coverage requirements. In addition, nursing homes often fail to comply with regulations designed to prevent overmedication of these powerful and at times dangerous drugs.

OIG's reports also found that atypical antipsychotics are frequently prescribed "off-label," that is, for uses that are not approved by the Food and Drug Administration (FDA). FDA has imposed a strong safety warning on atypical antipsychotics, emphasizing an increased risk of death when used by elderly patients with dementia. Yet we found that the large majority of claims for atypical antipsychotics were for elderly patients with dementia. These findings are

¹ "Atypical antipsychotic drugs" refers to second-generation antipsychotic drugs developed to treat psychoses and/or mood disorders.

² *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), issued May 2011. Available online at <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>.

also troubling given that there is ample evidence that some drug manufacturers have illegally marketed these drugs for off-label use.

Taken collectively, our findings raise concerns about whether atypical antipsychotic drugs are being prescribed and monitored appropriately. The Federal Government, health care providers, and families of nursing home residents all have roles to play in addressing these issues.

Half of Medicare Atypical Antipsychotic Drug Claims for Nursing Home Residents Did Not Meet Reimbursement Criteria

Atypical antipsychotic drugs that are provided to Medicare beneficiaries, including residents in nursing homes, are generally covered by the Medicare Part D program. Although physicians can prescribe drugs for any indications, to qualify for Medicare Part D reimbursement, the drugs must be used for medically accepted indications. These indications include both the uses approved by FDA and those uses (including off-label uses) supported by one or more citations in the compendia specified in the Social Security Act or designated by the Secretary.

Claims amounting to almost \$116 million did not meet Medicare coverage requirements for medically accepted indications

Based on review of a sample of medical records by expert psychiatrists, OIG determined that almost 723,000 of the 1.4 million atypical antipsychotic drug claims for elderly nursing home residents in the first half of 2007 did not comply with Medicare reimbursement criteria because they were not used for medically accepted indications. This high payment error rate may be partly due to PDP sponsors' lack of access to information necessary for appropriate reimbursement of Part D drugs.

PDP sponsors lack the information necessary to ensure that Part D drugs claims, including those for antipsychotics, meet coverage requirements

The Centers for Medicare & Medicaid Services (CMS) requires PDP sponsors to ensure that Medicare reimbursement for Part D drugs is limited to medically accepted indications. PDP sponsors employ a number of strategies to prevent inappropriate payments for drugs, including prepayment edits, prior authorization, and post-payment review. However, PDP sponsors often cannot determine whether a given drug claim was prescribed for a medically accepted indication, because:

- Prescriptions and claims data lack diagnosis information. Without medical record review, reviewers cannot routinely determine why drugs were prescribed.
- FDA label and compendia listings at the time of the dispensing, not at the time of review, govern eligibility for coverage. Compendia listings can change as frequently as every quarter. For retrospective review, PDP sponsors lack archival information to all compendia to determine what indications were listed at the time a drug was dispensed.

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PDP sponsors have reported to OIG that they do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not generally collect diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide them the diagnoses. Without diagnosis information on a Part D claim, determining whether a drug was provided for a medically accepted indication, and therefore was reimbursable by Medicare, is not possible using claims data alone. Sponsors reported to us that they do collect diagnosis information when using prior authorization, a utilization management tool that requires medical justification for covering a drug claim. The PDP sponsors indicated that prior authorization is the best tool that they currently have to compare the diagnosis provided by the prescriber to the medically accepted indications contained in the compendia. However, because antipsychotics are one of the six protected drug classes under Part D, the PDP sponsors indicated that they use prior authorization for antipsychotics only in limited circumstances.

PDP sponsors also reported using post-payment review as a general safeguard to prevent fraud and abuse. However, these reviews do not commonly focus on medically accepted indications. PDP sponsors reported that they have real-time access to all compendia, but do not have access to historical data. Because one of the compendia is published quarterly, it is possible that information about a particular drug may be updated between the time a drug is provided and the time payment review is conducted.

OIG has recommended that CMS facilitate PDP sponsors' access to information necessary to ensure accurate reimbursement of Part D claims. For example, expansion of the required data elements for Part D claims to include diagnosis codes could help both drug plan sponsors and CMS ensure that a drug is used for an FDA-approved indication or a medically accepted indication supported by the compendia. CMS did not concur with this recommendation, and in its comments on our report noted that Congress did not mandate diagnosis information on Part D claims. CMS has also stated that it does not have statutory authority to require physicians to include diagnosis information on prescriptions, which are generally governed by State law.

Antipsychotics Are Prescribed in Violation of Nursing Home Quality and Safety Standards

As a condition of participation in Medicare, nursing homes must comply with Federal nursing home quality and safety standards. One standard requires that nursing home residents' drug regimes be free from unnecessary drugs, which CMS defines as those that are used: (1) in excessive dose; (2) for excessive duration; (3) without adequate monitoring; (4) without adequate indications for use; or (5) in the presence of adverse consequences that indicate that the dosage should be reduced or discontinued.

Nursing homes' failure to comply with Federal standards regarding unnecessary drugs may affect their participation in Medicare because they would no longer be meeting their conditions of participation. However, nursing homes' noncompliance with these standards does not cause Medicare payments for the individual drug claims to be erroneous.

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Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes

For the 6-month review period, OIG determined that for more than 1 in 5 claims (or 317,971 of the 1.4 million Medicare claims), atypical antipsychotic drugs were administered in ways that did not meet CMS standards for drug regimens in nursing homes. Forty-two percent of these claimed drugs did not comply with CMS standards for more than one reason (e.g., the drug was in an excessive dose and for an excessive duration).

Failure to comply with CMS standards regarding unnecessary drugs may indicate that nursing homes are not adequately ensuring residents' health and safety. Our medical experts noted instances where nursing home beneficiaries were given antipsychotics to control symptoms like agitation without first receiving a workup to assess whether the symptom might be a sign of another treatable condition. For example, in one case, a workup of an agitated patient would have detected a urinary tract infection. Instead of properly diagnosing the urinary tract infection and treating it with antibiotics, the patient was given antipsychotic drugs to control the agitation.

The Vast Majority of Antipsychotic Drug Use in Nursing Homes Was Off-Label or Against Black Box Warning

FDA approves drugs based on scientific proof of safety and effectiveness for specific uses. If FDA determines that a drug's health benefits for its intended use outweigh its known risks, then it approves the drug for marketing for that use. After FDA approves a drug to be marketed for a specific use, then physicians are permitted to prescribe the drug for other uses. This practice is not uncommon and is referred to as off-label use. Medicare pays drug claims for off-label use, provided that the use is an accepted medical indication (i.e., supported by one or more citations in a designated compendia). However, although physicians may prescribe off-label, drug manufacturers are not permitted to promote off-label uses of their drugs.

FDA also reviews scientific evidence to determine what warnings a drug must carry. If a drug manufacturer or FDA determines that an approved drug may produce severe or life-threatening risks, then FDA requires that the manufacturer include a boxed warning (also referred to as a black-box warning) on the product's labeling to warn prescribers and consumers of these risks. Nevertheless, physicians are permitted to prescribe a drug for a patient with a condition specified in a boxed warning if such a treatment therapy is warranted in their clinical judgment. Atypical antipsychotic drugs carry a black-box warning emphasizing an increased risk of death when used in elderly people with dementia.

Some manufacturers have illegally marketed antipsychotics for patients with dementia

Despite the fact that elderly dementia patients who are treated with atypical antipsychotics face an increased risk of death, ample evidence exists that some drug companies have illegally marketed their products toward this vulnerable population for off-label uses. For example, with the sales slogan "5 at 5," Eli Lilly promoted its atypical antipsychotic, Zyprexa, for the treatment

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of elderly patients with sleep problems, behavioral issues, and dementia. The company directed its sales representatives to tell doctors that giving 5 milligrams of the drug at 5 pm would help their patients sleep. In January 2009, Eli Lilly agreed to plead guilty and paid \$1.4 billion for the illegal promotion of Zyprexa. Several other pharmaceutical companies have settled Government allegations that they improperly promoted their antipsychotic drugs for unapproved uses and/or have paid kickbacks to influence prescribing. Drug companies have paid more than a billion dollars to resolve civil and criminal liability for illegally marketing these drugs. Even after government action stops these illegal marketing campaigns, their effect on prescribing patterns may be long-lasting and difficult to undo.

Off-label use and use of atypical antipsychotics for patients with dementia were prevalent among nursing home residents

Based on a review of a sample of medical records by medical experts, OIG determined that 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were prescribed for off-label uses. Eighty-eight percent of atypical antipsychotic drugs claims were for residents with dementia, the condition specified in the boxed warning.

Physicians are permitted to prescribe drugs for off-label conditions or in the presence of the condition(s) specified in the FDA boxed warning. Such prescribing may be medically appropriate despite the risks – in fact, off-label prescribing is common for many classes of drugs.

However, our findings raise concerns. Through our enforcement and compliance monitoring activities, OIG has identified inappropriate use of psychotropic medications for nursing home residents as a risk area in at least two ways—inappropriate uses such as those identified through OIG’s work may violate the prohibition against inappropriate use of chemical restraints and the requirement to avoid unnecessary drug usage. OIG has issued guidance to nursing facilities on risks related to psychotropic medications (a category which includes antipsychotics).³ These risks include:

- use for staff convenience rather than providing appropriate non-pharmacological interventions;
- use without first determining the causal and contributing factors of the behavior;
- lack of specific and individualized care plans;
- lack of continued monitoring of the need for or the amount of the medication; and
- inappropriate admission of residents with mental health diagnoses that the facility is not prepared to treat.

In light of these risks, we recommended that nursing facilities ensure there is an adequate indication for the use of the medication and should carefully monitor, document, and review the use of each resident’s psychotropic drugs.

³ OIG’s Supplemental Compliance Program Guidance for Nursing Facilities is available online at: http://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf.

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Recommendations to Protect Nursing Home Patients From Unnecessary Drug Use

Medication therapy for nursing home residents is often complex. Many residents have multiple conditions that require management with multiple medications, as well as non-pharmacological interventions. Most physicians and nursing homes dispense antipsychotic drugs with the best interests of patients in mind. Physicians are permitted to prescribe drugs for unapproved indications, even in light of a black-box warning, but should use their best clinical judgment to determine that the benefits outweigh the risks.

However, OIG has found that all too often, nursing home patients receive antipsychotic drugs in ways that violate Federal standards designed to prevent overmedication and inappropriate use.

To ensure the safety of this vulnerable population, CMS should:

- Consider enhancing claims data to ensure accurate coverage and reimbursement determinations. For example, adding diagnosis codes to drug claims would help determine whether the prescription is for a medically accepted indication and the claim is payable.
- Hold nursing homes accountable for unnecessary drug use through the survey and certification process.
- Explore other options, such as incentive programs and provider education, to promote compliance with quality and safety standards. For example, CMS could require nursing homes to reimburse the Part D program when claimed drugs violate these standards.

The Government must also continue to monitor the marketing of antipsychotics. Some drug manufacturers have promoted these drugs for off-label use by the elderly with dementia. These practices can violate the law and even if the drug company is fined, the pernicious influence of such marketing campaigns can be difficult to undo.

Doctors, pharmacists, and nursing homes must carefully analyze the patient's best interests when prescribing or dispensing antipsychotics. Families, in partnership with these medical professionals, can serve as a crucial support by learning about appropriate use, proper dosages, and possible side effects of these drugs.

My office continues to examine protections and quality of care for patients who are receiving antipsychotic drugs. The extensive prescribing of these drugs and the concerning case examples we have encountered in the course of this work raise serious questions about whether nursing home residents are receiving high-quality, coordinated care. To further explore this issue, we are currently conducting a new review that will determine whether nursing facility patients taking atypical antipsychotic drugs have received the required patient assessments and thorough care planning that Federal standards require.

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CONCLUSION

Over the next 18 years, 10,000 Americans will become newly eligible for Medicare each day. As the baby boomer population ages, it is imperative to address the overuse and misuse of antipsychotic drugs among nursing home patients. Thank you for your interest in this issue and for your support of OIG's mission.

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Department of Health and Human Services
**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ATYPICAL
ANTIPSYCHOTIC DRUG CLAIMS
FOR ELDERLY NURSING HOME
RESIDENTS**



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Office of Inspector General

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► EXECUTIVE SUMMARY

OBJECTIVES

To determine the extent to which, from January 1 through June 30, 2007:

1. nursing home residents aged 65 and older had Medicare claims for atypical antipsychotic drugs,
2. Medicare claims for atypical antipsychotic drugs for nursing home residents aged 65 and older were associated with off-label conditions and/or the condition specified in the Food and Drug Administration's (FDA) boxed warning,
3. claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria, and
4. claimed atypical antipsychotic drugs were administered in accordance with Centers for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes.

BACKGROUND

Senator Charles Grassley requested that the Office of Inspector General (OIG) evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs and the associated cost to Medicare. Senator Grassley expressed concern about atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions (i.e., conditions other than schizophrenia and/or bipolar disorder) and/or for residents with the condition specified in the FDA boxed warning (i.e., dementia).

FDA has approved the use of eight atypical antipsychotic drugs for the treatment of schizophrenia and/or bipolar disorder. Side effects associated with these drugs include increased risk of death in elderly persons with dementia. Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement. CMS sets standards to ensure that nursing home residents' drug therapy regimens are free from unnecessary drugs, such as drugs provided in excessive doses or for excessive durations.

We used Medicare claims data from Part B and Part D and the Minimum Data Set to identify Medicare claims and payments for atypical antipsychotic drugs for elderly (i.e., aged 65 and older) nursing

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home residents from January 1 through June 30, 2007. Using medical record documentation, medical reviewers completed a medical record review instrument to determine the extent to which these drugs were provided to residents diagnosed with conditions that were off-label and/or specified in the boxed warning and whether Medicare erroneously paid for these drugs. Based on medical reviewers' responses, we also determined whether drugs associated with these claims were provided in compliance with CMS standards for drug therapy in nursing homes.

FINDINGS

Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs. Of the 2.1 million elderly nursing home residents, 304,983 had at least 1 Medicare claim for an atypical antipsychotic drug from January 1 through June 30, 2007. Claims for elderly nursing home residents accounted for 20 percent of the total 8.5 million claims for atypical antipsychotic drugs for all Medicare beneficiaries during the review period. Claims for these residents amounted to \$309 million.

Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions; 88 percent were associated with the condition specified in the FDA boxed warning. Using medical reviewers' responses, we determined that, during the review period, almost 1.4 million atypical antipsychotic drug claims were for elderly nursing home residents diagnosed with conditions that were off-label and/or were specified in the boxed warning. Physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of the condition(s) specified in the FDA boxed warning.

Fifty-one percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were erroneous, amounting to \$116 million. For the period of January 1 through June 30, 2007, we determined from medical record review that over 726,000 of the 1.4 million atypical antipsychotic drug claims for elderly nursing home residents did not comply with Medicare reimbursement criteria. The claimed drugs were either not used for medically accepted indications as supported by the compendia or not documented as having been administered to the elderly nursing home residents.

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Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes. For the 6-month review period, we determined using medical record review that 317,971 Medicare claims (\$63 million) were associated with atypical antipsychotic drugs that were not administered according to CMS standards for drug regimens in nursing homes. Nursing homes' noncompliance with these standards (e.g., providing drugs in excessive doses or for excessive durations) does not cause Medicare payments for these drugs to be erroneous because the payments are made on behalf of the residents, not the nursing homes. However, failure to comply with CMS standards may affect nursing homes' participation with Medicare.

RECOMMENDATIONS

To ensure that payments for atypical antipsychotic drugs are correct and that elderly nursing home residents are free from unnecessary drugs, we recommend that CMS:

Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.

Assess whether survey and certification processes offer adequate safeguards against unnecessary antipsychotic drug use in nursing homes.

Explore alternative methods beyond survey and certification processes to promote compliance with Federal standards regarding unnecessary drug use in nursing homes.

Take appropriate action regarding the claims associated with erroneous payments identified in our sample.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on the draft report, CMS shared the concern of OIG and Congress over whether atypical antipsychotics and other drugs are being appropriately prescribed for elderly nursing home residents. CMS concurred with the second, third, and fourth recommendations; however, CMS did not concur with the first recommendation and expressed several general concerns with the report.

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In response to the second recommendation, CMS concurred and stated that it has already assessed and made improvements to the survey and certification process. However, CMS acknowledged that other efforts are needed in combination with onsite surveys to achieve the progress desired to safeguard nursing home residents against unnecessary antipsychotic drug use.

Regarding the third recommendation, CMS concurred but did not believe the examples provided in the report to be practicable (excluding provider education). CMS stated that it continues to explore alternative strategies within its statutory authority that more directly address the financial incentives in contractual agreements among drug manufacturers, long term care (LTC) pharmacies, LTC facilities, and consultant pharmacists in nursing homes.

Regarding the fourth recommendation, CMS concurred and will consider what actions need to be taken when the claims data are received from OIG.

In response to the first recommendation, CMS did not concur, stating that diagnosis information is not a required data element of pharmacy billing transactions nor is it generally included on prescriptions. OIG recognizes that the industry has not developed a standardized way of collecting diagnosis information for prescription drugs. However, without access to diagnosis information, CMS cannot determine the indications for which drugs were used. For this reason, CMS is unable, absent a medical review, to determine whether claims meet payment requirements.

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OBJECTIVES

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3. claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria, and
4. claimed atypical antipsychotic drugs were administered in accordance with Centers for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes.

BACKGROUND

Senator Charles Grassley requested that the Office of Inspector General (OIG) evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs. For this evaluation, we are using the term "atypical antipsychotic drugs" for second-generation antipsychotic drugs developed to treat psychoses and/or mood disorders. Senator Grassley was specifically concerned about atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions (i.e., conditions other than schizophrenia and/or bipolar disorder) and/or for residents with the condition specified in the FDA boxed warning (i.e., dementia). Moreover, Senator Grassley was concerned about whether Medicare is paying for drugs that may not be in the best interest of elderly nursing home residents.

Atypical antipsychotic drug use by elderly nursing home residents has also been an issue in law enforcement activities. For example, in November 2009, the United States reached a \$98 million settlement with Omnicare, Inc. (a long-term care (LTC) pharmacy), to resolve allegations that it received kickbacks to recommend drugs, including Risperdal (an atypical antipsychotic), for use in nursing homes. In January 2010, the Department of Justice filed suit against the manufacturer of Risperdal and two subsidiaries alleging that the

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companies paid kickbacks to Omnicare, Inc., to induce it to purchase and recommend Risperdal and other drugs for use in nursing homes.¹ The United States has entered into settlements with the manufacturers of several other atypical antipsychotic drugs to resolve allegations that the manufacturers promoted their drugs for uses that were not approved by FDA and were not reimbursable under Federal health care programs. The marketing of atypical antipsychotic drugs was outside the scope of this evaluation.

The OIG mission is to protect the integrity of Department of Health & Human Services (HHS) programs and the health and welfare of the beneficiaries of those programs. In fulfilling this mission, OIG has conducted numerous studies examining the correctness of Medicare payments and the care of program beneficiaries residing in nursing homes. This study supports the OIG mission in that it seeks to identify vulnerabilities, detect waste and abuse, and promote efficiency and effectiveness in HHS programs. More specifically, this study addresses ongoing concerns regarding claims for atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning. Further, this study seeks to address OIG-identified top management challenges for HHS with regard to the integrity of Federal health care program payment methodologies and quality of care by seeking to identify claims for atypical antipsychotic drugs that were paid in error or not in accordance with standards regarding their use in nursing homes.

FDA Drug Approval, Including Atypical Antipsychotic Drugs

FDA has approved eight atypical antipsychotic drugs: Aripiprazole, Clozapine, Olanzapine, Olanzapine/Fluoxetine, Paliperidone, Quetiapine, Risperidone, and Ziprasidone.² At the time of our review, FDA had approved all of these drugs for use in the psychiatric treatment of schizophrenia and/or bipolar disorder.³

All drugs have benefits and risks. Risks can range from less serious (e.g., an upset stomach) to permanent and potentially life threatening

¹ United States ex rel. Lisitza and Kammerer v. Johnson & Johnson, et al., Civil Action Nos. 07-10288-RGS and 05-11518 RGS (D. Mass.).

² These are the generic names for these drugs.

³ FDA, *Drug Approvals List*. Accessed at <http://www.fda.gov> on February 22, 2008. At the time of our review, one of the eight atypical antipsychotic drugs was also approved to treat autism.

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(e.g., liver damage).⁴ If FDA determines that a drug's health benefits for its intended use outweigh its known risks, then FDA approves the drug for marketing for that use.⁵

Risks associated with the use of atypical antipsychotic drugs that apply to all persons and are included in product labeling include, but are not limited to: neuroleptic malignant syndrome, a life-threatening nervous system problem; tardive dyskinesia, a movement problem; high blood sugar and diabetes; and low blood pressure resulting in dizziness and possibly fainting. For a complete description of approved uses and risks of the eight FDA-approved atypical antipsychotic drugs at the time of our review, see Appendix A.

Off-Label Drug Use

After FDA approves a drug to be marketed for a specific use, physicians are permitted to prescribe that drug for other uses. This is commonly referred to as off-label use.

Off-label use is not uncommon. A 2006 study in the *Archives of Internal Medicine* found that off-label uses accounted for 21 percent of prescriptions written in 2001.⁶ Specific to atypical antipsychotic drugs, a 2007 Agency for Healthcare Research and Quality (AHRQ) report listed the most common off-label uses: the treatment of agitation in dementia, depression, obsessive-compulsive disorder, posttraumatic stress disorder, personality disorders, Tourette's syndrome, and autism.⁷ Additionally, a 2009 study examining antipsychotic drug use among patients in the Department of Veterans Affairs health care system found that 60.2 percent of the individuals who received an antipsychotic drug had no record of a diagnosis for which these drugs are FDA approved (i.e., the drug was used off-label).⁸

⁴ FDA, *Side Effects: Questions and Answers*. Accessed at <http://www.fda.gov> on November 12, 2009.

⁵ FDA, *Approved Drugs: Questions and Answers*. Accessed at <http://www.fda.gov> on December 30, 2009.

⁶ D.C. Radley, S.N. Finkelstein, and R.S. Stafford, "Off-Label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine*, Vol. 166, 2006, pp. 1021–1026.

⁷ AHRQ, *Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics* (07-EHCO03-EF), January 2007.

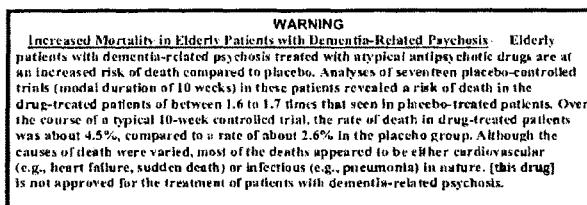
⁸ D.L. Leslie, S. Mohamed, and R.A. Rosenheck, "Off-Label Use of Antipsychotic Medications in the Department of Veterans Affairs Health Care System," *Psychiatric Services*, Vol. 60, No. 9, 2009, pp. 1175–1181.

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FDA's Boxed Warning

If drug manufacturers and/or FDA determine during the approval process or after a drug has been approved for marketing that the drug may produce severe or life-threatening risks, FDA requires that drug manufacturers include a boxed warning (also referred to as a black-box warning) on the product's labeling to warn prescribers and consumers of these risks.^{9, 10} Physicians are not prohibited from prescribing a drug in the presence of the condition(s) specified in the boxed warning.

In April 2005, FDA issued a public health advisory for atypical antipsychotic drugs.¹¹ FDA required manufacturers of these drugs to include a boxed warning regarding the increased risk of mortality when these drugs are used for the treatment of behavioral disorders in elderly patients with dementia. See Figure 1 for an example of a boxed warning.

Figure 1. Example of a Boxed Warning

Boxed warning taken from an FDA-approved atypical antipsychotic drug label. For the purposes of this report, OIG removed the name of the drug in this boxed warning.

Additionally in 2006, FDA revised its patient information sheets specific to each of the eight atypical antipsychotic drugs. These patient information sheets summarize the most important information specific

⁹ In 2006, FDA revised its regulations governing the content and format of labeling for drugs. 71 Fed. Reg. 3922 (Jan. 24, 2006). For categories of drugs described under 21 CFR § 201.56(b)(1), see the section entitled "boxed warnings" at 21 CFR § 201.57(c)(1) and the implementation schedule at 21 CFR § 201.56(c). For categories of drugs described under 21 CFR § 201.56(b)(2), see the section entitled "warnings" at 21 CFR § 201.80(e).

¹⁰ FDA, *An FDA Guide to Drug Safety Terms*. Accessed at <http://www.fda.gov> on December 29, 2009.

¹¹ FDA noted that mortality for elderly demented patients with behavioral disorders treated with atypical antipsychotics increased 1.6–1.7 times compared to mortality for those treated with a placebo. FDA, *Public Health Advisory: Deaths With Antipsychotics in Elderly Patients With Behavioral Disturbances*, April 2005. Accessed at <http://www.fda.gov> on February 22, 2008.

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to each drug, including risks and potential side effects. Among the risks and potential side effects listed for all eight atypical antipsychotic drugs is the increased chance of death in elderly persons. See Appendix B for an example of a patient information sheet for one of the eight atypical antipsychotic drugs.

Medicare Reimbursement Criteria for Drugs

Atypical antipsychotic drugs that are provided to Medicare beneficiaries, including those residing in nursing homes, are covered by both the Medicare Part D and Part B programs. Since January 1, 2006, most outpatient prescription drugs for Medicare beneficiaries and dually eligible beneficiaries (i.e., beneficiaries eligible for both Medicare and Medicaid) have been covered through Medicare Part D, which was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹²

For drugs to qualify for Medicare Part D reimbursement, the Medicare *Benefit Policy Manual* and the *Prescription Drug Benefit Manual*¹³ require that drugs be used for medically accepted indications.^{14, 15}

These indications include both the uses approved by FDA and those uses, including off-label, supported by one or more of three compendia: (1) the American Society of Health System Pharmacists, Inc.'s, *American Hospital Formulary Service Drug Information*; (2) the *United States Pharmacopeia-Drug Information* (or its successor publications);

¹² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 (Dec. 8, 2003).

¹³ CMS, *Medicare Benefit Policy Manual* (Internet-Only Manual), Pub. 100-02, ch. 15, § 50.4. CMS, *Medicare Prescription Drug Benefit Manual* (Internet-Only Manual), Pub. 100-18, ch. 6, § 10.6.

¹⁴ CMS, State Medicaid Director Letter, *Release #141*, May 4, 2006.

¹⁵ Medicare reimbursement criteria regarding medically accepted indications apply to all Part D drugs with the exception of anticancer drugs. The Medicare Improvements for Patients and Providers Act, or MIPPA, expanded the definition of medically accepted indications for anticancer drugs, effective January 1, 2009, to include drugs used in an anticancer chemotherapeutic regimen even if supported solely by peer-reviewed medical literature.

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and (3) Thomson Reuters' *DrugDEX Information System*.^{16,17} Hereinafter these are collectively referred to as the compendia.

For drugs to qualify for Medicare Part B reimbursement, the Medicare *Benefit Policy Manual*¹⁸ specifies conditions for coverage of drugs that are administered in an outpatient setting (e.g., physician's office).

CMS Standards Regarding Drug Use in Nursing Homes

As a condition for participation in Medicare, nursing homes must comply with Federal nursing home quality and safety standards.¹⁹ State agencies ensure that these standards are met through the State survey and certification process. For more information regarding the State survey and certification process, see Appendix C.^{20, 21} One standard requires that nursing home residents' drug regimens be free from what CMS terms unnecessary drugs.²² CMS defines unnecessary drugs as those that are used:

- in excessive dose,
- for excessive duration,
- without adequate monitoring,
- without adequate indications for use, and/or

¹⁶ The Social Security Act (the Act) § 1927(g)(1)(B)(i). 42 U.S.C. 1396r-8(g)(1)(B)(i). The compendia described at the Act § 1927(g)(1)(B)(i) are incorporated into the Part D definition of "medically accepted indication" through the Act § 1860D-2(e)(4)(A)(ii), 42 U.S.C. 1395w-102(e)(4)(A)(ii), which refers to the Act § 1927(k)(6), which, in turn, refers to the Act § 1927(g)(1)(B)(i).

¹⁷ Thomson Reuters' *DrugDEX Information System* is hereinafter referred to as *DrugDEX*.

¹⁸ CMS, *Medicare Benefit Policy Manual* (Internet-Only Manual), Pub. 100-02, ch. 15, § 50.

¹⁹ 42 CFR § 488.3(a)(2) (incorporating 42 CFR pt. 483).

²⁰ The Act § 1864(a), 42 U.S.C. 1395aa, directs the Secretary of HHS to use the help of State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards.

²¹ CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(l), Unnecessary Drugs.

²² 42 CFR § 483.25(l)(1).

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- in the presence of adverse consequences²³ that indicate that the dosage should be reduced or discontinued.²⁴

Nursing homes' failure to comply with Federal standards regarding unnecessary drugs may affect their participation in Medicare because they would not be meeting their conditions for participation.²⁵

However, Medicare drug reimbursement policy does not consider payments erroneous when claimed drugs are administered by nursing homes that fail to comply with standards regarding unnecessary drug regimens (e.g., providing drugs in excessive doses or for excessive durations), because drug claims are paid by or on behalf of individual residents, not nursing homes.²⁶

CMS requires that nursing home residents who have not previously taken antipsychotic drugs, including atypical antipsychotic drugs, not be given these drugs unless the drug therapy is necessary to treat a specific condition as diagnosed and documented in the medical record.²⁷ CMS also requires that nursing homes administering antipsychotic drugs ensure that the residents receive gradual dose reductions and behavioral interventions in an effort to discontinue these drugs unless such measures are clinically contraindicated.^{28, 29}

²³ An adverse consequence is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities.

²⁴ 42 CFR § 483.25(l)(1).

²⁵ Generally, see 42 CFR Part 488. More specifically, see 42 CFR § 488.406 listing available remedies in addition to termination of the provider agreement and 42 CFR § 488.414 describing actions that must be taken when there are repeated surveys with "substandard quality of care," as defined in CFR § 488.301.

²⁶ Medicare prescription drug insurance covers both brand-name and generic prescription drugs. As in other insurance policies, beneficiaries generally pay a monthly premium, which varies by plan, and a yearly deductible. Beneficiaries also pay a part of the cost of prescriptions, including a copayment or coinsurance. Everyone with Medicare is eligible for this coverage, regardless of income and resources, health status, or current prescription expenses. *Prescription Drug Coverage: Basic Information*, April 2, 2009. Accessed at <http://www.medicare.gov> on May, 10, 2010.

²⁷ 42 CFR § 483.25(l)(2)(i).

²⁸ 42 CFR § 483.25(l)(2)(ii).

²⁹ CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, §483.25(l) Unnecessary Drugs (describing circumstances under which gradual dose reduction is clinically contraindicated).

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Related Studies

A 2001 OIG study assessed the extent and nature of psychotropic drug use in nursing homes; that study included four of the eight atypical antipsychotic drugs.³⁰ The study determined that psychotropic drug use in nursing homes was generally appropriate according to CMS guidelines.

A January 2007 AHRQ report assessed the off-label use of atypical antipsychotic drugs. AHRQ found that all of these drugs increase the risk of death for elderly persons with dementia.³¹

Additionally, CMS issued a data analysis brief in June 2009 reporting that 3 of the top 10 drugs paid for by Medicare Part D in 2006 were atypical antipsychotic drugs. The brief cautioned that Part D data do not provide information about the diagnosis associated with the claimed drug, only that a pharmacy indicated that the drug was dispensed.³²

METHODOLOGY**Scope**

This study included nursing home residents aged 65 or older, hereinafter referred to as elderly nursing home residents, with claims for atypical antipsychotic drugs billed to Medicare Part D and/or Part B from January 1 through June 30, 2007. This study excluded payments for atypical antipsychotic drugs provided under the Medicare Part A Prospective Payment System for short-term stays in skilled nursing facilities.³³

We included elderly nursing home residents eligible for Medicare services, either as Medicare-only residents or those eligible for both Medicare and Medicaid services (i.e., dually eligible residents). Although we included dually eligible residents, we did not review Medicaid claims for atypical antipsychotic drugs. Elderly nursing home

³⁰ OIG, *Psychotropic Drug Use in Nursing Homes* (OEI-02-00-00490), November 2001.

³¹ AHRQ, *Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics* (07-EHCO03-EF), January 2007.

³² CMS, *Data Analysis Brief: Medicare Part D Utilization Trends for Atypical Antipsychotics: 2006-2008*, June 2009. Accessed at <http://www.cms.hhs.gov> on November 9, 2009.

³³ For skilled nursing facility stays of 100 days or less, prescription drug costs are included in the case-mix adjusted per diem Prospective Payment System rates covered by Part A. These costs were excluded from our analysis because they are not individually quantifiable based on claims data.

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residents not eligible for Medicare benefits (i.e., Medicaid-eligible-only residents or those covered solely by private pay) were excluded from this study.

Further, while this study evaluated the extent to which claims for atypical antipsychotic drugs met Medicare reimbursement criteria and determined whether these drugs were provided in accordance with CMS standards regarding unnecessary drug use, this study did not evaluate the medical decisions used to determine each resident's treatment. This study did not evaluate the conduct of drug manufacturers and/or LTC pharmacies with regard to atypical antipsychotic drugs. This study also did not evaluate nursing home survey and certification processes, including those used to review nursing homes' compliance with standards regarding unnecessary drug use.

Data Sources

Identifying atypical antipsychotic drug claims. From CMS, we obtained Medicare Part D Prescription Drug Event (PDE) data and Part B program data containing only final action claims for the period January 1 through June 30, 2007.³⁴ We used drug codes³⁵ associated with atypical antipsychotic drugs from these data to identify claims for atypical antipsychotic drugs.

From each of these claims, we matched the Health Insurance Claim Number to the Medicare Enrollment Database to identify Social Security numbers (SSN) for all Medicare beneficiaries with claims for these drugs. Medicare allowed 8.5 million claims for atypical antipsychotic drugs for all Medicare beneficiaries from January 1 through June 30, 2007.

Identifying elderly nursing home residents with antipsychotic drug claims. From CMS, we obtained 2007 Minimum Data Set (MDS) data for all nursing home residents. We used the nursing home admission and discharge dates in the MDS to identify beneficiaries residing in nursing homes at any time during our 6-month review period. We then identified elderly nursing home residents by date of birth. We

³⁴ PDE records may be amended or deleted up to 6 months after the end of the payment year. After that point, CMS considers them to be final action claims. Final action claims data include all adjustments.

³⁵ Drug codes included in Part D are National Drug Codes and drug codes included in Part B are Healthcare Common Procedure Coding System codes. See Appendix D for detailed methodology regarding drug codes.

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determined that 2,158,801 elderly beneficiaries resided in nursing homes at some time during our study period.

To identify elderly nursing home residents with atypical antipsychotic drug claims, we matched the SSNs from the data match described above when identifying atypical antipsychotic drug claims against the SSNs in MDS data. We identified 1,678,874 Part D and Part B claims for atypical antipsychotic drugs for elderly nursing home residents during the review period.³⁶

Data Stratification and Sample Selection

We used available diagnosis codes³⁷ to identify diagnoses for each elderly nursing home resident with claims for atypical antipsychotic drugs.³⁸ Using these data, we stratified claims based on whether the data indicated that the beneficiaries lacked an FDA-approved condition³⁹ for the drug associated with each claim (i.e., the drug was used off-label) and/or whether the beneficiaries had been diagnosed with dementia (i.e., the drug was used in the presence of the condition specified in the boxed warning).

The four strata are as follows:

- an FDA-approved condition and no dementia (i.e., the drug was used neither for an off-label condition nor in the presence of the condition specified in the boxed warning);
- an FDA-approved condition and dementia (i.e., the drug was used in the presence of the condition specified in the boxed warning only);
- no FDA-approved condition and no dementia (i.e., the drug was used for an off-label condition only); and
- no FDA-approved condition and dementia (i.e., the drug was used for both an off-label condition and in the presence of the condition specified in the boxed warning).

³⁶ We identified 1,678,441 Part D and 433 Part B claims for atypical antipsychotic drugs.

³⁷ Because Part D data do not include diagnosis codes, we used the following claims data from 2006 and 2007 to identify the diagnoses: MDS data; Medicare Part B physician and outpatient claims; and Medicare Part A home health, hospice, inpatient, and skilled nursing facility claims. See Appendix D for a more detailed methodology regarding diagnosis codes.

³⁸ We matched the beneficiaries' Health Insurance Claim Numbers and SSNs across MDS and Part A and Part B claims data to identify diagnosis codes.

³⁹ For the purposes of this report, an FDA-approved condition is a medical indication for which the FDA had approved the use of a drug at the time of our review period.

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The intent of this stratification was to enable us to determine whether the presence or absence of the conditions indicated in the strata affected compliance with Medicare reimbursement criteria and CMS standards regarding unnecessary drug use in nursing homes.

We selected a random sample of 175 claims from each of the 4 strata, for a total of 700 claims. This included oversampling by 100 claims (25 in each stratum) to account for nursing homes we might choose not to contact because of ongoing OIG investigations and nonrespondent nursing homes. Table D-1 in Appendix D shows the sample size and corresponding population of claims for each stratum.

Medical Record Review and Data Analysis

We consulted with a medical record review contractor to select board-certified psychiatrists knowledgeable in the prescribing of atypical antipsychotic drugs for the elderly (hereinafter referred to as medical reviewers). The contractor hired the medical reviewers to review requested documentation from residents' medical records and complete a medical record review instrument for each record.

We developed a letter to request documentation from the nursing home in which each resident lived at the time of the sampled claim.⁴⁰ The contractor sent this letter to each nursing home up to three times at predetermined intervals to obtain the requested documentation. For information about the specific documentation requested, see Appendix D.

We instructed the medical record review contractor to provide to the medical reviewers the first 150 complete records received for each stratum, for a total of 600 records.⁴¹ Therefore, our projections are based only on those claims for which medical review was conducted (600 of the 700 sampled claims) and will not equal the known universe of claims (1.7 million) during the study period. Although a nonresponse analysis showed statistically significant differences between the types of nursing homes from which claims were and were not reviewed, additional analysis found no statistically significant evidence that the results presented in our findings were biased because of nonresponse (see Appendix E).

⁴⁰ Nursing home contact information was obtained through MDS and Online Survey Certification and Reporting data.

⁴¹ Appendix D explains requirements for a medical record to be considered complete.

I N T R O D U C T I O N

Using the medical record documentation, medical reviewers completed a medical record review instrument for OIG to determine whether the claimed drug was used for an off-label condition and/or in the presence of the condition specified in the boxed warning, and whether the claim met Medicare reimbursement criteria. Based on medical reviewer responses, we also determined whether claimed drugs were administered in accordance with CMS standards regarding unnecessary drug use in nursing homes. We determined claims for drugs to be erroneously paid if they were undocumented⁴² or did not meet Medicare reimbursement criteria regarding medically accepted indications supported by the compendia. For detailed information regarding the use of the compendia in this study, see Appendix D. Medicare claims for drugs not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes were not considered erroneously paid.

In many cases, medical reviewers determined that documentation from the medical records supported diagnoses that were different from those listed in the data sources we used for stratification. For the purposes of our analyses and findings in this report, we used the diagnoses determined by medical reviewers and not the diagnoses indicated in claims data. See Table D-2 in Appendix D. Although we found no statistically significant differences in error rates among the strata, we did find differences in error rates among the diagnosis groups identified by medical reviewers. Appendix D explains these differences and error rates.

Limitations

Medical reviewers reviewed only the documentation provided by nursing homes. Medical reviewers did not conduct in-person observations of the residents, interview the residents or clinical staff, or conduct a pharmacist's medication regimen review.⁴³

⁴² Claims were undocumented if the medical record documentation provided by the nursing facility did not support the resident's receipt of the drug associated with the sampled claim.

⁴³ A pharmacist's medication regimen review is a thorough evaluation of a beneficiary's medication regimen, with the goal of promoting positive outcomes and minimizing adverse consequences associated with drugs. CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(l), Unnecessary Drugs.

I N T R O D U C T I O N

DrugDEX is an electronically created and maintained system in which quarterly updates replace older versions. We consulted several sources to obtain historical copies of *DrugDEX*, including CMS, FDA, the Library of Congress, and the National Institutes of Health, but none of these sources possessed a version that covered our review period. Therefore, we used the 2008 version of *DrugDEX*, which was the version we could access that most closely covered our review period.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

► FINDINGS

Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs

From January 1 through June 30, 2007, 304,983 (14 percent) of the 2.1 million elderly nursing home residents had at least 1 Medicare

claim for an atypical antipsychotic drug. Claims for elderly nursing home residents accounted for 20 percent (1,678,874) of the 8.5 million atypical antipsychotic drug claims for all Medicare beneficiaries during the review period. Table 1 provides an overview of the number of Medicare claims and dollar amounts for elderly nursing home residents by atypical antipsychotic drug from January 1 through June 30, 2007.

Table 1: Number of Medicare Claims and Amount for Each Atypical Antipsychotic Drug (January 1 through June 30, 2007)

Generic Drug Name	Claims	Amount
Quetiapine	627,661	\$85,847,131
Risperidone	536,600	\$87,161,507
Olanzapine	356,695	\$94,055,067
Aripiprazole	83,756	\$29,565,887
Ziprasidone	44,681	\$10,067,477
Clozapine	27,294	\$1,691,718
Olanzapine/Fluoxetine	1,521	\$431,799
Paliperidone	666	\$207,731
Total	1,678,874	\$309,028,317

Source: OIG analysis of Medicare Part B and Part D claims data, 2009.

The total dollar amount for atypical antipsychotic drug claims for elderly nursing home residents during the review period was \$309 million, with an average dollar amount of \$184 per claim. The average dollar amount for a 1-day supply of these drugs was \$7.26. Dollar amounts ranged from \$4.53 to \$13.28 per claimed drug, depending on the drug. Further, 17 percent of elderly nursing home residents with claims for atypical antipsychotic drugs had claims for more than one of these drugs during the review period.

F I N D I N G S

Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions; 88 percent were associated with the condition specified in the FDA boxed warning

For the 6-month review period, we determined through medical record review that 83 percent (1,197,442) of atypical antipsychotic drug claims were for elderly nursing home residents

diagnosed with conditions for which the drugs' use was not approved by FDA (i.e., the drugs were used off-label). Eighty-eight percent (1,263,641) of the drug claims were for residents diagnosed with dementia (the condition specified in the FDA boxed warning). In total, 95 percent (nearly 1.4 million) of Medicare claims for atypical antipsychotic drugs were for elderly nursing home residents diagnosed with off-label conditions and/or the condition specified in the boxed warning. Physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of the condition(s) specified in the boxed warning.

Table 2 provides an overview of the number and percentage of Medicare claims for atypical antipsychotic drugs used for off-label conditions and/or in the presence of the condition specified in the boxed warning. For point estimates and confidence intervals for selected statistics, see Appendix F.

Table 2: Number and Percentage of Medicare Claims for Atypical Antipsychotic Drugs (January 1 Through June 30, 2007)

Indication for Use of Claimed Drug	Number of Claims	Percentage of Reviewed Claims
For off-label conditions	1,197,442	83.1%
In the presence of the condition specified in the FDA boxed warning	1,263,641	87.7%
For off-label conditions and in the presence of the condition specified in the FDA boxed warning	(1,088,260)	(75.5%)
For off-label conditions and/or in the presence of the condition specified in the FDA boxed warning	1,372,823	95.3%
Neither for off-label conditions nor in the presence of the condition specified in the FDA boxed warning	68,277	4.7%
Total reviewed (net)	1,441,100*	100.0%
Records not reviewed	237,744	n/a
Total claims	1,678,874	n/a

Source: OIG medical record review analysis, 2009.

*Projection is based only on reviewed records for reviewed claims and will therefore not equate with the population size listed in Table 1.

F I N D I N G S

Medical reviewers determined that elderly nursing home residents who were prescribed atypical antipsychotic drugs for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning commonly had mental health conditions that required treatment, such as depression, dementia, psychosis not otherwise specified, and/or Alzheimer's disease. Additionally, 89 percent (1,216,823) of these residents exhibited symptoms that presented one or more of the following: a danger to themselves or others, significant inconsolable or persistent distress, a significant decline in functioning, or substantial difficulty in receiving needed care. Medical reviewers also expressed that it is not uncommon for atypical antipsychotic drugs to be used in nursing homes off-label for troublesome emotions or behaviors (e.g., anxiety, depression, complaining, or mild agitation) that may also exist in normal life.

Fifty-one percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were erroneous, amounting to \$116 million

For the 6-month review period, we determined using medical record review that over 726,000 of the 1.4 million claims for atypical

antipsychotic drugs did not comply with Medicare reimbursement criteria. The claimed drugs were either not used for medically accepted indications as supported by the compendia (50.2 percent of claims) or not documented as having been administered to elderly nursing home residents (0.3 percent of claims). Using the results of the medical record review, we evaluated only the extent to which claimed drugs met Medicare reimbursement criteria; we did not evaluate the clinical appropriateness of these drugs. Table 3 outlines the number and percentage of Medicare claims with dollar amounts for atypical antipsychotic drugs paid in error.

F I N D I N G S

Table 3: Erroneous Medicare Claims for Atypical Antipsychotic Drugs (January 1 Through June 30, 2007)

Reason for Error	Number of Claims	Percentage of Claims	Amount
Claimed drug not documented*	3,808	0.3%	\$559,333
Claimed drug not for medically accepted indications	722,975	50.2%	\$115,919,685
Total errors	726,783	60.5%	\$116,479,018

Source: OIG medical record review analysis of nursing home records, 2009.

*Undocumented claims are included only for the purposes of completing the table. There were only three undocumented claims in the sample, which is too few to calculate a 95-percent confidence interval for the projections.

Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes

For the 6-month review period, we determined from medical record review that 317,971 of the 1.4 million claims were associated with drugs that were not administered according to CMS

standards for drug therapy in nursing homes, which CMS terms unnecessary drug use. Claims for these drugs represent approximately \$63 million. Nursing homes' failure to comply with CMS standards for drug therapy in nursing homes may affect their participation in Medicare. However, nursing homes' noncompliance with these standards does not cause Medicare payments for these drugs to be erroneous. Forty-two percent of claimed drugs did not comply with CMS standards for more than one reason (e.g., the drug was in an excessive dose and for an excessive duration). Table 4 outlines the number and percentage of Medicare claims with dollar amounts for atypical antipsychotic drugs that did not meet CMS standards.

F I N D I N G S

Table 4: Medicare Claims for Atypical Antipsychotic Drugs Determined Unnecessary According to CMS Standards (January 1 Through June 30, 2007)

Reason Drug Did Not Meet CMS Standards	Number of Claims	Percentage of Claims	Amount
In excessive dose	150,106	10.4%	\$36,050,851
For excessive duration	135,199	9.4%	\$29,369,213
Without adequate indication(s) for use	115,818	8.0%	\$21,396,226
Without adequate monitoring	110,949	7.7%	\$18,150,616
In the presence of adverse consequences that indicate that the dosage should be reduced or discontinued	67,923	4.7%	\$11,479,869
Total (gross)*	579,994	40.2%	\$116,446,775
(Overlapping)	(262,023)	(16.2)%	(\$53,251,792)
Total (net)*	317,971	22.1%	\$63,194,984

Source: OIG medical review analysis of nursing home records, 2009.

*Totals may not sum exactly because of rounding.

Medical reviewers noted that some nursing homes that failed to comply with CMS standards regarding unnecessary drugs may not adequately ensure nursing home residents' health and safety. For example, a medical reviewer noted the following for a beneficiary who received an atypical antipsychotic drug without adequate indications for use: "It clearly seems like [the antipsychotic drug] was ineffective in treating her agitation. Since her agitation was associated with infection and pain, more efforts could have been placed on treating those conditions."

► R E C O M M E N D A T I O N S

We evaluated Medicare claims for atypical antipsychotic drugs from January 1 through June 30, 2007, and found that 14 percent of the 2.1 million elderly nursing home residents had at least 1 claim for these drugs. We determined through medical record review that 83 percent of claims were associated with atypical antipsychotic drugs used for off-label conditions and 88 percent with those used in the presence of the condition specified by the FDA boxed warning. While physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of conditions specified in an FDA boxed warning, Medicare will pay only for drugs that are used for medically accepted indications approved by FDA or supported by the compendia. Using medical record review, we also determined that 50 percent of claims did not meet these conditions, amounting to \$116 million. We further determined through medical record review that 22 percent of the atypical antipsychotic drugs associated with the sampled claims did not comply with CMS standards regarding unnecessary drugs in nursing homes, amounting to \$63 million. Nursing homes' failure to comply with these standards may affect their participation in Medicare. However, nursing homes' noncompliance with these standards does not cause Medicare payments for the individual drug claims to be erroneous.

To ensure that payments for atypical antipsychotic drugs are correct and that elderly nursing home residents are free from unnecessary drugs, we recommend that CMS:

Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations

Enhanced claims data could improve CMS's ability to enforce criteria for Medicare drug coverage and reimbursement and to determine whether a drug is covered by Medicare. For Part D claims, expansion of the required data elements to include diagnosis codes could help drug plan sponsors and CMS ensure that a drug meets the definition of a Part D-covered drug (i.e., is used for an FDA-approved indication or a medically accepted indication supported by the compendia). CMS should also consider what other claims data enhancements would facilitate ensuring accurate claims processing and program oversight.

R E C O M M E N D A T I O N S

Assess whether survey and certification processes offer adequate safeguards against unnecessary antipsychotic drug use in nursing homes

If any survey and certification processes are determined ineffective, CMS should develop improved mechanisms to ensure that all elderly nursing home residents are protected from unnecessary drugs.

Explore alternative methods beyond survey and certification processes to promote compliance with Federal standards regarding unnecessary drug use in nursing homes

Possible methods include provider education and incentive programs. Moreover, CMS should consider strategies to prevent Medicare payments for drugs by the Part D program and beneficiaries when those drugs were administered in violation of Federal standards. For example, CMS may want to consider making nursing homes responsible for reimbursing the Part D program when claimed drugs violate the CMS standards regarding unnecessary drug use.

Take appropriate action regarding the claims associated with erroneous payments identified in our sample

We will forward information on these claims to CMS in a separate memorandum.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on the draft report, CMS shared the concern of OIG and Congress over whether atypical antipsychotics and other drugs are being appropriately prescribed for elderly nursing home residents. CMS concurred with the second, third, and fourth recommendations; however, CMS did not concur with the first recommendation and expressed several general concerns with the report.

In response to the second recommendation, CMS concurred and stated that it had already assessed and made improvements to the survey and certification process. However, CMS acknowledged that other efforts are needed in combination with onsite surveys to achieve the progress desired to safeguard nursing home residents against unnecessary antipsychotic drug use, including efforts to address the financial incentives for unnecessary drug use. OIG recognizes CMS's previous efforts to improve the detection of unnecessary drug use through the survey and certification processes; however, OIG recommends that CMS

R E C O M M E N D A T I O N S

use its authority through the survey and certification processes to hold nursing homes accountable when unnecessary drug use is detected.

Regarding the third recommendation, CMS concurred but did not believe the examples provided in the report to be practicable (excluding provider education). CMS stated that although it can improve provider education in this area, establishing incentive programs and preventing Medicare drug payments and nursing home reimbursement are beyond its statutory authority. However, CMS stated that it continues to explore alternative strategies within its statutory authority that more directly address the financial incentives in contractual agreements among drug manufacturers, LTC pharmacies, facilities, and consultant pharmacists in nursing homes. OIG suggests that CMS either use its existing authority or seek new statutory authority to prevent payment and hold nursing homes responsible for submitting claims for drugs that are not administered according to CMS's standards regarding unnecessary drug use in nursing homes.

Regarding the fourth recommendation, CMS concurred and will consider what appropriate actions need to be taken when the claims data are received from OIG.

In response to the first recommendation, CMS did not concur, stating that diagnosis information is not a required data element of pharmacy billing transactions nor is it generally included on prescriptions. OIG recognizes that the industry has not developed a standardized way of collecting diagnosis information for prescription drugs. However, without access to diagnosis information, CMS cannot determine the indications for which drugs were used. For this reason, CMS is unable, absent a medical review, to determine whether claims meet payment requirements.

CMS also expressed a number of concerns regarding the report background and findings. Specifically, CMS was concerned about the nature of the contractual arrangements involving LTC facilities, LTC pharmacies, LTC consultant pharmacies, and drug manufacturers and/or distributors and the incentives such arrangements provide for inappropriate prescribing practices that may adversely affect the health and safety of LTC residents. CMS expressed the opinion that the report's combining of off-label uses cited in the compendia and uses in contraindication of the boxed warning overstates inappropriate use of atypical antipsychotic drugs. Finally, CMS requested that Part D

R E C O M M E N D A T I O N S

formulary policies relating to antipsychotic medications be included in the final report.

In response, although we evaluated the extent to which atypical antipsychotic drugs were prescribed for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning, we did not examine the medical decisionmaking regarding why elderly nursing home residents were prescribed these drugs. Our report is based on a medical record review. We did not examine the influence of arrangements between various actors in the nursing home market on the use of atypical antipsychotic drugs. Therefore, our report cannot comment on the relationship, if any, between atypical antipsychotic drug use and contractual agreements involving LTC facilities, LTC pharmacies, LTC consultant pharmacies, and drug manufacturers and/or distributors. However, based on CMS's comments, we did add background information regarding law enforcement issues with atypical antipsychotic drugs.

In regard to CMS's concern that the report was overstating inappropriate drug use, the report states that off-label prescribing is permissible and not uncommon and that evaluating the medical appropriateness of prescribed drugs was outside the scope of this study. The report does not make any statements regarding inappropriate drug use, although it does identify erroneous payments for atypical antipsychotic drug claims that were erroneous because the claims did not comply with the Medicare payment policy (i.e., claimed drugs were not used for medically accepted indications as supported by the compendia or were not documented as having been administered to elderly nursing home residents). Specifically in response to the congressional request, we included data regarding drugs prescribed for off-label conditions and/or in the presence of the condition specified by the FDA boxed warning. In response to CMS's concern, we changed the finding statement to separately address those atypical antipsychotic drug claims associated with off-label conditions and those associated with the condition specified in the FDA boxed warning. We still present the combined total in the text of the finding.

Lastly, we did not include Part D formulary requirements in the report because we do not believe this information is germane to the report's criteria and methodology.

The full text of CMS's comments can be found in Appendix G.

► A P P E N D I X A

Food and Drug Administration-Approved Atypical Antipsychotic Drugs

Descriptions of each atypical antipsychotic drug listed below are drawn from the Food and Drug Administration's approved labels at the time of our review. The most common side effects listed are those that were considered to be reasonably associated with the use of the drug.

Aripiprazole (Abilify). Indicated for the treatment of schizophrenia and acute manic and mixed episodes associated with bipolar disorder. Side effects include, but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; increased body temperature; and difficulty swallowing. The most common side effects (incidence $\geq 10\%$) in adult patients in clinical trials were nausea, vomiting, constipation, headache, dizziness, akathisia, anxiety, insomnia, and restlessness.

Clozapine (Clozaril). Indicated for the treatment of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for experiencing suicidal behavior. Side effects include, but are not limited to: increased chance of death in elderly persons, agranulocytosis, seizures, heart problems including myocarditis, lowering of blood pressure, neuroleptic malignant syndrome, tardive dyskinesia, high blood sugar and diabetes, fever, blood clots in the lung, increased blood sugar, and liver disease. The most common side effects (incidence $\geq 5\%$) in clinical trials were: central nervous system complaints, including drowsiness/sedation, dizziness/vertigo, headache, and tremor; autonomic nervous system complaints, including excessive salivation, sweating, dry mouth, and visual disturbances; cardiovascular findings, including tachycardia, hypotension, and syncope; gastrointestinal complaints, including constipation and nausea; and fever.

Olanzapine (Zyprexa). Indicated for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and agitation associated with schizophrenia and bipolar I mania. Side effects include, but are not limited to: increased chance of death in elderly persons, neuroleptic malignant syndrome, tardive dyskinesia, high blood sugar and diabetes, strokes, low blood pressure seen as dizziness and possibly fainting, cardiac irregularities, seizures, liver problems, increased body temperature, and difficulty swallowing. The most common side effects (incidence $\geq 5\%$ and at least twice that for placebo) include: weight gain, dizziness, postural hypotension, constipation, personality disorder, akathisia, dry mouth, dyspepsia, increased appetite, somnolence, and tremor.

Olanzapine/Fluoxetine (Symbyax). Indicated for the treatment of depressive episodes associated with bipolar disorder. Side effects include, but are not limited to: suicidal thoughts or actions; increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; bleeding problems; sexual problems; mania; weakness, confusion, or trouble thinking caused by low salt levels in the blood; low blood pressure seen as dizziness and possibly fainting; cardiac irregularities; seizures; liver problems; increased body temperature; and difficulty swallowing. The most common side effects (incidence $\geq 5\%$ and at least twice that for placebo) include: disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, tremor, blurred vision, and weight gain.

Paliperidone (Invega). Indicated for the acute and maintenance treatment of schizophrenia. Side effects include, but are not limited to: increased chance of death and strokes in elderly patients with dementia; QT prolongation; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; dizziness and fainting caused by a drop in blood pressure; impaired judgment, thinking, or motor skills; overheating and dehydration; seizures; difficulty swallowing; suicidal thoughts or actions; persistent erection; fever; and bruising. The most common side effects (incidence $\geq 5\%$ and at least twice that for placebo) include: extrapyramidal symptoms, tachycardia, akathisia, somnolence, dyspepsia, constipation, weight gain, and nasopharyngitis.

Quetiapine (Seroquel). Indicated for the treatment of schizophrenia and both depressive episodes associated with bipolar disorder and acute manic episodes associated with bipolar I disorder. Side effects include, but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; cataracts; seizures; low thyroid; elevated cholesterol or triglycerides; liver problems; persistent erection; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence $\geq 5\%$ and at least twice that for placebo) in adults include: somnolence, dizziness, dry mouth, constipation, increase in alanine aminotransferase, weight gain, and dyspepsia.

Risperidone (Risperdal). Indicated for the treatment of schizophrenia and short-term treatment of acute manic or mixed episodes associated with bipolar I disorder. Side effects include but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; persistent erection; thrombotic thrombocytopenic purpura; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence $\geq 10\%$) include: somnolence, increase in appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, excessive saliva, constipation, fever, Parkinsonism, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash, akathisia, and dyspepsia.

Ziprasidone (Geodon). Indicated for the treatment of schizophrenia and acute agitation in people with schizophrenia. Side effects include, but are not limited to: dangerous problems with heart rhythm; increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; persistent erection; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence $\geq 5\%$ and at least twice that for placebo) include: somnolence, respiratory tract infection, extrapyramidal symptoms, dizziness, akathisia, abnormal vision, asthenia, and vomiting.

► A P P E N D I X B

**Example of the Food and Drug Administration Atypical
Antipsychotic Drug Patient Information Sheet**



Patient Information Sheet

{Generic drug name}
(marketed as {brand name})

This is a summary of the most important information about {drug name}. For details, talk to your healthcare professional.

What Is {drug name}?

- {Drug name} is in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs or unusual suspiciousness.
- {Drug name} is used to treat mixed or manic episodes in adults who have a condition called Bipolar I disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

What Are The Risks?

The following are the risks and potential side effects of {drug name} therapy. However, this list is not complete.

- **Increased chance of death in elderly persons.** Elderly patients treated with atypical antipsychotics, such as {drug name}, for dementia had a higher chance for death than patients who did not take the medicine. {Drug name} is not approved for dementia.
- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD).** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- **Strokes** have happened in older patients treated for mental illness from dementia. {Drug name} is not approved for this use.
- **Other serious side effects** with {drug name} may include low blood pressure seen as dizziness, increased heart beat and

possibly fainting, seizures, increased body temperature, and difficulty swallowing.

- **The most common side effects** may include headache, weakness, nausea, vomiting, constipation, anxiety, problems sleeping, lightheadedness (dizziness), sleepiness, restlessness and rash.

What Should I Tell My Healthcare Professional?

Before you start taking {drug name}, tell your healthcare professional if you:

- have or had heart problems
- have or had seizures
- have or had diabetes or increased blood sugar
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with {drug name} review all medications that you are taking with your healthcare professional, including those that you take without a prescription.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following:

- blood pressure medicines
- ketoconazole
- quinidine
- carbamazepine
- fluoxetine or paroxetine

Avoid drinking alcohol while taking {drug name}.

Is There Anything Else I Need to Know?

- {Drug name} may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how {drug name} affects you.
- It is important to avoid overheating and dehydration lower while taking {drug name}. {Drug name} may make it harder to lower your body temperature.

{Drug name} FDA Approved 2002
Patient Information Sheet Revised 09/2006



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@fda.hhs.gov

► A P P E N D I X C

Survey and Certification and Examples of Nursing Home Noncompliance Related to Unnecessary Drugs

To determine a nursing home's compliance with the unnecessary drug requirement, the Centers for Medicare & Medicaid Services (CMS) completes a review for unnecessary drugs through the nursing home's survey and certification process. The objectives of this review are to determine whether (1) each resident is administered only those drug(s) that are clinically indicated in the dose and for the duration to meet the resident's assessed needs; (2) nonpharmacological approaches or alternatives are used when clinically indicated; and (3) gradual dose reduction is attempted, unless clinically contraindicated. This review should also determine whether the nursing home, in collaboration with a drug's prescriber, is monitoring the effectiveness of drug(s) by identifying the parameters for drug monitoring or drug combinations that could pose a risk of adverse consequences. The review should also determine whether the nursing home, in collaboration with a drug's prescriber, recognizes and evaluates the onset or worsening of signs or symptoms or a change in condition to determine whether these effects may be related to a drug regimen and follows up as necessary.

Examples of noncompliance related to unnecessary drugs in nursing homes drawn from CMS's *State Operations Manual* are listed below:⁴⁴

Excessive Dose (Including Duplicate Therapy). Examples of noncompliance related to excessive dose include, but are not limited to: giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition without a documented clinically pertinent rationale; failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication (i.e., gradually reducing the dose); and failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

Excessive Duration. Examples of noncompliance related to excessive duration include, but are not limited to: (1) continuation beyond the manufacturer's recommended timeframes, the stop date or duration

⁴⁴ CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(f), Unnecessary Drugs.

A P P E N D I X C

indicated on the medication order, facility-established stop order policies, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice without documented clinical justification; and (2) continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit.

Inadequate Monitoring. Examples of noncompliance related to inadequate monitoring include, but are not limited to: failure to monitor the responses to or effects of a drug and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal or the emergence of an adverse consequence; failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; and failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences.

Inadequate Indications for Use. Examples of noncompliance related to use of a medication without adequate indications include, but are not limited to: failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using drug(s) for a specific resident; failure to provide a clear clinical rationale for continuing a drug that may be causing an adverse consequence; and initiation of an antipsychotic drug to manage distressed behavior without considering a possible underlying medical cause (e.g., urinary tract infection, congestive heart failure) or environmental or psychosocial stressor.

Adverse Consequences. Examples of noncompliance related to adverse consequences include, but are not limited to: failure to act (i.e., discontinue a drug, reduce the dose, or provide clinical justification for why the benefit outweighs the adverse consequences) upon a report of the risk for or presence of clinically significant adverse consequence(s).

Use of Antipsychotic Medications Without Gradual Dose Reduction and Behavioral Interventions, Unless Clinically Contraindicated. Examples of noncompliance related to this requirement include, but are not limited to: failure to attempt gradual dose reduction in the absence of identified and documented clinical contraindications, prolonged or indefinite antipsychotic use without attempting gradual dose reduction, and failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

▶ A P P E N D I X D

Detailed Methodology

Data Sources

Identifying Atypical Antipsychotic Drug Claims. We obtained final action claims for Medicare Part D program Prescription Drug Event (PDE) and Part B program data. The PDE data are not the same as individual drug claim transactions; they are summary extracts that document the final adjudication of a dispensing event using the Centers for Medicare & Medicaid Services-defined standard fields. However, because these data contain claim-level information, we refer to the PDE and Part B records collectively as claims for the purposes of this study.

Additionally, the Food and Drug Administration (FDA) identifies a drug product by using a National Drug Code (NDC), which is a unique, universal three-segment numerical product identifier for human drugs. NDCs are listed directly in PDE data and crosswalked through Healthcare Common Procedure Coding System (HCPCS) codes in Part B data. At the time of our review, 909 NDC and 11 HCPCS codes were associated with the 8 atypical antipsychotic drugs. We calculated dollar amounts for claims by adding the ingredient cost, dispensing fee, and sales tax for Part D claims and using the allowed payment amount for Part B claims.

Identifying Elderly Nursing Home Residents With Atypical Antipsychotic Drug Claims. We analyzed Medicare Part A inpatient and skilled nursing facility claims data to determine whether a beneficiary's nursing home stay was interrupted by an admission to a different medical facility (i.e., hospital) during our 6-month review period. If these data indicated that a resident was not in the nursing home as identified through the Minimum Data Set (MDS) data at the time of a drug claim, we excluded that beneficiary from our universe of elderly nursing home residents.

Identifying Elderly Nursing Home Residents' Diagnoses for Stratification. For purposes of this report, we identified diagnoses of interest (bipolar disorder, schizophrenia, and dementia) using the following indicators:

- ten fields for International Statistical Classification of Diseases and Related Health Problems (ICD-9) codes listed in Part A home health, hospice, inpatient, and skilled nursing facility claims and Part B outpatient claims;
- two fields for ICD-9 codes in Medicare Part B physician data;

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- five fields for ICD-9 codes in MDS data; and
- one specific data field in MDS data for each of the following: dementia, Alzheimer's disease, schizophrenia, and manic depression (i.e., bipolar disorder).

Requesting Medical Records. Documentation requested from nursing homes for each sampled elderly nursing home resident included:

- the first mental health or medical evaluation upon admission to the facility if the beneficiary was already receiving the drug at the time of admission, or
- the hospital discharge summary or evaluation if the drug was first administered during a hospital stay, or
- the evaluation immediately preceding the initiation of the drug if the drug was initiated at the facility.

Additional information requested included documentation for the 6 months prior to and after the date of the sampled claim: pharmacy review documents/drug utilization review forms; daily Medication Administration Records; resident care plans; history and physical notes; physician orders, progress notes, evaluations, and consults; nurses' progress notes; behavior monitoring notes/logs; social services records/notes; and MDS/Resident Assessment Protocol assessments.

A medical record was considered complete and forwarded to medical reviewers if (1) the nursing home provided the resident's date of admission to the facility and information regarding when the drug associated with the sampled claim was first administered to the resident and (2) all requested documents were received or the reason(s) for any missing requested documents were provided.

Identifying Medically Accepted Indications for Use of Atypical Antipsychotic Drugs. We identified the medically accepted indications from each of the three statutorily named compendia for the use of the eight atypical antipsychotic drugs included in our review.⁴⁵ If an indication was noted in

⁴⁵ At the time of our review, the three statutorily named compendia were: (1) the *American Hospital Formulary Service Drug Information*, (2) the *United States Pharmacopeia-Drug Information* (or its successor publications), and (3) the *DrugDEX Information System*. Prior to our review period, the *American Medical Association Drug Evaluations* was included in the list of statutorily named compendia but was incorporated into the *United States Pharmacopeia-Drug Information* in 1994 and discontinued in 1996.

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any of the three compendia for a drug, we included that indication on that drug's list of accepted indications.⁴⁶ Medically accepted indications identified from each compendium included both FDA-approved and off-label uses.

Data Analysis

Identifying Claimed Drugs That Met Medicare Reimbursement Criteria. We used the diagnosis determined by medical reviewers for each resident to determine whether the claimed drug met Medicare reimbursement criteria. We matched the resident's diagnosis to the list of medically accepted indications for the claimed drug that each resident received. If the resident's diagnosis was not found on the claimed drug's list of medically accepted indications, then the claimed drug did not meet Medicare reimbursement criteria. We determined claims for drugs to be erroneously paid if they were undocumented or did not meet Medicare reimbursement criteria.

Sampling Frame and Strata. We stratified claims based on whether the data indicated that the claimed drug was used off-label and/or in the presence of the condition specified in the boxed warning (see Table D-1).

Table D-1: Original Sampling Frame and Number of Claims in Each Stratum

Stratum	Stratum Definition (Diagnoses)	Claims (Population)	Claims (Sample)
1	FDA-approved condition* and no dementia	149,301	175
2	FDA-approved condition and dementia	510,725	175
3	No FDA-approved condition and no dementia	77,795	175
4	No FDA-approved condition and dementia	941,053	175
Total**		1,678,874	700

Source: Office of Inspector General (OIG) analysis of 2008 MDS and Medicare Part A, Part B, and Part D claims data. *For the purposes of this report, an FDA-approved condition is a medical indication for which FDA had approved the use of a drug at the time of our review period.

**The population figures are based on diagnosis data in the Medicare Part A and Part B claims and MDS system.

⁴⁶ We used the versions of the compendia published closest to our review period. We used the 2007 versions of *American Hospital Formulary Service Drug Information* and *United States Pharmacopeia-Drug Information*. We used the 2008 version of *DrugDEX*; see the Limitations section of this report for more information.

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Medical reviewers determined that elderly nursing home residents' diagnoses in the medical record were sometimes different from the diagnoses in the data sources we used for sample stratification (see Table D-2).

Table D-2: Sampling Frame With the Number of Claims in Each Diagnosis Group After Medical Reviewers Determined Diagnoses

Stratum	FDA-Approved Condition and No Dementia	FDA-Approved Condition and Dementia	No FDA-Approved Condition and No Dementia	No FDA-Approved Condition and Dementia	Claims (Medical Review)
1	54	19	50	27	150
2	6	49	5	90	150
3	2	1	76	71	150
4	0	3	4	143	150
Total	62	72	135	331	600

Source: OIG medical review analysis of nursing home records, 2009.

Determining Relationship of Diagnosis Groups to Error Rates. Our analysis identified differences in rates of payment error among the four diagnosis groups (see Table D-2 above). Because FDA-approved conditions are medically accepted indications, claims for atypical antipsychotic drugs prescribed to elderly nursing home residents diagnosed with such conditions were not considered errors. For the claimed drugs that were determined to be used off-label, 62 percent did not have medically accepted indications and were therefore in error.

Our analysis also identified differences in rates of compliance with CMS standards regarding unnecessary drugs among the diagnosis groups. The 34 percent of claims for drugs prescribed for residents who were not diagnosed with dementia were significantly more likely to comply with CMS criteria regarding unnecessary drugs than the 21 percent of claims for drugs prescribed for residents who were diagnosed with dementia (i.e., the condition specified in the FDA boxed warning).⁴⁷

⁴⁷ All references to error rates are statistically significant at the 95-percent confidence level.

 **A P P E N D I X E****Nonresponse Analysis**

We examined the potential for effects of nonresponse bias on key statistics. We analyzed how nonresponse of the 100 sampled claims for which medical review was not conducted may have affected our estimates used in this report.

For the purposes of this analysis, we considered all records that were not reviewed as nonrespondents. A total of 100 sampled claims did not receive medical review because 1 nursing home was under investigation, 39 provided the requested documentation after 150 records had already been received for the corresponding stratum, 21 did not provide sufficient records for review, 3 indicated that the beneficiary was not a resident at the time of the sampled claim, and 36 did not respond to our record request.

We compared reviewed claims to nonreviewed claims according to the following six variables: type of nursing home ownership, whether the nursing home was part of a chain, the nursing home's total number of beds, beneficiary age, beneficiary gender, and beneficiary race. We determined whether reviewed and nonreviewed claims differed statistically at the 95-percent confidence level on these variables and found only two statistically significant differences. Claims for residents in for-profit nursing homes were less likely to have been reviewed (83.1 percent) compared with not-for-profit (92.8 percent) and government (90.1 percent) nursing homes. Also, claims for residents in nursing homes that were part of a chain were less likely to have been reviewed (81.8 percent) compared with all other claims (90.0 percent).

Because claims for residents in for-profit nursing homes and in chain nursing homes were underrepresented in our sample, we investigated whether this might bias our results. To do this, we first classified the reviewed claims into six categories corresponding to the ownership and chain variables. Then we assigned the average of reviewed values to nonreviewed claims within the same ownership and chain categories. Finally, we determined whether estimates based on both reviewed actual values and nonreviewed imputed values differed significantly from the estimates based only on the reviewed values. Based on this analysis, we found no statistical evidence that our results were biased because of nonresponse.

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Point Estimates and Confidence Intervals for Selected Statistics

Description	Sample Size (n)	Point Estimate	95-Percent Confidence Interval
Percentage of claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (net)	600	95.3	94.0-96.5
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (net)	600	1,372,823	1,354,910-1,390,736
Percentage of claims for drugs used for off-label conditions	600	83.1	80.3-85.9
Claims for drugs used for off-label conditions	600	1,197,442	1,157,388-1,237,495
Percentage of claims for drugs used in the presence of the condition specified in the FDA boxed warning	600	87.7	85.6-89.8
Claims for drugs used in the presence of the condition specified in the FDA boxed warning	600	1,263,641	1,233,763-1,293,500
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (gross)	600	2,461,083	2,409,185-2,512,981
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (overlapping)	600	1,088,260	1,043,144-1,133,377
Percentage of claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (overlapping)	600	75.5	72.4-78.6
Percentage of claims for drugs used neither for off-label conditions nor in the presence of the condition specified in the FDA boxed warning (net)	600	4.7	3.5-6.0
Total claims for drugs neither off-label nor in the presence of the condition specified in the FDA boxed warning (net)	600	68,277	50,364-86,190
Total claims for which records were reviewed	700	1,441,100	1,379,118-1,492,003
Total claims for which records were not reviewed	700	237,774	186,871-299,756
Percentage of claims for elderly nursing home residents who exhibited symptoms that presented one or more of the following: a danger to themselves or others, inconsolable or persistent distress, a significant decline in functioning, and/or substantial difficulty in receiving needed care	535	88.6	85.3-91.9
Number of claims for elderly nursing home residents who exhibited symptoms that presented the conditions listed above	535	1,216,823	1,171,381-1,262,265
Total errors: percentage (net)	600	50.4	45.5-55.3
Total errors: dollar amount (net)	600	\$116,479,018	\$100,800,390-\$132,157,646
Total errors: claims (net)	600	726,782	655,956-797,608
Number of claims for undocumented drugs	600	3,807	0-9,868
Percentage of claims for undocumented drugs	600	0.3	0.0-0.7
Dollar amount for claims for undocumented drugs	600	\$559,333	\$0-\$1,318,866
Number of claims for drugs without medically accepted indication	600	722,975	652,242-793,706
Percentage of claims for drugs without medically accepted indication	600	50.2	45.3-55.1
Dollar amount for claims for drugs without medically accepted indication	600	\$115,919,685	\$100,243,543-\$131,595,627

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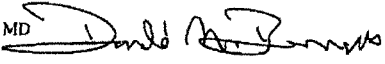
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Description	Sample Size (n)	Point Estimate	95-Percent Confidence Interval
Percentage of claims for drugs that did not comply with CMS* standards regarding unnecessary drug use in nursing homes (net)	600	22.1	17.8-26.3
Total claims for drugs that did not comply with CMS standards regarding unnecessary drug use in nursing homes (net)	600	317,971	257,214-378,729
Dollar amount for claims for drugs that did not comply with CMS standards regarding unnecessary drug use in nursing homes (net)	600	\$63,194,984	\$48,933,121-\$77,456,846
Percentage of claims for drugs determined to be unnecessary for more than one reason	149	42.4	31.7-53.3
Number of claims for drugs taken in excessive dose	600	150,106	107,499-192,713
Percentage of claims for drugs taken in excessive dose	600	10.4	7.4-13.4
Dollar amount for claims for drugs taken in excessive dose	600	\$36,050,851	\$24,142,398-\$47,959,303
Number of claims for drugs taken for excessive duration	600	135,199	91,706-178,692
Percentage of claims for drugs taken for excessive duration	600	9.4	6.4-12.4
Dollar amount for claims for drugs taken in excessive duration	600	\$29,369,213	\$17,510,089-\$41,228,337
Number of claims for drugs taken without adequate indications for use	600	115,818	75,136-156,500
Percentage of claims for drugs taken without adequate indications for use	600	8.0	5.2-10.8
Dollar amount for claims for drugs taken without adequate indications for use	600	\$21,396,226	\$13,220,119-29,572,334
Number of claims for drugs taken without adequate monitoring	600	110,849	69,948-151,950
Percentage of claims for drugs taken without adequate monitoring	600	7.7	4.8-10.5
Dollar amount for claims for drugs taken without adequate monitoring	600	\$18,150,616	\$10,772,976-\$25,528,257
Number of claims for drugs taken in the presence of adverse consequences	600	67,923	36,021-99,824
Percentage of claims for drugs taken in the presence of adverse consequences	600	4.7	2.5-6.9
Dollar amount for claims for drugs taken in the presence of adverse consequences	600	\$11,479,869	\$6,088,283-\$16,871,455
Total claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	579,994	437,574-722,414
Percentage of claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	40.2	30.4-50.1
Dollar amount for claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	\$116,446,775	\$84,276,682-\$148,616,869
Total claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	262,023	161,822-362,163
Percentage of claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	18.2	11.2-25.1
Dollar amount for claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	\$53,251,792	\$32,241,106-\$74,262,477

Source: Office of Inspector General medical review analysis of nursing home records, 2009.
 *CMS is the Centers for Medicare & Medicaid Services, and FDA is the Food and Drug Administration.

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Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Centers for Medicare & Medicaid Services
		Administrator Washington, DC 20201
<p>DATE: MAR 11 2011</p> <p>TO: Daniel R. Levinson Inspector General</p> <p>FROM: Donald M. Berwick, MD Administrator </p> <p>SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," (OEI-07-08-00150)</p> <p>Thank you for the opportunity to review and comment on the subject draft report "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents." The OIG study examined claims for the period January 1 through June 30, 2007. Specifically, the study determined the extent to which:</p> <ul style="list-style-type: none"> • Nursing home residents aged 65 and older had Medicare claims for atypical antipsychotic drugs; • Medicare claims for atypical antipsychotic drugs for nursing home residents aged 65 and older were associated with conditions off-label and/or specified in the Food and Drug Administration's (FDA) boxed warning; • Claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria; and • Claimed atypical antipsychotic drugs were provided in accordance with Center for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes. <p>The concern over whether atypical antipsychotics and other drugs are being appropriately prescribed to elderly nursing home residents is one we share with the OIG and Congress. In particular, we are very concerned about the nature of the contractual arrangements involving long-term care (LTC) facilities, LTC pharmacies, LTC consultant pharmacists, and pharmaceutical manufacturers and/or distributors, and the incentives such arrangements provide for inappropriate prescribing practices that may adversely affect the health and safety of LTC residents. Based on the November 2009 Omnicare settlement, the OIG identified these contractual relationships as the cause of the inducement to over-utilize antipsychotics in nursing</p>		

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homes, and we strongly believe this should be referenced in this report. We are very concerned that if an official OIG report ignores the causative behavior of the LTC pharmacies, and instead suggests that the problem is limited to a Medicare Part D claims payment issue, the issuance of this report may be used as a defense of the practice, and may seriously interfere with any future efforts of OIG, Department of Justice, and CMS to correct the fundamental problem.

Below is CMS response to the OIG recommendations and additional general comments:

General Comments on OIG Findings

The CMS has additional comments with regard to other study findings. The OIG found that 95 percent of Medicare claims associated with atypical antipsychotic drugs used off-label and /or against the FDA black-box warning. Although a member of Congress requested that the OIG evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs, the off-label uses that are cited in the compendia are still considered by law to be medically accepted indications. We believe that reporting these uses together with uses against the boxed warning incorrectly overstates inappropriate use.

The CMS requests that Part D formulary policies relating to antipsychotic medications be included in the final report. With few exceptions (such as brand/generic substitution), all antipsychotics must be on all Part D formularies. Further, Part D sponsors may not impose step therapy or prior authorization requirements for beneficiaries who are taking the drug. Part D sponsors are required to perform retrospective drug utilization reviews and are able to identify non-medically accepted uses through this mechanism.

OIG Recommendation

CMS facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.

CMS Response

We do not concur with OIG's recommendation. Currently, diagnosis information is not a required data element on pharmacy billing transactions nor is it generally included on prescriptions. As such, this information is not readily available to dispensing pharmacists.

The industry has not developed a standardized process to collect diagnosis related information as part of the prescription drug claim. Until such time as state boards of pharmacy require that this information be included on prescriptions, and the industry agrees upon an industry standard for reporting diagnosis-related information as part of the claim, CMS will not add any new data fields to the prescription drug event (PDE) elements until such data is useful and can be used to determine if Part D reimbursement was appropriate.

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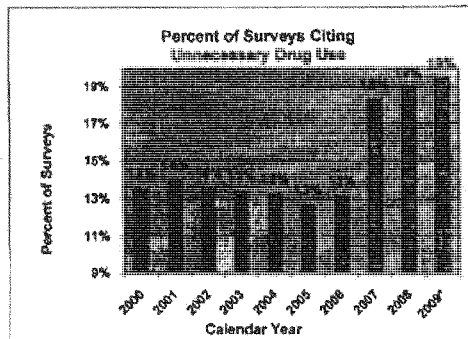
OIG Recommendation

CMS assess whether survey and certification processes offer adequate safeguards against unnecessary antipsychotic drug use in nursing homes.

CMS Response

We concur and have already assessed the survey & certification process and made improvements.

We have assessed survey & certification processes and in late 2006 implemented substantial improvements to the CMS onsite surveys, as described below. One result was a substantial increase in the number of deficiencies cited for unnecessary drug use. As shown in the following graph, the percent of onsite surveys in which the facility was cited for unnecessary drug use increased from 13 percent in 2003-2006 to 18 percent in 2007 and 19 percent in 2008-2009. We noted that the level of deficiencies identified through onsite surveys did not decrease after the reforms were implemented in late 2006, despite the added scrutiny and enforcement that CMS put in place. We therefore concluded that the survey process is pushing against very strong counter-forces, such as financial counter-forces, that require other actions to address the financial incentives for unnecessary drug use.



In September 2006, CMS released S&C Memorandum 06-29 which provided much more information regarding the issuance of Revised Surveyor Guidance for Unnecessary Medications (F329) and the entire Pharmacy Services section at §483.60. We combined current regulatory language into three tags (F425, F428, and F431) in Appendix PP of the State Operations Manual, as well as medication related revisions in Appendix P Task 5 and Sub-Tasks 5A, 5C, and 5E. The memo identified not only the changes to the guidelines and survey process, but also included information regarding training surveyors regarding these changes.

The CMS entirely revised interpretive guidelines for F329 (Unnecessary Medications), including clarifications of several aspects of medication management and a new medication table that includes medications that are problematic to the nursing home population. We provided an Investigative Protocol that also covers both Medication and Medication Regimen Review issues and severity guidance for F329. This guidance was developed with experts in the area of medications and with survey agency, nursing home advocates and nursing home provider input.

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For Pharmacy Services at §483.60, we combined regulatory guidance Tags F425-431 into three tags, F425 Pharmacy Services, F428 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. The guidance addresses the provision of pharmaceutical services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. In addition, we provided severity guidance for each of these F Tags. The guidance is available on the CMS Website - http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltrf.pdf at CFR 483.25(l) F329 – Unnecessary Drugs and CFR 483.60, F425 – F431 Pharmacy Services.

Training materials on these revisions were provided through various methods:

- Power point training materials;
- Two, two-day train-the-trainer sessions in Baltimore in November 2006; and
- A satellite presentation on F329 on December 15, 2006.

We believe that the surveyor guidelines and protocols provide effective direction for surveyors in determining the presence of an unnecessary medication, but that other efforts are needed in combination with onsite surveys to achieve the progress desired to also address the financial incentives for unnecessary drug use.

OIG Recommendation

CMS explore alternative methods beyond survey and certification processes to promote compliance with established Federal standards regarding unnecessary drug use in nursing homes.

CMS Response

CMS concurs with this recommendation, but do not believe the examples provided in the report are practicable (excluding provider education). The report recommendations suggest CMS adopt (1) provider education and incentive programs, (2) strategies to prevent Medicare payments, and (3) requirements for nursing homes to reimburse for claims not meeting CMS standards. Although CMS can identify opportunities to improve provider education in this area, the remaining recommendations (incentive programs, prevention of payment, and nursing home reimbursement) are beyond our statutory authority. CMS is, however, continuing to explore alternative strategies within our statutory authority that more directly address the financial incentives in contractual arrangements among pharmaceutical manufacturers, LTC pharmacies, facilities and consultant pharmacists that are responsible for the increased and unnecessary use of atypical antipsychotics by patients in nursing homes.

OIG Recommendation

CMS should take appropriate action regarding the claims associated with erroneous payments identified in the OIG's sample.

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CMS Response

CMS concurs and will consider what appropriate actions need to be taken when the claims data are received from the OIG.

Thank you for the opportunity to review and comment on the draft report.

► A C K N O W L E D G M E N T S

This report was prepared under the direction of Brian T. Pattison, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Deborah K. Walden, Deputy Regional Inspector General.

Amber Meurs served as the project leader for this study. Other principal Office of Evaluation and Inspections staff from the Kansas City regional office who contributed to the report include Julie Dusold and Rae Hutchison; central office staff who contributed include Robert Gibbons, Sandy Khoury, and Julie Taitsman.

STATEMENT OF

DR. PATRICK CONWAY

CHIEF MEDICAL OFFICER AND DIRECTOR, OFFICE OF CLINICAL STANDARDS AND
QUALITY

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

THE OVERUTILIZATION OF ATYPICAL ANTIPSYCHOTICS IN LONG-TERM CARE
SETTINGS

BEFORE THE

UNITED STATES SENATE SPECIAL COMMITTEE ON AGING

NOVEMBER 30, 2011

U.S. Senate Special Committee on Aging
Hearing on the Overutilization of Atypical Antipsychotics in Long-Term Care Settings
November 30, 2011

Chairman Kohl, Ranking Member Corker, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to improve dementia care and reduce the use of antipsychotic drugs for residents of nursing homes and other long-term care facilities. CMS is committed to ensuring that every Medicare and Medicaid beneficiary receives appropriate and high-quality health care, in every health care setting. I share your concerns about the potential for inappropriate use of these medications, and appreciate the Committee's efforts to bring attention to this important topic.

Background

All beneficiaries, including those with dementia, deserve high quality, patient-centered care. Without question, a dementia diagnosis presents a host of health and safety challenges for a patient and his or her family. Caring for individuals with Alzheimer's disease and related dementias is challenging for families, caregivers and our health care system, with 5.4 million Americans living with Alzheimer's disease today.¹ This number is expected to grow significantly as the Baby Boom generation ages, with estimates suggesting that as many as 16 million Americans will have the disease by 2050.² Nursing homes play an important role in providing care for those with dementia; any discussion of how to best improve the quality of health care for Alzheimer's and dementia patients must necessarily involve this component of the health care delivery system. According to the Alzheimer's Association, 75 percent of people with Alzheimer's will be admitted to a nursing home by age 80.³

While there is still much we do not understand about the causes, diagnosis, and treatment of Alzheimer's disease, there are concerns that the use of certain medications, including atypical antipsychotics, to treat the behavioral symptoms of Alzheimer's or other dementias may not be appropriate. CMS recognizes that a crucial component to improving the quality of care for

¹ http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf

² Ibid

³ Ibid

beneficiaries with dementia is eliminating the inappropriate or harmful use of medications. We share the concern of the Committee and others that some residents of nursing homes and other long-term care facilities are receiving antipsychotic medications that may have a detrimental impact on their health and safety. The Food and Drug Administration (FDA) has approved eleven atypical antipsychotic drugs for various indications, including the treatment of schizophrenia and the treatment of certain symptoms associated with bipolar disorder.⁴ The FDA has warned that antipsychotic medications are associated with an increased risk of death when used for the treatment of behavioral disorders in elderly patients with dementia, and requires manufacturers of these drugs to include in the drugs' labeling boxed warnings that discuss this risk.⁵ While these drugs are a critically important treatment for patients with certain mental health conditions, the "off-label" use, or the use of drugs for conditions other than those approved by the FDA, is also widespread.

Despite these warnings, evidence suggests that a significant number of elderly patients are receiving these medications. Recent work by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that 14 percent of elderly nursing home residents had Medicare claims for antipsychotic drugs in the first six months of 2007 and 83 percent of these claims were associated with off-label conditions.⁶ CMS has already taken steps to eliminate the inappropriate use of antipsychotic drugs in nursing homes, updating guidance relating to Survey and Certification of nursing homes to better measure and address potentially inappropriate prescribing. While the progress that has been made is encouraging, CMS continues to explore new ways to strengthen enforcement of current rules, eliminate conflicts of interest that may influence prescribing, and better educate providers, prescribers, and patients' families to eliminate inappropriate prescribing in nursing homes.

⁴ Approved atypical antipsychotic drugs are Aripiprazole, Asenapine Maleate, Clozapine, Iloperidone, Lurasidone, Olanzapine, Olanzapine/Fluoxetine, Paliperidone, Quetiapine, Risperidone, and Ziprasidone (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm>)

⁵ *Ibid.*

⁶ Department of Health and Human Services Inspector General, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," May 2011.

Survey and Certification Improvements

To help ensure that nursing homes meet both Federal and State standards, CMS conducts initial and ongoing inspections of all facilities participating in the Medicare or Medicaid program. This Survey and Certification process is an important tool in CMS' efforts to ensure that beneficiaries receive high quality health care and to monitor nursing home compliance with requirements relating to unnecessary drug use. In September 2006, CMS implemented substantial improvements to onsite surveys to help address these concerns. Specifically, CMS revised interpretive guidelines for unnecessary medications, including clarifying several aspects of medication management and developing a new medication table that includes medications that are problematic for nursing home populations. These Survey and Certification reviews are designed to determine whether residents receive only drugs that are clinically indicated in an appropriate dose and duration, whether non-pharmacological interventions are considered, and whether gradual dose reduction is attempted when clinically appropriate. Examples of noncompliance can include excessive dosing of medication, prolonged use of antipsychotic medications without attempting dose reduction, or failure to implement behavioral interventions to enable attempts to eliminate or reduce antipsychotic medication. This process is carefully balanced with the need to protect the ability of physicians to make a clinical decision on the use of atypical antipsychotics in patients with dementia, based on the needs of the individual patient.

Since the implementation of this guidance in December 2006, the percent of surveys with citations for unnecessary drug use has increased significantly. In the seven years prior to implementation of this change, 12.6 percent to 14.0 percent of facilities were cited for unnecessary drug use; this has grown to 18.2 percent in 2007 and 19.4 percent in 2009.⁷ Accurate detection is the first stage in identifying potential harm and eliminating it. We are in the process of determining how we could use this information to target educational programs and technical assistance to providers in States or regions with high citation rates or target surveys on low performers.

Providing appropriate care to beneficiaries with dementia is also more complex than simply avoiding the inappropriate use of medication. The guidance also requires providers to use non-

⁷ Federal Register, Volume 76, No. 196, October 11, 2011. Pg. 63039.

pharmacological interventions to help manage behavioral or other health issues. Possible interventions may include increasing exercise or time outdoors, monitoring for and managing acute and chronic pain, or planning individualized activities for beneficiaries.

CMS has also worked to ensure that as part of routine onsite reviews, Survey and Certification personnel have the tools and resources necessary to effectively monitor nursing homes' compliance with these policies. For example, offsite preparation in advance of the survey may include review of the rate of antipsychotic drug use for that facility. This enables surveyors to target specific residents, families and staff (including physicians), to interview during the survey.

Eliminating Conflicts of Interest for Long-Term Care Pharmacists

Despite the improvements CMS has initiated in the Survey and Certification process, CMS understands that the overuse of antipsychotics in nursing homes remains a serious problem. CMS is very concerned about the nature of contractual arrangements involving long-term care (LTC) facilities, LTC pharmacies, and LTC consultant pharmacists and the incentives these arrangements may provide for inappropriate prescribing practices. LTC facilities are required to employ or retain the services of a licensed pharmacist to consult on all aspects of pharmacy services, including a monthly review of each resident's drug regimen. This consultant pharmacist can notate a patient's medical record with recommendations for medication changes, and physicians frequently follow these recommendations. As a result, these consultant pharmacists can have significant influence over the drugs that many LTC facility residents receive.

CMS is concerned that various financial relationships and arrangements may provide incentives to these consultant pharmacists to make prescription recommendations with a possible negative impact on residents' health and safety. The practice of LTC pharmacies providing consultant pharmacists to nursing homes below cost or below fair market value is one such type of arrangement. We are concerned that these arrangements may also be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs.

Further, we are greatly concerned with any financial arrangement that involves payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists, which may be designed to increase use of the manufacturer's drugs. For example, the Department of Justice reached a \$98 million settlement with Omnicare, Inc. in November 2009, resolving allegations that it received kickbacks to recommend drugs, including an atypical antipsychotic, in nursing homes.⁸ Financial arrangements or payments from manufacturers have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations and may create perverse incentives for the LTC consultant pharmacist to make recommendations that are in conflict with the best interests of nursing home residents, as well as with Part D sponsors' formularies and/or drug utilization management programs. As a result, the arrangements bring into question the ability of the LTC consultant pharmacists to provide impartial reviews of the residents' drug regimens, which in turn raises concerns regarding the quality of those reviews and potential impact on resident health and safety.

Taking action to address these concerns, as part of the proposed changes to Medicare Advantage and Medicare Part D programs for contract year (CY) 2013 (CMS-4157-P), CMS is considering changes to the Conditions of Participation for Long-Term Care Facilities that would require LTC consultant pharmacists to be independent from LTC pharmacies, pharmaceutical manufacturers and distributors, or affiliates of these entities. Severing the relationship between consultant pharmacist and other pharmaceutical interests could help to protect LTC residents by assuring that prescription decisions are made free from the possible influence of financial arrangements. Although we outlined a specific approach under consideration and solicited comments on that approach, we are open to alternative solutions that address the conflict of interest we have identified. Consequently, we have requested comments on any alternative approaches that would reduce or eliminate this conflict of interest and potential overprescribing that exist in nursing homes today. CMS will carefully consider all comments that are made on this proposed regulation and evaluate them as plan guidance is developed for CY 2013. The comment period for the proposed rule closes on December 12, 2011.

⁸ Department of Health and Human Services Inspector General, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," May 2011. Page 1.

Ongoing CMS Initiatives to Improve Care for Patients with Alzheimer's or Dementia*Research and Quality Measures*

In addition to survey oversight and this potential change in LTC facilities' conditions of participation, CMS recognizes that eliminating improper use of medications and encouraging non-pharmacological approaches to care will require an ongoing, multifaceted approach. First, CMS is interested in a better understanding of the factors that influence prescribing practices in nursing homes, to help identify additional interventions that may be effective. To that end, we have awarded a new contract to conduct a study in 20 to 25 nursing homes that will evaluate nursing home decision-making related to the use of antipsychotic medications in dementia residents. Findings will be used to target and implement interventions to improve the overall management of residents with dementia, including reducing the use of antipsychotic drugs in this population.

CMS is also seeking to encourage the development of quality measures addressing antipsychotic medication use. Beneficiaries and their families should have access to clear information about nursing home performance, and providing this information through the Nursing Home Compare website or other means would help make this information more accessible.

Using Quality Improvement Organizations

Quality Improvement Organizations (QIOs) can also play an important role in ensuring the nursing homes' prescribing practices are medically appropriate. QIOs, under the auspices of the 10th Scope of Work, are working to reduce adverse drug events, including high risk beneficiaries taking short or long acting antipsychotics of any class. The QIO 10th Scope of Work includes a metric for quality improvement of patient care by reducing these adverse events, with a goal of reducing the number of beneficiaries who are taking long or short acting antipsychotic medication and are prescribed a potentially inappropriate medication by 25 percent from baseline at 18 months, with a final target reduction by at least half at the end of the three year period. The QIOs have a history of successfully working in quality improvement with nursing homes in the areas of physical restraints and pressure ulcers.

Improving Training and Education

CMS is also working to improve training for both providers and surveyors to emphasize non-pharmacological interventions for nursing home residents who do not have a diagnosis of psychosis or may not be candidates for atypical antipsychotic drugs. Under provisions in Section 6121 of the Affordable Care Act, CMS added language to the State operations manual to make dementia care and abuse prevention issues a mandatory part of annual training. Additionally, CMS is currently producing educational information DVDs for surveyors and providers regarding the care of residents with dementia that emphasize non-pharmacological interventions and approaches. These will be distributed to all nursing homes and State survey agencies. CMS is also working to improve surveyor skill at detecting unnecessary medication use in nursing homes by improving the curriculum for new surveyor training and strengthening surveyor interpretive guidance. Additionally, CMS is actively collaborating with several Federal partners, including the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Administration on Aging (AoA) to promote non-pharmacological behavioral interventions and staff and facility training to prevent the use of seclusion and restraint.

New Statutory Authorities

CMS is an active participant in the efforts of HHS to implement the National Alzheimer's Project Act (P.L. 111-375). This law requires the creation and maintenance of an integrated plan to overcome Alzheimer's, including coordination of research and service across agencies. As a part of these implementation efforts, the Department has convened a subgroup to examine issues relating to the long-term care supports and service needs for those with Alzheimer's, which will examine gaps in the current system of long-term care services and supports and develop priorities for the National Plan. The Department's work surrounding the National Alzheimer's Project Act will help to identify needs in our health care infrastructure and improve the quality of care that these patients receive.

Partnership with States and Stakeholders

Many of these efforts would not be possible without an ongoing commitment and partnership with stakeholders, including States, provider groups, and patient advocates. State officials and organizations are important partners in efforts to ensure that current rules and regulations are enforced. CMS is also interested in partnering with States that are taking innovative approaches

to this health challenge, to help identify and spread best practices more widely. For example, the State Survey Agency in Massachusetts convened a task force, including nursing homes, physicians, nurses, social workers, researchers, government agencies, advocates and consumers to address antipsychotic drug use and measure outcomes in the next one to two years. CMS is also funding work with the Illinois Survey Agency and Drug Control Program to use enhanced nursing home drug data to detect and monitor issues related to antipsychotic use in dementia residents.

CMS is also engaged in ongoing dialogue with several professional associations and consumer organizations, such as the American Medical Directors Association (AMDA) the American Society of Consultant Pharmacists (ASCP), the American Health Care Association (AHCA), LeadingAge, Consumer Voice and others to deliver educational programs for prescribers on eliminating or reducing the off-label use of antipsychotic drugs for nursing home residents with dementia. We are committed to working collaboratively with organizations such as these to accomplish our shared goal of eliminating inappropriate treatments for dementia.

Conclusion

CMS seeks to function as a major force and trustworthy partner for the continual improvement of health and health care for all Americans. As a practicing physician and son of a Medicare beneficiary, I personally take this commitment to serve and improve our health system very seriously. This commitment includes ensuring that all of our beneficiaries receive high-quality, safe, and appropriate care, at all times. For patients suffering from Alzheimer's or dementia, this involves comprehensive, behavioral health by an interdisciplinary team of geriatric professionals who are knowledgeable in the use of non-pharmacologic interventions and appropriate and judicious use of medication when indicated. While we have made significant strides in addressing over-medication, our commitment to continual improvement means that CMS will seek new approaches and partnerships to improve care for Americans with Alzheimer's and dementia.

I look forward to working with the Committee on this issue and to answering any questions you may have.



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UNITED STATES SENATE SPECIAL COMMITTEE ON AGING

Overprescribed: The Human and Taxpayers' Costs of Antipsychotics
in Nursing Homes

Testimony of Dr. Jonathan M. Evans, MD, MPH, FACP, CMD

November 30, 2011

I am a doctor who specializes in the care of frail older people. I have spent the last quarter century trying to learn about older people and improve their care through clinical practice, research, and education. I have treated many thousands of patients with dementia in many different care settings.

Although my remarks today are quite personal, I also represent AMDA—Dedicated to Long Term Care Medicine, the professional association for long term care physicians, an organization whose stated mission is to improve the quality of care through education. AMDA has worked hard to educate physicians in the principles and practice of medicine in long term care settings, to promote awareness of and compliance with federal regulation of nursing homes among physicians, to train and certify nursing home medical directors, and to promote and improve interdisciplinary patient-centered care.

My personal story is this: I practice mostly in nursing homes and other long term care settings. I am Medical Director of two skilled nursing facilities. I have been well educated by AMDA about federal regulations pertaining to physicians practicing in nursing homes, and I am quite conscious of those regulations when I provide care to patients as well as when I review the care provided by others. I do use antipsychotic drugs for ongoing treatment of patients with schizophrenia and bipolar disease living in nursing homes, many of whom previously lived in state mental hospitals that no longer exist, and who have little or no access to mental health services in the community. I do not prescribe antipsychotic drugs for treatment of agitation or other behaviors in patients with dementia and I know that the leadership of AMDA acknowledges the use of these medications in patients with dementia only as a last resort, and only when all else has been tried and failed, which is rare.

Nevertheless, I and other like-minded physicians feel tremendous pressure in all care settings to prescribe medication to make patients with dementia behave. Most of the time, this equates to chemically restraining the patient. This pressure most often comes from frustrated caregivers but also from family members who have been led by other healthcare professionals to believe that these drugs are essential. My desire to avoid or eliminate antipsychotic drug prescription for treatment of behavior in patients with dementia has at times put me at odds with facility staff, patient's families, and other healthcare professionals.

In approximately 20 years of providing geriatric consultation at some of the most prestigious American medical centers, my recommendations to reduce and eliminate antipsychotic and other medications in hospitalized patients whom I believed were experiencing adverse drug consequences were frequently ignored.

Moreover, in a number of instances over the last decade, psychiatrists providing consultation in nursing homes and assisted living facilities where I work have ordered antipsychotic drugs on my patients without my knowledge, and without the knowledge and consent of my patients and their family members.

As a consequence, I have chosen to focus my practice in facilities where I feel most comfortable. Even so, I routinely receive urgent requests from nursing and administrative staff and family members to prescribe antipsychotic medications including specific drugs by name. Studies have show that the use of antipsychotic drugs in patients with dementia varies several fold from facility to facility, and that higher prescribing rates are based upon the 'culture' of the facility, and not based upon patient characteristics such as the severity of their illness or their symptoms.

In taking on the care of new nursing home patients transferred from the hospital, many of whom receive a dozen or more prescription medications, I discontinue or reduce the dosage of some medication in almost every instance because of concerns about safety. The information that accompanies these patients from the hospital is often of extremely limited utility.

I also routinely discontinue antipsychotic drugs in elderly patients that have been admitted to my care, even though doing so may put me at odds with the doctor that prescribed them. These medications have often been started in the hospital for reasons that are unknown to me, my patients, and their families. I have seen antipsychotic drugs prescribed in hospitalized patients for use as sleeping pills.

Federal regulations regarding antipsychotic drugs, unnecessary medications, and chemical restraints do not apply to hospitals and assisted living facilities, nor do they apply to nursing facilities that do not accept Medicare or Medicaid payment. In fairness to nursing homes, the problem of overprescribing of antipsychotic drugs in elderly patients with dementia is by no means limited to nursing homes. In fact, according to Medicare claims data the majority of antipsychotic drug prescribing for elderly Medicare beneficiaries occurs outside of nursing home setting. Moreover, the quality of care by a number of measures is higher in nursing homes than in hospitals and other care settings where federal regulations do not apply. For example, you are far more likely to develop a pressure ulcer or be physically restrained in the hospital than in a nursing home. I do not believe that hospitals and the doctors who work there should be held to a lower standard.

Moreover, I do not believe that dementia, or even undesirable behavior in dementia in most instances is a drug deficiency (requires a medication or prescription).

There is a firm, fixed belief among many healthcare professionals that difficult or disruptive behaviors such as hitting, wandering, yelling, and agitation, are cause for medication and that medication is likely to be beneficial for that purpose. Very few people working in health care, including physicians, receive any training in understanding and responding to challenging behaviors by any means other than medication. In fact, few physicians practicing in this country today received any meaningful training in nursing homes and other long-term care settings during medical school or residency training.

Most doctors treat unwelcome behavior in hospitals, nursing homes, and other care settings as a disease that requires a medication to modify the symptoms. These drugs are used as chemical restraints. Consequently, if the use of antipsychotic drug is restricted, other sedating drugs with other adverse consequences will quickly take their place, as is already beginning to happen. In that regard, the concern should not be for the use of antipsychotic drugs alone, rather the concern should be to avoid any medication that affects brain function if its intended use is as a chemical restraint. Likewise, and even more importantly, the concern should be for improved dementia care in all settings that focuses on understanding behavior and its meaning, in order to meet the patient's own needs and goals. The use of medications to treat behavior creates unrealistic expectations and distracts caregivers from solving the underlying problems associated with undesirable behaviors.

I believe that behavior itself is not a disease. Simply put, behavior is communication. In people whose ability to communicate with words is limited (such as patients with dementia), communication tends to be more nonverbal (i.e. behavioral). Our challenge is to figure out what they are trying to say, and if they are in distress, to identify the underlying causes and precipitants. Many of the behaviors that are commonly observed in patients with dementia and that are often labeled as difficult, challenging, or bad, such as agitation, wandering, yelling, inappropriate urination, and hitting are typically reactive, almost reflexive behaviors that occur in response to a perceived threat or other misunderstanding among patients who by the definition of their underlying illness have an impaired ability to understand.

Moreover, all of the challenging behaviors exhibited by confused elderly patients in every health care setting across the country every day are identical to those behaviors observed among normal, healthy, very young children every day in day care centers and preschools across the country. While the behaviors are often the same, the expectations, and responses are often quite different, particularly in health care settings. What is necessary for caregivers is to try to figure out the meaning of the behavior- what are they trying to say? What are they responding to? And what is our behavior telling them?

Identifying underlying factors, such as pain, anxiety, a search for a familiar object, person or place may be invaluable in developing an appropriate response. Difficult behaviors in dementia typically represent a conflict between an individual and their environment- often the human environment. Health care environments are on the whole quite restrictive and generally inflexible. All patients seeking health care are expected to conform to the

environment. Patients with dementia often have trouble comprehending their environment, resulting in misperceptions that are often perceived as threats. In most instances, the key to behavior management in dementia is environmental modification, especially the human environment, which may be as simple as changing our approach and our response in order to prevent and minimize distress. The fundamental basis of health care is caring for others. The fundamental basis of caring is love, acceptance, and respect for persons.

AMDA believes in and promotes a multidisciplinary team approach to patient centered-care and is working with the Centers for Medicare & Medicaid Services (CMS) and the Pioneer Network to change the culture of health care in the United States. A minimum requirement of patient-centered care is informed consent. We strongly believe that patients and their families should be afforded sufficient information and dialogue to make appropriate treatment decisions regarding potentially harmful medications. Likewise we respect and agree with existing federal regulations regarding the avoidance of chemical restraints and unnecessary drugs.

We are developing core competencies for physicians in long term care. We believe in raising the bar for dementia care and helping dedicated and caring individuals to leap over that bar. We are working to educate and empower physician medical directors in long term care, to educate attending physicians, to develop strong relationships with patients and their advocates, and to support caregivers in long term care. We believe that these efforts will lead to the kind of health care quality we all want without increasing cost. We believe there is no substitute for good doctors spending the time their patients and families need to solve problems and relieve suffering. Doctors who are more often present and engaged in nursing facility care use fewer health care resources. Physician training does work to reduce antipsychotic drug prescribing. AMDA provides physician training on good dementia care at its annual symposium and other events and is working to provide more education and training to the entire interdisciplinary team. AMDA has had a representative working with CMS for the development of a training program for nurses aides in areas of care for persons with dementia and prevention of abuse.

We acknowledge that virtually every dollar of health care spending at some point occurred as a result of a physician's order. We also recognize that many worthy causes deserve funding that currently does not exist. Being a good physician therefore requires being a good steward of scarce resources and focusing on what works. What the money is spent on should be a reflection of what we value most as a society. What my colleagues and I value most is loving care.

Jonathan M. Evans, MD, MPH, FACP, CMD
Vice President, AMDA—Dedicated to Long Term Care Medicine

United States Senate
Special Committee on Aging

Testimony of Tom Hlavacek
Executive Director
Alzheimer's Association of Southeast Wisconsin

November 30, 2011

"The Overutilization of Atypical Antipsychotics in Long-term Care Settings"

Good afternoon Chairman Kohl, Ranking Member Corker and distinguished members of the Committee. I am Tom Hlavacek, Executive Director of the Alzheimer's Association of Southeast Wisconsin. Thank you for the opportunity to discuss the very serious problems that overutilization of atypical antipsychotics present for people with Alzheimer's disease, particularly those who reside in long-term care settings.

Today, there are an estimated 5.4 million Americans living with Alzheimer's disease; approximately 30 percent (1.8 million individuals) reside in long-term care or skilled nursing facilities. In 2010, approximately 110,000 Wisconsin residents had Alzheimer's disease. In 2008, of the 74,000 nursing home residents in Wisconsin, almost 70 percent had a cognitive impairment. During the course of their disease, many individuals living with Alzheimer's disease and related dementias will experience behavioral and psychotic symptoms. Depression, hallucinations, delusions, aggression, agitation, wandering, and "sundowning" are hallmark behavioral and psychotic symptoms of dementia (BPSD). Many of these symptoms are the impetus to falls, weight loss, infection, incontinence, and institutionalization for individuals with dementia.

Despite the severity and frequency of these symptoms, there is currently no FDA approved therapy used to treat BPSD. As a result, many types of medications, including atypical antipsychotics, have been used "off-label" in an attempt to mitigate these symptoms. In 2005, the FDA examined this issue and found that the use of atypical antipsychotics in people with dementia over 12 weeks helped to reduce aggression, but was also associated with increased mortality. Subsequently, the FDA issued a black box warning that requires physicians who prescribe antipsychotics to elderly patients with dementia-related psychosis to discuss the risk of increased mortality with their patients, patients' families, and caregivers. Research indicates these drugs also cause additional side effects including stroke, tardive dyskinesia, weight gain, diabetes, sedation, parkinsonism, and worsening of cognition. Thus they must be used with caution and at the lowest effective dose.

Recently, the Office of Inspector General released a report, *Medicare Atypical Antipsychotic Drugs Claims for Elderly Nursing Home Residents*, which found that 88 percent of the reviewed claims for atypical antipsychotic drugs were for elderly nursing home residents with dementia. The report's findings are of concern given the increased mortality risk and the federal regulations and surveyor guidance that specifies each nursing facility resident's drug regimen must be free from unnecessary drugs. The guidance also restricts the use of antipsychotic drugs for nursing facility residents, unless, based on a comprehensive assessment of a resident, the antipsychotics are necessary to treat a specific condition as diagnosed and documented in their clinical record. Instead, the Inspector General's report found that 22 percent of antipsychotic drugs claimed did not comply with CMS standards regarding

unnecessary drugs in nursing homes. The Alzheimer's Association strongly believes that non-pharmacologic approaches should be tried as the first-line alternative to pharmacologic therapy for treatment of BPSD.

Unfortunately, we have seen first-hand what can happen when an individual with dementia is prescribed antipsychotics without proper precautions. At the time of his death, Richard "Stretch" Petersen, a friend of Senator Kohl's, was an 80 year old gentleman with late stage dementia who exhibited challenging behaviors in a long-term care facility. After being at two hospitals in an effort to have his behaviors treated via antipsychotics, he was placed under emergency detention, and was transferred by police in a squad car in handcuffs to the Milwaukee County Behavioral Health Psychiatric Crisis Unit, where his family found him tied in a wheelchair with no jacket or shoes. In spite of his family's efforts to intervene and seek better care, he very quickly developed pneumonia, then was transferred to a hospital, and died. Richard Petersen worked hard all his life, raised his family, and contributed to his community in many ways. He did not deserve to die in the way he did.

Mr. Petersen's death was the latest in a series of incidents in Southeast Wisconsin brought to our attention regarding negative outcomes related to Alzheimer's behaviors. In response to this growing problem, the Alzheimer's Association of Southeast Wisconsin and other concerned stakeholders created the Alzheimer's Challenging Behaviors Task Force. The Task Force's goal is to review and try to resolve problems related to the involuntary commitment and treatment of people with dementia who exhibit challenging behaviors. Through our work, it became clear that everyone works in underfunded and understaffed systems of care, and are often without needed tools and resources.

Our Task Force investigations unfortunately concur with what is contained in the Inspector General's report. Locally, we found these drugs are often poorly prescribed, administered and monitored, leading to negative health outcomes for many persons with dementia. Through our work, we quickly found that negative outcomes were often associated with the relocation of individuals in and out of hospitals, mental health, and long-term care facilities; and a heavy reliance on atypical antipsychotics. In turn, these care transitions for people with dementia often exacerbate challenging behaviors and leads to negative outcomes. The Task Force also found that the use of antipsychotic drugs is often a default to compensate for broader systemic inadequacies in health and long-term care settings.

Rather than focusing on assigning blame, members came together with a willingness to improve care for people living with dementia. The Challenging Behaviors Task Force eventually included 115 members from all sides of the issue including law enforcement, courts, human services, legal advocacy, family caregivers, community and facility long-term care providers, and physicians and nurses from hospital systems. Much of the Task Force's success came from our members' "roll up your sleeves" attitude, which allowed us to publish *Handcuffed*. *Handcuffed* is intended to provide a basic understanding of challenging behaviors among people with Alzheimer's disease and approaches to addressing the problem in facilities and across systems. I have included our report for the record. I am also pleased to report the Task Force is engaged in a second year of activity.

The Task Force is one local example of how, for many years, the Alzheimer's Association has advocated for quality care in long-term care settings across the nation, including the reduction of inappropriate use of antipsychotics to address behavioral problems for individuals with dementia. Recently, the Alzheimer's Association's Board of Directors approved a position statement titled "Challenging Behaviors," which discusses the treatment of BPSD. The

Association maintains the position that non-pharmacologic approaches should be tried as a first-line alternative for the treatment of BPSD. Further, restraint therapies including long-term antipsychotics should be avoided in the treatment of behavioral and psychotic symptoms. Antipsychotic therapy should be utilized only after non-pharmacologic alternatives have been unsuccessful. In addition, antipsychotics must be used carefully and are most effective when combined with non-drug approaches to behavior management. The Association recommends training and education on psychosocial interventions for all professional caregivers. Specifically, the Alzheimer's Association believes "in making the decision to utilize antipsychotic therapy the following should be considered:

- *Identify and remove triggers for behavioral and psychotic symptoms of dementia: pain, under/over stimulation, disruption of routine, infection, change in caregiver, etc;*
- *Initiate non-pharmacologic alternatives as first-line therapy for control of behaviors;*
- *Assess severity and consequences of BPSD. Less-severe behaviors with limited consequences of harm to individual or caregiver are appropriate for non-pharmacologic therapy, not antipsychotic therapy. However, more severe or "high risk" behaviors such as frightening hallucinations, delusions or hitting may require addition of antipsychotic trial;*
- *Determine overall risk to self or others of BPSD, and discuss with doctor the risks and benefits with and without antipsychotics. Some behaviors may be so frequent and escalating that they result in harm to the person with dementia and caregiver that will in essence limit the life-expectancy and or quality of life of the person with Alzheimer's disease; and*
- *Accept that this is a short-term intervention that must be regularly re-evaluated with your health care professional for appropriate time of cessation."*

A copy of this position statement has been included for the record.

The Alzheimer's Association strongly believes one mechanism for assessing and responding to behavioral symptoms, as well as improving overall care for residents in long-term care settings, is to raise the level of expertise of nursing facility staff through training and education. To that end, the Alzheimer's Association developed two dementia care training programs specifically for staff in the nursing facility setting: *Foundations of Dementia Care* and the *CARES Program*. Both of these training programs have been identified by the CMS Survey and Certification Group as options for nursing facilities to satisfy the requirements of Section 6121 of the Affordable Care Act, which calls for dementia care training for certified nurse aides (CNAs) working in nursing homes.

The *Foundations of Dementia Care* program provides direct care staff and supervisors with an understanding of dementia and individual resident needs. This training is classroom-based and can be customized to address the needs of each nursing facility, including meeting relevant state regulations. The *CARES Program* is an online training program that provides a variety of modules designed to provide comprehensive dementia education. A new module, *CARES Dementia-Related Behavior*, focuses on non-pharmacologic strategies for reducing or eliminating challenging behaviors. Since the *CARES Program* is an online, modular program, nursing facility staff can be trained as individual schedules permit, rather than in large groups. This allows nursing facilities to mitigate scheduling issues that could otherwise complicate coordinating staff training. Local Alzheimer's Association chapters across the country are excellent resources for these and other training programs to enhance care and support for persons with dementia and caregivers.

Lastly, the Alzheimer's Association *Dementia Care Practice Recommendations for Assisted Living Residences and Nursing Homes* were developed six years ago from the latest evidence in dementia care research and the experience of professional direct care experts. More than twenty organizations supported the recommendations that can improve the care and quality of life for individuals with dementia who reside in these facilities. These recommendations are the basis for every aspect of our Campaign for Quality Residential Care, which establishes standards of dementia care to improve quality of life for people with dementia living in long-term care settings.

Recently, the Alzheimer's Association has participated in discussions with the Centers for Medicare and Medicaid Services (CMS) on the challenges of inappropriate prescribing of antipsychotics in long-term care facilities. These discussions highlighted a variety of reasons that caring for individuals with dementia who experience behavioral and psychotic symptoms is challenging. We look forward to continued dialogue with the Committee, as well as CMS, to promote quality dementia care for all nursing home residents, especially for individuals, exhibiting challenging behaviors.

On behalf of the Alzheimer's Association, I would like to thank the Committee for the opportunity to testify on this important issue. The Alzheimer's Association is committed to ensuring people with dementia have access to high quality care, and as such strongly believes that non-pharmacologic approaches should be tried as the first-line alternative for treatment of behavioral and psychotic symptoms for dementia residents. Chairman Kohl and Ranking Member Corker, we greatly appreciate the opportunity to address this issue and look forward to working with the Committee in the future.

CHALLENGING BEHAVIORS

QUESTIONS

- Are antipsychotic medications an acceptable therapy for the treatment of behavioral and psychotic symptoms of dementia (BPSD)?
- Do non-pharmacologic alternatives to antipsychotics help in the treatment of BPSD?

BACKGROUND

Individuals living with dementia may experience behavioral and psychotic symptoms (BPSD) during the course of their disease due to the alteration in processing, integrating and retrieving new information that accompanies dementia. Studies have found that more than 90 percent of people with dementia develop at least one BPSD with a significant percentage of these individuals having serious clinical implications.

Depression, hallucinations, delusions, aggression, agitation, wandering and "sundowning" are hallmark behavioral and psychotic symptoms of dementia, commonly manifested in moderate-to-severe stages of disease. These symptoms cause considerable caregiver stress, and frustration is often the breaking point prior to institutionalization in long-term care facilities. Many of these (BPSD) are also the impetus to falls, weight loss, infection and incontinence in individuals with dementia.

Given the severity and frequency of these symptoms and lack of Food Drug Administration (FDA) approved drug treatment of BPSD, many classes of drugs (antipsychotics, antidepressants, anticonvulsants) have been utilized off-label to treat these distressing features of dementia. No drug class has been utilized as often for BPSD, and shown such benefit in short-term use, as antipsychotic drugs.

The FDA weighed in on the use of atypical (second generation) antipsychotics in the treatment of BPSD and found that treatment of behavioral disorders in elderly persons with dementia by antipsychotic medications was associated with increased mortality. This was based on evidence of 17 placebo-controlled trials over a 6-to-12-week period showing significant benefit in aggression over 12 weeks; however, there was a 1.6-1.7 increased risk for mortality in the antipsychotic versus the placebo group. The sources of mortality were variable in studies, but cardiovascular and infectious causes predominated. The FDA went on to state that first generation antipsychotics have equivalent mortality risk.

Given the documented evidence of mortality risk and side effects such as abnormal motor function events and strokes with antipsychotics, the prescribing of this class of drugs for elderly with dementia has dramatically declined. However, there are instances where BPSD pose a greater risk to individuals and families living with dementia than antipsychotic medications. This is especially true in cases of individuals with recurrent behaviors that pose a threat to life, progressive decline in nutrition and mobility related to BPSD and severe-stage dementia with terminal delirium. In these instances the greater harm may result from lack of aggressive control of behaviors with antipsychotic therapy.

ASSOCIATION POSITION

Non-pharmacologic approaches should be tried as a first-line alternative to pharmacologic therapy for the treatment of BPSD. Large population-based trials rigorously supporting the evidence of benefit for non-pharmacological therapies are presently lacking. While evidence may be lacking, there are studies that meet scientific inclusion and there is anecdotal evidence to support the benefit of non-pharmacologic therapies for some individuals. Such therapies could include validation therapy and aromatherapies.

Restraint therapies should be avoided in treatment of BPSD. This includes physical or mechanical devices which confine or restrict the physical activity of individuals with dementia and should be used only in extreme situations in order to protect the person and/or others from harm. This can include railings on beds, belts on chairs, wheelchair trays, wrist and waist restraints, vest restraints or tied sheets and long-term antipsychotics. The use of restraints is highly correlated with falls, incontinence and pressure ulcerations. In addition, restraints contribute to emotional distress including an assault on personal integrity and freedom of movement.

Use of locks on doors to secure safe areas or other deterrents such as disguising doors or door knobs can be helpful in maintaining safety but should not be used to lock persons in a space by themselves.

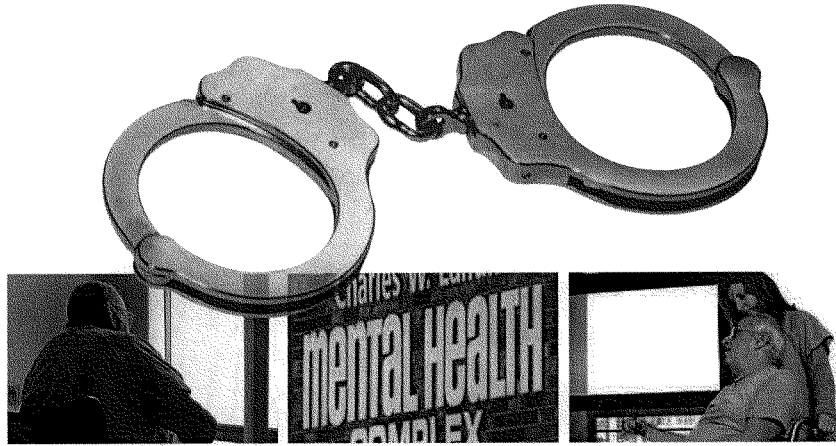
The Association recommends training and education for both professional and family caregivers on psychosocial interventions that might include:

- Routine activity
- Separate the person from what seems to be upsetting him or her.
- Assess for the presence of pain, constipation or other physical problem.
- Review medications, especially new medications
- Travel with them to where they are in time.
- Don't disagree; respect the person's thoughts even if incorrect.
- Physical interaction: Maintain eye contact, get to their height level, and allow space.
- Speak slowly and calmly in a normal tone of voice. The person may not understand the words spoken, but he or she may pick up the tone of the voice behind the words and respond to that.
- Avoid point finger-pointing, scolding or threatening.
- Redirect the person to participate in an enjoyable activity or offer comfort food he or she may recognize and like.
- If you appear to be the cause of the problem, leave the room for a while.
- Validate that the person seems to be upset over something. Reassure the person that you want to help and that you love him or her.
- Avoid asking the person to do what appears to trigger an agitated or aggressive response.

In making the decision to utilize antipsychotic therapy the following should be considered:

- Identify and remove triggers for BPSD: pain, under/over stimulation, disruption of routine, infection, change in caregiver, etc.
- Initiate non-pharmacologic alternatives as first-line therapy for control of behaviors
- Assess severity and consequences of BPSD. Less-severe behaviors with limited consequences of harm to individual or caregiver are appropriate for non-pharmacologic therapy, not antipsychotic therapy. However, more severe or "high risk" behaviors such as frightening hallucinations, delusions or hitting may require addition of antipsychotic trial.
- Determine overall risk to self or others of BPSD, and discuss with doctor the risks and benefits with and without antipsychotics. Some behaviors may be so frequent and escalating that they result in harm to the person with dementia and caregiver that will in essence limit the life-expectancy and or quality of life of the person with Alzheimer's disease.
- Accept that this is a short-term intervention that must be regularly re-evaluated with your health care professional for appropriate time of cessation.

HANDCUFFED



A Report of the
Alzheimer's Challenging Behaviors Task Force

December, 2010



"People come to us to be housed, they are out of their homes, they are not in complete charge of their affairs, and we are responsible for them."



"People come to us to be housed, they are out of their homes, they are not in complete charge of their affairs, and we are responsible for them."



"People come to us to be housed, they are out of their homes, they are not in complete charge of their affairs, and we are responsible for them."

Acknowledgements

This report was made possible with the generous support of the Helen Bader Foundation, the Greater Milwaukee Foundation, and the Faye McBeath Foundation. Support was also provided by Mark Wrobel, a family advocate. Tom Hlavacek, Executive Director of the Alzheimer’s Association of Southeastern Wisconsin, initiated the Alzheimer’s Challenging Behaviors Task Force and guided the process.

More than 115 Task Force members attended five large scale community meetings, shared input, and built a common understanding of issues facing people who exhibit challenging behaviors as a result of Alzheimer’s disease or related dementias. A complete listing of participants is included in the report. Particular thanks go to those who made presentations, participated on panels, or shared information with Task Force members at these meetings.

In addition to the larger meetings, 25 people participated in five listening sessions. They candidly shared information and addressed what is and is not working for people who exhibit challenging behaviors as a result of dementia. Many people were extremely helpful in gathering information to advance this effort: Cindy Paulsen, Ramona Williams, John Chianelli, James Gresham, Bill Henricks, Mark Eberhage, Eva Williams, Captains Carianne Yerkes and James Shepard, Anthony Reeves, Dinh Tran, Susan Crowley, Otis Woods and Sherri Olson.

The following Planning Council staff members contributed to this effort: Kathleen Pritchard, President and CEO; Lonna Kruse, Assistant Planner; Troy Mrkvicka, UW-Oshkosh Student Intern; Danny Henken, UW-Madison Student Intern; Catherine Uggeri, Intern; Robert Williams, Intern; Erin Shawgo, Marquette University Student Intern; Ashley Tikkanen, Marquette Trinity Fellow; and Quinton D. Cotton, Associate Planner. The following staff from the Alzheimer’s Association also contributed to the Task Force: Krista Scheel, Program Director; Wendy Betley, Family Services Manager; and Paul Golueke, Information and Referral Coordinator.

The quotations found throughout the report are pulled from the conversations, presentations, interviews and listening sessions of the Task Force. The perspectives and wisdom of those who contributed are appreciated. The Resource section identifies helpful materials and tools that were suggested by Task Force members and have

helped contribute to the collective knowledge of the group. More detailed notes of meetings as well as materials cited are available from the Alzheimer’s Association of Southeastern Wisconsin.

Finally, appreciation is extended to all those in the community who help people who exhibit challenging behaviors as a result of Alzheimer’s disease or related dementias. Particular thanks are extended to the members of the Petersen family, who bravely recounted their father’s story and joined in searching for solutions. This report is dedicated to the memory of Richard “Stretch” Petersen.

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Task Force Meetings and Activities

TASK FORCE MEETINGS

April 14 – The initial meeting identified the purpose of the Task Force. Members provided initial suggestions for system-level improvements, and barriers and gaps in the current approach to addressing the problem.

May 18 – The Task Force focused on assessment and intervention models including the Star Method and methods for addressing pain. Available data was discussed.

June 22 – The Task Force heard from a panel that addressed Chapter 51 and 55, and received reports on the work of the Mental Health Complex Community Advisory Council. Additional data was reviewed.

July 21 – Discussion focused on “person-centered care” and the presentation of a panel on nursing home regulations from different perspectives. Data needs were also discussed.

September 23 – The Task Force discussed what had been learned and what still needed to be learned. They made recommendations for improvement.

LISTENING SESSIONS

April 20 – Representatives from the Wisconsin Hospital Association and Wheaton Franciscan Healthcare discussed current efforts and system issues.

May 17 – Legal professionals discussed system challenges.

June 23 – Community providers described system challenges.

July 28 – Assisted living providers discussed system challenges.

August 25 – Behavioral health representatives described their role in working with people who have challenging behaviors as a result of Alzheimer’s disease and related dementias.

KEY INFORMANT INTERVIEWS

May 13 – James Gresham, President of Continuing Care and Allied Services, discussed data.

July 15 – John Chianelli, former Administrator of Milwaukee County Behavioral Health Division, discussed system issues from a behavioral health perspective.

July 20 – Bill Henricks, Chief Operations Officer of Rogers Partners in Behavioral Health, discussed system issues from a health care perspective.

August 2 – Mark Eberhage, President and Chief Psychologist of Behavioral Solutions, Inc., discussed system issues from a mental health perspective.

August 3 – 2010 Eva Williams, of Milwaukee County CMO, discussed data.

September 22 – Captain Carianne Yerkes and Captain James Shepard described the Milwaukee Police Department’s role in working with people who have challenging behaviors as a result of Alzheimer’s.

November 4 – Richard Rau, Keri Gerlach and Ruth Hovland of Clement Manor, gave input on the Task Force findings to date.

OTHER ACTIVITIES

July 8 – A workgroup met to interpret Act 281 and its ramifications.

October 4 – Task Force findings to the use of Chapter 51 for people with Alzheimer’s disease was provided to the Legislative Study Committee.

 Executive Summary and Recommendations

EXECUTIVE SUMMARY

The Alzheimer's Challenging Behaviors Task Force was called together by the Alzheimer's Association of Southeastern Wisconsin in April of 2010 following the tragic death of Mr. Richard Petersen. Mr. Petersen, an 85 year old gentleman with late stage dementia who exhibited challenging behaviors, was placed under emergency detention after being at two hospitals, and was eventually transferred by police to the Milwaukee County Behavioral Health Division where his family found him tied in a wheel chair with no jacket or shoes. In spite of his family's efforts to intervene, he later developed pneumonia, was transferred to a hospital, and died.

The Alzheimer's Association and scores of members of the community were deeply concerned, not only about the treatment of Mr. Petersen and his family, but about others in the Milwaukee County area who are in the



same or similar circumstances. The Alzheimer's Association sought and obtained support from the Faye McBeath Foundation, the Greater Milwaukee Foundation, and the Helen Bader Foundation to partner with the Planning Council for Health and Human Services, Inc., to staff a Task Force and produce a report to the community. The Planning Council is a private, non-profit organization that works with others to advance health and human services through planning, evaluation and research. Under the Alzheimer's Challenging Behaviors Task Force, stakeholders from all sides of the issue came together to develop a set of common understandings of the associated problems, explore solutions and recommend changes.

The full Task Force came together over the course of five community meetings. More than 115 individuals representing a cross-section of the legal, medical, behavioral, service provider and caregiver communities came together to help address the problem. In addition to the plenary sessions, five listening sessions with key stakeholder groups, including legal, medical, and behavioral health experts, and providers were convened. Seven key informant interviews with a number of experts in the mental health, medical, provider, and law enforcement fields supplemented the work.

This report is intended to provide a basic understanding of "challenging behaviors" among people with Alzheimer's disease, and approaches to addressing the problem in facilities and across systems. Based on the work of the Task Force, basic recommendations for future action were generated and a series of next steps are identified.

RECOMMENDATIONS**A. Find alternatives to using Chapter 51 and the Milwaukee County Mental Health Complex for people with Alzheimer's disease and related dementias.**

1. Convene a panel with expertise in Alzheimer's disease, mental health, geriatrics, criminal justice, health and long-term care to identify the implications of stopping the application of Chapter 51 and the use of the Milwaukee Mental Health Complex for patients with Alzheimer's and age related dementias.
2. Explore mechanisms for diverting these resources to the development of the Alzheimer's network of services.
3. Continue to provide input to the State Legislative Committee that is reviewing revisions to Chapter 51.

B. Establish a network of Alzheimer's care centers.

1. Work with providers, hospital systems and nursing homes to establish a network in which adequate and defined "levels of care" are available for people with dementia in the community, skilled nursing homes and hospital emergency rooms and inpatient units.
2. Identify "lead agencies" to assure accountability at all levels.
3. Develop cost sharing and blended funding approaches to support the effort and reduce duplication by concentrating resources and developing a larger number of small sites and a smaller number of specialized sites.
4. Create a centralized resource and assessment center to serve as the hub of the network, providing:
 - a. A multi-disciplinary, mobile "triage team" to help address challenging behaviors on-site at the time an intervention is needed.
 - 1) Conduct an assessment using antecedent-behavior-consequence (ABC) model.
 - 2) Assess for and make recommendations to manage pain.
 - 3) Coach caregivers and consult with families.
 - 4) Recommend appropriate placement, services, and follow-up.
 - 5) Have authority to initiate change in placement if needed.
 - b. A combined medical, psychiatric and social service unit to integrate care for those who need to be stabilized, assessed and prepared to return to the most appropriate site and receive follow-up care.
 - c. A training resource for first-responder Emergency Medical Service (EMS) and police on topics such as identifying and responding to calls involving persons with dementia, intervention practices, and the existence, location, and services of the centers described above and their designated level of care.
 - d. Support for facilities and families.

C. Provide adequate and appropriate training.

1. Acknowledge and address the need for broad-based understanding of Alzheimer's disease, associated challenging behaviors and the factors which can influence their occurrence.
2. Establish a system to provide specialized training for:
 - a. Family members.
 - b. Community providers of residential and adult day care.
 - c. Emergency responders (police, EMS and emergency room personnel).
 - d. Nursing home and other facility staff and supervisors on all shifts.

3. Provide training that:

- a. Encourages family members to be advocates.
- b. Uses a multi-disciplinary team approach.
- c. Includes real time, on-site, case specific coaching.
- d. Emphasizes the importance of a "person-centered" approach.
- e. Stresses the significance of the interaction between the person, caregiver and environment.
- f. Identifies procedures for seeking appropriate interventions.
- g. Identifies resources and support available to families and facilities for follow-up care.
- h. Is ongoing.

D. Create an ongoing system for capturing data.

1. Establish a pilot program to:

- a. Collect data through the Emergency Medical System (EMS).
- b. Identify facilities that are calling for emergency interventions.
- c. Document the number of people coming into hospital emergency rooms with acute changes in mental state related to dementia.
- d. Document the number of Chapter 51 petitions involving dementia-related challenging behaviors.

2. Document the trajectory and outcomes for individuals with challenging behaviors as well as the treatment of the family.

3. Use the data to:

- a. Target interventions.
- b. Demonstrate the economic aspects, including costs and potential savings.
- c. Prepare for future response to challenging behaviors.

E. Support the next steps and follow-up work of the Task Force.

To begin to implement the recommendations above, the following action steps will be undertaken.

1. Participate in the design of the Alzheimer's State Plan, beginning with the release of this report on December 14, 2010. See the "Hand in the Plan" website at http://www.planningcouncil.org/CMS/alt_login.php.
2. Provide training and information on the topic of challenging behaviors at the Alzheimer's Association's 2011 Statewide Network Conference.
3. Increase awareness and training for law enforcement personnel in more municipalities on the topic of challenging behaviors among people with dementia.
4. Convene a work group to produce recommendations on Chapter 51 and continue to provide input to the State legislature.
5. Convene a work group to recommend approaches to reducing the use of psychotropic drugs for people with Alzheimer's exhibiting challenging behaviors.
6. Convene a work group on training to refine and recommend curricula and approaches.
7. Work with health care systems and the Wisconsin Hospital Association to develop interim and long-range approaches to improve and coordinate emergency and inpatient hospital care.
8. Meet with individual nursing home administrators and state-level nursing home associations to identify interim and long-range strategies.
9. Reconvene the full Task Force regularly to report on progress and seek additional input.

Alzheimer's Challenging Behaviors Task Force Report

I. Background and introduction

The Alzheimer's Challenging Behaviors Task Force was called together by the Alzheimer's Association of Southeastern Wisconsin in April of 2010 following the tragic death of Mr. Richard Petersen. Mr. Petersen, an 85 year old gentleman with late stage dementia who exhibited challenging behaviors, was placed under emergency detention after being at two hospitals, and was eventually transferred to the Milwaukee County Behavioral Health Division where his family found him tied in a wheel chair with no jacket or shoes. In spite of his family's efforts to intervene, he later developed pneumonia, was transferred to a hospital, and died.



Like Mr. Petersen, too many other older adults with dementia who exhibit aggressive and agitated behaviors have found themselves caught up in the legal and involuntary commitment systems and experienced

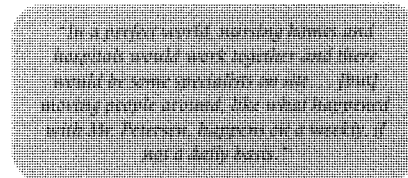
disturbing treatment and tragic outcomes. Most often Chapter 51 emergency detention petitions originate in long-term care facilities that provide care to older adults. When Chapter 51 petitions are initiated for people with Alzheimer's and related dementias, it may be a vehicle to involuntarily medicate these individuals with psychotropic drugs despite the fact that the federal Food and Drug Administration (FDA) has issued "black box" warnings regarding such use.

The series of events that leads to the origination of a Chapter 51 petition can be very disturbing. Police are called to a facility, oftentimes a nursing home; the resident with dementia who has exhibited agitated behavior is charged with disorderly conduct or battery. The resident is taken in a squad car to one of several local hospitals for medical clearance. Commonly, the individual does not want to leave and is restrained and handcuffed in order for the law enforcement official to transport him or her.

At the hospital emergency room, the individual and police officer are required to wait in an environment that, to the individual with dementia, is chaotic and confusing. If the person with dementia is medically

cleared, the Chapter 51 petition is initiated so the person can be involuntarily committed to a psychiatric facility. On rare occasions, the psychiatric care is found at a private hospital. More often than not, residents of Milwaukee County are transferred to the Mental Health Complex, an environment that almost everyone agrees is not appropriate for older adults with dementia.

These transfers to another facility, in and of themselves, create trauma for the individual and can worsen the individual's health and behavioral issues. A person with Alzheimer's often becomes disoriented due to a move, regardless of the distance, and a change in environment is almost a guaranteed way to exacerbate difficult behavior. Reportedly, Chapter 51 is being used as a vehicle to do exactly this, to move a person out of an environment. After the person is removed, it is not unusual for a facility to "close the bed" and refuse to allow the person to return.



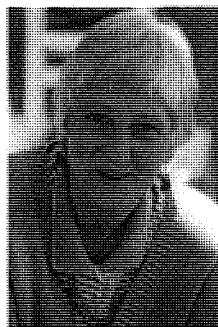
The Alzheimer's Association and scores of members of the community were deeply concerned, not only about the treatment of Mr. Petersen and his family, but about others in Milwaukee County who are in the same or similar circumstances. A series of articles that appeared in the *Milwaukee Journal Sentinel* helped to bring the issue before the general public.

The Alzheimer's Association sought and obtained support from the Faye McBeath Foundation, the Greater Milwaukee Foundation, and the Helen Bader Foundation to partner with the Planning Council for Health and Human Services, Inc. to staff a Task Force and produce a report to the community. The Planning Council is a private, non-profit organization that works with others to advance health and human services through planning, evaluation and research. Under the Alzheimer's Challenging Behaviors Task Force, stakeholders from all sides of the issue came together to develop a set of common understandings of the associated problems, explore solutions and recommend changes.

The full Task Force came together over the course of five community meetings. More than 115 individuals representing a cross-section of the legal, medical, behavioral, service provider and caregiver communities came together to help address the problem. In addition to the plenary sessions, five listening sessions with key stakeholder groups, including legal, medical, and behavioral health experts, and providers were convened. Seven key informant interviews with a number of experts in the mental health, medical, provider, and law enforcement fields supplemented the work.

This report is intended to provide a basic understanding of "challenging behaviors" among people with Alzheimer's disease, and approaches to addressing the problem in facilities and across systems. Based on the work of the Task Force, basic recommendations for future action were generated at a meeting on September 23rd and reviewed by this group of Task Force members. This report was released in December 2010 in conjunction with the Helen Bader Foundation's Speaker Series and the State of Wisconsin Department of Health's input sessions on a state plan for people with Alzheimer's. For additional information see "Hand in the Plan" at http://www.planningcouncil.org/CMS/alt_login.php.

II. What are "challenging behaviors?"



While termed "challenging behaviors" in the work of this Task Force, the set of behaviors on which this report focuses is also referred to as "difficult behavior," "disruptive behaviors," "behavioral symptoms related to dementia," "Alzheimer's behaviors," "behavioral issues," "behavioral and psychological symptoms of dementia" (BPSD), and "inappropriate

behaviors in dementia" in both the academic literature and public parlance. To understand the scope of behaviors, some discussion of these terms is warranted.

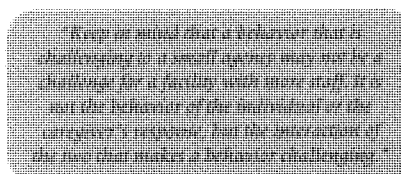
The Alzheimer's Association, in offering advice on living with Alzheimer's disease and related dementias, lists the following range of behaviors associated with the disease: aggression, agitation, confusion, hallucinations, repetition, sleeplessness or sun-downing, suspicion, apathy, and wandering.¹

Others define "difficult" behavior as "any behavior that causes distress to the resident and/ or those observing the behavior," noting that the behavior may or may not be dangerous and that it may range from mildly irritating to severely disruptive, as well as being acute or chronic.²

A definition used by the State of Wisconsin details disruptive behaviors toward staff and other residents and includes verbally abusive behavior, physically abusive behavior, socially inappropriate or disruptive behavior and resisting care.³

Still others refer to "behavioral symptoms related to dementia or BSRD" particularly in long-term care residents. These symptoms include verbal, vocal or motor activities that are considered to be aggressive, excessive or lack adherence to social standards.⁴

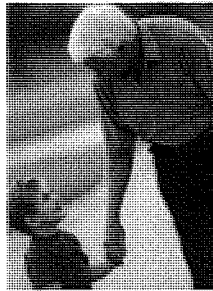
Another variant refers to "behavioral symptoms" such as physical and verbal aggression, wandering, agitation, sexual disinhibition and screaming, and includes psychological symptoms of depression, anxiety, delusions and hallucinations which affect behavior.⁵



In a comprehensive study on the topic, yet another author refers to "inappropriate behaviors" defined as "inappropriate verbal, vocal or motor activity that is not judged by an outside observer to be an obvious outcome of the needs or confusion of the individual." This work identifies the following references in the research and literature: problem behaviors, disruptive behaviors, disturbing behaviors, behavioral problems and agitation resulting in hitting, kicking or biting.⁶

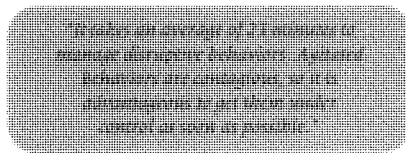
III. Why are these important?

Regardless of the technical term, these behaviors are important for several reasons. First, as the Alzheimer's Association indicates, they are the source of misunderstanding, frustration and tension, particularly between the person with dementia and the caregiver. By whatever term or measure, they are very common and impose an enormous toll, both emotionally and economically. They reduce the quality of life and increase suffering for the person with Alzheimer's and the burden for the caregiver. In turn, these behaviors



are often prominent factors in the decision to seek more restrictive care and earlier institutionalization.⁷ Studies and real world experience among people with dementia have shown that these behaviors may lead to inappropriate treatment with psychotropic medications, physical restraints, or seclusion.

Caregivers, staff or fellow residents may be endangered as a result of these behaviors. They are common stressors resulting in caregiver and staff burnout and turnover. These behaviors, common among so many people suffering with Alzheimer's disease, are indeed "challenging" to all concerned.



IV. What causes these behaviors?

Challenging behaviors may be a result of the deterioration by Alzheimer's disease of specific parts of the brain that regulate emotions and impulse control. Behaviors may also be a response to physical pain that cannot be isolated or articulated by the person with dementia, or by an underlying medical problem such as an infection. They may also be the result or side effect of a number of medications inappropriately administered to the person with Alzheimer's.

Challenging behaviors may also be triggered by the setting – environmental conditions, noise, agitated behavior of others, or the confusion produced by the introduction of a new or different location. Whatever the source, the caregiver's response may help ameliorate or exacerbate the behavior. In this way, behaviors are best seen as a dynamic interaction between the person with dementia, the caregiver and the specific environment.



V. How prevalent are these behaviors?

Just as there are different terms used to describe the behavior, there is considerable variation in reported prevalence. Due to differing definitions, lack of recognition of symptoms and the under-reporting and diagnosis of Alzheimer's disease in general, the magnitude of the problem is difficult to determine with certainty. There is inconsistency in the literature regarding prevalence and the factors associated with their incidence among people with dementia. For these reasons, data should be interpreted with caution. Nonetheless, studies provide some useful findings.

One noted study found that the prevalence of behavioral and psychological symptoms of dementia (BPSD) in nursing homes varies between 43 and 93% in the United States due to different definitions and diagnostic tools.⁸ However, using a standardized test, others found that more than 90% of nursing home residents with dementia exhibited at least one behavioral disturbance with 60% experiencing psychosis, 42% experiencing depression and the greatest percentage (82%), exhibiting activity disturbance or aggression.⁹ Still other studies indicate that between 60 and 90% of people with dementia will

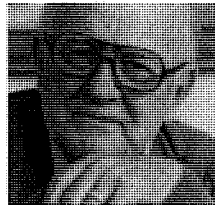
experience behavioral or psychological symptoms at some time during the course of their illness.¹⁰ According to another study depending on measurement and the setting, the prevalence of behavioral symptoms related to dementia in long term care, including nursing homes, residential care and assisted living varies from 40-90%.¹¹



While the challenging behavior may be common, most often it can be successfully managed. Studies confirm that two thirds of people displaying behavioral symptoms related to dementia can be successfully managed.¹² One authority that specializes in staff training reports that the industry standard for hospitalization of nursing home patients due to behavioral issues is 17%, which, after appropriate staff training, can be reduced to 2%.¹³

VI. What do local data indicate?

Alzheimer's is the most common type of dementia accounting for 60-80% of total dementia cases. The number of people affected by Alzheimer's disease in the United States is reported to be 5.3 million. In Wisconsin, the number is estimated at 110,000 persons, with approximately 16,800 in Milwaukee County and approximately 8,000 in Waukesha County.¹⁴



The State of Wisconsin¹⁵ provides the following information on prevalence in nursing homes, based on a single "point in time" (April 30, 2010). Numbers should be interpreted cautiously, however, due to the known under reporting and diagnosis of dementia. Throughout the State on this single date, there were more than 15,000 people with a diagnosis of dementia living in nursing homes (See Table 1). Of these, nearly 4,900 were reported to have exhibited a recent (within the last seven days) incident of disruptive behavior. Of those, more than 1,200 were in an Alzheimer's "special unit" although it should be noted that there is no official definition or standard procedures associated with this designation in statute or regulation.

In Milwaukee, more than 2,100 people diagnosed with dementia were in nursing homes on this particular date, with more than 500 recently having exhibited disruptive behavior. Note that in Milwaukee, unlike the balance of the State, nearly all of those with dementia and recent disruptive behavior in nursing homes are living in a "special care unit." Note too, that there is no formal designation or specification of such units. The data also indicates that people in special care units in Milwaukee were significantly younger than people in special care units in other counties through the State.

TABLE 1:
Nursing home residents with dementia
April 30, 2010

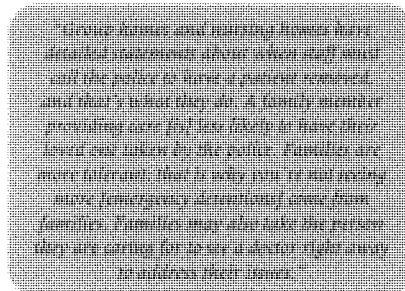
	Diagnosis of dementia	Recent disruptive behavior	In Alzheimer's special unit
Wisconsin	15,264	4,839 (32%)	1,241
Milwaukee	2,150	521 (24%)	500
Waukesha	944	223 (24%)	49

TABLE 2:
People with diagnosis of dementia receiving home health services
May 1, 2009-April 30, 2010

	Diagnosis of dementia	Recent disruptive behavior	Receiving psychiatric nursing services at home
Wisconsin	1,927	238 (12%)	12
Milwaukee	358	37 (10%)	6
Waukesha	148	23 (16%)	0

Although the number of people receiving home health services (Table 2) represents an incomplete percentage of those being served in the community, annual figures of people with a diagnosis of dementia in Wisconsin receiving home health service suggest there are nearly 2,000 in this category. Of these, nearly 240 are reported to have exhibited a recent incident of disruptive behavior (within the last 14 days). In Milwaukee, the number of people with a dementia diagnosis is more than 350 with approximately 10% exhibiting disruptive behavior.

While these numbers may be incomplete, they do confirm the general trend that incidents of disruptive behavior are more common among people with dementia who reside in nursing homes than those who are in the community. Understandably, prevalence among patients in nursing homes has been found to be higher than in community dwelling patients¹⁶ but data should be interpreted with caution since this may reflect severity of dementia or nursing home entry, the use of psychotropic medications, physical restraints or isolation.



For people with irreversible dementia or Alzheimer's disease needing special programs, Milwaukee County has 83 Adult Family Homes with a capacity of 324, and

123 Community Based Residential Facilities (CBRFs) with a capacity of 2,624.

Information gathered from the City of Milwaukee Police Department (MPD) provides one measure of law enforcement involvement in dealing with challenging behaviors. MPD indicates that the calls which they receive from private homes or community-based

Department-initiated emergency detentions is approximately four percent of the total calls made although again, in some districts the number was nearly twice as high. Not surprisingly, District 4, the area where the greatest number of nursing homes placed calls accounts for nearly half the calls leading to emergency detentions. Projecting these six month figures to the full

year, Milwaukee Police may receive nearly 775 calls per year, with approximately 30 of these resulting in police-initiated emergency detention.

However, as Mr. Petersen's story illustrates, not all Chapter 51 petitions are police-initiated. In his case, as well as in others reported by the State Public Defender's Office, the Chapter 51 petition was initiated by a treating hospital. In addition, there are many suburban law enforcement agencies in the greater Milwaukee area that respond to similar calls from nursing homes under their jurisdiction. Because of this, the total number of persons with dementia-related challenging behaviors that have been the subject of Chapter 51 emergency detentions in the greater Milwaukee area remains unknown.

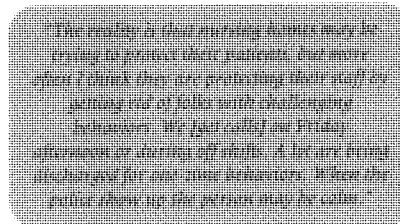
TABLE 3:
Calls from nursing homes to the City of Milwaukee Police Department
January-June, 2010

City of Milwaukee Police District	# of nursing homes calling	Total # of beds	Total # of calls to MPD	Call to bed ratio	# of calls resulting in emergency detention
1	5	574	147	.26	4 (.03)
2	2	110	16	.15	0
3	1	95	26	.27	2 (.08)
4	6	775	103	.13	7 (.07)
5	0	0	0	-	0
6	4	372	58	.16	1 (.02)
7	1	106	36	.34	0
Total	19	2,032	386	.19	14 (.04)

facilities are associated primarily with wandering behavior rather than aggressive or challenging behaviors. On the other hand, calls associated with challenging behaviors are reported to be more commonly coming from nursing homes.

A total of 19 nursing homes totaling over 2,000 beds placed calls for assistance to the seven districts of the City of Milwaukee Police Department. The number of nursing homes making calls per district was as great as six in District 4 while Districts 3 and 7 received calls from just one nursing home within its boundary and District 5 received no calls from nursing homes. While not all calls are resident related, overall, the total number of calls made to police in the first half of the year was 386, averaging approximately one call for every five beds in a six month period. Note however that one District had calls as high as one call for every three beds, while others had as few as one per nearly nine beds. The analysis of individual nursing homes shows at least one home where the number of calls was almost two times the number of beds.

In fourteen of the incidents when police were called to a facility, the officer initiated a Chapter 51 emergency detention proceeding. The number of Milwaukee Police



VII. What systemic barriers were identified?

A. Nursing home regulations

Representatives of the Wisconsin Association of Homes and Services for the Aging, Wisconsin Health Care Association, the Division of Quality Assurance (DQA), and the State Ombudsman program provided the Task Force with differing perspectives on nursing home regulations and the extent to which they contributed to the problem of appropriately addressing challenging behaviors. From the perspective of the Ombudsman office, which can serve as a resource to facilities, the "best practice" is to intervene and treat residents on site



rather than removing them from the home. From this vantage, aspects of the regulations were described as "handcuffing" nursing homes, and forcing them to remove residents from the facility when they exhibit challenging behaviors. Representatives of nursing homes expressed concern for the safety and care of other patients and staff as well as fear of fines and citations which can clearly interfere with the facility's willingness to deal with the behavior on site. Nursing home staff, administrators, and representatives of statewide nursing home trade associations identified current federal nursing home regulations, and the enforcement of those regulations by DQA nursing home inspectors as a significant barrier. Data presented by representatives of the DQA, however, suggest that very few citations have been filed for failure to remove difficult residents.

"Inspectors say it's one marking system that are all fault and nursing homes say it's the inspectors that refuse to take people. I think we all need to get together to address the issue. Nursing homes often don't have the staff to stabilize a person with the challenging behaviors because they might not have a psychiatrist or medical doctor onsite. If a person is sent out of a nursing home it should be with the guarantee that they can come back. Nursing homes will take chances with some residents but be hesitant for residents who are too challenging for them. The State is central to these issues. Nursing homes are between a rock and a hard place."

Currently, there are no state regulations defining a dementia-care facility, although several attempts have been made to pass legislation with this goal. In reporting to the Task Force, representatives of the nursing home association indicated that attempts to further regulate nursing homes would be met with stiff opposition and that because the problem is in interpretations of federal

regulations, new state regulations will not help address the problem. Short of a regulatory solution, local facility administrators and state associations have agreed to participate in a work group to explore what can be done to improve practices regarding the handling of challenging behaviors among residents with Alzheimer's and other dementias.

"The Wisconsin, a facility can't do it the facility as being a special care facility. This is not regulated and there are regulatory agencies of medical services that are not set to meet patients. There are so much instances of what they currently provide."

B. The "disappeared system"

Despite the growth in the population likely to need services for Alzheimer's and related dementias, systems of delivering care and services that once existed are either no longer available or are unable to meet capacity. The numbers of inpatient psychiatric facilities in general, and facilities with specific expertise in geriatrics have declined. Psychiatric beds in private hospitals have been reduced over the years. Hospital units that were once able to care for both the medical and psychiatric needs of older adults (formerly "Med/Psych" or "Gero/Psych" units) have been closed or scaled back. Without the proper facilities, hospital systems are reluctant to admit patients with challenging behaviors due to dementia. If they do accept the patient, hospitals report difficulty discharging the patients because the nursing home from which they came "closed the bed" and no new facility will accept the person.

The only crisis treatment facility in Milwaukee County is the Mental Health Complex. Given the reduction in facilities, increased use of mobile crisis teams that enabled problems to be addressed on-site might be expected. However, these resources have also been reduced and their services are now reportedly understaffed and usually unavailable due to budget cuts. Ironically, cutting resources for earlier interventions has created greater costs at the deep end of the system.

"Addressing the challenging behaviors that stem from Alzheimer's is difficult because of the complexity of the issues and because of the scarcity of resources."

C. The scarcity of staff

Despite the growing number of people who will be affected by Alzheimer's in the future, there is an alarming lack of qualified medical and psychiatric treatment professionals who are equipped to deal with this population. According to the American Association for Geriatric Psychiatry, there are about 2,590 board certified geriatric psychiatrists in the United States right now. Current estimates are that about 54,000 are needed. The 60 geriatric psychiatry fellowship programs now produce about 80 board-certified geriatric psychiatrists nationally on an annual basis. There are currently 21 doctors in the Milwaukee area that list Geriatric Psychiatry as an area of specialty. The outcome of these scarcities is that older adults with dementia often do not receive the highly specialized assessment and intervention services they require.

"Finding a geriatric psychiatrist who understands dementia and wants to work in nursing homes is quite hard. The ones that are doing it are almost to retire and there are not many new people to replace them."

VIII. What is being done to deal with challenging behaviors?

Task Force members identified a number of strategies that are used to deal with challenging behaviors among people with Alzheimer's and related dementias. Two of these, the use of Chapter 51 emergency detentions and the administration of psychotropic drugs, while common, are controversial. Other approaches reflect promising practices including activities and interventions that incorporate the interaction of the person with dementia, the caregiver and the environment in which the behaviors occur. These include formal support for caregivers, training in promising methods of assessment and intervention, a culture shift toward "person-centered" care, pain management, use of the Star Method, and instituting appropriate policies and guidelines within facilities regarding the management of challenging behaviors among people with Alzheimer's disease and other dementias. This report highlights examples of systemic changes that have been put in place to better address the challenging behaviors issue.

A. The controversial use of Chapter 51 for persons with dementia

Chapter 51 of the Wisconsin Statutes provides a means

to place persons with mental illness who are considered to be a danger to themselves or others in emergency detention and to administer involuntary treatment. For persons with Alzheimer's and related dementias, the usual treatment under a Chapter 51 petition is the involuntary administration of psychotropic drugs to reduce agitation and aggression and produce a state of sedation.

"People come to us for psychiatric help, they are part of their solution. There are just too many times that I've had to admit people and they're administered to drugs. They don't manage their situation. If they manage it without doctors, they won't be there."

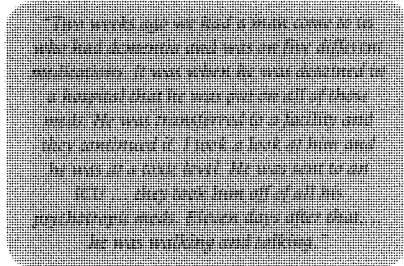
Across the State, there is variation in the way different counties apply Chapter 51 to people who have Alzheimer's and related dementias. At least two counties do not believe Chapter 51 should apply to this population and will not prosecute older adults with dementia under Chapter 51.¹⁷ Using Chapter 51 as a vehicle to deal with challenging behaviors in persons with dementia has been found to lead to transfer trauma, medical complications, exacerbated behaviors, and even death. Based on the work of the Task Force, the use of Chapter 51 in Milwaukee County to intervene in behavioral issues regarding older adults is seen as a symptom of larger systemic problems. It is the basis of the recommendation that the use of Chapter 51 to detain and force treatment on older adults is inappropriate, dangerous and should be stopped.

"Chapter 51 represents one of the things that have the use of it has increased and there are 72 interpretations of it. There is an overuse of Chapter 51, people are using it as the entry to treatment. Institutionalizing an elderly person and putting them in the back of a car will not make them calm down. It's hard to believe what we are doing this to our parents."

A Legislative Council Study Committee on Chapter 51, led by State Representative and Task Force member Sandra Pasch received testimony from the Task Force and will address implications of Chapter 51 for older adults with dementia in the Committee's final report recommending changes to the Legislature.

B. The controversial use of psychotropic medications for persons with dementia

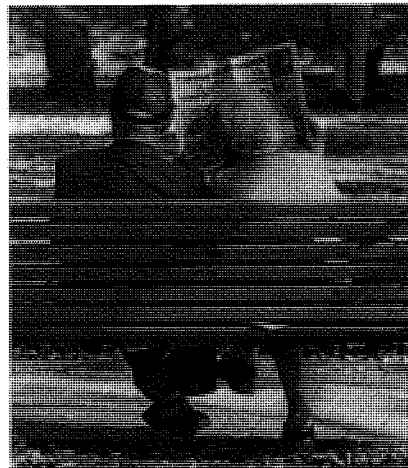
Whether administered voluntarily or involuntarily, there is considerable debate about the use of psychotropic medications in dementia care. The federal Food and Drug Administration (FDA) has found many of the commonly prescribed psychotropic drugs to be dangerous for persons with Alzheimer's and has added "black box" warnings to the packaging of some, calling for extreme caution in their use because of dangerous side effects. There are in fact no FDA-approved psychotropic medications to treat the behavioral symptoms of Alzheimer's disease and related dementias.



A newly passed Wisconsin law, Act 281, appears to make the administration of these drugs easier in certain circumstances. Representatives of the State Department of Health Services and the Chief Pharmacist of the Division of Quality Assurance (DQA) have committed to making changes in the roll-out of the new law based on the input of members of the Task Force. To assure further progress on this issue, the Task Force recommends establishing a work group to reduce the inappropriate use of antipsychotic medications for residents with dementia and promote alternate approaches to behavior management. Work currently underway in the state of Massachusetts can help inform this effort.¹⁸

IX. What alternative strategies are available?

While securing a Chapter 51 petition and administering psychotropic drugs may be common current approaches to dealing with challenging behaviors among people with Alzheimer's and related dementias, there are alternative strategies and promising practices that are both more humane and effective. Challenging behaviors are best understood as an interaction among the person with dementia, their caregivers, and elements of the



environment. There is an extensive field of research regarding appropriate treatment modalities for agitated behaviors. There are assessment tools, intervention approaches, and treatment practices that have been shown to be effective in addressing challenging behaviors, yet members of the Task Force report that they are not being used widely. The following sections highlight some of the strategies reviewed and recommended by the Task Force.

A. Assessment and pain management

Behavioral issues related to dementia are serious and can be challenging, but there may be an underlying medical cause that has gone untreated. Too often, the person may be in pain due to conditions such as dental problems, dislocated joints, or even broken bones. From this point of view, the "challenging behavior" may be a form of communication that is going unheeded. The use of psychotropic drugs to control behaviors does nothing to address the underlying medical conditions. Thorough examinations to rule out pain should be undertaken before psychotropic drugs are considered.

Challenging behaviors can actually be caused by pain or infection. Task Force member Dr. Christine Kovach has done extensive research into pain as an underlying cause and reported that the person with dementia may be unable to describe her or his pain. That is, while the person's physical sense is not altered, he or she may

have a decreased ability to report pain or threatening experiences. Resistance to certain activities may be interpreted as a problem behavior when the person is actually attempting to avoid pain.

In some instances, it was taking more than 20 days to recognize that a patient had a fractured hip or abscessed tooth. Post assessments usually led to a delay in the identification of problems.

Ruling out physical pain requires a thorough examination. According to Dr. Kovach, The examination process should begin with a physical assessment, including urine analysis to rule out urinary tract infections. Antipsychotic drugs used to sedate patients may leave symptoms untreated or the medications may actually exacerbate the behavior. In many cases, behaviors related to pain can be reduced with the use of analgesics.

If the physical assessment does not reveal a source of pain but the behavior persists, a social assessment should be undertaken. The process should include an assessment of environmental stressors such as noise, light, and over-stimulation.



If the behaviors continue after making social or environmental adjustments, other non-pharmacological interventions, like changes in diets or the use of cues can be explored. If the non-pharmacological interventions do not work, patients may receive an analgesic such as Extra Strength Tylenol or an increase in the existing dose of analgesic medication. Following the administration of analgesics, there are reports that people who were withdrawn, disengaged, or agitated were able to participate in activities.

"A close attention with people on a pathway to hospice care. There was a vein in his left leg with some of a lot of pain and was treated. He was very verbal. He was to be transferred to hospice, but his last medical examination revealed a abscessed tooth. When his pain was addressed, he returned to a less agitated state."

B. Person-centered care

Another promising alternative to removing a person from their setting and administering psychotropic drugs is to see in an approach known as "person-centered care." This approach originated in England where no facility can provide care without being licensed as a "Person-Centered Care Provider." The model has been pioneered in the United States by Tom Kitwood and advanced today through the Bradford Dementia Group.¹⁹ Locally, Beth Meyer Arnold, Director of Adult Day Services at Luther Manor and a member of the Task Force, is considered an expert and advocate in this approach. It is cited as an effective, measurable and practical model that enhances the quality of life of persons living with dementia and those who care for them. It involves a continuous process of listening, trying new things, seeing how they work, and changing things in an effort to individualize care and de-institutionalize the nursing home environment. Person-centered care seeks to maximize choice and autonomy, and can thus reduce the presence of challenging behaviors.

"You never take the person in. There is a team of people that are used what is tailored to them, what their needs are. Placements are adapted for each and every person."

Person-centered care is provided according to residents' needs, desires, and preferences and staff are expected to be sufficiently flexible to accommodate these individual conditions. Staff at all levels and from all departments must be engaged in the design of the care and



committed to success. Implementation requires that person-centered care practices be viewed as part of the organization's core mission and not as a project that can be completed or set aside. Systems to support and sustain practice changes should be in place, including ongoing education, policies and procedures, and job descriptions.

Although person-centered care may require changes in the culture and the approach to care giving including care practices, workplace practices, and the physical environment, the results are more humane and effective in addressing challenging behaviors.

"Success is really dependent on staff. You have to teach them to be passionate and motivated about the work they're doing. People don't get culture change from theory. They need to do it themselves."

C. The Star Method

The Star Method developed by Dr. Tim Howell, a geriatric psychiatrist and Task Force member, is a simple, concrete, easy to use, remember, and replicate tool for addressing the problem of complexity in geriatrics.²⁰ A 5-pointed star is drawn on a clear surface (paper or whiteboard). It enables clinical data about a person to be mapped onto a single field with five domains: medications, medical, behavioral, personal, and social. The available data for each arm of the star are written as lists. The medication arm includes an individual's medications (prescribed, over-the-counter, and "borrowed"). The medical and behavioral arms list known diagnoses, functional impairments, and/or symptoms. The personal arm highlights a person's individual traits, cultural values, and coping styles. The

social arm covers interpersonal and environmental problems and assets, such as family support, finances, housing and transportation.

Each piece of data listed thus becomes an element in a network of potentially interacting variables, with the ties between them ranging from very weak to very strong. Each arm of the star represents a different ecological level on which problems are occurring. The primary identifiable clinical challenge (e.g. client is exhibiting challenging behaviors) is written in the center of the star. In some cases the primary challenge may not be entirely clear at the onset, but gradually emerges as the situation is reviewed.

Use of the Star Method is growing in Milwaukee and is reportedly used in the Milwaukee County Department on Aging (MCDA) with Adult Protective Services (APS) and Elder Abuse cases; Aurora Health Care employees use the Star Method at patients' bedsides and in their charts; Abundant Life Manor and the State of Wisconsin Board on Aging and Long Term Care also use this Method. Its application in addressing challenging behaviors is promising.

"We had an older man at the hospital who had multiple challenging behaviors and we used the Star Method to look at the various pieces. Part of this work is getting close to the patient's personal life. We had him put on his favorite clothes and his glasses and hearing aid before we talked with him. This helped break the paradigm. We thought our team had said that he liked protein shakes so we made sure they were available to him. By doing these things, we were able to get the top of his problematic behaviors and he was sent home from the hospital within a handful of days."

X. What is being done elsewhere?

The Task Force discussed at least two examples of other communities that are undertaking systemic changes to their treatment of people with Alzheimer's who exhibit challenging behaviors.

A. The Ontario Model

The Ontario Model uses Psycho-geriatric Resource Consultants (PRC) to support staff in long-term care homes and community service agencies on caring for

individuals with dementia, complex mental health needs and associated behaviors.²¹ PRCs serve three primary roles: educator, consultant and networker/developer. Rather than working directly with patients, trained psycho-geriatric experts work to train others and consult with staff and facilities. Given the shortage of trained experts and the limits of the mobile crisis team, this model could be used to assist staff in addressing challenging behaviors by providing real time coaching and consultation.

The benefits of this approach include: increased knowledge and skills among staff in Long Term Care (LTC) homes and community agencies; improved networking and collaboration among LTC homes, community agencies, and other services; increased number and coordination of educational opportunities; and more appropriate utilization of external resources. The Canadian model utilizes a single-payer system, requires full support of the facility and requires ongoing training regarding the model and use of PRCs.

B. The Dane County Model

Begun as a cross-systems model to assist persons with challenging behaviors in reintegrating to the community, the Dane County Model also uses a team approach to conduct a social-psychiatric intervention where the person is (whether that is in Mendota, a hospital, or in the community). This is a strength-based approach designed to determine who the person is, what their needs are, and to recommend an appropriate placement. In many cases entirely new placements are created for the person. Dane County funds community placements and providers receive a reasonable reimbursement rate. While some placements (and the overall model of care) involve considerable costs, they are less expensive than keeping the person in a more restrictive psychiatric facility, so they save dollars for the State-County system. This model has been in use for over a year as of May 2009 and has worked with 25 patients, all of whom were reintegrated into the community.

XI. What role does training play in addressing challenging behaviors?

Based on the presentations and discussions, the Task Force concluded that any serious attempt to transform current systems of care will require extensive training. Whether in regard to understanding and dealing with dementia, pain and behaviors, or in regard to culture change in facilities, training stood out as the lynchpin between successful and failed approaches to care.

The Task Force found that for people working with individuals with dementia, training does not occur as often as necessary. Training resources were not well known, nor was there agreement regarding the kind of training needed. The lack of incentives or requirements for facilities to provide training was clear. Specialty training does not result in higher reimbursement rates and some providers went so far as to indicate that they



do not wish to provide advanced training or be seen as specializing in dementia care for fear of attracting difficult residents. The cost of training is perceived as too high, and some point to high staff turnover as a reason not to invest in training. Others pointed out that proper and sufficient training may be the antidote to turnover.

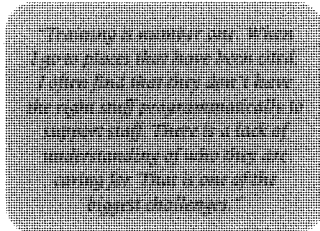
The Task Force recommends the formation of a work group to focus on training and offers the following suggestions.

To better address challenging behaviors among individuals with Alzheimer's and other dementias, training should be:

- Integrated (different levels and disciplines of staff being trained together) to strengthen greater understanding of roles, challenges, and shared expectations.
- Ongoing and continuous.
- Convenient (both online and onsite).
- Available for all who come in contact with persons with dementia including families, Emergency Medical Technicians (EMTs) and other first responders, emergency room workers, police, Certified Nursing Assistants (CNAs), primary care physicians, direct care staff, doctors, students, mental health professionals, administrators, dietary staff, security, janitorial staff and others.

To assure humane and effective treatment, content should include fundamental information regarding:

- Dementia, challenging behaviors, appropriate treatments, and basic geriatric needs.
- Methods to increase understanding of the people being cared for (focusing on the individual, personal needs and family dynamics).



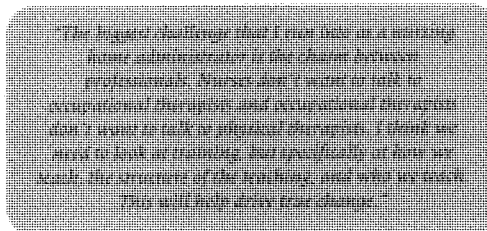
- Behavioral management techniques that distinguish between "fixing" problems and managing them.
- Available resources, including appropriate placements.
- Alternatives to medication and sedation.
- How to de-escalate situations, effectively communicate with residents, and techniques to calm someone down when a situation has escalated.
- The use and importance of pre-admission forms, general assessments, and proper chart documentation.

In addition, training should be available to families to help them better understand the health and long-term care systems they will encounter and to equip them with advocacy strategies.

XII. What are the next steps?

Based on the work of the Task Force, a number of recommendations are put forth in the Executive Summary of the report. To begin to implement these recommendations, the following action steps will be undertaken.

1. Participate in the design of the Alzheimer's State Plan, beginning with the release of this report on December 14, 2010. See the "Hand in the Plan" website at http://www.planningcouncil.org/CMS/alt_login.php.
2. Provide training and information on the topic of challenging behaviors at the Alzheimer's Association's 2011 Statewide Network Conference.
3. Increase awareness and training for law enforcement personnel in more municipalities on the topic of challenging behaviors among people with dementia.
4. Convene a work group to produce recommendations on Chapter 51 for the State legislature.
5. Convene a work group to recommend approaches to reducing the use of psychotropic drugs for people with Alzheimer's exhibiting challenging behaviors.
6. Convene a work group on training to refine and recommend curricula and approaches.
7. Work with health care systems and the Wisconsin Hospital Association to develop interim and long-range approaches to improve and coordinate emergency and inpatient hospital care.
8. Meet with individual nursing home administrators and state-level nursing home associations to identify interim and long-range strategies.
9. Reconvene the full Task Force regularly to report on progress and seek additional input.



Notes

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12. Ibid.
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14. Alzheimer's Association, "2010 Alzheimer's Disease Facts and Figures," Alzheimer's & Dementia 6 (2010): 1-72. Additional information provided by Krista Scheel of the Alzheimer's Association.
15. Wisconsin Department of Health Services, op. cit.
16. Brodaty et al., op. cit., p. 505.
17. Based on information obtained in an informal survey conducted by Task Force member Dennis Purtell.
18. For more information on the Massachusetts effort to reduce the use of psychotropic medication see http://www.boston.com/news/health/articles/2010/11/18/mass_aims_to_cut_drug_overuse_for_dementia/.
19. For more information see <http://personcenteredcareadvocate.org/manual-history> or <http://www.centeredcare.org/default.asp>.
20. For more information see <http://wgpi.org/starmethod.cfm>.
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- Raters' Criteria
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- Assessing Danger to Self
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- Interventions for Residents Suffering from Depression
- Working with Residents who Ask for Control
- Working with Residents who Suffer from Anxiety Disorders
- Interventions for Residents who Suffer from Anxiety Disorders
- Interventions for Reducing Anger and Aggression

Understanding Difficult Behaviors: A Visual Worksheet Approach, Dori Ann Bischmann, PhD and Mark Eberhage, PhD, Behavioral Solutions, Inc.

- A Visual Worksheet Approach
- Worksheet A: ABC Behavioral Analysis
- Worksheet B: Ruling out Medical Causes of Behavior
- Worksheet C: Assessing Danger to Self or Others
- Worksheet D: Strategies for Reducing Potential Danger to the Self or Others
- Worksheet E: Initiating Emergency Detention
- Worksheet F: Referring to Inpatient Psychiatric Hospital Greater Milwaukee Area-Voluntary Patients
- Worksheet G: Referring to Your Behavioral Solutions On-Site Provider
- Worksheet H: Which practitioner should you refer to: the psychiatrist or behavioral consultant?

Serial Trial Intervention, Dr. Christine Kovach

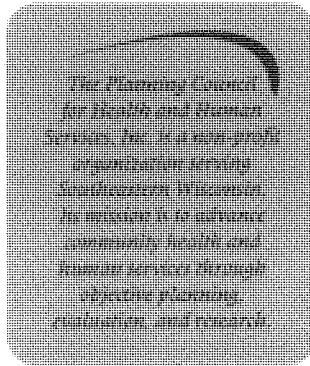
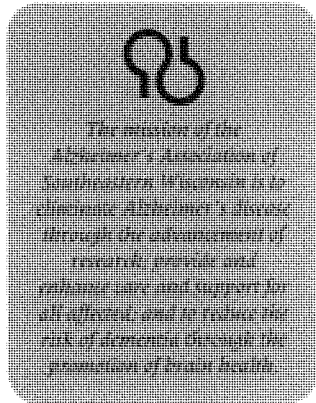
- C-NDB Model
- Examples of Cascading Effects

NOPPAIN (Non-Communicative Patient's Pain Assessment Instrument), A U.S. Veterans Affairs METRIC™ Educational product.

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UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
OVERPRESCRIBED: THE HUMAN AND TAXPAYERS' COSTS OF
ANTIPSYCHOTICS IN NURSING HOMES

November 30, 2011

Testimony of Toby S. Edelman
Senior Policy Attorney
Center for Medicare Advocacy

The misuse of antipsychotic drugs as chemical restraints is one of the most common and longstanding, but preventable, practices causing serious harm to nursing home residents today. We thank the Senate Special Committee on Aging for holding today's hearing.

In May 2011, the Inspector General of the Department of Health and Human Services issued a report indicating that

- 304,983 elderly nursing home residents (14%) received atypical antipsychotic drugs between January 1 and June 30, 2007, at a cost of hundreds of millions of dollars for the six-month period;
- 83% of the claims were for off-label conditions, including 88% for conditions specified in the black-box warning given to antipsychotic drugs by the Food and Drug Administration (FDA).¹

¹ Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011), <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>. In April 2005, the FDA issued "black box" warnings against prescribing atypical antipsychotic drugs for patients with dementia, cautioning that the drugs increased dementia patients' mortality. FDA, "Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances" (April 5, 2005), <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm>. In June 2008, the FDA extended its warning to all categories of antipsychotic drugs, conventional as well as atypical, and directly and unequivocally advised health care professionals, "Antipsychotics are not indicated for the treatment of dementia-related psychosis." FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm>.

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Advancing Fair Access to Medicare and Health Care

The Inspector General's report actually understates the inappropriate use of antipsychotic drugs with nursing home residents because it does not evaluate the inappropriate use of conventional antipsychotics drugs, which are still used in nursing facilities. Nursing facilities' self-reported data, publicly reported by the Centers for Medicare & Medicaid Services (CMS), indicate that in the third quarter of 2010, 26.2% of residents received an antipsychotic drug in the previous seven days.² Facilities reported to CMS that they gave antipsychotic drugs to many residents who did not have a psychosis or related condition, including 39.4% of residents at "high risk" of receiving antipsychotic drugs because of "behavior problems."³

As Inspector General Daniel Levinson wrote in a May 9, 2011 statement, "Too many [nursing homes] fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use."⁴ He concluded, "Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions."⁵

We agree with General Levinson that the misuse of antipsychotic drugs with nursing home residents who suffer from dementia is outrageous. But what is even more shocking is that this problem is not new. More than twenty years ago, this Committee held a Workshop on "Reducing the Use of Chemical Restraints in Nursing Homes" that identified the same issues we are discussing today.⁶ Several months later, in February 1992, in the preamble to proposed regulations that would have given residents new protections from chemical restraints, the Health Care Financing Administration (HCFA) (predecessor agency to CMS) described the long-standing and "significant public health problem in many, but not all of this nation's long-term care facilities."⁷ The problem described by HCFA was, even then, more than 15 years old:

For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with the subject have appeared in a number of medical journals. These papers generally question the extent of the use

² CMS, "MDS Active Resident Information Report: Third Quarter 2010," http://www.cms.gov/MDSPubQIandResRep/04_activeresreport.asp?isSubmitted=res3&var=O4a&date=32.

³ CMS, "Psychotropic Drug Use – July/September 2010,"

http://www.cms.gov/MDSPubQIandResRep/02_qmreport.asp?isSubmitted=qm3&group=10&qtr=23.

⁴ Daniel R. Levinson, "Overmedication of Nursing Home Patients Troubling" (Statement, May 9, 2011), http://www.oig.hhs.gov/testimony/levinson_051011.asp.

⁵ *Id.*

⁶ Senate Special Committee on Aging, *Reducing the Use of Chemical Restraints in Nursing Homes*, (Workshop, July 22, 1991), <http://aging.senate.gov/publications/7221991.pdf>.

⁷ 57 Federal Register 4516, 4519 (Feb. 5, 1992), 1992 West Law 17302 (F.R.).

of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.⁸

Since at least 1975, we have been on notice as a country that nursing home residents have been overmedicated with antipsychotic drugs. Yet the problem persists. It is long past time to change this shameful record.

The Nursing Home Reform Law prohibits the antipsychotic drug practices that we see in too many nursing homes

The federal Nursing Home Reform Law, enacted in 1987, limits the use of psychopharmacologic drugs. The law expressly provides:

Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.⁹

Implementing regulations explicitly limit the use of antipsychotic drugs (under a subsection of the regulations entitled Unnecessary Drugs):

(2) *Antipsychotic Drugs*. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.¹⁰

The federal regulations also require monthly review of each resident's entire drug regimen by a pharmacist, who must report "irregularities":

(c) *Drug regimen review*. (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.¹¹

⁸ *Id.*

⁹ 42 U.S.C. §§1395i-3(c)(1)(D), 1396r(c)(1)(D), Medicare and Medicaid, respectively.

¹⁰ 42 C.F.R. §483.25(l)(1).

CMS guidance to surveyors in the State Operations Manual¹² encourages facilities to use non-pharmacological alternatives, identifies situations where antipsychotic medications are not indicated,¹³ and provides an investigative protocol for unnecessary drugs, including antipsychotic drugs.

Despite these strong provisions, antipsychotic drug use remains a serious concern, in part because the law, regulations, and surveyor guidance are inadequately and ineffectively enforced. Stronger enforcement of these standards would make an enormous difference.

Changing current practice is an important goal of residents' advocates, as demonstrated by the Resolution passed this month by members of the National Consumer Voice for Quality Long-Term Care (Consumer Voice). (The resolution is attached to my testimony.)

Why antipsychotic drugs are inappropriately prescribed for nursing home residents

There are many reasons why antipsychotic drugs are inappropriately prescribed for nursing home residents who have dementia, despite the strong statutory and regulatory protections against such use.¹⁴ I offer several additional reasons here.

Nursing facilities have insufficient numbers of appropriately trained staff

The most significant cause of the inappropriate use of antipsychotic drugs is the serious understaffing in nursing facilities.¹⁵ Most facilities do not have enough staff and enough staff with specialized and professional training to meet the needs of their residents who have dementia.

This point was bluntly made by the American Society of Consultant Pharmacists (ASCP). In a Policy Statement about "Use of Antipsychotic Medications in Nursing Facility Residents," issued in response to the Inspector General's May 2011 report, ASCP

¹¹ 42 C.F.R. §483.60(c).

¹² State Operations Manual, Appendix PP, https://cms.gov/manuals/Downloads/som107ap_pp_guidelines_itcf.pdf (scroll down to page 344 for the beginning of guidance for §483.25(l)).

¹³ *Id.* 386 ("1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under 'indications' and do not represent a danger to the resident or others").

¹⁴ See David S. Sherman, "Psychoactive Drug Misuse in Long-Term Care: Some Contributing Factors," *Journal of Pharmacy Practice*, Vol. 1, No. 3 (Dec.), 1988: 198-194. Mr. Sherman identifies, among other reasons, "the desire to help residents," "belief in psychoactive drug efficacy," "underestimation of drug toxicity," "family concerns," "nursing staff stress," "inadequate training," and "influence of drug manufacturers." Many of these reasons remain valid today.

¹⁵ Lucette Lagnado, "Prescription Abuse Seen In U.S. Nursing Homes; Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense," *Wall Street Journal* (Dec. 4, 2007). This article, which led to Senator Charles Grassley's requesting review by the Office of Inspector General, cited a statement by Bruce Pollock, president-elect of the American Association of Geriatric Psychiatry, that high use of antipsychotic drugs in a nursing facility can reflect inadequate staffing.

acknowledges that “non-pharmacological approaches are generally preferred as initial therapy when possible,” but then states:

Nursing homes have evolved to the point where the vast majority of residents have one or more mental health problems, yet few nursing homes have staff with specialized training in psychology or behavior management. The result is that medications have become the dominant approach to management of BPSD [Behavioral and Psychological Symptoms of Dementia].¹⁶

Jonathan Evans, M.D., incoming president of the American Medical Directors Association, has called for “a different paradigm” – a recognition that “behavior is communication, . . . not a disease.”¹⁷ He urges that caregiving staff learn new methods to figure out the meaning of residents’ behaviors and to address the behaviors creatively, without drugs.

Two additional staffing issues – the enormous turnover in staff and lack of consistent assignment of staff to residents – both contribute to the inappropriate medication of residents with antipsychotic drugs in order to address behavior issues. When staff do not know the residents they are caring for, they are less able to recognize and understand residents’ non-verbal communications or changes in condition that could warrant a care intervention.

Physical restraints are used less often

General recognition that physical restraints are not appropriate has led nursing facilities to use drugs as an alternative way to deal with residents with behavior issues. When the 1987 Nursing Home Reform Law was implemented in 1990, the federal government made a strong effort through the survey and certification system to reduce the use of physical restraints. Strong federal regulations and guidance were supported by residents’ advocates’ and nursing facilities’ recognizing the dangers of physical restraints and promoting alternative methods of care. While physical restraints are still used far more widely than they should be, they are less common than they were 20 years ago. But physical restraints have been replaced by less visible chemical restraints.

Some drug companies have engaged in illegal off-label marketing of antipsychotic drugs for nursing home residents

The aggressive off-label marketing of antipsychotic drugs, especially the atypical antipsychotic drugs that were promoted as having fewer side effects than conventional

¹⁶ American Society of Consultant Pharmacists, “Use of Antipsychotic Medications in Nursing Facility Residents” (Policy Statement), <https://www.ascp.com/sites/default/files/ASCP-antipsychotics-statement.pdf>.

¹⁷ Jonathan Evans, MD, MPH, CMD, “The Ethics of Antipsychotics in Alzheimer’s,” *Caring for the Ages* (May 1, 2011), <http://www.caringfortheages.com/issues/may-2011/single-view/the-ethics-of-antipsychotics-in-alzheimers/ba6ff721b07f61a5d15888345dd9e1bc.html/>.

antipsychotic drugs, led to their expanded use after a brief period of declining use.¹⁸ To cite one example: In January 2009, the Eli Lilly Company settled civil and criminal charges under the federal False Claims Act, paying \$1.45 billion in civil and criminal fines.¹⁹ The United States alleged that between September 1999 and March 31, 2001, the company engaged in off-label promotion of Zyprexa “as treatment for dementia, including Alzheimer’s dementia.”²⁰ Eli Lilly had trained its long-term care sales force to promote Zyprexa for the treatment of dementia, depression, anxiety and sleep problems in nursing home and assisted living residents.

Consultant pharmacists often work for long-term care pharmacies

Consultant pharmacists, who are critical to implementing the federal provisions governing drug regimen review, have not been independent.

One example: In January 2010, the United States sued drug manufacturer Johnson & Johnson for paying kickbacks to Omnicare, the nation’s largest nursing home pharmacy, so that Omnicare’s pharmacists would recommend Johnson & Johnson’s drugs, including Risperdal, for use by nursing home residents. The Justice Department’s January 2010 press release described the government’s allegations:

In its complaint against J&J, the United States alleges that the company paid kickbacks to Omnicare to induce the nursing home pharmacy company to purchase and recommend J&J drugs, including the anti-psychotic drug Risperdal, for use in nursing homes. According to the complaint, J&J understood that Omnicare’s pharmacists reviewed nursing home patients’ charts at least monthly and made recommendations to physicians on what drugs should be prescribed for those patients. The government further alleges that J&J knew that physicians accepted the Omnicare pharmacists’ recommendations more than 80 percent of

¹⁸ G.C. Alexander, S.A. Galiher, A. Mascola, R.M. Moloney, R.S. Stafford, “Increasing off-label use of antipsychotic medications in the United States, 1995-2008,” *Pharmacoepidemiology and Drug Safety* (2011); Brenda Goodman, “Study: Newer Antipsychotic Drugs Are Overused,” *WebMD Health News* (Jan. 7, 2011).

¹⁹ U.S. Department of Justice, “Pharmaceutical Company Eli Lilly to Pay Record \$1.45 Billion for Off-Label Drug Marketing; Criminal Penalty is Largest Individual Corporate Criminal Fine” (News Release, Jan. 15, 2009), <http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf>. See also the Criminal Information at <http://www.usdoj.gov/usao/pas/News/Pr/2009/jan/lillyinfo.pdf>; the guilty plea agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyguiltypleaagreement.pdf>; the 65-page government memorandum for entry of plea and sentencing, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillygovtmententrypleasent.pdf>; the 67-page Corporate Integrity Agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillycorpintegagreement.pdf>; and the 35-page settlement agreement, at <http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillysignedsettlementagreement.pdf>.

²⁰ *United States of America v. Eli Lilly and Company* (E.D. Pa., Jan. 15, 2009) Guilty Plea Agreement ¶6.A.(4).

the time, and that J&J viewed such pharmacists as an "extension of [J&J's] sales force."²¹

Two months earlier, in November 2009, the government had settled a False Claims Act case with Omnicare. Under the settlement, Omnicare paid \$98 million and the drug manufacturer IVAX Pharmaceuticals agreed to pay \$14 million to the United States to resolve allegations involving kickbacks paid to Omnicare by Johnson & Johnson in exchange for Omnicare's consultant pharmacists' recommending the antipsychotic drug Risperdal for nursing home residents.²²

Although these False Claims Act cases arose prior to implementation of Medicare Part D, problems with drug regimen reviews continue under Part D. Long-term care pharmacies often provide consultant pharmacist services to nursing facilities, at low or no cost. Long-term care pharmacies receive rebates from drug manufacturers, leading to "a very strong incentive to promote utilization of drugs for which they receive rebates."²³ In a study of antipsychotic drug use in nursing facilities between May 2010 and June 2011, the California Department of Public Health found that consultant pharmacists failed to identify inappropriate antipsychotic use in 18 of 20 facilities (90%).²⁴

Antipsychotic drugs are a protected class under Medicare Part D

The Inspector General recently reported that the utilization control mechanism of prior authorization is prohibited "in most instances" for drugs that are protected classes under Part D, including antipsychotic drugs.²⁵ Post-payment strategies for utilization control "do not focus on medically accepted indications" for drug use. Psychoactive drugs, once prescribed, face little scrutiny from Part D prescription drug plans.

²¹ U.S. Department of Justice, "United States Files Suit against Drug Manufacturer Johnson & Johnson for Paying Kickbacks to Nation's Largest Nursing Home Pharmacy," (News Release, Jan. 15, 2010), <http://www.justice.gov/opa/pr/2010/January/10-civ-042.html>.

²² U.S. Department of Justice, "Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay \$112 Million to Settle False Claims Act Cases; U.S. Also Files Complaint Against Two Atlanta-Based Nursing Home Chains and Their Principals" (News Release, Nov. 3, 2009). Complaint of the United States, <http://www.phillipsandcohen.com/News-Reports-of-P-C-Cases/Omnicare-Mariner-complaint.pdf>; Department of Justice News Release, <http://www.justice.gov/opa/pr/2009/November/09-civ-1186.html>.

²³ Michael McCaughan, "Are Long Term Care Rebates Dangerous? One CMS Official thinks it is time for big changes in the long term care pharmacy model – to protect patients, manufacturers and Part D plans," *The RPM Report* (Jan. 2007).

²⁴ "CDPH/DHCS Antipsychotic Collaborative" (powerpoint), slide 9.

²⁵ OIG, "Memorandum Report: *Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications*," OEI-07-08-00152 (Nov. 14, 2011) (Memorandum from Stuart Wright, Deputy Inspector General for Evaluation and Inspections, to Donald M. Berwick, M.D., Administrator, CMS), <http://oig.hhs.gov/oei/reports/oei-07-08-00152.pdf>.

The high costs of using antipsychotic drugs

Antipsychotic drugs are expensive. They are the top-selling class of drugs in the United States, generating annual revenues of \$14.6 billion.²⁶ While all of these drugs are not used with nursing home residents,²⁷ a significant portion is. Drastically reducing the use of these drugs with residents for whom they are not appropriate would not only result in better care for the residents; it would also save the health care system billions of dollars.

But the costs of inappropriately using antipsychotic drugs extend far beyond the costs of the drugs themselves. Residents who are inappropriately given antipsychotic drugs experience a number of bad health outcomes that are expensive to try to correct. There is a high financial cost to the inappropriate use of antipsychotic drugs with nursing home residents.

Twenty years ago, efforts were made to quantify the “hidden costs” of antipsychotic drug use. David Sherman described research documenting that “elderly long-term care residents receiving antipsychotic drug therapy are two to three times more likely to experience a fractured hip than residents not receiving these medications.”²⁸ He identified increased urinary incontinence resulting from use of antipsychotic drugs²⁹ as well as an increase in falls and hip fractures.³⁰

More than 20 years ago, the Senate Labor and Human Resources' Subcommittee on Aging issued a staff report that identified the high cost of poor care and quantified the costs, citing research literature. The report quantified \$3.26 billion to pay for incontinence care; \$746.5 million for hip fractures for 18,500 residents (\$40,000 per person); and nearly \$1 billion for hospitalizations – all poor outcomes of care caused, in part, by antipsychotic drugs.³¹

A new report issued in April 2011 by Consumer Voice provides additional research-based data on the high costs of poor care.³² Consumer Voice cites reports by the Centers for Disease Control and Prevention (CDC) that falls and fractures in older people account

²⁶ Duff Wilson, “Side Effects May Include Lawsuits,” *The New York Times* (Oct. 3, 2010), <http://www.nytimes.com/2010/10/03/business/03psych.html?scp=1&sq=%22Side%20Effects%20May%20Include%20Lawsuits%22&st=cse>.

²⁷ Benedict Carey, “Drugs Used for Psychotics Go to Youths in Foster Care,” *The New York Times* (Nov. 20, 2011), http://www.nytimes.com/2011/11/21/health/research/study-finds-foster-children-often-given-antipsychosis-drugs.html?_r=1&ref=benedictcarey.

²⁸ David Sherman, “Using Common Sense to Reduce Antipsychotic Drug Use,” *Contemporary Long Term Care* (Oct. 1991).

²⁹ *Id.*

³⁰ David Sherman, “Medication Use and Falls,” *Contemporary Long Term Care* (Nov. 1991).

³¹ Subcommittee on Aging, Senate Committee on Labor and Human Resources, “Nursing Home Residents Rights: Has the Administration Set a Land Mine for the Landmark OBRA 1987 Nursing Home Reform Law?” pages 175-177, 102nd Cong., First Sess. (June 13, 1991).

³² The National Consumer Voice for Quality Long-Term Care (Lani G. Gallaher), *The High Cost of Poor Care: The Financial Case for Prevention in American Nursing Homes* (April 2011), <http://www.theconsumervoice.org/sites/default/files/advocate/action-center/The-High-Cost-of-Poor-Care.pdf>.

for \$31 billion in costs to the health care system (although not all of these costs, of course, reflect nursing home residents).³³ CDC also reports that in 2004, 8% of nursing home residents nationwide – 123,600 individuals – had an emergency department (ED) visit in the prior 90 days and that 40% of the ED visits, involving 50,300 residents, were preventable.³⁴ The leading cause of residents' potentially avoidable ED visits was injuries from falls.

Solutions

A problem as far-reaching as the chemical restraint of nursing home residents cannot be resolved by a single solution. Many solutions, simultaneously implemented, are necessary. Residents' advocates do not recommend an absolute prohibition against prescribing antipsychotic drugs for residents who have dementia, but no diagnosis of psychosis or related conditions. However, the fact that off-label use of drugs may be appropriate under some circumstances does not provide wholesale justification for the extensive use of antipsychotic drugs with residents who have dementia. The FDA's black box warnings on antipsychotic drugs should call into question most off-label use of antipsychotic drugs with such residents.

What we recommend is implementing what virtually all commenters on all sides of this issue agree on – that non-pharmacologic approaches should be tried first. To achieve that end, we recommend a number of approaches that would call prescribers' attention to the issue of antipsychotic drug use, slow down the process of prescribing antipsychotic drugs, teach better non-drug alternatives, and create and impose stronger sanctions for inappropriate antipsychotic drug use.

Survey

- CMS should revise the federal survey protocol and the new Quality Indicator Survey to require surveyors to include residents using antipsychotic drugs in the resident sample in every survey.
- CMS should require its Regional Offices to focus the federal surveys they undertake as part of their oversight function on facilities with high rates of antipsychotic drug use.

Training and education

- CMS should issue a Survey & Certification Letter, outlining the importance of surveyors' determining compliance with CMS's regulations and guidance on the use of antipsychotic drugs. The Letter could highlight the recent decision in *Washington Christian Village v. CMS*, Docket Nos. C-10-456 and C010-602,

³³ *Id.* 2.

³⁴ Christine Caffrey (CDC), "Potentially Preventable Emergency Department Visits by Nursing Home Residents: United States, 2004," NCHS Data Brief, No. 33 (April 2010), <http://www.cdc.gov/nchs/data/databriefs/db33.pdf>.

Decision No. CR2403 (July 27, 2011), which sustained an unnecessary drug deficiency for antipsychotic drugs.

- CMS should conduct a Satellite broadcast and in-person trainings on CMS's existing (and new) regulations on antipsychotic drugs. More than twenty years ago, surveyor training on physical restraints presented the importance of the issue and information on how to provide care without physical restraints. Similar training should be provided on chemical restraints.

New legislation and regulations

- The Prescription Drug Cost Reduction Act, S. 1699, §7, introduced by Senator Kohl on October 12, 2011, requires physician certification that off-label prescription of an antipsychotic drug with a nursing home resident "is for a medically accepted indication."³⁵ This is an excellent legislative proposal that we strongly encourage Congress to enact.
- CMS recently proposed amending the consultant pharmacist regulations, 42 C.F.R. §483.60(b) to require that consultant pharmacists be independent and have no conflict of interest; prohibit rebates, kickbacks, bonuses, fee arrangements, and gain-sharing. 76 Federal Register 63018, 63038-63041 (Oct. 11, 2011). This is an excellent proposal that we strongly encourage CMS to adopt.
- CMS should adopt the 1992 proposed rules on chemical restraints. These regulations require that residents or their legal representatives give specific written informed consent for antipsychotic drug use. They also require that physician orders specify "the dose, duration and reason for the use of the drug;" that a psychopharmacologic drug "not be used unless it can be justified in the clinical record that the potential beneficial effects of the drug clearly outweigh its potential harmful effect;" that residents taking psychopharmacologic drugs "be monitored closely;" that drugs "be gradually withdrawn at least semi-annually in a carefully monitored program conducted in conjunction with the interdisciplinary team;" and that residents' drugs "be reviewed at least annually by a physician who has training or experience in geriatrics and psychopharmacology." Proposed 42 C.F.R. §483.13(a)(2).
- CMS should amend the Requirements of Participation for nursing facilities to require Medical Directors, Quality Assurance Committees, Administrators, and Pharmacists to certify that they have reviewed the facility's use of antipsychotic drugs and that the use is in compliance with 42 C.F.R. §483.25(l) (unnecessary drugs) and §483.60 (pharmacy services and drug regimen review).

³⁵ <http://thomas.loc.gov/cgi-bin/query/z?c112:S.1699>.

Transparency

- CMS should post facility rates of antipsychotic drug use on *Nursing Home Compare*.
- CMS should develop a quality measure on antipsychotic drug use in nursing facilities.

Medicare Part A

- CMS needs to explore ways to prevent the prescribing of antipsychotic drugs during nursing home residents' Medicare Part A stays. Depending on how prescriptions are physically transmitted to pharmacists, a program in a Boston hospital establishing a computerized warning system might provide a useful model.³⁶ Under the authority of section 6114 of the Affordable Care Act, a demonstration could test a computerized order entry warning system for antipsychotic drugs in nursing facilities.

Medicare Part D

- CMS needs to consider utilization control mechanisms that would establish greater oversight of the use of antipsychotic drugs *before* they are prescribed and given to residents.

Stronger enforcement of federal law, regulations, and guidance

- Stronger enforcement of limitations on antipsychotic drug use can be effective in ensuring compliance with the requirements of law and regulations. Following both the federal FDA's 2005 warning about the death risks resulting from antipsychotic prescriptions in nursing homes and CMS's 2007 revised surveyor guidance on drug use, the state of Minnesota "responded with training for inspectors on how to spot cases of unnecessary medication and for nursing home administrators on how to prevent them."³⁷ In 2007, Minnesota cited 53% of

³⁶ Melissa L.P. Mattison, Kevin A. Afonso, Long N. Ngo, Kenneth J. Mukamal, "Preventing Potentially Inappropriate Medication Use in Hospitalized Older Patients With a Computerized Provider Order Entry Warning System," *Arch Intern Med*, Vol. 170 (No. 15), Aug. 2/23, 2010. In the Boston hospital, the computerized warning system flagged medications in three primary classes of medications (not-recommended medications, dose-reduction medications, and unflagged medications) identified by the Beers criteria as inappropriate for older people. In the study, the prescribing physician could bypass the warning and order the medication, but was required to choose a reason. Three choices were offered: (1) "Patient stabilized on regimen; will monitor appropriate drug levels or laboratory values, (2) "Interaction noted, regimen clinically indicated, will closely monitor," or (3) "Other: A fourth choice was added during the study, "Warning noted, will use smaller doses and monitor for side effects." The result of the study was a reduction in the prescribing of potentially inappropriate medications to patients over age 65.

³⁷ Jeremy Olson, "Drugs often a shortcut for care; Antipsychotics can calm nursing home patients, but also can be misused," *Pioneer Press* (Nov. 29, 2008).

nursing homes in the state for unnecessary medications. As a result of the deficiencies and enforcement, Minnesota nursing facilities' use of antipsychotic drugs with nursing home residents who do not have a diagnosis of psychosis declined between 2005 and 2008.

What can eliminating antipsychotic drugs mean for residents?

A researcher working in New York State to translate the research literature about the dangers of antipsychotic drugs into practice at nursing facilities wrote me about a small facility whose Director of Nursing had heard her speak about how to provided care to residents without using antipsychotic drugs.

This young DON heard me speak and said that will never be possible, but decided to give it a go, and got her medical director involved and consultant pharmacist on board, and they now have 2 residents only on antipsychotics and they have schizophrenia diagnosis. . . . one man they found had severe back pain from a spinal injury from a car accident years ago that was never addressed, but his dementia prevented his communicating the pain and they had him in a deep seated Geri chair which only exacerbated the pain, poor man, so he had behavior issues and was on antipsychotic meds, couldn't communicate or feed himself. He now eats lunch in the dining room and converses with his wife, participates in activities, etc. They have taken away the antipsychotic and replaced with pain medication. . . . one story makes it all worth it.

But the story this researcher told could be replicated hundreds of thousands of times in nursing homes across the country. Drastically reducing the use of antipsychotic drugs with nursing home residents would vastly improve the lives of hundreds of thousands of residents and would save hundreds of millions, if not billions, of dollars. After 35 years of studies, reports, and hearings, it is time to eliminate the epidemic use of antipsychotic drugs in nursing homes.

The Center for Medicare Advocacy is a private, non-profit organization, founded in 1986, that provides education, analytical research, advocacy, and legal assistance to help older people and people with disabilities obtain necessary health care. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. The Center provides training regarding Medicare and healthcare rights throughout the country and serves as legal counsel in litigation of importance to Medicare beneficiaries nationwide. Toby S. Edelman is a Senior Policy Attorney with the Washington, D.C. office of the Center. She has advocated on behalf of nursing home residents at the national level since 1977.



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National Consumer Voice for Quality Long-Term Care

Resolution To Request the Department of Health and Human Services to Address the Misuse of Antipsychotic Drugs in Nursing Homes

WHEREAS the chemical restraint of nursing home residents is a leading form of elder abuse that causes misery, loss of independence, over-sedation, confusion, falls, severe medical side effects and death;

WHEREAS many nursing homes commonly use antipsychotic drugs to chemically restrain elderly residents with dementia and as a substitute for needed care;

WHEREAS 26% of U.S. nursing home residents – more than 350,000 residents – are given antipsychotic drugs;

WHEREAS nearly 40% of U.S. nursing home residents who have cognitive impairments and behavioral symptoms are given antipsychotic drugs despite the absence of psychotic or related conditions;

WHEREAS the Centers for Medicare & Medicaid Services guidelines on unnecessary drugs state that analysis of antipsychotic drug use by 693,000 Medicare nursing home residents found that 28.5% of the doses received were excessive and 32.2% lacked appropriate indications for use;

WHEREAS the United States Food and Drug Administration (FDA) has not approved antipsychotic drugs for the treatment of dementia and has issued advisories and "black box" warnings that antipsychotic drugs greatly increase the risk of death for persons with dementia;

WHEREAS nursing home residents who receive antipsychotic drugs and their representatives are often not properly informed about the dangers of these drugs or of alternative forms of care and treatment;

WHEREAS the HHS Office of Inspector General issued a prominent report in May 2011 revealing that – despite FDA warnings on the greatly increased risk of death – 88 percent of the nursing home residents who are subjected to powerful antipsychotic drugs are elderly persons with dementia; and that Medicare overpaid \$116 million for erroneous nursing home claims for atypical antipsychotic drugs in a six-month period of 2007;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that "government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions" concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents.

The National Consumer Voice for Quality Long-Term Care (formerly NCCNHR) is a 501(c)(3) nonprofit membership organization founded in 1975 by Elma L. Holder that advocates for quality care and quality of life for consumers in all long-term-care settings.

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WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors as a treatment for dementia; and whereas one large national long-term care pharmacy has entered into agreements with the Department of Justice and several state governments to settle charges that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug it manufactures;

WHEREAS a large national long-term care pharmacy continues to provide drugs to residents of hundreds of long-term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS the Nursing Home Reform Law of 1987 and implementing regulations prohibit the unnecessary use of antipsychotic drugs and chemical restraints;

WHEREAS the Department of Health and Human Services (HHS) published proposed regulations on February 5, 1992 that would significantly strengthen the protections for nursing home residents against chemical restraint and prohibit the use of psychoactive drugs without written informed consent; and whereas, however, the proposed regulations have not been finalized.

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform a monthly drug regimen review for each resident and provide consultation on all aspects of pharmacy services within the facility; however, this requirement is not serving its purpose of independent analysis of nursing home drug use because most consultant pharmacists work for large long term care pharmacies that are the exclusive provider of drugs to the nursing homes, and the long term care pharmacies often subsidize the cost of consultant pharmacist services;

WHEREAS the Affordable Care Act of 2010 requires the Centers for Medicare & Medicaid Services to review and modify the Nursing Home Compare website to provide clear, timely and comprehensive information of value to consumers;

WHEREAS numerous studies have found that antipsychotic drugs are generally ineffective in treating behavioral symptoms of dementia, and that they are sometimes outperformed by placebos; studies also show that it is often a nursing home's drug use rate, not a resident's medical condition, which determines the likelihood of whether a resident will be given antipsychotic drugs and put at risk of serious harm and premature death;

WHEREAS, a growing number of nursing homes are proving there is a better way of caring for residents with dementia that focuses on ensuring their comfort and on timely assessment and response to the underlying causes of any behavioral symptoms;

THEREFORE BE IT RESOLVED that Congress hold hearings to address the rampant misuse of antipsychotic drugs to sedate and chemically restrain nursing home residents and that Congress enact legislation to ensure that antipsychotic drugs are not given to nursing home

residents without medical justification and without the specific informed consent of residents and their representatives.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services publish up-to-date information on each nursing home's use of antipsychotic drugs on Nursing Home Compare and that it factor antipsychotic drug use into its Five-Star Rating System for nursing homes.

BE IT FURTHER RESOLVED that HHS adopt the 1992 proposed regulations on chemical restraint, subject to modifications that nursing homes be required to inform residents and their representatives in writing of the known risks of psychoactive drugs, including any black box warnings, and to advise them if the drugs are being prescribed for off-label purposes.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies strengthen enforcement of existing chemical restraint and unnecessary drug requirements by carefully examining antipsychotic drug use during surveys and complaint investigations, by consulting with consumer stakeholders on needed modifications to survey and enforcement procedures for this purpose, and by promulgating new regulatory methods to prevent or discourage the prescribing of antipsychotic drugs for residents in the absence of psychotic or related conditions (such as implementing computerized warning systems particularly related to the use of antipsychotic drugs).

BE IT FURTHER RESOLVED that HHS establish and implement effective procedures to prevent Medicare payment for non-therapeutic use of antipsychotic drugs and to recover erroneous payments for these drugs.

BE IT FURTHER RESOLVED that when the HHS Office of Inspector General and the Department of Justice find that a provider of pharmacy services is illegally engaged in marketing and promoting antipsychotic drugs to long-term care facilities, they exclude the long-term care pharmacy from Medicare and Medicaid.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies establish high-profile education campaigns to advise consumers, nursing home employees, and physicians about the dangers associated with the misuse of antipsychotic drugs and to inform them of alternative forms of care and treatment for symptoms of dementia.



Testimony
United State Senate
Special Committee on Aging
November, 30, 2011

Thank you Chairman Kohl, Ranking-member Corker and Committee Members for the opportunity to speak to you today regarding the important issue of reducing the inappropriate use of antipsychotics in the nursing home and improving the care of individuals with Alzheimer's Disease and related dementia.

My name is Cheryl Phillips. I am a fellowship-trained geriatric physician and have spent over two decades in long term care. I am now the senior vice-president for Advocacy at LeadingAge, formerly known as the American Association of Homes and Services for the Aging

The members of LeadingAge serve as many as two million people every day through mission-driven, not-for-profit organizations dedicated to expanding the world of possibilities for aging. Our 5,700 members, many of whom have served their communities for generations, offer the continuum of aging services: adult day services, home health, community services, senior housing, assisted living residences, continuing care retirement communities and nursing homes. Together, we advance policies, promote practices and conduct research that supports, enables and empowers people to live fully as they age. LeadingAge's commitment is to create the future of aging services through quality people can trust.

According to the Alzheimer's Association in 2011, 13% of Americans 65 years of age and older are diagnosed with dementia, and that number reaches 43% for those 85 and older. It is the 6th leading cause of death in seniors and two-thirds of persons with dementia die in the nursing home. Of those seniors 80 years old and older who have a diagnosis of dementia, 75% will be admitted to a nursing home for long term care. By CMS's own reports between 50 and 75% of long-stay residents in nursing home have some degree of dementia. This is a profound

challenge that faces health care, long term care, and most importantly, the seniors and their families who are in this challenging journey.

But it is important to note that this is neither an issue limited to nursing homes, nor to the United States. Across the globe providers and health policy leaders are grappling with how best to provide care for individuals with dementia, including when and how medications should be used and what are non-medication alternatives. In a recent report to the Minister of the State for the National Health Service in the UK, Dr. Sube Banerjee outlined the challenges of reducing the use of antipsychotics for the management of behaviors related to dementia in the acute hospital, in the community, as well as in the nursing home. He presented eleven recommendations to the NHS, many that closely parallel the approaches proposed below. <http://psychrights.org/research/Digest/NLPs/BanerjeeReportOnGeriatricNeurolepticUse.pdf>

First of all, it is important to recognize that the use of antipsychotics is related to the much larger challenge of how to provide care for people with dementia. Medications are used often as the first intervention because family members, care givers, nurses and doctors in ALL settings lack information or training regarding alternatives. To merely target this one class of drug as the “problem to be fixed” will have the unintended consequence of increasing the use of other, equally risky medications, such as benzodiazepines, anti-seizure medications and sedative-hypnotics, all of which have side effects that include confusion, falls, and risk of death. Furthermore, if the focus is only on the nursing home, we will create barriers to access for care that patients and families desperately need. In some states, such as California where consent rules regarding the use of any psychoactive medications in nursing homes are in place, some nursing homes have declined admissions because of a “history of behavior problems requiring psych meds”, creating real challenges for caregivers and often requiring patients to stay for long periods in the acute care hospital. The solution to this challenge is not a short-term fix, but rather a two-fold strategy that involves systemic application of non-pharmacological behavioral interventions as the first line of treatment, with close monitoring for *appropriate* and limited use of medications when the non-pharmacological approaches have not worked.

We currently have an excellent framework for the definition and avoidance of unnecessary drugs in the nursing home setting in the language of F-329 in the Federal Regulations. The CMS State Operations Manual Appendix PP defines *Unnecessary Drugs* when used;

- i. In excessive dose; or
- ii. For excessive duration; or
- iii. Without adequate monitoring; or
- iv. Without adequate indication for its use; or
- v. In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combination of the above.

The guidelines further require that based on a comprehensive assessment of a resident, the facility must ensure that;

- i. Residents who have not used antipsychotics drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record and
- ii. Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

In addition to having antipsychotics prescribed in the nursing home, individuals diagnosed with dementia are frequently admitted to the nursing home already on multiple psychoactive medications (antipsychotics, benzodiazepines, antidepressants and others to manage behavior) that were started in the hospital, in assisted living or in the community, and they are merely continued as part of the dementia treatment plan.

There are five simple questions that should be asked when a person is admitted on antipsychotics or when a consideration is made to start them.

1. What was/is the *specific* reason for their use? Far too often the answer is reported simply as "aggression" or the normal behaviors related to dementia such as wandering or repetitive vocalizations. If there is no valid indication requiring their use, then dosage reduction and discontinuation should be considered, or the drug should not be started.
2. If there was an indication that required the short-term use, does that indication still exist? If not, then dosage reduction and discontinuation should be considered. And if

the behavior (example: transient agitation related to an event or other health care condition) has resolved then the medication should not be started

3. If the person is already on antipsychotics are there any undesirable side effects? If so, dosage reduction and discontinuation should be considered.
4. Has the person or their family or caregiver been given information about the use, risks and potential benefits (if any) of the medication being used? If not, then dosage reduction and discontinuation should be considered or the medication not started, except for very short-term use in valid emergencies that pose health or injury risks to the person or others.
5. Is there any history that appropriate behavioral therapies have been attempted in lieu of medication management? If not, such should be initiated and there should be a concurrent dosage reduction and discontinuation of the antipsychotic medications and these drugs should not be started, except in short term emergencies without first using these behavioral approaches.

Employing these simple strategies alone will result in significant reductions in the use of antipsychotic medications. But they are not enough to truly change care. The long term answer, much like how physical restraint reduction was implemented, comes from a sustained campaign that teaches caregivers how to provide real person-centered care alternatives. It takes direct care workforce training to apply evidence-based tools and approaches to care for persons with dementia. It takes dissemination of knowledge to nurses and physicians regarding the effectiveness of non-pharmacological interventions and to appreciate the risks of managing behaviors through medications alone, and it requires specific interdisciplinary team monitoring of patients when these medications are used to ensure the indication, dose, duration and response is appropriate for that individual.

This will take a collaborative partnership of ALL stakeholders; CMS, clinical staff and physicians across the health care continuum, pharmacists, direct care workers, and caregivers and families to move toward true “culture change” to improve how we care for people with dementia. It will require accurate aggregate data to measure incidence and prevalence of antipsychotic use with

timely feedback to prescribers and providers of care. It will require large-scale replication research and dissemination of evidence-based behavioral therapies that are effective in the care of people with dementia. It will require enhanced surveyor training, and an investment in meaningful workforce training across ALL settings of care.

We, at LeadingAge are committed to work on this. We have already convened a group of innovative LeadingAge member leaders to share their experiences of how they have improved dementia care in their communities and settings. We have begun an educational campaign to our members regarding avoiding the use of Unnecessary Drugs and Antipsychotics. We look to Advancing Excellence, an established coalition of multiple stakeholders that includes CMS, AHRQ, the Quality Improvement Organizations (QIOs), ASPE, nurses, administrators, consumers, direct care workforce, medical directors and nursing home associations, including LeadingAge, committed to improving the quality of care and life for people living in nursing homes. The work of Advancing Excellence is structured through LANEs (Local Area Networks for Excellence) that draw on regional stakeholders such as Ombudsmen, QIOs, and providers, to implement improvement changes at the local level. It is this level of collaborative work that will be required to both drive true change and sustain quality improvements over time.

In summary, the issue of the inappropriate use of antipsychotics is a symptom of the greater challenge, and if we merely target these drugs we will miss the opportunity to achieve the real improvement we seek. This is also not a “nursing home problem”, but rather a systemic health care dilemma. We at LeadingAge recognize that the true measure of quality care for people with dementia is care that is person-centered and based in dignity and compassion for the residents and their families. We can help transform nursing homes into centers of excellence for the care of people with advanced dementia and serve as the learning laboratory for other settings of care.

Respectfully submitted,

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Special Committee on Aging Hearing
“Overprescribed: The Human and Taxpayers’ Costs of Antipsychotics in Nursing Homes”
November 30, 2011

Questions for the Record

Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services

- 1. Mr. Levinson, you stated that you found a 51% error rate for Medicare atypical antipsychotic drug claims. But, you didn’t include dementia as a medically necessary indication. You claim that dementia did not comply with Medicare reimbursement criteria. However, under the CMS Medicare Benefit Policy Manual requirements, it specifically includes authoritative medical literature and/or accepted standards of medical practice as acceptable. In the response from CMS, they stated that dementia is a medically accepted indication. The Veterans Administration recognizes atypicals as an option for care for people with dementia. Why didn’t you include those considerations and only whether it was on label or in the compendia?**

Answer: Our report focused on Medicare Part D reimbursement requirements as established by the Social Security Act and CMS guidance documents. These requirements dictate that drugs must be provided for medically accepted indications, which are defined as uses approved by FDA and off-label uses supported by one or more of three compendia.

The diagnosis of dementia alone is neither an FDA-approved condition nor an indication included in any of the compendia. However, in some instances, dementia with specific associated behaviors or symptoms is considered a medically accepted indication and is listed in the compendia. For example, dementia associated with inappropriate sexual behavior, dementia associated with a psychotic disorder or psychotic symptoms, and dementia associated with anxiety are medically accepted indications for certain, but not all, antipsychotic drugs. These indications were included in our analysis, and if a drug was provided for one of these indications, it was deemed appropriate according to Medicare reimbursement criteria. We recognize that other health care providers and programs may use different definitions of what is an appropriate or approved use for a drug.

- 2. CMS sent OIG a letter in October challenging a significant conclusion of a 51 percent error rate in the OIG report stating that “the number of erroneous payments cited in the OIG report was grossly inflated due to the exclusion of dementia as a medically accepted indication for certain atypical antipsychotics”. Could you please explain CMS’s disagreement with your estimate of erroneous payments?**

Answer: Medicare Part D coverage requires that a drug be prescribed for an FDA-approved indication or an indication included in one of three compendia. The diagnosis of dementia alone is neither an FDA-approved condition nor an indication included in any of the compendia. However, in some instances, dementia with specific associated behaviors or symptoms is considered a medically accepted indication and is listed in the compendia. For example, dementia associated with inappropriate sexual behavior, dementia associated with a psychotic disorder or psychotic symptoms, and dementia associated with anxiety are

medically accepted indications for certain, but not all, antipsychotic drugs. These indications were included in our analysis, and if a drug was provided for one of these indications, it was deemed appropriate according to Medicare Part D coverage criteria.

3. **Are you aware that the American Psychiatric Association -- an independent, authoritative third-party -- concluded in 1997 and again in 2007 (after the FDA black box warning) that antipsychotics were “recommended for the treatment of psychosis in patients with dementia and for the treatment of agitation”?**

Answer: The effectiveness of antipsychotics for the treatment of dementia and associated psychosis and agitation was outside the scope of this study. Also, we did not seek to question the appropriateness of the Medicare coverage policy with this study. Our study sought to determine the extent to which claims for these drugs complied with Federal requirements regarding Medicare Part D reimbursement criteria. Accordingly, we used Medicare coverage policy as our criteria for what is considered to be medically accepted indications for drugs. We did consider dementia associated with a psychotic disorder or psychotic symptoms and dementia associated with anxiety as medically accepted indications for some antipsychotic drugs if such conditions were listed in one or more of the compendia.

4. **In September 2011, another branch of HHS, the Agency for Healthcare Research and Quality, contracted for a study in which medical experts found statistically significant evidence that antipsychotics were effective in treating dementia and associated psychosis and agitation. Are you aware of this study and did you consider it before sending your follow-up letter to CMS on November 14 regarding Medicare Part D reimbursement?**

Answer: The purpose of the followup memorandum report was limited to identifying the strategies that Prescription Drug Plan sponsors we contacted use to ensure that Medicare reimbursement for Part D drugs is limited to drugs provided for Part D-defined medically accepted indications. We did not assess the appropriateness of the Part D reimbursement policies or the effectiveness of antipsychotics for the treatment of dementia and associated psychosis and agitation.

5. **Your report’s conclusion is based on the assumption that claims for uses that lack FDA approval or support in the compendia were erroneously paid. Under Medicare Part B and Part D, don’t payors have the discretion to cover off-label uses if they determine that use is reasonable and necessary based on support in authoritative medical literature or just based on commonly accepted medical practice? Are you saying it was improper to pay claims for those uses that Medicare payors affirmatively decided to cover?**

Answer: Our report looked at coverage of atypical antipsychotics drugs under Medicare Part D. Medicare Part D reimbursement requirements are established by the Social Security Act and CMS guidance documents. These requirements dictate that to be reimbursed by Medicare Part D, drugs must be provided for medically accepted indications, which are defined as uses approved by FDA or off-label uses supported by one or more of three

compendia. Our study looked at whether drugs were used for medically accepted indications, as statutorily required.

Medicare reimbursement criteria regarding medically accepted indications apply to all Part D drugs. We note that the Medicare Improvements for Patients and Providers Act, or MIPPA, expanded the definition of medically accepted indications for anticancer drugs, effective January 1, 2009, to include drugs used in an anticancer chemotherapeutic regimen even if supported solely by peer-reviewed medical literature. This expanded definition does not affect coverage requirements for atypical antipsychotic drugs.

- 6. Are you contending that when drug plans make coverage decisions, they should be restricted to what is on label and what is in the compendia? How would this impact the practice of medicine?**

Answer: The Part D reimbursement criteria are established by the Social Security Act and implemented by CMS guidance. We evaluated compliance with those criteria. We did not evaluate the appropriateness of the criteria or the impact of reimbursement decisions on the practice of medicine.

- 7. How realistic is it to include the diagnosis on the prescription and with the part D claim? What sort of systematic changes would have to be made and how much would that cost?**

Answer: Currently, two States, Utah and Hawaii, require diagnosis information on prescriptions for their Medicaid programs. We would encourage consultation with these States to determine the cost and feasibility. In addition, we note that other Medicare Part A and B services require diagnosis codes on claims and may offer insights into associated costs.

- 8. You note Part D plan sponsors have asserted to the OIG that they are reluctant to impose prior authorization on antipsychotic medications because they are one of the six protected classes policy under which plans must include "all or substantially" of the drugs within the class on their plan formularies. Can you verify that this assertion on the part of Part D plan sponsors is accurate? I have heard from organizations representing beneficiaries that prior authorization requirements have been increasing in recent years across the six protected classes and with atypical antipsychotics in particular. Can you please verify the accuracy of this assertion by Part D plan sponsors that OIG has interacted with?**

Answer: The three selected PDP sponsors indicated that they use prior authorization for antipsychotic drugs in limited circumstances. We did not independently verify these sponsors' reports. While this may not be representative of all PDP sponsors, the sponsors we interviewed represent more than 30 percent of the beneficiaries enrolled in Part D plans for 2011.

- 9. You referred in your testimony to the black box warning that the FDA has included on the label of the antipsychotics. Common over-the-counter drugs that people take every day like ibuprofen, for example, have black box warnings (for heart attack and stroke).**

Are you saying a black box warning is a blanket determination that a drug is unsafe? Because that is not the position of either the FDA or CMS.

Answer: No. Our report does not assert that a black box warning is a blanket determination that antipsychotics or other drugs with boxed warnings are unsafe.

10. If at any point the FDA had determined that antipsychotics were unsafe, couldn't it have withdrawn them from the market, contraindicated them for particular patient populations or particular uses, recommended a risk management plan, or imposed specific marketing restrictions?

Answer: Our report did not conclude that antipsychotics are unsafe. We defer to FDA regarding its authority to regulate drug safety.

11. Is there ever a situation where it is appropriate to prescribe an antipsychotic for a nursing home resident?

Answer: Our work did not assess the medical appropriateness or necessity of atypical antipsychotic drug claims. However, we did assess compliance with Part D coverage criteria, and 49 percent of claims for atypical antipsychotic drugs prescribed for nursing home residents in our study met those criteria and were properly covered by Medicare Part D.

Special Committee on Aging Hearing
“Overprescribed: The Human and Taxpayers’ Costs of Antipsychotics in Nursing Homes”
November 30, 2011

Questions for the Record

Dr. Patrick Conway, Director and Chief Medical Officer, CMS

- 1. Dr. Conway, CMS sent OIG a letter in October challenging a significant conclusion of the 51 percent error rate OIG report stating that “the number of erroneous payments cited in the OIG report was grossly inflated due to the exclusion of dementia as a medically accepted indication for certain atypical antipsychotics”. Could you please explain CMS’s disagreement with the OIG’s estimate of erroneous payments? Does CMS stand by their original response to the OIG on this?**

Answer: CMS continues to believe that the OIG overstated the number of erroneous payments because the OIG assumed that no antipsychotic is ever coverable for Medicare Part D beneficiaries with dementia. Further, OIG recommended that diagnosis information should be included on the prescription drug event (PDE) record for Part D sponsors to use in validating that the prescribed medication was for a medically accepted indication. CMS also did not concur with this recommendation for a number of reasons. Diagnosis information is not typically included on prescriptions (including non-Part D prescriptions) and the diagnosis coding may not be specific enough to determine if the prescription was for a medically accepted indication. CMS is looking into the root cause of this problem and believes that the issue needs to be addressed in a multifaceted manner. We believe the actions outlined in our response to OIG, along with enhanced retrospective drug reviews, is a more effective strategy for combating this problem.

- 2. What percentages of patients with dementia are initially prescribed an atypical antipsychotic across the different care settings like acute care, long-term care, outpatient care, etc? In which care setting is an initial prescription for an atypical antipsychotic most commonly made?**

Answer: This is one of the aspects of the overutilization of atypical antipsychotics that CMS is studying. It is important to better understand the extent to which patients are initially prescribed these medications from physicians in the community, during an acute care hospital stay, in nursing homes, or in other health care settings.

CMS has contracted with the University of Massachusetts for a study examining 200 nursing home records to better understand the factors influencing anti-psychotic prescribing practices and patterns of prescribing. CMS also has a research project underway to study prescription drug use for a 5 percent nationwide sample of nursing home residents who are enrolled in Medicare and Medicaid. These studies should provide additional valuable information about the patterns behind inappropriate prescribing that will allow us to develop additional effective interventions.

3. How common is it for a long-term care patient to be admitted to a new long-term care facility already prescribed with an atypical antipsychotic?

Answer: CMS hopes to learn more about prescribing patterns through ongoing research. As previously mentioned, CMS has contracted with the University of Massachusetts for a study examining 200 nursing home records to describe factors influencing anti-psychotic prescribing practices and patterns of prescribing. CMS also has a research project underway to study prescription drug use for a 5 percent nationwide sample of nursing home residents. These studies should provide additional valuable information about the patterns behind inappropriate prescribing that will allow us to develop additional effective interventions.

4. What percent of nursing home residents admitted to a facility already on an antipsychotic are being followed by a physician that was not the original prescriber of the antipsychotic medication?

Answer: CMS does not track this information.

5. Is CMS committed to assisting the long-term care community with extracting data to help identify when and where an LTC resident may have first been prescribed an atypical antipsychotic, in order to help address concerns associated with overprescribing?

Answer: CMS is seeking a comprehensive approach to address the issue of potential overutilization of antipsychotics and is committed to working with States, regions and facilities to identify where a resident may have first been prescribed an antipsychotic agent. We are also committed to working with the American College of Emergency Room Physicians (ACEP) and the Society of Hospital Medicine (SHM) on acute care prescribing of these agents. We are already working with the American Medical Directors Association (AMDA) and other physician organizations on prescribing that begins in the nursing home.

6. How can we do better to coordinate across care settings to make sure patients are appropriately prescribed these medications in the first place?

Answer: CMS is working to educate providers across the health care delivery system to ensure that they better understand the possible risks of inappropriate use of atypical antipsychotics in some patients. Additionally, as use of electronic health records expands, physicians will have more tools at their disposal for identifying drug interactions and other potential adverse events.

For example, in the GRACE (Global Risk Assessment and Careplan for Elders) program at Beth Israel Deaconess Medical Center in Boston, Massachusetts, alert messages appear in the electronic pharmacy ordering system that notifies a physician when a more appropriate drug or dose should be selected for a geriatric patient. Similar systems operate in other hospitals, but only a few exist in nursing homes. Further, we are collaborating with the HHS Office of the National Coordinator (ONC) on one of their HITECH grants focused on using HIT to coordinate care across settings, including nursing homes.

- 7. If CMS is using FTag 329 citations data to determine the increase trends related to the inappropriate prescribing of antipsychotics, how is CMS able to tell which citations are related to unnecessary indications for antipsychotics and which are other drugs that do not have necessary indication, dose, or duration?**

Answer: CMS would only be able to discern the trends by reviewing the 2567 forms directly (review of survey records from each survey).

- 8. In the proposed rule to require nursing homes to employ or contract with an independent consultant pharmacist, does CMS intend to require consultant pharmacists have no financial relationships with any pharmacies? Or only pharmacies that provide pharmacy services to the same nursing homes serviced by the consultant pharmacist?**

Answer: The proposed rule (CMS-4157-P) states that we are considering requiring that long term care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent; that is, not employed, under contract, or otherwise affiliated with the long-term care facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities. The proposed rule did not say that we are considering a bar on a pharmacist's ability to have a financial relationship with a pharmacy unaffiliated with the LTC facility's pharmacy.

- 9. How does CMS envision the process for transition for mandatory independence of the consultant pharmacist to take place? How long do you think this process will take and will it be disruptive to patient access to consultant pharmacist services?**

Answer: As discussed in the proposed rule, we anticipate that if we were to require that LTC facilities engage independent consultant pharmacists, this would cause consultant pharmacists to reorganize to achieve independence from the parties (facility pharmacies, pharmaceutical manufacturers and distributors, and affiliated entities) with which the consultant pharmacists are currently affiliated. That is, we believe the consultant pharmacists currently assigned to LTC facilities would seek to retain relationships with those facilities, either through direct employment or by banding together with other consultant pharmacists, for instance, in professional corporations. We believe that if the changes under consideration in the proposed rule were to take effect beginning January 2013, such a time frame would provide sufficient time for implementation of the requirement. However, we recognized that there might be an argument for a longer implementation period in certain circumstances, in particular for LTCs in rural areas, and requested comment on whether the requirement under consideration should have a later effective date or other accommodation for rural facilities.

The public comment period for the proposed rule closed on December 12, 2011, and we currently are considering the comments on this issue.

- 10. How would requiring the separation of consultant pharmacists impact rural areas where there just aren't enough nursing home beds to support a full-time consultant pharmacist?**

Answer: We anticipate that long-term care facilities in rural areas would face the greatest challenges in recruiting qualified consultant pharmacists, particularly if the consultant pharmacists currently serving the rural facilities do not reorganize in order to continue to provide services. To that end, we recognize that the changes under consideration or the timeframe for implementation may need to be modified to assist these facilities. Therefore, in the proposed rule we solicited public comment on whether we should implement this change under consideration as of a later effective date for rural facilities or make other accommodations for their special circumstances.

11. What recourse will nursing homes have if they are unable to retain the services of a consultant pharmacist, as may be the case in rural areas?

Answer: In the proposed rule, in addition to soliciting comment on whether to provide a later effective date for rural facilities or make other accommodations for their unique circumstances, we solicited comment on whether to waive the independence requirement to permit alternative approaches. We requested that the descriptions of other approaches address the protections that would be implemented to reduce the risk of conflict of interest due to the lack of independence of the consultant pharmacists.

12. CMS proposes to allow rural nursing homes a delay of up to a year to allow additional time to retain independent consultant pharmacist services. What criteria would have to be met for a "rural" facility and how will a delay benefit a facility that has perpetual difficulties with access to resources?

Answer: As noted above, we recognize that some long-term care facilities in rural areas may face particular challenges in recruiting qualified consultant pharmacists, and have invited comment on whether we should implement this change under consideration as of a later effective date for rural facilities or make other accommodations for their special circumstances.

The comment period for the proposed rule closed on December 12, 2011, and we currently are considering the comments on this issue.

13. Currently New Jersey requires consultant pharmacists to be independent. I understand that in meetings with industry, CMS has committed to analyzing the data it has on New Jersey. How does the New Jersey data differ from the rest of the states to support your proposed rule? Have they been able to achieve significant cost and quality improvements?

Answer: We are not aware of data from New Jersey that demonstrates the impact of the State's implementation of a similar policy. CMS's consideration of this change in requirements for LTC facilities is not based on New Jersey's action or another State law, but due to widespread concerns about the relationships throughout the country between long-term care consultant pharmacists, pharmacies, and drug companies.

14. Is there ever a situation where it is appropriate to prescribe an antipsychotic for a nursing home resident?

Answer: CMS' efforts are designed to ensure that atypical antipsychotics are covered by CMS programs only when their use is medically appropriate, not to eliminate all uses of these medications.

Without knowing the specifics of any patient's medical history, it is difficult to definitively say what particular course of treatment would be appropriate. However, generally speaking, atypical antipsychotics may be appropriate for some nursing home patients with psychosis or mental illness, depending on their individual diagnoses. Our goal is to see that every beneficiary receives coverage for medically appropriate treatment, as determined by their health care practitioner.

15. How many nursing home residents are on antipsychotics because they are an on-label indication? Has this number changed over the last decade or so?

Answer: Diagnosis information is not included on prescriptions for Part D drugs, and as a result, CMS does not have a simple way to determine whether a particular prescription is on-label or off-label. Further, because Medicare Part D is a relatively new program, we can't speak to beneficiary experiences before the program began in 2006.

Special Committee on Aging Hearing
“Overprescribed: The Human and Taxpayers’ Costs of Antipsychotics in Nursing Homes”
November 30, 2011

Questions for the Record

Toby Edelman, Senior Policy Attorney, Center for Medicare Advocacy

- 1. On page 7 of your written statement you note that antipsychotic medications are a protected class under Part D and that once prescribed, antipsychotics "face little scrutiny from Part D prescription drug plans." Is the Center for Medicare Advocacy advocating for stricter limits on prescribing of antipsychotic medications in Part D**

Answer: The information about antipsychotic drugs facing little scrutiny by Part D plans comes from the Inspector General, who recently reported that the utilization control mechanism of prior authorization is prohibited “in most instances” for drugs that are protected classes under Part D, including antipsychotic drugs. OIG, “Memorandum Report: *Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications*,” OEI-07-08-00152 (Nov. 14, 2011) (Memorandum from Stuart Wright, Deputy Inspector General for Evaluation and Inspections, to Donald M. Berwick, M.D., Administrator, CMS), <http://oig.hhs.gov/oei/reports/oei-07-08-00152.pdf>.

The Center is not advocating for stricter limits on prescribing of antipsychotic medications in Part D. Medicare beneficiaries for whom these medications are medically appropriate and necessary should not have to overcome new barriers to get them. The testimony and our recommendations are focused solely on nursing home residents with diagnoses of dementia for whom antipsychotic drugs are medically inappropriate. Our concern is with residents receiving antipsychotic drugs, whether under Medicare Part A or under Medicare Part D.

- 2. What specific measures would the Center for Medicare Advocacy recommend with respect to Part D? Removal of antipsychotic medications from the six protected classes? Mandatory prior authorization for antipsychotic medications across indications and treatment settings?**

Answer: No, we are not recommending either of these proposals. We are not trying to make it more difficult for Medicare beneficiaries to get medically necessary drugs under Part D. We know that off-label prescriptions can be medically appropriate in many situations. What we are saying is that because the overwhelming numbers of prescriptions for antipsychotic drugs for *nursing home residents* (and likely assisted living residents as well) are medically inappropriate and contraindicated, these medications could kill residents with dementia, there should be multiple steps taken to slow down and rethink any decision to give those medications to nursing home residents. Existing control mechanisms have been insufficiently implemented and enforced to

protect residents. We support more effective use of existing mechanisms and additional mechanisms.

We support CMS's proposed regulation to require that consultant pharmacists (mandated by the Nursing Home Reform Law) be independent from long-term care pharmacies. We support rules proposed in 1992 that would require that nursing home residents give informed consent before being given antipsychotic drugs. We support use of Part D's medication therapy management tools, such as prior authorization, to require another evaluation of a nursing home resident's need for antipsychotic drugs. We support stronger and more effective enforcement of Requirements of Participation for nursing facilities that limit the use of antipsychotic drugs for residents. My written testimony sets out these recommendations in greater detail.

- 3. Does the Center for Medicare Advocacy support the OIG's recommendation for expanding the required data elements for all claims under Part D to include diagnostic codes? Would the Center for Medicare Advocacy support mandating that physicians include diagnostic information on all prescriptions? Thus denying all beneficiary claims for prescription drugs that do not include a diagnostic code?**

Answer: No, we do not support expanding Part D data elements to include diagnostic codes or mandating that physicians include diagnostic information on all prescriptions. Such requirements would violate patients' right to privacy and would make it more difficult for Medicare beneficiaries to get medically necessary and appropriate medications. That is not our goal. We focused in this testimony solely on reducing or eliminating the inappropriate use of antipsychotic drugs for nursing home residents because the use of these medications with residents who have dementia is medically inappropriate, can be life-threatening, and destroys residents' quality of life.

To: Senate Special Committee on Aging
From: Toby Edelman, Center for Medicare Advocacy
Re: Studies about nursing home residents' pain, finding that pain is underreported in the nursing home assessment process (MDS 2.0) for residents with dementia
Date: Dec. 23, 2011

Abt Associates, which designed the Nursing Home Quality-Based Purchasing Demonstration, declined to use CMS's pain measure for a variety of reasons, including the following: "Previous studies (e.g., Cohen-Mansfield (2004), Fisher, Burgio, Thorn, et al. 2002) have found that the MDS underreports pain in cognitively impaired residents." Abt Associates, Inc., *Quality Monitoring for Medicare Global Payment Demonstrations: Nursing Home Quality-Based Purchasing Demonstration, Final Design Report*, page 43 (June 2006), http://www.cms.gov/DemoProjectsEvalRpts/downloads/NHP4P_FinalReport.pdf

These are the articles that Abt cited:

Cohen-Mansfield J. 2004. The adequacy of the minimum data set assessment of pain in cognitively impaired nursing home residents. *J Pain Symptom Manage.* Apr;27(4):343-51. The full article is available at <http://download.journals.elsevierhealth.com/pdfs/journals/0885-3924/PIIS0885392404000089.pdf>

Fisher SE, Burgio LD, Thorn BE, et al. 2002. Pain assessment and management in cognitively impaired nursing home residents: association of certified nursing Assistant pain Report, Minimum Data Set pain report, and analgesic medication use. *Journal of the American Geriatrics Society* 50: 152-156. I can only get the abstract of this article, <http://onlinelibrary.wiley.com/doi/10.1046/j.1532-5415.2002.50021.x/abstract>

Senator Robert P. Casey, Jr.

Opening Statement

“Overprescribed: The Human Taxpayers’ Cost of Antipsychotics in
Nursing Homes.”

November 30, 2011

Thank you Senator Kohl for giving us the opportunity to talk about an important issue- the over prescribing of antipsychotic drugs to older citizens with dementia who live in nursing homes- and specifically those without a history of mental illness.

I also want to thank Senator Kohl for his commitment to addressing the needs of our aging population. We have to make a commitment to improving the lives of our older Americans. It is estimated that the number of older Americans over the age of 65 will double from 37 million to over 70 million by 2030.

We must ensure our older citizens receive quality health care, both physical and mental. From the information we will hear today it seems many older Americans who suffer from Alzheimer’s and dementia are being prescribed antipsychotic drugs as a way to restrain or sedate them. It is worrisome to me that these patients are being chemically restrained with antipsychotic drugs even if they do not have a history of mental illness. Some doctors are writing prescriptions for off label drugs that have nothing to do with the conditions that they older citizens have been diagnosed with. Because of this, Medicare is reimbursing pharmaceutical companies for prescriptions that are unnecessary. This is costing Medicare hundreds of millions of dollars a year. By eliminating these unnecessary prescriptions Medicare is covering, we

will be able to save money and strengthen the Medicare program at the same time allowing it to offer better for to beneficiaries.

I understand that these types of drugs are useful for some patients in certain situations however I believe we should look in to all options when caring for older citizens. We cannot allow antipsychotic drugs to be marketed as a panacea for all symptoms that dementia and Alzheimer's patient's exhibit.

While I understand patients and their caregivers can have difficulty communicating with each other, prescribing patients unnecessary medications for these problems does not aid in their overall comfort, or health and ultimately does not always alleviate the situation. It is also important that doctors and caregivers discuss all treatment options with the patients and their families. There are often alternative treatments to chemical restraints. Families need to be aware of the risks that antipsychotic drugs pose on their loved one.

Pennsylvania has one of the largest percentages of older Americans. As their representative it is my duty to look out for their wellbeing. I look forward to hearing the testimonies of the panelists about this situation and their suggestions on alternative treatments. Those who directly care for these patients are the best people to hear from when taking suggestions to aid our older citizens and those who have lost the ability to speak for themselves.

I will end this as I want to keep my remarks brief in order to hear from everyone else. I thank you for taking the time to listen, and hope that you will all help me to learn about and understand new ways to improve the daily lives of our aging population. and be the voice of reason from those who have lost their ability to speak for themselves.



*Our mission is "to provide optimal care and services to individuals confronting dementia,
and to their caregivers and families—through member organizations dedicated to improving quality of life."*

**STATEMENT OF ERIC J. HALL
FOUNDING PRESIDENT AND CEO
ALZHEIMER'S FOUNDATION OF AMERICA
ON
THE OVERUTILIZATION OF ATYPICAL ANTIPSYCHOTICS IN NURSING HOME SETTINGS
BEFORE THE
UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
November 30, 2011**

**FOR INCLUSION IN THE RECORD
December 14, 2011**

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On behalf of the Alzheimer's Foundation of America (AFA), a New York-based national nonprofit organization that unites more than 1,600 member organizations nationwide with the goal of providing optimal care and services to individuals confronting dementia, and to their caregivers and families, I wish to thank Chairman Kohl, Ranking Member Corker and the Committee for holding a hearing on the use of antipsychotic drugs in nursing home settings, an issue of great importance to people with Alzheimer's disease and their caregivers.

Caring for an individual or loved one with Alzheimer's disease is often challenging and beyond the capacity of some family caregivers. As a result, a majority of our nation's long-term nursing home residents are living with Alzheimer's disease. Nursing homes ideally provide people with Alzheimer's disease with a safe environment, skilled nursing care, socialization, custodial care services, and behavioral management interventions. They may also provide various medications to residents.

With the large number of nursing home residents having Alzheimer's disease or some other form of dementia, AFA has concerns about the inappropriate use of antipsychotics in these settings. Two recent studies conducted by the Office of the Inspector General (OIG) with the Department of Health and Human Services (HHS) found that over 14 percent of all nursing home residents had Medicare claims for atypical antipsychotic drugs, half of which were not used for medically accepted indications.¹ Taken together, these findings raise questions about whether atypical antipsychotic drugs are being prescribed and monitored appropriately.

AFA is committed to ensuring that people with Alzheimer's disease are not treated with inappropriate or harmful medications. The OIG concerns question whether certain atypical antipsychotics to treat behavioral symptoms of Alzheimer's disease and other dementia are appropriate.

Yet there is an, albeit, limited role for the appropriate use of antipsychotics in the treatment of nursing home residents with Alzheimer's disease. Violence is a significant clinical challenge in Alzheimer's disease treatment, and estimates are that approximately 57 percent to 67 percent of all individuals with dementia manifest some form of aggressive behavior, including violence in approximately 18 percent of cases.² In fact, there are some instances where the behavioral and psychotic symptoms of a person with Alzheimer's disease or other dementias pose a greater risk to the nursing home resident, staff or family member than the use of antipsychotic medication.

AFA also has concerns that increased restrictions on the use of antipsychotic medications in nursing homes could lead to access issues. People with Alzheimer's disease are often placed in a nursing facility because family members could not manage their behavior. Nursing home facilities could restrict or deny admission to people with Alzheimer's disease if they perceive behavioral difficulties and lack the effective tools to keep residents, staff and family members safe.

The Centers for Medicare and Medicaid Services (CMS) has taken steps, supported by AFA, to reduce the inappropriate use of antipsychotics. These actions include updating guidance related to the survey and certification of nursing homes to better measure and target inappropriate prescribing.

¹ *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, (OEI-07-08-00150)(May, 2011).

² Paveza, et. al., *Severe Family Violence and Alzheimer's Disease: Prevalence and Risk Factors*, 32 *The Gerontologist*, No. 4, 493-7 (1992).

AFA supports further CMS initiatives, spelled out in its testimony before the Committee³, including ways to strengthen enforcement, eliminate conflicts of interests between long-term care pharmacists and nursing homes, and better training and outreach to all stakeholders.

We are also supportive of CMS proposals to improve care for individuals with Alzheimer's disease and other related dementias, including new research and quality measures to better understand the factors that influence prescribing practices in nursing home settings and to help identify additional effective intervention strategies. Quality Improvement Organizations (QIOs) can also be utilized to reduce inappropriate prescribing of antipsychotics and work with nursing homes to increase quality while lowering the number of incidences of adverse drug events.

As a member of the federal Advisory Board on Research, Care and Services, AFA is working with CMS, HHS and other stakeholders on a National Alzheimer's Plan that will be a catalyst for improved Alzheimer's disease care, provide greater awareness of Alzheimer's disease, lead to new tools and strategies for family caregivers, ensure training of healthcare professionals working with the dementia population, and increase resources for targeted investment in Alzheimer's disease research.

To that end, AFA makes the following additional recommendations to ensure proper behavioral intervention strategies are employed by nursing home staff, including:

- **Increased Funding and Training for Nursing Home Surveyors**

Survey and certification personnel need to have the proper tools to effectively monitor nursing home compliance with current policies and regulations. Funding is needed to ensure that surveyors are trained in noninvasive behavioral intervention techniques. Surveyors will also need to have the resources to monitor the rate of antipsychotic drug use in the facility, prior to a site visit, so that proper scrutiny and intervention can be targeted to facilities with high atypical antipsychotic drug utilization.

- **Funding for Nursing Homes Targeted to Increasing Staff Training and Ensuring Proper Staffing Levels**

Personnel shortages and the constant churning of nursing home staff leaves facilities underserved and undertrained. This lack of training leads to instances where aggressive behavior is dealt with through medication as opposed to effective non-pharmaceutical interventions.

Both professional and family caregivers need to learn and employ non-pharmaceutical intervention strategies as a first response. These strategies may include:

- Assessing the resident for pain
- Maintaining eye contact with the resident
- Avoiding finger pointing, shouting, arguing or disagreeing with the resident
- Avoiding disruption in routine, or
- Redirecting the resident to another activity

³ See, Testimony of Dr. Patrick Conway, Chief Medical Officer, Office of Clinical Standards, Centers for Medicare and Medicaid Services before the Senate Special Committee on Aging, November 30, 2011.

Funding also needs to be targeted to develop “best practices” for non-pharmaceutical interventions, including research into efficiency and effectiveness, to determine which strategy works best in a given situation.

- **Promote Early Detection of Alzheimer’s Disease Through Memory Screenings**

Memory screenings are a significant first step toward finding out if a person has signs of dementia and/or Alzheimer’s disease. Early recognition of mild cognitive impairment and early detection of Alzheimer’s disease can improve quality of life, allowing individuals with Alzheimer’s disease and their caregivers to seek treatment and learn more about the disease, including behavioral intervention strategies. Early recognition and appropriate treatment, moreover, seem to be associated with a decrease in the development of problematic behaviors that could lead to antipsychotic treatment. Consequently, early recognition is an excellent strategy to minimize the use of antipsychotic medications.

- **Enforcement of the CMS State Operations Manual**

CMS’ State Operations Manual requires a nursing home facility to avoid use of anti-psychotics in most circumstances⁴. Under these guidelines, nursing homes must ensure that:

- Residents who have not used antipsychotic drugs not be given antipsychotics unless such treatment is deemed necessary to treat a specific condition as diagnosed in the clinical record; and
- Residents who are given antipsychotic drugs receive gradual dose reductions and alternative behavioral interventions, in an effort to discontinue the use of antipsychotics.

CMS has to ensure that these guidelines are enforced through the survey and certification process, while recognizing that there’s a risk of worsening symptoms upon dose reduction or withdrawal. CMS, moreover, should consider development of additional quality measuring tools, as part of the nursing home “report card,” that indicates the facility’s utilization of antipsychotic drugs and the number of incidences of adverse drug effects.

- **Full Implementation of the National Alzheimer’s Plan**

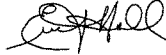
The National Alzheimer’s Project Act (NAPA) (P.L. 111-375) creates a coordinated national plan to overcome the Alzheimer’s disease crisis and ensure the coordination and evaluation of all national efforts in Alzheimer’s research, clinical care, institutional, and home- and community-based programs and their outcomes.

As a member of NAPA’s Advisory Board, AFA will offer recommendations to enhance the care and treatment of people with Alzheimer’s disease, including development of alternative strategies to pharmaceutical behavioral intervention. To ensure its implementation, however, we will need to fund these initiatives and make the necessary statutory changes to enact new programs, tools and strategies that will help people with various forms of dementias to live with dignity and respect.

⁴ Centers for Medicare and Medicaid Services, State Operations Manual, Appendix PP Sec.483.25(1)(2).

AFA looks forward to working with the Committee, CMS, nursing home advocates, beneficiary groups and all other interested stakeholders to reduce and ultimately eliminate the need to prescribe antipsychotic drugs to treat behavioral problems in nursing home residents with dementia.

Sincerely,



Eric J. Hall
Founding President and Chief Executive Officer

STATEMENT

Of



For the

U.S. SENATE SPECIAL COMMITTEE ON AGING

Hearing on

"OVERPRESCRIBED: THE HUMAN & TAXPAYERS' COSTS OF ANTIPSYCHOTICS IN NURSING HOMES"

NOVEMBER 30, 2011

The American Health Care Association (AHCA) appreciates the opportunity to offer this statement for the record to Chairman Kohl, Ranking Member Corker, and Members of the U.S. Senate Special Committee on Aging for this important hearing on the use of antipsychotic medications.

According to the Alzheimer's Association, "Antipsychotic drugs have long been used to treat aggression and other mental problems related to Alzheimer's disease." Thanks to the greater attention and research into the causes and symptoms related to Alzheimer's and other forms of dementia, we are learning more about how best to treat individuals diagnosed with these cognitive disorders. Better yet, the Alzheimer's Association has translated much of the latest research, along with the expertise and experience of professionals who provide direct dementia care, into practice recommendations. AHCA collaborated with the Alzheimer's Association in the development of its *Dementia Care Practice Recommendations for Assisted Living Residences & Nursing Homes*, as well as its *Campaign for Quality Residential Care*, which AHCA and nearly 30 other national groups have supported and promoted over the past five years.

In May 2011, the Department of Health & Human Services' (HHS) Office of the Inspector General (OIG) released a report entitled, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents (OEI-07-08-00150)*. The OIG report raises important questions about the use of antipsychotic drugs in nursing homes. The report reveals that the majority of nursing home residents – 86 percent of residents in this study from 2007 – were not on antipsychotic drugs. Of the 14 percent of residents receiving such medications, the OIG found 22 percent of related Medicare claims did not meet the medication administration standards outlined by the Centers for Medicare & Medicaid Services (CMS), which is approximately 3 percent of such claims for all nursing home residents. Such administrative discrepancies are important when reviewing compliance with CMS reimbursement requirements. What should not be overlooked in reviewing this report is that the OIG does not indicate such instances reflect any impropriety from a clinical or patient care perspective. Even so, AHCA believes that the overall increased use of antipsychotic medications in all care settings warrants review, which is why AHCA is working with other professional associations and CMS to reduce the use of antipsychotic medications. AHCA has incorporated this effort as a significant part of our ongoing quality improvement and member education initiatives.

American Health Care Association

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OFF-LABEL USE DOES NOT MEAN INAPPROPRIATE USE

The OIG study reveals that 83 percent of the antipsychotic medications prescribed to nursing home patients in this study were given for so-called “off-label” use. The use of medications for off-label reasons is a common medical practice, across all care settings; so, the OIG’s report of such off-label uses should not be misconstrued or misinterpreted to mean inappropriate use. In fact, a recent meta-analysis by RAND reviewing all drug trials of off-label use of antipsychotic medications found that these medications are associated with small improvements in behavior (see September 28, 2011 *JAMA* article, “Efficacy & Comparative Effectiveness of Atypical Antipsychotic Medications for Off-Label Uses in Adults: A Systematic Review & Meta-analysis” by AR Maher, M. Matlone, S. Bagely et al). Antipsychotic medications do provide a legitimate clinical benefit for many patients. In the case of an individual with dementia who may be experiencing a period of extreme agitation, for example, these medications can offer some measure of relief that can make a real difference in that individual’s quality of life.

Safe, effective, and appropriate administration of drugs to long term care patients is a key component of good quality care. It is as fundamental and important as the availability of appropriate drugs. Many individuals with dementia and their families benefit from access to such medications. Often, individuals entering a skilled nursing or other long term care facility may already be taking these prescription medications. When the facility begins to care for patients with Alzheimer’s or other forms of dementia, it takes on responsibility for administering such medications and continuing to monitor and treat the patient based on the legitimate physician orders prescribed for a diagnosed patient condition. We believe patients and family members should understand both the potential risks and benefits of these medications before their use.

As Members of the Senate Special Committee on Aging are acutely aware, nursing homes that receive Medicare or Medicaid funding must meet federal standards, many of which trace back to the *Omnibus Budget Reconciliation Act of 1987 (OBRA ‘87)*, which established a comprehensive set of nursing home regulations. The overarching goal of *OBRA ‘87* is that each individual receives care—to attain or maintain the highest practicable physical, mental and psychosocial well-being.

Medication management is one of the quality measures that skilled nursing facilities must address from a regulatory standpoint. We have invested considerable time and effort in finding ways to adequately and compassionately improve on this measure in particular.

CMS places the responsibility on the facility for patient safety, including safety with regard to the administration of pharmacy services. CMS recognizes that, unlike the typical ambulatory senior, patients in long term care facilities usually are older, in poorer health, and in need of greater care. Facilities are responsible the quality of care that their patients receive and federal guidelines and state licensing agencies require that the patients receive needed medication in a timely manner.

DRIVING TOWARD PATIENT-CENTERED CARE

Certainly, the use of antipsychotic medications is a question best addressed by physicians and other medical professionals. Given all that we are learning about the causes of Alzheimer’s and other forms of dementia, now is the time to focus on alternate and better ways to treat people dealing with such cognitive disorder. By focusing on the symptoms and understanding the communication barriers that exist in working with patients with dementia, AHCA believes that the number of patients in nursing homes being prescribed such medications can be reduced as we continue to explore ways to both prevent and manage difficult behaviors in nursing home residents with dementia without medications. For example, knowing the individual’s abilities

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and life story helps caregivers to tailor an effective care plan to meet the individual's care needs and helps to direct future care planning in accordance with the patient preferences.

AHCA'S QUALITY IMPROVEMENT EFFORTS

AHCA has long focused on ways to improve and sustain quality long term and post-acute care to include educating our members about the use of antipsychotic and psychotropic drugs. Currently, we are examining issues such as reducing rehospitalizations. Because off-label use of antipsychotic medications is associated with an increase in hospitalizations, we have added the reduction of off-label use of antipsychotic medications in nursing facilities as part of our ongoing quality improvement efforts.

AHCA has reached out to our colleagues in the profession, most notably AMDA and LeadingAge and consulted with experts at CMS regarding this new initiative that we believe can significantly reduce the use of these prescription medications while focusing on better managing an individual's condition and behavior without medication.

While reducing the use of existing antipsychotic medications is a primary goal, we wish to do so in a way that addresses the underlying clinical and behavioral issues – rather than simply causing a shift from the prescribing of antipsychotics to other medications.

At its core, AHCA's plan is to develop more effective strategies for managing certain behaviors often exhibited by individuals with dementia or other cognitive impairments. We believe that the following three-pronged approach can achieve our goal of reducing antipsychotic use in nursing homes over the next year.

Clearly, our most immediate focus must be on those patients now prescribed antipsychotics, especially those that are considered for "off-label" use. Next, we will focus on training staff in non-pharmacological approaches to preventing and managing behavior problems in individuals with dementia. We recognize that there may be increases in behavior problems or unwanted outcomes during this phase as patients transition from currently prescribed medications. Dealing with these anticipated patient care issues underscores our belief that, ultimately, training in non-pharmacological approaches to manage unwanted behaviors must extend beyond facility staff to physicians, other medical professionals and families if we are to achieve long-lasting reductions in the use of antipsychotics. We also acknowledge that developing such broad-based training will take considerable time and effort, and require assistance and support from CMS and other partners. The third phase in addressing this complex issue demands broad, systemic changes in management and quality improvement systems in order to solidify and sustain the lasting effect of improved care quality and quality of life for people with dementia accomplished in the first two phases.

QUALITY FIRST = PATIENTS FIRST

Quality remains our focus – quality of care and quality of life for the millions of Americans who work in our profession caring for some of our most vulnerable citizens. We continue to challenge ourselves to improve, and enhance quality, as we prepare for the increased demand for long term and post-acute care in the future.

American Psychiatric Association
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Statement of

**JAMES H. SCULLY, Jr., M.D. MEDICAL DIRECTOR
AND CEO
ON BEHALF OF
THE AMERICAN PSYCHIATRIC ASSOCIATION
For the**

Senate Special Committee on Aging

*Overprescribed: The Human and Taxpayers' Costs of
Antipsychotics in Nursing Homes*

November 30, 2011

2:00 p.m.



The American Psychiatric Association (APA), the medical specialty society representing over 36,000 psychiatric physicians nationwide, appreciates the opportunity afforded by Chairman Kohl and Senator Corker to submit the following statement regarding today's hearing: *Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes*.

Nursing home patients experience high rates of Alzheimer's disease and other forms of dementia. The Alzheimer's Association has estimated that at least half of all patients in nursing homes or assisted living facilities exhibit a form of dementia or cognitive impairment. Based on numerous studies conducted worldwide using various standardized tests, it is appropriate to conclude that a majority of dementia patients experience at least one behavioral disturbance, such as psychosis, depression, and aggression.

APA has developed practice guidelines for our members (*Treatment of Patients with Alzheimer's Disease and Other Dementias*, 2007). APA believes these practice guidelines are equally appropriate for patients who reside independently, with a caregiver, or in a nursing home facility. We would like to take this opportunity to submit for the record with this statement the quick reference guide for these guidelines. The guidelines themselves may be accessed at <http://psychiatryonline.org/guidelines.aspx>.

APA's practice guidelines for treating patients with Alzheimer's disease and other dementias recommend a set of core psychiatric management practices designed to treat a patient safely and comprehensively. These practices include: 1) constructing an alliance between the physician, patient, families, and other care providers; 2) educating and supporting the patient and family concerning diagnosis, expected symptoms, and basic principles of care; 3) a thorough diagnostic evaluation coordinated with the patient's primary care practitioner; and 4) regular and comprehensive assessment and monitoring of the patient's psychiatric status and the safety of both the patient and others.

APA strongly supports the use of non-pharmacological interventions and regular psychosocial treatments for patients with dementia. Given an elderly individual's decreased renal clearance and slowed hepatic metabolism, which often alter the pharmacokinetics of medications, pharmacological treatments must be considered carefully by a physician in consultation with the patient and family. When pharmacological treatments are deemed appropriate as a part of a patient's treatment regimen, APA recommends using low starting doses, small dose increases, and long intervals between dose increases. APA explicitly cautions physicians to be wary of medication side effects that may pose particular problems for patients with dementia.

APA recommends Food and Drug Administration (FDA)-approved cholinesterase inhibitors (donepezil, galantamine, or rivastigmine) for patients with mild to moderate Alzheimer's disease, as well as patients with mild to moderate dementia associated with Parkinson's disease or Lewy bodies. APA also recommends FDA-approved memantine to patients with moderate to severe Alzheimer's disease, and donepezil (FDA-approved), galantamine, or rivastigmine for late-stage disease. APA recommends trial periods to determine whether these medications are proving beneficial or not to the patient.

Our guidelines recommend that off-label usage of antipsychotics in low doses be considered as a treatment option when a moderately, severely, or profoundly impaired patient's psychotic symptoms cause significant distress or threaten the lives and safety of others. We urge physicians to weigh very carefully the potential benefits of antipsychotics (e.g., increasing patient comfort and safety) with their potential drawbacks. APA also recommends thoroughly evaluating the ongoing use of any intervention (including antipsychotics) since a patient's psychosis and agitation may change over time. *APA strongly opposes any practice or pattern of prescribing antipsychotics for reasons of convenience or without clear medical indicators.*

APA is troubled by the report of the Department of Health and Human Service Office of Inspector General that uncovered high rates of antipsychotic prescriptions in nursing homes across the country. APA supports ongoing efforts to gain more helpful information about these prescriptions provided those efforts do not seek to breach sacrosanct confidentiality between a patient and physician. APA also supports efforts being undertaken by the Centers for Medicare and Medicaid to improve the care of patients with dementia in nursing homes, such as greater survey and certification improvements, encouraging the use of non-pharmacological treatments, improving quality measures concerning the use of antipsychotics, using Quality Improvement Organizations to ensure appropriate prescribing practices, and improving training and education of physicians and other providers.

APA is particularly supportive of greater training and education of physicians and other providers. Given the shortage of psychiatrists, and particularly geriatric psychiatrists nationwide, it is likely non-psychiatric physicians and other prescribing professionals write the majority of antipsychotic prescriptions in nursing homes. Widely disseminating important information about these medications and their side effects, as well as appropriate practice guidelines such as those promulgated by the APA, would constitute an important step towards ensuring that antipsychotics are prescribed only when deemed safe and appropriately necessary for a patient's overall well-being.

Furthermore, APA believes more resources must be devoted to the expansion of the mental health workforce, particularly geriatric psychiatric physicians. APA identifies a current need for 5,000 geriatric psychiatrists nationwide. Only 2,100 geriatric psychiatrists were actively practicing in 2005. As alluded to above, nursing home patients are routinely forced to see practitioners that may not be adequately trained or experienced in best practices for diagnosis and treatment of dementia and other mental illness. Investing in initiatives, such as the National Health Service Corps and Graduate Medical Education residency training, promises a return of greater numbers of accessible professionals fully qualified to meet the mental health needs of elderly Americans.

Once again, APA appreciates the opportunity afforded by Chairman Kohl and Senator Corker to provide this statement on behalf of its members. Should you have any questions or need further information, please do not hesitate to contact my staff, Jeffrey P. Regan at (703) 907-7800 or jregan@psych.org.

TREATING ALZHEIMER'S DISEASE AND OTHER DEMENTIAS: A Quick Reference**Guide**

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Based on *Practice Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias*, originally published in December 2007. A *guideline watch*, summarizing significant developments in the scientific literature since publication of this guideline, may be available.

A. Psychiatric Management**Establish and maintain an alliance with the patient and the family.**

- A solid therapeutic alliance is essential for good care.
- Family members and other caregivers are an important source of information, since the patient is frequently unable to give a reliable history.
- Because families are often responsible for implementing and monitoring treatment plans and because burden is often high among dementia caregivers, caregivers' attitudes and behaviors can have a profound effect on the patient, and they often need the treating physician's compassion and concern.
- Clinical judgment is needed to determine under what circumstances it is appropriate or necessary to speak with caregivers without the patient present, as well as how to proceed with clinical care when there are disputes among family members.

Provide education and support to patients and families.

- Education should address the diagnosis, expected symptoms, and basic principles of care.
 - Understand that patients vary in their ability and desire to understand and discuss their diagnosis.
 - It may be helpful to reassure patients and their families that behavioral and neuropsychiatric symptoms are part of the illness and are direct consequences of the damage to the brain.
 - Respite care may be available from local senior services agencies, the local chapter of the Alzheimer's Association, religious groups, or Veterans Administration facilities. Other supportive resources may include social service agencies, community-based social workers, home health agencies, cleaning services, Meals on Wheels, transportation programs, geriatric law specialists, and financial planners. Useful information for caregivers is available from the Family Caregiver Alliance (www.caregiver.org).
- Watch for signs of caregiver distress, including increased anger, social withdrawal, anxiety, depression, exhaustion, sleeplessness, irritability, poor concentration, increased health problems, and denial.

- For caregivers, support groups, psychoeducational programs, psychotherapy, exercise interventions, and stress management workshops can be helpful. The local chapter or national office of the Alzheimer's Association (1-800-272-3900; www.alz.org), the Alzheimer's Disease Education and Referral Center (ADEAR) (1-800-438-4380; www.nia.nih.gov/Alzheimers/), and other support organizations may provide hotlines, educational materials, and information on other resources.

Perform a diagnostic evaluation and refer the patient for any needed general medical care.

- A thorough evaluation is often coordinated with the patient's primary care physician.
- The evaluation serves to identify the specific etiology of the dementia syndrome that may guide treatment decisions, as well as to reveal any treatable psychiatric or general medical conditions that might be causing or exacerbating the dementia. Components of a basic evaluation are described in [Table 1](#).

Neuroimaging

- The use of a structural neuroimaging study, such as a computerized tomography (CT) or a magnetic resonance imaging (MRI) scan, is generally recommended as part of an initial evaluation, particularly for patients with a subacute onset (less than 1 year), age at onset less than 65 years, vascular risk factors, or possible focal lesion. The value of imaging in patients with late-stage disease who have not been previously evaluated has not been established. Functional neuroimaging using positron emission tomography (PET) may contribute to diagnostic specificity (e.g., to differentiate Alzheimer's disease and frontotemporal dementia).
- Neuropsychological testing may be helpful to differentiate among dementias, evaluate a patient with subtle or atypical symptoms, characterize the extent of cognitive impairment, establish baseline function, and guide treatment.

Genetic Testing

- Except in rare circumstances (notably the use of CSF-14-3-3 protein when Creutzfeldt-Jakob disease is suspected and recent stroke or viral encephalitis can be excluded), biomarkers remain investigational, and there is insufficient evidence for their utility in routine clinical practice. However, this area is evolving rapidly.
- Genes involved in a small number of dementia syndromes have been identified, and genetic testing for these genes is available commercially or through research studies. However, genetic testing is generally not part of the evaluation of patients with dementia. If testing is obtained, pre- and post-test counseling is recommended.

Assess and monitor psychiatric status.

- Ninety percent of patients with dementia develop a neuropsychiatric or behavioral symptom during the course of the disease. Regular monitoring allows detection of new and evolving symptoms and adaptation of treatment strategies. It is particularly important to monitor symptoms after a medication dose has been lowered or discontinued.
- Symptoms to assess include depression, suicidal ideation or behavior, hallucinations, delusions, agitation, aggressive behavior, disinhibition, sexually inappropriate behavior, anxiety, apathy, and disturbances of appetite and sleep. Cognitive symptoms include impairments in memory, executive function, language, judgment, and spatial abilities. Functional status may also be helpful to track over time.
- Acute worsening of mood, behavior, cognition, or function may be associated with delirium, an occult general medical condition (e.g., urinary tract infection, dehydration), untreated or undertreated pain, or physical or emotional discomfort. For this reason, thorough assessment must precede intervention with psychotropic medications or physical restraint, except in an emergency.

Monitor and enhance the safety of the patient and others.

- Patients who live alone require careful attention. Events that indicate the patient can no longer live alone include several falls, repeated hospitalization, dehydration, malnutrition, dilapidated living conditions, or other signs of self-neglect.
- All patients (and their caregivers) should be asked about suicidal ideation, plans, and history. If suicidal ideation occurs in patients with dementia, it tends to be early in the disease, when insight is more likely to be preserved. Interventions to address suicidal ideation are similar to those for patients without dementia and include psychotherapy; pharmacotherapy; removal of potentially dangerous items such as medications, guns, or vehicles; increased supervision; and hospitalization.
- Agitation (e.g., physical aggression, combativeness, threatening behavior, hyperactivity, disinhibition) is most likely to occur later in the course of dementia, and often has multiple causes. The first step in treating agitation should be to investigate and address any underlying cause such as general medical conditions, depression, psychosis, pain, hunger, sleep deprivation, change in living situation, frustration, boredom, loneliness, or overstimulation. If the agitation is deemed dangerous to the patient or others, additional interventions may include providing one-on-one care, behavioral therapies, pharmacological treatment, or hospitalizing the patient.
- Decisions about supervision should consider the patient's cognitive deficits, his or her environment, and the risk of dangerous activities.
- Falls are a common and potentially serious problem for all elderly individuals, especially those with dementia. When appropriate, interventions include withdrawing medications that are associated with falls, central nervous system sedation, or cardiovascular side effects (especially orthostatic hypotension); modifying the environment (e.g., removing loose rugs, lowering the bed); and providing programs to strengthen muscles and retrain balance.
- It is important to be alert to the possibility of elder abuse, financial exploitation, and neglect. Any concern, especially one raised by the patient, must be thoroughly evaluated.
- Wandering may be associated with more severe dementia; dementia of longer duration; and depression, delusions, hallucinations, sleep disorders, neuroleptic medication use, and male gender. Preventive strategies include adequate supervision, environmental changes, a more complex or less accessible door latch, and electronic devices. Pharmacotherapy is rarely effective unless the wandering is due to an associated condition, such as mania. Provision should also be made for locating patients should wandering occur (e.g., by sewing or pinning identifying information onto clothes, placing medical-alert bracelets on patients, and filing photographs with local police departments).

Advise the patient and family concerning driving and other activities that put others at risk.

- The risks of driving should be discussed with all patients with dementia and their families, and these discussions should be documented. The patient's driving history, current driving patterns, transportation needs, and potential alternatives should be discussed. For patients with dementia who continue to drive, the issue should be raised repeatedly and reassessed over time. This is especially true for patients with Alzheimer's disease or other progressive dementias.
- At this time, there is no clear consensus about the threshold level of dementia at which driving should be curtailed or discontinued.
- For patients with mild impairment who are unwilling to give up driving, it may be helpful to advise them to limit their driving to conditions likely to be less risky (e.g., familiar locations, modest speeds, good visibility, clear roads).
- There is some evidence and strong clinical consensus that individuals with moderate impairment should be instructed not to drive because of unacceptable risk of harm. Those with severe impairment are generally unable to drive and certainly should not do so.

- Psychiatrists should familiarize themselves with state motor vehicle regulations for reporting individuals with dementia. In some states, disclosure is forbidden. In others, a diagnosis of dementia or Alzheimer's disease must be reported, and the patient and family should be so informed.
- Similar principles apply to the operation of other equipment (e.g., firearms, heavy machinery, aircraft, lawn mowers) that puts the patient and others at risk.

Advise the family to address financial and legal issues.

- Advance planning may allow the patient to participate in decision making and may prevent families from having to petition the courts later for guardianship. Issues to address include the following:
- The patient's preferences about the use of medications, feeding tubes, and artificial life support
- The patient's preferences about participation in research studies
- The need for a durable power of attorney, a living will, or an advance directive
- The need to transfer financial responsibilities
- The patient's vulnerability to financial exploitation
- The need for planning to finance home health care and institutional care
- Updating the patient's will
- Referral to financial and legal experts may be necessary



B. Mildly Impaired Patients

Help the patient and family recognize and accept the illness and its limitations.

- Suggest pragmatic coping strategies such as making lists, using a calendar, and avoiding overwhelming situations.
- Consider referring the patient to health promotion activities and recreation clubs.
- Identify specific impairments and highlight remaining abilities.
- Provide psychotherapeutic interventions for patients struggling with the diagnosis.
- Address caregiver well-being, driving, and legal and financial issues, as already described.

Offer patients with early Alzheimer's disease a trial of donepezil, galantamine, or rivastigmine.

- These three cholinesterase inhibitors are approved by the U.S. Food and Drug Administration (FDA) for the treatment of the cognitive symptoms of mild to moderate Alzheimer's disease and are commonly used.
- Given the possible risks of long-term high-dose vitamin E and selegiline and the minimal evidence for their benefit, they are no longer recommended. Nonsteroidal anti-inflammatory agents, statin medications, and estrogen supplementation have shown a lack of efficacy and safety in placebo-controlled trials in patients with Alzheimer's disease and therefore are not recommended.
- A cholinesterase inhibitor should also be considered for patients with mild to moderate dementia associated with Parkinson's disease. Only rivastigmine has been FDA approved for this indication, but there is no reason to believe the benefit is specific to rivastigmine.
- A cholinesterase inhibitor can be considered for patients with dementia with Lewy bodies.
- The constructs of mild cognitive impairment and vascular dementia are evolving and have ambiguous boundaries with Alzheimer's disease. The efficacy and safety of cholinesterase inhibitors

for patients with these disorders is uncertain; therefore, no specific recommendation can be made at this time, although individual patients may benefit from these agents.

- There is some evidence of the benefit of memantine in mild Alzheimer's disease and very limited evidence of its benefit in vascular dementia.
- Patients may be interested in referrals to local research centers for participation in clinical trials of experimental agents.

Evaluate for depression and treat if present.

- The best approach to diagnosing depression co-occurring with dementia is not yet clear. In addition to the symptoms outlined in DSM-IV-TR, irritability, social withdrawal, and isolation may indicate depression needing treatment. Symptoms may be unstable and fluctuate over time.
- Conditions that may cause or contribute to depression include other psychiatric disorders (e.g., alcohol or sedative-hypnotic dependence), other neurologic problems (e.g., stroke, Parkinson's disease), general medical problems (e.g., thyroid disease, cardiac disease, cancer), and the use of certain medications (e.g., corticosteroids, benzodiazepines).

Treatment

- Depression may worsen cognitive impairment associated with dementia. Therefore, one goal of treating depression in dementia is to maximize cognitive functioning. Treatment of depression may also reduce other neuropsychiatric symptoms associated with depression such as aggression, anxiety, apathy, and psychosis.
- Clinical consensus supports a trial of an antidepressant to treat clinically significant, persistent depressed mood in patients with dementia. Selective serotonin reuptake inhibitors (SSRIs) may be preferred because they appear to be better tolerated than other antidepressants. Alternative agents to SSRIs include but are not limited to venlafaxine, mirtazapine, and bupropion.
- Electroconvulsive therapy (ECT) may be considered for patients with moderate to severe depression that is life-threatening or refractory to other treatments.

Evaluate for sleep disturbance and treat if present.

- Sleep problems have been reported in 25%–50% of patients with dementia. Major causes include physiological changes associated with aging, pathological involvement of the suprachiasmatic nucleus, the effects of co-occurring medical or psychiatric disorders or medications, untreated pain, and poor sleep hygiene. Cholinesterase inhibitors can also cause insomnia.
- Some over-the-counter sleep medications (e.g., diphenhydramine) can contribute to delirium and paradoxically worsen sleep. Thus, it is important to ask if the patient is using over-the-counter or herbal preparations to treat sleep disturbance and to recommend discontinuance of diphenhydramine if it is being used.

Treatment

- Treatment goals include decreasing the frequency and severity of insomnia, interrupted sleep, and nocturnal confusion; increasing patient comfort; decreasing disruption to families and caregivers; and decreasing nocturnal wandering and nighttime accidents.
- When sleep disturbance is an isolated problem, clinical practice favors beginning with nonpharmacological approaches, such as training caregivers in the importance of sleep hygiene, establishing regular sleep and waking times, limiting daytime sleeping, avoiding fluid intake in the evening, establishing calming bedtime rituals, and providing adequate daytime physical and mental activities.

- Underlying medical and psychiatric conditions that could disturb sleep should be evaluated and treated. Medications that could interfere with sleep should be adjusted if possible.
- Pharmacological treatment should be instituted only after other measures have been unsuccessful and the potential benefits outweigh the risk of side effects. It is particularly important to identify sleep apnea, which may affect 33% of patients with dementia. This condition is a relative contraindication to the use of benzodiazepines or other agents that suppress respiratory drive.
- If another behavioral or neuropsychiatric condition is present and medications used to treat that condition have sedative properties, clinical practice favors prescribing that agent at bedtime, if appropriate (e.g., an antidepressant with sedative properties, a second-generation antipsychotic).
- Pharmacological interventions include trazodone or a non-benzodiazepine hypnotic such as zolpidem or zaleplon. Benzodiazepines may be used but are generally recommended only for short-term sleep problems because of the possibility of tolerance, daytime sleepiness, rebound insomnia, worsening cognition, falls, disinhibition, and delirium. Rebound insomnia and daytime sleepiness can occur with any of these agents. Triazolam is not recommended for individuals with dementia because of its association with amnesia.



C. Moderately Impaired Patients

Assess whether the patient requires supervision to remain safe.

- Safety issues should be addressed at every evaluation.
- Families should be advised about the possibility of accidents (e.g., fires while cooking), difficulties coping with household emergencies, and wandering.
- Family members should also be advised to determine whether the patient is handling finances appropriately and to consider taking over the paying of bills and other responsibilities.
- At this stage, nearly all patients should not drive, and families should be counseled to undertake measures to prevent patients from driving, as many patients lack insight into the risks.

Consider treating cognitive symptoms with a combination of a cholinesterase inhibitor plus memantine.

- Evidence suggests that the combination is more likely to improve cognitive function or delay symptom progression than a cholinesterase inhibitor alone.

Treat psychosis and agitation, which commonly occur in moderately impaired patients.

- Treatment of psychosis and agitation can increase the comfort and safety of the patient and ease care by the family and other caregivers.
- Consideration of the risks and benefits of treatment, discussion of these with the patient and caregivers, and documentation of these discussions should precede treatment.
- If psychotic symptoms cause minimal distress to the patient and are unaccompanied by agitation or combativeness, they are best treated with environmental measures, including reassurance and redirection.
- If the symptoms do cause significant distress or are associated with behavior that may place the patient or others at risk, treatment with low doses of antipsychotic medication is indicated in addition to nonpharmacological interventions. Treatment with an antipsychotic medication is also indicated if a patient is agitated or combative in the absence of psychosis, because antipsychotics have the most support in the literature. However, the potential benefits of antipsychotic medications need to be

weighed against the potential for increased mortality when they are used by individuals with dementia.

- When antipsychotics are ineffective, carbamazepine, valproate, or an SSRI may be used in a careful therapeutic trial. If behavioral symptoms are limited to specific times or settings (e.g., a diagnostic study), or if other approaches fail, a low-dose benzodiazepine may prove useful, although side effects in the elderly can be problematic. Although mood stabilizers and SSRIs are commonly used in clinical practice to treat agitation, delusions, and aggression, they have not been consistently shown to be effective in treating these symptoms, nor is there substantial evidence for their safety. Thus, in making decisions about treatment, these agents should not be seen as having improved safety or comparable efficacy compared with antipsychotic medications.
- As a dementing illness evolves, psychosis and agitation may wax and wane or may change in character. As a result, the continued use of any intervention for behavioral disturbances or psychosis must be evaluated and justified on an ongoing basis.



D. Severely and Profoundly Impaired Patients

Consider prescribing memantine or a cholinesterase inhibitor to treat cognitive impairment.

- Memantine, which is FDA approved for use in patients with moderate and severe Alzheimer's disease, may provide modest benefits and has few adverse events.
- Donepezil is FDA approved for severe Alzheimer's disease. Galantamine and rivastigmine have not been approved for late-stage disease, but they may be helpful.
- A brief medication-free trial may be used to assess whether a medication is still providing a benefit.

Assess and treat other psychiatric symptoms.

- Depression may be less prevalent and more difficult to diagnose, but if present, should be treated vigorously, using strategies already described.
- Psychotic symptoms and agitation are often present and should be treated pharmacologically if they cause distress to the patient or significant danger or disruption to caregivers or to other residents of long-term care facilities, as already described.
- Sleep disturbance should be treated as already described.

Help the family prepare for the patient's death.

- Ideally, discussions about feeding tube placement, treatment of infection, cardiopulmonary resuscitation, and intubation will have taken place when the patient could participate. If they have not, it is important to raise these issues with the family before a decision about one of these options becomes urgent.
- Hospice care can provide physical support for the patient and emotional support for the family during the last months of life. A physician must certify that the patient meets hospice criteria for dementia for hospice benefits to be available.



E. Implementation of Psychosocial Treatments

Use specific psychosocial interventions to modify problem behaviors, improve mood, and address issues of loss.

- Behavior-oriented treatments may modify problem behaviors by identifying the antecedents and consequences of problem behaviors and directing changes in the environment.

- Stimulation-oriented treatments, such as recreational activity, art therapy, music therapy, and pet therapy, along with other formal and informal means of maximizing pleasurable activities for patients, may improve behavior, mood, and, to a lesser extent, function. Common sense supports their use as part of the humane care of patients.
- Among the emotion-oriented treatments, supportive psychotherapy can be employed to address issues of loss in the early stages of dementia.
- Cognition-oriented treatments, such as reality orientation, cognitive retraining, and skills training focused on specific cognitive deficits, are unlikely to have a persistent benefit and have been associated with frustration in some patients.

Generally, provide several such treatments at the same time, on a daily or weekly basis.

- Because psychosocial treatments generally do not provide lasting effects, those treatments that can be offered regularly may be the most practical and beneficial.
- Choice of therapy is generally based on patient characteristics and preference, availability, and cost.



F. Implementation of Pharmacological Treatments

In general, use low starting doses, small dose increases, and long intervals between dose increases.

- Elderly individuals have decreased renal clearance and slowed hepatic metabolism, which alters the pharmacokinetics of many medications. Moreover, because elderly individuals may have multiple coexisting medical conditions and therefore may take multiple medications, it is important to consider how these general medical conditions and associated medications may interact to further alter the absorption, serum protein binding, metabolism, and excretion of the medication.
- Some patients may ultimately need doses as high as would be appropriate for younger patients.
- See [Tables 2, 3, 4, and 5](#) for usual doses and side effects for commonly prescribed first-line medications.

Be cautious about medication side effects that may pose particular problems for elderly patients and those with dementia.

- Anticholinergic side effects (e.g., from antipsychotics, antidepressants, diphenhydramine) are problematic in individuals with dementia and can also exacerbate coexisting cardiovascular disease, prostate or bladder disease, or other general medical conditions. Anticholinergic medications may also lead to worsening cognitive impairment, confusion, or even delirium.
- Elderly patients, especially if suffering from dementia, are more prone to falls and associated injuries because of orthostasis.
- Medications associated with central nervous system (CNS) sedation (e.g., benzodiazepines) may worsen cognition, increase the risk of falls, and put patients with sleep apnea at risk of additional respiratory depression.
- Use of antipsychotics may be associated with worsening cognitive impairment, oversedation, falls, tardive dyskinesia, and neuroleptic malignant syndrome, as well as with hyperlipidemia, weight gain, diabetes mellitus, cerebrovascular accidents, and death. The elderly, particularly those with Parkinson's disease or dementia with Lewy bodies, are especially sensitive to extrapyramidal side effects.



G. Special Issues for Long-Term Care

Care should be organized to meet the needs of patients, including those with behavioral problems.

- Employing staff with knowledge and experience about dementia and the management of difficult behavior is important.
- Limited evidence suggests that special care units may offer more optimal care than traditional units.

Appropriate use of medications can relieve psychiatric symptoms and reduce distress and increase safety for patients, other residents, and staff.

- As already described, it is important to consider the risk of side effects, periodically reevaluate the use of antipsychotics and consider alternatives, and appropriately document decision making.
- A structured education program for staff may help to both manage patients' behavior and decrease the use of antipsychotic medications.

Physical restraints are rarely indicated and should be used only for patients who pose an imminent risk of physical harm to themselves or others.

- Reasons for the use of physical restraints should be carefully documented.
- The need for restraints can be decreased by environmental changes that decrease the risk of falls or wandering and by careful assessment and treatment of possible causes of agitation.

Table 1. Components of a Basic Evaluation for Patients With Dementia

A clear history of the onset and progression of symptoms.
A review of the patient's medical problems and medications (including over-the-counter and herbal medications).
Assessment of functional abilities.
A complete physical and a focused neurological examination.
A psychiatric examination, including a cognitive assessment which should at least briefly assess the cognitive domains of attention, memory, language, and visual-spatial skills, ideally used with age- and education-adjusted norms.
An assessment for past or current psychiatric illnesses that might mimic or exacerbate dementia, such as schizophrenia or major depressive disorder.
Laboratory studies including a complete blood count (CBC), blood chemistry battery (including glucose, electrolytes, calcium, and kidney and liver function tests), measurement of vitamin B ₁₂ level, and thyroid function tests.
For some patients, toxicology studies, syphilis serology, erythrocyte sedimentation rate, HIV testing, serum homocysteine, a lumbar puncture, or an electroencephalogram may also be indicated.

Table 2. Cholinesterase Inhibitors and Memantine

Medication	Usual Starting Dose (mg/day)	Usual Target Dose (mg/day)	Side Effects
Donepezil	5	10	Cholinergic effects, including nausea, vomiting, decreased appetite and weight, Bradycardia, muscle cramps, and increased gastrointestinal acid
Galantamine	8	16-24	May induce or exacerbate urinary obstruction, worsen asthma or chronic obstructive pulmonary disease, cause seizures, induce or worsen sleep disturbance, and exaggerate the effects of some muscle relaxants during anesthesia.
Rivastigmine	3	6-12	
Memantine	5	20	Infrequent effects: mild confusion, dizziness, headache, sedation, agitation, falls, and constipation.

Table 3. Second-Generation Antipsychotics

Available evidence suggests that 5 mg/day of aripiprazole may be a safe starting dose for most patients.

Medication	Usual Starting Dose (mg/day)	Usual Maximum Dose (mg/day)	Side Effects
Aripiprazole	Unknown*	15	
Olanzapine	1.25-5	10	Pled to moderate effects include anorexia, parkinsonism, sedation, peripheral and central anticholinergic effects, delirium, postural hypotension, cardiac conduction defects, urinary tract infections, urticaria
Quetiapine	12.5-50	200-300	hypotension, and falls. Serious effects include tardive dyskinesia, orthostatic hypotension, and falls. Serious effects include tardive dyskinesia, neuroleptic malignant syndrome, hyperlipidemia, weight gain, diabetes mellitus, cerebrovascular accidents, and death.
Risperidone	0.25-1	1.5-2	
Ziprasidone	Unknown	Unknown	

Table 4. Antidepressants

Medication	Usual Starting Dose (mg/day)	Usual Maximum Dose (mg/day)	Side Effects
Citalopram	5-10	40	Nausea and vomiting, agitation and akathisia, sexual dysfunction, weight loss, hyponatremia, increased risk of falls.
Bupropion	45	135	
Duloxetine	20-40	60-80	
Escitalopram	5	20	
Mirtazapine	7.5	45-60	
Paroxetine	5-10	40	
Sertraline	12.5-25	150-200	
Venlafaxine	25	375	
Venlafaxine, extended release	37.5	225	

Table 5. Medications to Treat Sleep Disturbance

Medication	Usual Dose (mg)	Side Effects
Trazodone	25-100	Postural hypotension, which may lead to falls
Nonbenzodiazepine hypnotics		
Zolpidem	5-10	Daytime drowsiness
Zaleplon	5-10	Daytime drowsiness

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Note

The authors have worked to ensure that all information in these books concerning drug dosages, schedules, and routes of administration is accurate as of the time of publication and consistent with standards set by the U.S. Food and Drug Administration and the general medical community. As medical research and practice advance, however, therapeutic standards may change. For this reason and because human and mechanical errors sometimes occur, we recommend that readers follow the advice of a physician who is directly involved in their care or the care of a member of their family.



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Statement for the Record
By
The American Society of Consultant Pharmacists
Submitted to the Senate Special Committee on Aging
“Overprescribed: The Human and Taxpayers’ Costs
of Antipsychotics in Nursing Homes”
November 30, 2011

The American Society of Consultant Pharmacists appreciates this opportunity to submit a statement for the record regarding the use of antipsychotics for nursing home residents and the proposal by the Centers for Medicare & Medicaid Services (CMS) to require independent consultant pharmacist services for nursing home residents.

ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for all older persons. ASCP’s members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

Use of Antipsychotics in Nursing Homes

Approximately 25% of nursing facility residents receive antipsychotic medications. In this population, antipsychotics are generally used for three purposes:

- Treatment of psychotic disorders (e.g. schizophrenia)
- Treatment of psychotic symptoms (e.g. delusions, hallucinations) associated with other conditions (e.g. Alzheimer’s disease or delirium)
- Treatment of behavioral and psychological symptoms associated with dementia (BPSD), when these symptoms present a risk of harm to the resident or others

Antipsychotics are also occasionally used for other purposes, such as in conjunction with an antidepressant in the treatment of refractory depression.

More than half of nursing home residents have dementia, and many of these residents experience BPSD. The preferred therapies for management of these symptoms are non-pharmacologic, including environmental modifications. If an

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underlying cause or reason for the behaviors can be identified, a non-pharmacologic approach that addresses this underlying cause can be effective and safe.

Medications for the treatment of BPSD should only be considered in emergency situations, where rapid action is needed to prevent harm, or when non-pharmacologic strategies do not achieve resolution of the problem. When used, medications should generally serve as an adjunct to non-pharmacologic measures rather than as an alternative.

Prior to initiation of drug therapy, expected benefits and potential risks of the medication should be considered and discussed with the patient and/or family or legal guardian. Although no medications have been approved by the Food and Drug Administration for use in BPSD, the class of medications with the best evidence of benefit in older adults with dementia is atypical antipsychotics, according to the Agency for Healthcare Research and Quality. (1) Although antipsychotics have significant risks in this population, including an increased risk of mortality, no good medication alternatives are available.

ASCP has a long history of working with CMS to develop and implement guidelines for use of antipsychotic medications in nursing facility residents. Current guidance from CMS to nursing facilities on the use of these medications is found in Appendix PP of the State Operations Manual, especially pages 383-389 in Table 1 at tag F329. (2)

ASCP, in conjunction with the Long Term Care Pharmacy Alliance, the National Community Pharmacists Association, and the Pharmacy Quality Alliance, recently submitted a letter (dated November 9, 2011) to CMS affirming the LTC pharmacy community's commitment to addressing concerns related to antipsychotic drug use in nursing facilities. In addition to providing a summary of current initiatives already in progress, the letter also contains a summary of existing tools and resources available to the public as well as recommendations for future programs and areas of study. A copy of that letter is attached to this statement. ASCP has also established a Web page with more information and resources about the use of antipsychotics in residents of nursing facilities. This page is available at: <http://www.ascp.com/antipsychotic>

Consultant pharmacists regularly work with physicians and nursing facility staff to help reduce doses and discontinue antipsychotics when feasible. We welcome the opportunity to work with CMS or other interested stakeholders to help ensure the appropriate use of antipsychotic medications in nursing facility residents.

CMS Proposal to Require Independent Consultant Pharmacist Services

In a recent Federal Register notice, CMS announced that it is "considering requiring that LTC consultant pharmacists be independent of any affiliations with the LTC

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facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities." (3)

Nursing facilities are served by specialized LTC pharmacies that deliver medications to the facility in specialized packaging, are available around the clock for emergency services, and offer other specialized services needed by these facilities. At the present time, the consultant pharmacist that serves the nursing facility is often employed by the same LTC pharmacy that provides medications to that facility.

With respect to independence of the consultant pharmacist from the LTC pharmacy that dispenses medications to that facility, ASCP has a policy statement, which is attached to this statement. Here is an excerpt from the ASCP statement:

ASCP recommends that consultant pharmacists who serve long-term care facilities should be independent of the long-term care pharmacy that provides medications to residents of the facility.

In the absence of separation:

- Separate contracts for pharmacy dispensing and consultant pharmacist services should be used to delineate the distinct responsibilities of each service provider
- Payment for consultant pharmacist services should be provided at market-based rates that are based upon the true costs incurred for providing those services
- Employers of consultant pharmacists should ensure that consultant pharmacists are empowered to make independent judgments about appropriateness of medication use for each patient

ASCP recognizes that not every nursing facility will have the ability to hire or contract with an independent consultant pharmacist. Based on input from our members and other stakeholders, we expect that facilities in certain rural areas may have particular difficulty in this regard. In rural areas, some community pharmacies also provide specialized packaging and services to one or more local LTC facilities. When rural facilities use a local pharmacy for provision of medications to residents, it may not be possible to find a qualified consultant pharmacist who is independent of that pharmacy. It may be the only pharmacy in the vicinity. In addition to the large corporate LTC pharmacy chains, it is estimated that over 1,200 independent LTC pharmacies serve a major portion of LTC residents in skilled nursing facilities and many of these are located in rural areas.

In rural areas, the number and distribution of nursing facilities may be few and far between. There may not be an adequate supply of long-term care beds within a reasonable geographic area to support a full-time or part-time independent consultant pharmacist. In addition, a facility that is able to procure an independent consultant pharmacist may experience great difficulty finding a qualified replacement if that pharmacist leaves the geographic area or has an extended illness.

In situations where a nursing facility cannot find an independent consultant pharmacist, ASCP believes it is important for CMS to establish an alternative

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approach to ensure that consultant pharmacist services are provided to that facility. We recommend that CMS establish a procedure for these rural facilities to apply for a waiver, modeled upon the provision for a facility to apply for nursing waivers §483.30(c), tag F355 of Appendix PP, State Operations Manual.

In the absence of independence, alternative safeguards can be put into place to mitigate the potential for conflict of interest. This could include separate contracts for dispensing and consultant services, where specific responsibilities and expectations are delineated. This would be relatively easy for a surveyor to confirm.

Surveyors should also confirm that payment for consultant pharmacist services are provided at market-based rates that are based upon the true costs incurred for providing those services. The state of California has already incorporated this step into the survey process for nursing facilities.

When the employer of the consultant pharmacist is the LTC pharmacy that provides medications to the facility, that employer should provide a statement to the facility to affirm that the consultant pharmacist is empowered to make independent judgments about appropriateness of medication use for each patient. Surveyors could check for these statements as part of the survey process.

ASCP believes that concerns about relationships between consultant pharmacists and pharmaceutical manufacturers or distributors could be addressed through a requirement to disclose the existence and nature of these relationships to nursing facility clients. This approach is already used when physicians and pharmacists speak at continuing education programs or submit articles to professional journals for publication.

When these relationships are transparent, other health professionals, including the medical director, can have a way to verify that these relationships do not interfere with placing the best interests of the patient as the primary priority.

The CMS proposal for independence of the consultant pharmacist relates to the structure of care delivery. A change in structure, by itself, may or may not lead to improvement in outcomes of care. For this reason, regardless of CMS' ultimate decision on the independence issue, ASCP would welcome the opportunity to work with CMS to develop appropriate process and outcome measures to help evaluate and improve the quality of consultant pharmacist services in LTC facilities.

Appendix N of the State Operations Manual was developed in the early days of drug regimen review as a guide for surveyors. The concept was to provide surveyors with a tool to evaluate whether the consultant pharmacist was addressing common drug therapy problems in nursing facility residents. The Appendix was never updated and eventually become obsolete. It was withdrawn by CMS from the State Operations Manual in 2004.

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ASCP would like to work with key stakeholders to develop and maintain a Web-based list of “indicators” that could be used by surveyors as a tool to evaluate the quality of drug regimen review in the nursing facility. The American Geriatrics Society has recently announced a project to develop and maintain an updated version of medications considered to be potentially inappropriate for use in the elderly, based on the 2003 Beers criteria. This AGS updated list could be incorporated into the LTC indicator project.

ASCP believes that consultant pharmacists are committed to achieving quality outcomes for their patients, regardless of employer. We welcome the opportunity to work with CMS, and other stakeholders who share these goals, to help ensure optimum outcomes from drug therapy for all nursing facility residents. This may include working to develop training materials, tools, and resources for surveyors, consumers and caregivers, nursing facility staff, and health professionals involved in the care of LTC residents.

References:

1. AHRQ report - Off-Label Use of Atypical Antipsychotics: An Update, September 2011. <http://tinyurl.com/bla3jvy>
2. Centers for Medicare & Medicaid Services, Appendix PP of State Operations Manual, available online at: http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf, accessed November 30, 2011.
3. Federal Register October 11, 2011; 76(196):63040.

Attachments:

1. ASCP letter to the Centers for Medicare & Medicaid Services, dated November 9, 2011, on “Recommendations Related to the Use of Antipsychotic Drugs in LTC Facilities”
2. ASCP Policy Statement: Separation of Consultant Pharmacists and Long-Term Care Pharmacy Providers

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CANHR *Long Term Care Justice and Advocacy*
CALIFORNIA ADVOCATES FOR NURSING HOME REFORM

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**OVERPRESCRIBED: THE HUMAN AND TAXPAYERS' COSTS OF
 ANTIPSYCHOTICS IN NURSING HOMES**

**UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
 November 30, 2011**

Statement of California Advocates for Nursing Home Reform

The misuse of antipsychotic drugs to chemically restrain residents is one of the most serious and common forms of elder abuse in nursing homes today. About one of every four nursing home residents – most of them with dementia – are given these powerful, dangerous medications to drug them into submission. Nursing homes often give residents antipsychotic drugs instead of needed care, leaving their pain and infections untreated, their fears and worries uncomforted, their hunger and thirst unquenched, and their environment unsafe and unfriendly.

CANHR is thankful that the Committee is holding today's hearing to address this longstanding problem and urges it to take the strongest possible action to end the rampant use of antipsychotic drugs as chemical restraints in nursing homes. We strongly support the written and verbal testimony and recommendations of Toby Edelman, senior policy attorney of the Center for Medicare Advocacy, and of Dr. Jonathan Evans, the president-elect of the American Medical Directors Association. Additionally, we strongly endorse the two resolutions adopted this month by members of the National Consumer Voice for Quality Long-Term Care that identify a national action plan for reform.

For nearly 30 years, our organization has heard first-hand the confusion, distress, and loss that is associated with the misuse of antipsychotic drugs and other psychoactive medications to

chemically restrain nursing home residents who have dementia. The following statement on nursing home drugging aptly describes the suffering associated with misuse of these drugs:

“Excessive use of tranquilizers can quickly reduce an ambulatory patient to a zombie, confining the patient to a chair or bed, causing the patient’s muscles to atrophy from inaction and causing general health to deteriorate quickly . . . it appears many doctors give blanket instructions to nursing home staffs for the use of tranquilizer drugs on patients who do not need them.”

This statement sounds as if it was made very recently but it was actually made before Congress in 1970 and included in a 1975 report prepared by the Senate Special Committee on Aging titled “Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks.” Unbelievably, the problems have worsened in the 35 years since the Senate detailed them.

Today, the drugging problem has reached epidemic levels. Nationally, more than 350,000 nursing home residents are given antipsychotic drugs such as Seroquel, Risperdal, Zyprexa and Haldol. An astonishing 83 percent of the use is for off-label conditions (meaning the drugs are provided to control behavior and not to treat a diagnosed mental illness) and 88 percent of the time the drugs are given for conditions (i.e., dementia) specified in the black-box warning given to antipsychotic drugs by the Food and Drug Administration (FDA).¹

The way antipsychotic drugs are used in nursing homes is a dangerous and often deadly form of abuse. Instead of providing individualized care, many homes indiscriminately use these drugs to sedate and subdue residents. Antipsychotic drugs nearly double a person with dementia’s risk of death, but nursing home residents and their representatives are rarely informed about the FDA black box warnings that are intended to alert them to this risk. Antipsychotics don’t just hasten death, they often turn elders into people their own families barely recognize by dulling their memories, sapping their personalities and crushing their spirits.

¹ Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011).

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The deadly nature of these drugs was bluntly described by Dr. David Graham, a FDA drug safety expert, during a 2007 House hearing:

“...you have probably got 15,000 elderly people in nursing homes dying each year from the off-label use of antipsychotic medications for an indication that the FDA knows the drug doesn’t work... With every pill that gets dispensed in a nursing home, the drug company is laughing all the way to the bank... We have got so many clinical trials that show these drugs don’t work, that it is like malpractice to be using it.”²

Do No Harm

After years of studying the impact of antipsychotics on elderly people with dementia, the scientific conclusion is clear: antipsychotics are deadly in the long-term, no better than placebos in “treating” dementia in the short-term, and much less effective than vastly cheaper non-pharmacological options.

The list of studies showing significant adverse health outcomes, including death, for elderly people with dementia who are administered antipsychotics is long and growing.³ Antipsychotics are associated with increased strokes, heart attacks, and respiratory failure. The drugs also increase the risk of falls, which can be catastrophic for an elderly person, and significantly decrease a person’s activity levels which contributes to weight loss (from less eating), pressure sores (from lying in bed), and infection (from incontinence and less physical vigor). The drugs’ lethality led the FDA to require black-box warning labels for all antipsychotics, cautioning that the drug nearly doubles the risk of death for elderly people with dementia.

² Testimony of Dr. David Graham, FDA, at the February 13, 2007 hearing of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: The Adequacy of FDA Efforts to Assure the Safety of the Nation’s Drug Supply.

³ An excellent review of the health risks associated with antipsychotics and dementia care is “ACNP White Paper: Update on Use of Antipsychotic Drugs in Elderly Persons with Dementia,” Dilip V. Jeste, et al., *Neuropsychopharmacology* (2007).

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Aside from their severe side effects and risk of death, antipsychotics have proven no better than costless placebos as a treatment for dementia.⁴ Study after study has shown that antipsychotics are rarely more effective than inert pills when treating dementia-related behavior. There is no scientific support for the notion that disrupting and eventually damaging a brain's normal neurotransmission with antipsychotics improves the functioning of a person with dementia. When side effects are taken into consideration, the deleterious effects of antipsychotics significantly outweigh any perceived benefits. A 2011 study demonstrated that simple prophylactic administration of acetaminophen was more effective than antipsychotics in reducing agitation in patients with dementia, indicating that untreated pain is often the source of "behaviors."⁵

The continued use of antipsychotics to "treat" dementia despite their lethality and clinical shortcomings is particularly troubling in light of the myriad superior non-pharmacological options for addressing dementia-related behaviors.⁶ Patient-directed care, focusing on addressing the patient's needs and comfort, such as increased activity and social interaction, pain-relief, and more appealing food, is a simple solution to most caregiver challenges. Such interventions are much less costly than monthly drug prescriptions and have the additional benefit of reducing expensive hospitalizations and continued institutional treatment. Considering costs, harm, benefits, and efficacy, non-pharmacological treatment is vastly superior to antipsychotics as the front-line treatment for dementia-related behavior.

⁴ For a review of the applicable studies, see CANHR's review of studies at <http://www.canhr.org/stop-drugging/news-and-resources>

⁵ "Efficacy of Treating Pain to Reduce Behavioural Disturbances in Residents of Nursing Homes with Dementia," Bettina S. Husebo, et al., *British Medical Journal* (2011, 343).

⁶ see "Cost-benefit Analysis of Second-Generation Antipsychotics and Placebo in a Randomized Trial of the Treatment of Psychosis and Aggression in Alzheimer Disease," Robert A. Rosenheck, et al., *Arch Gen Psychiatry* (Vol. 64, No. 11, Nov. 2007).

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The Proliferation of Chemical Restraints

There are several reasons that many nursing homes and their doctors have made antipsychotics and other types of psychoactive drugs their first choice for responding to symptoms of residents with dementia. Drugs are cheaper than staff – at least on a short-term basis - as most of these drugs are paid for by Medicare. Additionally, many doctors who prescribe these drugs and the pharmacists who dispense them for those with dementia are ignorant of the risks and effects of the drugs prescribed and, in some cases, are intentionally misled by pharmaceutical companies. Just since 2009, over four billion dollars has been paid to the federal government by drug manufacturers to settle charges of fraudulent marketing, false claims, and kickback schemes. Finally, reimbursement for alternative therapies, particularly for therapists, psychologists and psychiatrists are limited under both Medicare and Medicaid.

Solutions

It is a shameful situation, but the good news is that proven solutions are at hand. The biggest problem with drugging, the pervasive culture that treats drugs as the first measure in behavioral control for people with dementia, is also a gateway to the inevitable solution. If we are able to shift this culture and de-emphasize drugging, we can dramatically reduce the misuse of antipsychotic drugs for people with dementia and, most importantly, improve their quality of life.

We already know what an effective campaign to shift this culture looks like: over the last 25 years there has been a pronounced effort by consumers, advocates, the government, providers and others to stop the inappropriate use of physical restraints in nursing homes. The result has been startling. Physical restraint use has dropped from more than 25% of all residents to less

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than 3%. The key has been concentrated, sustained education, awareness, effort, oversight and enforcement.

CANHR has initiated a campaign to stop drugging in California and is working closely with national advocates to help it take root nationally. Our campaign combines practical advice for residents and their families on how to stop misuse of the drugs, along with a broad movement to raise awareness, strengthen laws and enforcement, and target offenders. It features a first-of-its-kind website that includes a great deal of information to help consumers learn about their rights, the risks of the drugs, and most importantly, effective non-pharmacologic options. The site includes a well-received video series and a free advocacy guide, "Toxic Medicine", that we have previously distributed to the Committee.

We've also posted specific information on each California nursing home's use of antipsychotic drugs to help consumers avoid facilities that are using these drugs indiscriminately. The information shows that a resident's risk of being drugged varies tremendously by nursing home, with some facilities reporting no use of antipsychotic drugs while others drug all or nearly all of their residents. CANHR is urging the Centers for Medicare and Medicaid Services (CMS) to follow suit by posting the same information on Nursing Home Compare for all Medicare and Medicaid certified nursing homes.

Over the last year, CANHR teamed with three local long-term care ombudsman programs⁷ to co-sponsor four exceptionally well-received symposia on dementia care without drugs in California, drawing over 1,000 providers, advocates, consumers and other interested citizens. The symposia have highlighted residents' right to be free from chemical restraints and

⁷ The co-sponsoring ombudsman programs – Long Term Care Services of Ventura County, Ombudsman Services of Northern California, and Ombudsman Services of San Mateo County – hosted the seminars in their regions and led marketing and registration for the events.

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the dangers of antipsychotic drugs, but their leading purpose is to educate providers on better ways to care for residents with dementia. Tena Alonzo, the former administrator and current research director of Beatitudes' acclaimed Vermillion Cliffs dementia care unit in Phoenix, has provided inspiring direction on replacing a drug-first model with a "comfort-care" focus that successfully identifies and responds to the underlying needs of residents who have dementia.⁸ CANHR is planning additional symposia throughout California in 2012 and 2013.

The Campaign also has a political component, including a petition to the Governor and proposed legislation to strengthen informed consent requirements. We cannot emphasize enough the importance of informed consent in resolving this problem. It's not just about informing people about the risks and alternatives to these drugs, it's about treating people who suffer from dementia with dignity and respect by recognizing their right to make decisions about their medical treatment. A culture of respect for victims of this disease will go a long way toward curbing the drugging problem.

CANHR's campaign is a good model for a national campaign on this issue. We urge the Committee and Congress to embrace the recent recommendations made by Consumer Voice and the Center for Medicare Advocacy to stop the chemical restraint of nursing home residents. We will briefly touch on a few of the key recommendations.

First, CMS should adopt the 1992 proposed rules on chemical restraints. These regulations require that residents or their legal representatives give specific written informed consent for antipsychotic drug use. American common law and various state statutes protect the right of informed consent, but it does not appear in federal nursing home law or regulations.

⁸ The New York Times published a feature story on Beatitudes' successful use of non-pharmacological options on December 31, 2010 at: http://www.nytimes.com/2011/01/01/health/01care.html?_r=1

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Codifying the informed consent requirements would give national priority to the concept that people with dementia (and their representatives), as any other health care recipients, deserve complete information about proposed treatments and the right to ultimately decide what medications they take.

Second, Congress should adopt The Prescription Drug Cost Reduction Act, S.1699, §7, introduced by Senator Kohl on October 12, 2011. It would require physicians to certify that there is a medically accepted indication whenever they prescribe an antipsychotic drug for a nursing home resident.

Third, CMS should make it a top priority to identify misuse of antipsychotic drugs during nursing home inspections and greatly strengthen enforcement actions for violations of existing requirements on chemical restraints and unnecessary drugs.

Fourth, we strongly support the current CMS proposal to require that consultant pharmacists who work for nursing homes to be independent and free from conflict of interest. It is very apparent that consultant pharmacists often work to promote sales for drug manufacturers rather than protect residents from inappropriate drug use. A recent series of investigations by the California Department of Public Health found that consultant pharmacists failed to detect or respond to inappropriate nursing home use of antipsychotic drugs 90 percent of the time.

Fifth, Congress should investigate and the U.S. Government should continue to aggressively pursue drug companies marketing of off-label uses of antipsychotic drugs for nursing home residents. It is of great concern that big pharma has displaced the defense industry as the biggest defrauder of the federal government. Future enforcement actions should be designed to actually deter illegal marketing of these dangerous drugs.

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Finally, we propose an education campaign to elevate the issue of antipsychotic drugs for people with dementia into the national consciousness. The campaign would focus on people with dementia, their families and advocates, as well as health care providers. For people with dementia and their families and advocates, the campaign would offer information about antipsychotic drugs - from the types of medications that are most often abused, to side effects and Black Box warnings, to the supremacy of alternative approaches. As part of the education campaign, CMS should post each nursing home's drugging rate on Nursing Home Compare so that consumers can locate nursing homes that don't use antipsychotic drugs as a substitute for basic dementia care.

For health care providers, the education campaign would offer best practices for doctors, pharmacists and facilities, stressing that, if antipsychotic drugs are to be used at all, they should only be used as a last resort after all non-pharmacological interventions have been attempted and failed. The essence of these practices should be the promotion of individualized care.

Individualized care fosters non-pharmacological interventions by placing a premium on relationships with people who have dementia and dignified care approaches such as increased exercise, formal activities, and pain management. A recent study in Vermont was able to dramatically reduce the use of antipsychotics in nursing homes by focusing on relatively simple alternatives. One alternative was learning more about a resident's past, so as to better understand the resident's needs and personality. Another alternative was giving nursing home staff more consistent schedules so they work with the same residents and learn to pick up on early signs of trouble and circumvent bad behaviors.

What is especially helpful about non-pharmacological interventions is that they are less costly than drugging. Aside from the obvious high costs of the drugs themselves is the very

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expensive health outcomes they often precipitate – falls, infections, strokes, and hospitalizations that add to the escalating costs of Medicare and Medicaid. Using pills to substitute for one-on-one care or for adequate staffing turns out to be, not only bad medicine, but also a poor use of resources.

Heightened awareness and increased information can make a major difference in the quality of lives of people with dementia. The massive reduction in physical restraint use in nursing homes is concrete evidence that federal leadership, coupled with an empowered consumer voice, can reach the far corners of the local nursing home, change the practices of health care providers and influence care in a way that dramatically improves the lives of our citizens with dementia.

Here is what we know:

- 1) The misuse and overuse of psychotropic drugs for people with dementia is at an all-time high;
- 2) There are many non-pharmacological alternatives to drugging that not only lead to better outcomes for people with dementia, but are also much less costly; and
- 3) A campaign to end over-drugging could improve the lives of perhaps millions of people with dementia.

Thirty-five years ago, the Senate Special Committee on Aging urged a “coordinated attack” on dangerous drug misuse in nursing homes, led by federal and state officials. With the Committee’s help, we can finally begin that attack. We call upon our national leaders to not only join a campaign to end over-drugging but to lead it.

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**Testimony For Official Hearing Record
United States Senate Special Committee on Aging Hearing
Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes
November 30, 2011 - 2:00PM**

Testimony of: Linda J. Fullerton

December 13, 2011

Members of the Committee:

My name is Linda J. Fullerton, and it is with great sadness, anguish, frustration, and despair that I submit this testimony to you today. I watched with great interest via the Internet, your most recent hearing on the improper prescribing and administration of antipsychotic drugs in nursing homes. This issue is one that is very personal to me since my mother and I just experienced every topic you touched on, and more, which I intend to make you aware of by this testimony. Unfortunately I must report that my mother was a victim of this ever-growing problem and it ultimately took her life. For the record this testimony is based on my own personal knowledge, experience and observations, and a very personal, knowledgeable, communicative, extensive relationship with my mother for almost 55 years. It is also based on a complete set of her medical records and documents from both the hospital and nursing home where she was a resident, other treating doctors, agencies, and other related areas, which I have very carefully reviewed and are in my possession, by exercising rights provided by both state and Federal laws in order to properly obtain them. I wish to share some of this experience with you as it fully illustrates the problems that you are trying to address. I also encountered other problems that I wish to alert you to as well, since I feel they also contributing factors to this ever-growing problem.

In January of 2009, my mother at age 79 was independent, living in her own home, driving her car to doctor's appointments, shopping, and loved to read and do crossword puzzles. She hated to take medicines, and took very few of them throughout her life except for those, which were used to control her blood pressure, cholesterol, and to prevent fluid retention. When she was in pain for any reason, she rarely took anything to control it, and was highly allergic to many medications. She was a very stable, pleasant, kind, generous, smart and savvy person, and except for a few "senior moments," had a very good memory. She had no medical history of mental problems. She always had impeccable personal grooming and dental hygiene habits. Some would even say to excessive standards. At times she would get frustrated and complain that she could not get around, or have the energy she did when she was younger, and that would make her sad. She had severe curvature of the spine (Kyphosis) and saw her primary care physician and chiropractor regularly for a physical back/neck injury that she acquired on her job as a school bus matron. She had very sensitive skin, several chemical, food, and medicine allergies, and suffered from pressure Urticaria. My mother looked and acted much younger than her physical age, and always told the family that she never wanted to end up in a nursing home no matter what the circumstances. In hindsight she was totally correct in her feelings about that. She was by most people's standards doing pretty well for her age. Unfortunately in that same month, my mother lost her footing and fell down the stairs in her home and landed on her head while answering the door to my sister. My mother kept saying that she was ok, but my sister took her to the hospital to get checked out anyway. The hospital agreed that she was ok and told the family that because her spine was so curved and throwing off her bodily center of gravity, that was probably the cause of her fall. They suggested that she start using a walker and cane for support. My mother was very stubborn and didn't like that idea and most of the time wouldn't use them. As a result she fell again a few weeks later and was taken to the hospital where she was kept for a few days for observation. It was then determined that she couldn't go back to her home at that time, but needed to go to a nursing home for rehab and get therapy for a few weeks. After receiving the therapy she needed it was determined that she didn't need to be in the nursing home any longer, and that an assisted living facility would be a good option till she improved even more.

Before I go any further I must tell you that I myself am permanently disabled with several incurable autoimmune disorders, and many other physical medical conditions that prevented me from being able to care for my parents and keep them out of an assisted living facility or nursing home. My parents were divorced and my father was already in an assisted living facility. I have agonized over this fact every day of my life since they both got sick. So in order to keep track of their care in the best way possible considering my situation, I had to make sure that they were both in places that were in very close proximity to each other and to myself, as I cannot travel far from home, especially in the winter. Because of my immune system problems, every time I would see either parent I would be putting my own health at great risk and going against my doctor's advice. My mother's home was very old and needed major renovations in order for her to ever possibly live there safely again, which I always hoped would be the case if she got the proper therapy that she needed to recover. My sister due to her work schedule and the type of apartment complex that she lived in was also unable to physically care for my mother or father. I ask that you please keep this in mind as you read the rest of this testimony.

For a few weeks in February & March of 2009 my mother was living in as assisted living facility. On 3/5/09 my mother fell at the facility and was sent to the hospital ED. They checked her out, said she was ok, and sent her back to the facility the same day. The following day on 3/6/09 in the morning, my mother fell a second time at the facility, again was sent to the hospital ED, was checked out and sent back to the facility. On the same day of 3/6/09 my mother fell again in the afternoon (twice in one day - 3 falls total in 2 days), and again was sent to the hospital ED. This time they admitted her to the hospital for frequent falls and a urinary tract infection/UTI. The plan was that she was to be kept there until the UTI was cured, and that she was to get physical and occupational therapy in the transitional care unit of the hospital to prevent her from falling, until she was strong enough to go back to the assisted living facility.

Keep in mind that is a known medical fact that UTI's are known to cause mental confusion and other problems in the elderly. Also factor in that my mother had just been moved out of her home, into a nursing home, then into an assisted living facility, fell and went to the hospital five times, all in the span of a three month time period. All that moving around from place to place is enough to cause major stress, anxiety, and confusion in an elderly person. My mother was not incontinent and didn't want to wet herself, so when she needed to go to the bathroom frequently due to the UTI, and the aides didn't come right away to toilet her, she would try and take herself to the bathroom. She became very vocal and frustrated about that, so she was physically tied to her bed for several days. That upset her even more and she became more frustrated and extremely agitated. On 3/13/09, the hospital staff started to administer Ativan, Haldol and Risperidone all at the same time to her according to her medical records. These medicines were given with absolutely no approval by the patient or by myself as her proxy, and I was never even told that she was on them until 5 days later. Apparently no regard was given to the FDA Black Box, state, and drug mfg warnings, precautions, drug interaction concerns, risks, side effects, adverse reactions or overdose information listed for these drugs. **Several times it is noted in her medical records that these drugs were administered to "decrease agitation."**

On 3/13/09 the day she was given the antipsychotic drugs for the first time, it is documented by an attending physician in her medical records (who never signed their name) that "the patient probably has dementia." That diagnosis followed her for the rest of her life and from that point on my mother was given Aricept as well as the antipsychotic drugs. On 3/14/09 one day after being given the Haldol and Risperidone and Ativan for the first time, my mother started continually screaming and yelling out, and making several attempts to climb out of her bed and to remove the physical restraints on her. She got a very severe reaction to these medications both physically and mentally. Throughout the rest of her time at the hospital she had many different reactions to the meds. She had trouble breathing, and complained of heaviness in her chest. She had trouble eating, and swallowing to the point where they had to give her only very soft foods, and crush her medications. She was drooling, had watery eyes and a runny nose. She had developed both facial and hand tremors. She was very weak and could not even hold a Kleenex to blow her nose or a fork to eat. She fell 3 times during this period, was very weak and lethargic, and at one point both her and I thought she was going to die. I even called all the family members to tell them they had better get up to see her as I feared the worst. My mother mentally and behaviorally, had suddenly turned into a person that I did not recognize. She became very anxious, agitated, and even suicidal, begging me at one time to have a doctor give her a shot to kill her, because she did not want to live like that anymore. She knew something was wrong but could not properly verbalize it to me. She was having hallucinations, saying that she felt that "the hand of death was pulling her away." was extremely confused and delirious. When she would attempt to do any sort of activity she would say that she couldn't do it, even though she was actually doing it at the time, her brain did not recognize that she was doing it. She would ask me in a panic to take her to the emergency room because she was so scared, not realizing that she was already in the hospital. She would often have the aides call me so she could tell me on the phone, or beg me when I was there to take her home ASAP, and she would say "you don't know what they are doing to me here."

When she was first admitted to the hospital she would do her crossword puzzles and read to pass the time. Once she was given these antipsychotic drugs she was never able to read or do crossword puzzles much ever again. She never was able to get the proper physical or occupational therapy that she needed to recover because the medications among other side effects made her too lethargic, weak and confused. During this time I talked to several people at the hospital, begging them to stop giving these medications to her when I saw what was happening. I even tried twice to fight her discharge from the hospital, but they kept saying there was nothing else they could do for her there. On 3/31/09 after less than 3 weeks on Haldol, Risperidone, my mother, ended up having to be admitted to a nursing home where she spent the last 1-1/2 years of her life from 3/31/09 -- 9/18/10. She was never able to go back to the assisted living facility ever again. She also still had a very rare strain of urinary tract infection, according to her primary care physician and the staff at the nursing home after she arrived there. I felt it necessary to report my concerns about her hospital treatment to the NYS Department of Health.

The nursing home that she was transferred to was affiliated with the hospital, and she was so messed up both mentally and physically, that she needed an additional 24 hour round the clock personal aide to be with her at all times for several weeks, in addition to the regular staff, to take care of her. In just a three months time period, she went from being an independent person living in her own home, to being totally needy and not able to function at all on her own - a very major and rapid decline. Because of my mother's experience at the hospital, I wanted to do something to prevent those problems from happening again in the nursing home, so as her health care proxy and power of attorney I composed a document, had it notarized and gave it to the nursing home to keep at all times with her medical records. Here are some excerpts from that document which stated very clearly the following:

URGENT NOTICE: April 2, 2009 - This notice is to be kept with patient's medical records at all times - My name is Linda J. Fullerton, and I am the daughter of, health care proxy and Attorney-In Fact for (my mother's name). Please be advised that as of 4/2/09, NO prescription drugs/narcotics are ever to be given to (my mother's name), without prior verbal or written approval from me, unless it is a fully documented life-threatening emergency to my mother, not to have the medication. Also be it known, that I have the authority, and reserve the right, to have any previously approved medications discontinued, or their dosage adjusted, which may present a health concern to my mother as well...Anyone who attempts to violate this request, or if any harm should come to (my mother's name) as the result of any violations of this request, will be subjected to legal action, and you will be held responsible for any damages to her health that are caused.

In an attempt to make sure that there was no way that she could be given drugs without my consent or have dosages improperly altered, I also sent the same document to Omnicare, the pharmacy that supplied my mother's medications to the nursing home. It was brought up

as part of this hearing, that Omnicare is being investigated by the Federal Government and in fact being sued over kickbacks given by the drug companies to this pharmacy and doctors who improperly prescribe and supply these medications. My mother was given all three of the drugs: Risperdal, Seroquel and Zyprexa which are involved in these investigations and lawsuits.

NOTE: Unbelievably, and much to my dismay, this document was ignored repeatedly throughout my mother's entire stay at the nursing home as if it did not exist. Which brings up the issue of consent that was mentioned during this hearing. I had to repeatedly remind the nursing home staff that they had to first get my approval/consent before giving new meds or changing meds or dosages. Informed consent means you have to know PRIOR to the action happening in order to be able to make a decision as to whether or not you will allow the action to happen. Doing what you want and telling the party after the fact automatically takes away the right to consent. Often times the tactic that is used to get around the consent issue is the "as needed" excuse for not getting consent before medications are administered, and this is still not in keeping with how the laws are written. For the record, at no time whatsoever during my mother's ENTIRE hospital or nursing home stay was I, or any other family member ever told about the FDA Black Box, state, and drug mfg warnings, precautions, drug interaction concerns, risks, side effects, adverse reactions or overdose information listed for any of the antipsychotic medications and many of the other drugs my mother was given such as Ativan, Trazodone, Aricept, Baclofen etc. In most cases we were not even told what type/class of drugs they were. We were sometimes told they were to be used to "calm her down," relax her, or help relieve her pain. Any information that I was able to obtain, I had to try and find out on my own. When my sister or I would see that our mother was having a bad reaction of any kind to her meds, we tried to tell the staff that we thought it was the medications that were causing the problems, but her reactions were blamed on other things instead. It is even documented in her medical records that my mother herself stated that she "did not want any more medication," and "patient has repeatedly stated she does not want "extra" medicine," yet in spite of her objections she was given the drugs anyway.

New medications were given, or medications dosages were changed/increased several times without my prior knowledge or approval and I had several confrontations with the staff about this. When I would agree to a certain dosage of a medication for 1 pill a day AT NIGHT ONLY, one way that I would know the meds were changed/dosage increased would be to notice that my mother was getting new or increased side effects, was more lethargic during the day. I saw staff giving her pills during the day and when asked what they were they admitted that they were giving her the unapproved dosages. Another major way I also discovered that there were problems, was when I would get her Medicare Advantage insurance prescription drug summaries, or bills from the pharmacy Omnicare. When she was only supposed to be getting one pill a day, which would be 30 - 31 pills per month, several hundred pills of that medication were ordered per month. My mother and her health insurance company were getting billed for all of them. At one point my mother's prescription drug bill totaled over \$3000 in out of pocket costs that she had to pay. I was never able to properly get to the bottom of what was REALLY going on. I alerted my mother's health insurance company MVP Healthcare, and the pharmacy (Omnicare) and also questioned them about the problems. They both did nothing about it and told me, that a hospital or nursing home could order whatever they want, whenever they want, with no questions asked. I personally have a Medicare Advantage plan, and if I need a medicine and try to get a refill even the slightest bit too early, I am turned away until closer to the end of the month, and they will not give me my meds and sooner. The only way to prevent this sort of abusive medication ordering, and improper administration of drugs to the patient, is to institute a strict monitoring system for the hospitals and nursing homes similar to what an individual person who gets prescription medicines is subjected to.

After my mother was tapered off the Risperdal she was given in the hospital I told the nursing home staff that she was not to be given any more antipsychotic drugs. She was still having a severe reaction to Haldol and Risperidone and I feared that it had permanently damaged her both mentally and physically. There would be no way to know for sure until all those medications were out of her system for good. In spite of my concerns, they insisted on putting my mother on Trazodone (an antidepressant) in hopes of stabilizing her condition. It had the total opposite effect on her and made her even worse. She became even more anxious, aggressive, would not eat, sleep and exhibited unusual behaviors. It is also important to note that while my mother had already been given both antipsychotic and anti-anxiety medications in the hospital, she did not actually see a psychiatrist until 4/2/09, a few days after she entered the nursing home.

Another thing that must be taken into consideration is how the lack of proper care and the environment of a nursing home can affect a person's health both physically and mentally. An elderly person may not adequately be able to express their concerns about their care or surroundings and may act out in a verbal or physical way to get attention from staff to provide properly for their needs. Often when patients express themselves in this way, especially in my mother's case, they are given even more antipsychotic drugs to "shut them up." In June of 2010 the nursing home had completed construction of new "home style" facilities consisting of several individual "cottage" style structures. My mother had to be disrupted and moved again into new surroundings, which presented new challenges causing additional stress, anxiety and confusion for her. While the structural environment had been greatly improved, the quality of care that was provided did not, in fact it got much worse. Many of the staff was let go, and the remaining staff now had to not only take care of patients, but were given additional duties such as cleaning, cooking, laundry. This took away critical time that was needed to properly care for the residents.

Almost the entire last 1-1/2 years of her life she was subjected to an extremely high risk of death and it is amazing that she even survived as long as she did. The antipsychotic drugs totally diminished her quality of life and rapidly weakened her both mentally and physically. She fell 24 times in the nursing home, hitting her head, getting bruises and cuts - one that got infected with Cellulitis as a result. She constantly was battling edema, which is a known side effect of the antipsychotic drugs she was given, and her legs, ankles

and feet were very red and swollen. She had frequent urinary tract infections, and urinary urgency, which is also a known side effect of the antipsychotic drugs she was given. Just like in the hospital when she would call for help and when the staff did not come, and not wanting to wet herself, she would attempt to take herself to the bathroom. This caused her great discomfort, frustration and anxiety and she would verbalize it. That was often treated with another dosage increase of the antipsychotic drugs. She was prone to and acquired frequent very painful pressure sores, especially on her buttocks. Lethargy from the drugs prevented her from getting the proper therapies, exercise, and participate in activities, which she desperately needed to get better. Both pressure sores and lethargy are also listed side effects of antipsychotic drugs. Many times when I would visit my mother (mostly during daytime hours between noon and 5:00 PM), I would find her asleep in her wheelchair when I arrived and I would have to wake her up. She was often severely groggy and would drift in and out of sleep during our visits, and one time I could not wake her up at all no matter how much I shook her or called out to wake up. She was in a comatose type of state, and that was very scary to say the least. Whenever I saw her I would ask her how she was doing. She complained almost every time that she was bored and tired and would often say that she "wanted to go home."

For many days, as per the autopsy report, blood clots moved throughout my mother's body that had originated in her legs, which caused her extreme pain and gradually killed her. She kept yelling "ow, ow, ow" complaining of "pain all over," for 11 days up until her death. It was wrongly assumed it was her dementia getting worse. She was given more drugs in an effort to try and shut her up, and to try and relieve the horrible physical pain, yet they never properly checked the physical source of it. They kept refusing to acknowledge despite our continued concerns, that it could be the antipsychotic and other drugs she was given, that were creating all the problems that had been having over time contributing to her rapid continuing decline. I saw her one last time the day before she died, she could barely speak now except for her continuing to say "ow, ow, ow," and her eyes were cloudy, gray and glazed over like a dead fish.

On 9/18/10 my mother died, ultimately losing her battle against the side effects and adverse reactions of antipsychotic drugs when they are not used properly. For over a week before she died, the family asked repeatedly for extra 24 hour one on one patient care, like she had received when she first entered the nursing home, because we knew that she was in trouble, and we wanted the staff to get to the bottom of what was really wrong with her. After her death while reviewing my mother medical records, I noticed that in June 2010 several months before my mother died, two doctors raised concerns and if they had been taken seriously, my mother might still be alive today. Her foot doctor noted in his report that she had "Peripheral vascular changes. Pitting edema." Her primary care physician notes that "family concerned re: chronic LE edema. Consider vascular consult (to reaffirm our Dx's and Rx's). This was never done. In the pages of both my mother's hospital and nursing home records, it is reflected very clearly that my mother was in anguish and miserable most of the time. It's very hard to read how she suffered both physically and mentally; during all the times I could not physically be there myself more often to comfort her, especially in the last moments of her life. She died in a very lonely, painful manner. It breaks my heart every time I see them. The very last memory I have of my mother was very frightening, and will haunt me until the day I die myself. When I went to the hospital to identify her body, I was in no way prepared for what I saw. She lay there with her head and neck arched, her eyes were squinted shut, her facial and neck muscles were stretched taught and her mouth was frozen open like she had been screaming in agony and terror when she died. It was a visage like something you would see in a very scary horror movie. I'm very sad to say that this seemed to be an accurate reflection of the great pain and suffering that the antipsychotic drugs and negligent treatment caused her in the last 1-1/2 years of her life. Nobody should ever have to see their loved one like that. As I stood over her cold lifeless body, I promised her I would do whatever I could to get justice for her, and make sure that it never happens to anyone else. The cause of death listed was Myocardial Infarction (Heart Attack). I insisted that an autopsy and toxicology screen be done at an independent facility outside of the hospital, which revealed that she actually died of Multiple Pulmonary Thromboemboli. The toxicology screen showed that she still had traces of Baclofen and Zyprexa in her system even though I was told she was taken off of the Zyprexa several days earlier. I had the NYS Department of Health change the death certificate to correctly reflect the autopsy results.

The autopsy comments stated: "The presence of acute pulmonary thromboemboli, organizing pulmonary thromboemboli of varying histopathological ages, and a healing infarct of the right middle lobe is consistent with multiple episodes of thromboembolism occurring prior to death. The most histopathologically mature thromboemboli in this case show fibrosis, which is indicative of development at least several weeks prior to death. As no source of venous thromboemboli was identified in the thorax or abdomen, pulmonary thromboemboli in this case most likely resulted from deep leg vein thrombosis. Deep leg vein thrombosis is the most common cause of pulmonary thromboembolism and would account for the history of recent lower extremity pitting edema. An increased risk for venous thromboembolism recently has been reported in association with the use of atypical antipsychotics. (Parker C. et al. antipsychotic drugs and the risk of venous thromboembolism: nested case-control study. British Medical Journal 2010; 341:e4245)"

"The patient had a clinical history of dementia. The lack of both neocortical neuritic plaques and beta amyloid immunoreactivity excludes a diagnosis of Alzheimer disease. Contributing factors to the patient's dementia include both bilateral hippocampal sclerosis (with tau-positive neuronal inclusions) and subcortical arteriosclerotic encephalopathy."

**Antipsychotic Drugs And Risk Of Venous Thromboembolism: Nested Case-Control Study – British Medical Journal – 9/21/10 - Chris Parker, medical statistician, Carol Coupland, associate professor in medical statistics, Julia Hippisley-Cox, professor of clinical epidemiology and general practice
<http://www.bmj.com/content/341/bmj.e4245.full>**

My mother's medical history was blatantly ignored as it related to the extensive list of side effects and adverse reactions for the antipsychotic drugs that she was given Haldol, Risperidone, Seroquel, & Zyprexa, along with other medications such as Ativan, Trazodone, Baclofen, Aricept and many more. These side effects included increased risk of falls, lethargy, edema, urinary tract infections, pressure sores and many others, which was what these facilities were supposed to be trying to treat, but yet these medications only exacerbated her original health problems even more. She also developed new medical problems, which she never had before that were listed as side effects/adverse reactions. The mental behavioral changes included hallucinations, suicidal tendencies, many behavioral changes such as aggression, agitation, fear, and anxiety, physical and mental dependence on others, withdrawal, and depression. The physical problems included tremors, drooling, watery eyes, runny nose, constipation, difficulty swallowing and talking, loss of appetite, jerky movements, and overall weakness with increased pain throughout different areas of her body. It is important to note that she went from taking less than 5 medications when she was on her own at home, to over 30 various medications and supplements during the time she was at the nursing home in the span of 1-1/2 years. The drug interactions for these antipsychotic drugs and many of her other medications were ignored as well. Over 75% of the medications that she was given had either a major or moderate interaction with other medications that she was given simultaneously. Several times she was given more than one antipsychotic drug at a time, which is extremely dangerous: Haldol and Risperidone – in the hospital, and Seroquel and Zyprexa – in the nursing home

Many times during my mother's stay at the nursing home I tried to get outside intervention when I saw how she was deteriorating so quickly. I contacted the NYS Department of Health, the Ombudsman, many local eldercare agencies and at one point I was so scared about what was happening to her I even called the police. Unfortunately I did not get much help from any of them and I could not save her no matter how hard I tried. I am in the process of filing a complaint against the nursing home with the NYS Department of Health and will eventually be doing the same with Medicare. I can only hope that they both do right by my mother and the others out there who are still suffering. I believe that any facilities that operate in this way should be totally and permanently shut down.

In regards to the financial issues you have mentioned, my mother's care was paid for out of her own personal funds for Medicare A & B, insurance premiums and co-pays to her Medicare Advantage plan through MVP Healthcare, and Medicaid. Because of the improper use of antipsychotic drugs she ended up in a nursing home, and going through her financial resources very quickly to pay for the cost of that care and the expensive medications that were destroying her life. When she ran out of her life savings, she then ended up on Medicaid too. So if these drugs were never given to her it definitely would have saved not only her, but also the taxpayers a great deal of money.

I must also alert you to a cold hard truth regarding the problems that you are trying to address with this hearing. Unfortunately a very important fact that I discovered since this happened to my mother, is that there seems to be a very low value placed on human life especially that of an elderly or very young person, which this type of abuse targets. As I try to seek justice for my mother through the legal system, I can't even begin to tell you how many attorneys have told me what was done to my mother was wrong and agreed that laws were broken. But in the next breath they tell me that because of the work involved to prosecute a case and the little amount of "awards" that they might recover based on her age, their expenses would not be met etc. so they do not want to pursue it. To be literally told over and over again that a human life, especially that of a loved one, is worth nothing is disgusting to say the least. So based on this experience it seems to me that getting justice in this country is only for the rich and well connected, even if many laws are broken, which result in a person's death.

I didn't hear this fact mentioned at the hearing, but it plays a major role in why this problem is so rampant. State and Federal laws protect those who violate the laws/regulations from having to pay any substantial amount of damages after they ruin a person's life, so therefore these offenses are often not prosecuted, as they should be. Since all the violators understand is money, they will continue to profit by destroying the lives of their victims, unless you change the laws so they can be penalized monetarily with huge fines and punitive damages to the victims or their families. Until we start putting a "higher value" on human life, they will arrogantly carry on their "business as usual." Any reimbursements to Medicaid and Medicare should be required to be paid back **IN ADDITION** to any monetary settlement and not taken out of the damages that are awarded to the victims. No matter how many people cry out that this is wrong, unless you start putting some "financial teeth" into the laws for damage recovery, nothing is really going to make a large enough impact to change things properly. It totally disgusts me, and I'm sure it would have angered my mother, that for all the years she worked sometimes two jobs at a time, to save her money to have a decent life and provide for her children after she died, that her hard earned money ended up having to be spent on substandard, even abusive treatment, and drugs that totally destroyed her life.

As you can see, this is literally a matter of life and death, and I would be willing to bet my own life that my mother is not the only person in this country to have suffered in this way, therefore it is crucial that these problems be addressed and resolved ASAP. I am speaking out now because I don't want my mother's death to be in vain, and I don't want to see another person die or have their quality of life be destroyed like hers was. I want preventative measures to be instituted, and I hope you will join me in the effort to make that happen. I would be happy to provide you with any additional information that you may need. Thank you for your time and consideration.

Sincerely,

Linda J. Fullerton
ssdcoalition@hotmail.com



**United States Senate
Special Committee on Aging**

**Overprescribed: The Human and Taxpayers' Costs of
Antipsychotics in Nursing Homes**

November 30, 2011

Statement by the Long-Term Care Community Coalition

Introduction

The Long Term Care Community Coalition (LTCCC) is a New York State based non-profit organization dedicated to improving care for the elderly and disabled and ensuring that long-term care consumers in all settings are cared for safely and treated with dignity. To those ends, LTCCC researches national and state policies, laws and regulations affecting care for the elderly and disabled; advocates for policies to improve care; addresses systemic problems in the delivery of long term care; identifies good practices and develops recommendations to improve care and dignity of the elderly and disabled, and better conditions for professional caregivers; and educates and facilitates the advocacy of the elderly and disabled.

We commend the Special Committee on Aging for putting the spotlight today on this serious and pernicious issue. Inappropriate drugging of nursing home residents is a silent epidemic in our nation's nursing homes. Every day, approximately one out of four nursing home residents is given powerful antipsychotic drugs, despite the FDA's black box warning that they are dangerous and contraindicated for the elderly and people with dementia. In addition to being physically dangerous, antipsychotic drugs have enormous emotional and intellectual consequences for the elderly; in short, they render residents sedated and stupefied. While reliance on inhumane physical restraints to control nursing home residents has decreased markedly over the years, the increasingly widespread use of antipsychotics signifies an equally abhorrent, yet more insidious, reliance on chemical restraints to subdue and control residents without regard for their needs, underlying conditions or basic humanity.

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We strongly support the written and oral testimony and recommendations of Toby Edelman, senior policy attorney of the Center for Medicare Advocacy, the testimony of Dr. Jonathan Evans, president-elect of the American Medical Directors Association, and the findings and recommendations in the two resolutions adopted this month by members of the National Consumer Voice for Quality Long-Term Care that address this critical issue. In addition, we would like to submit the following comments for the Committee's consideration.

I. Federal Law and Standards Provide Strong Protections Against Unnecessary Drugging

The federal Nursing Home Reform Law¹, promulgated almost 25 years ago, and implementing regulations set forth strong standards for care of nursing home residents. Under the law, each resident must be provided the care he or she needs, as an individual, to attain and maintain his or her highest practicable physical, emotional and psychosocial well being. As well noted in other testimony and statements to the Committee for this hearing, the law includes explicit safeguards to prevent the widespread inappropriate use of antipsychotics on nursing home residents.

Importantly, in recent years federal law and standards have made substantial and substantive advances in fighting resident abuse and recognizing the right to individualized care and decent quality of life for all residents (including individuals with dementia). For instance, in 2009, CMS issued guidance to the state survey agencies on resident dignity and autonomy.² This guidance does not promulgate new standards but, rather, was meant to improve enforcement of the longstanding requirements pertaining to specific indicia of resident self-direction, choice and self-determination. The goal of the new Quality Indicator Survey, now undergoing implementation across the country, is "to improve the consistency and accuracy of care and quality of life problem identification for LTC residents."³ The 2010 Affordable Care Act includes a number of important provisions aimed at reducing elder abuse and, specifically, improving care, quality of life and accountability in our nation's nursing homes. These include provisions to increase adoption of nursing home culture change (the movement to provide care that is resident centered and resident directed in a home-like environment), to improve identification and reporting of suspected crimes and abuse against nursing home residents and to expand the ways in which Civil Money Penalties are used to improve resident care and quality of life beyond regulatory minimums.

Underlying this movement to a large degree, at least intellectually, is the U.S. Supreme Court's ruling in *Olmstead*,⁴ in which the Court held that disabled individuals, including those with mental disabilities, have the right to receive care in the least restrictive setting possible for them as individuals. While that case has been most influential in the movement to access long term care outside of nursing homes, it is hard to imagine any situation more restrictive (or

¹ Omnibus Budget Reconciliation Act of 1987, Pub.L. 100-203, 101 Stat. 1330.

² CMS Manual System, Pub. 100-07 State Operations Provider Certification, Transmittal 48 (June 12, 2009).

³ Klusch, L., "Are You Ready for the New Survey: The QIS (Quality Indicator Survey) is coming—and now is a good time to start gearing up," *Long-Term Care Living* (December 2008).

⁴ *Olmstead v. L.C.*, 527 U.S. 581 (1999).

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emblematic of the horrors of institutionalization) than being chemically restrained with powerful antipsychotics, as thousands of Americans in nursing homes are every day.

As progress made over the years in the law and our understanding of (and perceptions about) aging and disability indicates, it is now incontrovertible that everyone, no matter their age and/or frailty, retains the right to be cared for as an individual and to receive services that meets their needs and helps them to maintain their health and functioning in a humane setting.

II. Widespread Antipsychotic Drug Use: A Significant Systemic Failure With Catastrophic Personal Consequences

Unfortunately, the ordinary experience of nursing home residents in this country often runs counter to our present-day understanding of human dignity and fundamental rights. Perhaps nowhere is this more evident than in the situation with antipsychotic drugs. As noted above and in other statements and testimony made to the Committee today, an astounding number of nursing home residents are given antipsychotic drugs every day, despite the black box warning that they are extremely dangerous (potentially life-threatening!) for the elderly, despite the studies indicating that they are largely ineffective as a treatment and despite the fact that they are outrageously expensive, both in terms of human life and suffering for residents and families and financially, for the American public as a whole.

What does this systemic failure mean for elderly nursing home residents and their families? Following are a few cases that came in to our local hotline:

1. A caller's father is living with dementia in a nursing home. The nursing home informed the family that his father was annoying other residents because he screams at night. Therefore the nursing home wanted to give his father Seroquel. The family has initially agreed but has seen their father become lethargic and more disoriented. The nursing home now wished to increase the Seroquel dosage but the family is considering refusing. The family feels the nursing home has intimidated that they will ask the resident to leave the facility if the family refuses more Seroquel.
2. A caller's mother entered nursing home and was given Haldol and Depakote. The caller noted a marked decrease in her mother's ability to communicate, eat and ambulate. The nursing home recognized the caller as the health care proxy but allegedly told her that she could not make decisions about medication because she was not a doctor. Therefore she could not ask for discontinuation of the Haldol and Depakote. The caller had her lawyer write a letter to the nursing home stating they must recognize a health care agent's right to refuse medication for an incapacitated loved one. The physician's assistant stopped the medication but the nursing home medical director reinstated the order to give Haldol and Depakote. The caller then filed a complaint with the Department of Health which was unsubstantiated. Subsequently, the DOH entered the nursing home for yearly inspection and as per DOH advice caller is not trying to reopen the complaint.

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3. A caller placed his friend in a nursing home which touted its person centered care. However, the nursing home not only fed the friend breakfast while making her sit in her soiled night briefs, but also forced the resident to bathe when she did not want to bathe. As a result the resident became agitated and kicked her legs at staff. The nursing home subsequently medicated her with Haldol. The friend, who is the health care proxy noted a marked decline in the resident's condition following Haldol and asked that the medication be discontinued. The nursing home complied. After 6-8 weeks the facility stated they would have to reinstate Haldol because the resident continued to be agitated. No behavioral redirection or person centered care was offered, according to caller. Caller told facility he did not want Haldol restarted and the facility allegedly responded, "Then we will have to send your friend to the psych hospital."

III. Recommendations and Conclusion

As noted above, LTCCC strongly supports the recommendations made in the written statement and oral testimony of Toby Edelman and in the two resolutions relating to antipsychotic drugs submitted by the National Consumer Voice for Quality Long-Term Care (of which LTCCC is a longstanding member).

Fundamentally, the problems resulting from the inappropriate, non-therapeutic use of powerful antipsychotic drugs lay bare the significant underlying problems in our nursing home system. As research data and direct experience indicate, the widespread use of these drugs by nursing homes to manage residents (and, specifically, residents' behavior) functions, in effect, as a band-aid that stanches the symptoms of poor care and minimizes cost to the facility, with little to no regard for the financial costs to taxpayer or the staggering personal toll on residents and their loved ones.

These problems include:

1. **Inadequate Staffing.** From federal and academic studies to anecdotal reports from LTC Ombudsmen and consumer groups across the country, year after year, we are well informed as a nation that the vast majority of U.S. nursing homes lack sufficient staff to provide the care and quality of life that residents need. Yet (and despite the fact that the American public pays for the majority of nursing home care), there are no federal requirements whatsoever for nursing home staffing. State requirements are inadequate in the minority of states where they exist. The result is that that the U.S. nursing home industry is entrusted with the care of close to 1.4 million vulnerable residents, at a cost of many billions of dollars a year, with no meaningful requirements as to levels of direct care staff. The industry has been very successful, on both the state and national levels, in preventing promulgation of meaningful staffing requirements. One of the consequences of the lack of staffing standards, however, is the widespread use of chemical restraints, and the resulting harm to residents, loss to families and enormous costs to the public in terms of billions spent on unnecessary drugs and costs to care for the harmful effects of the antipsychotic drugs.

LTCCC Statement on Antipsychotic Drug Use: U.S. Senate Special Committee on Aging,
November 30, 2011

2. **Inadequate and Circumscribed Enforcement.** Though current law and regulation merit improvement, strong protections already exist in the current laws and standards which nursing homes are obliged to follow. Unfortunately, all too often, these obligations are ignored with impunity. As noted above, the Nursing Home Reform Law has long required that nursing homes provide a quality of life and quality of care sufficient to ensure that every individual entrusted to their care is able to attain and maintain their highest practicable physical, emotional and social well-being. "Highest practicable" does not refer to what the providers deem they are willing to provide, or feel they can afford to supply or what coincides with their goals for their bottom-line that month or year; it refers to what they are promising to provide for each and every individual that they take in, in particular what they agree to when they participate in the Medicare and Medicaid programs. Whose mother should be zonked out on powerful and dangerous medications, because they have dementia and are unable to verbally express when their back is out and their pain is excruciating? Who deserves to be sedated on Seroquel because their behavior is annoying or cumbersome to their nursing home's staff?

Unfortunately, our system has evolved in a way that often results in accountability being a last resort. State and federal oversight agencies are regularly compelled to work "collaboratively" with providers that fail to meet minimum standards. Our studies of state and national enforcement indicate longstanding weaknesses in the identification and rating of nursing home deficiencies, including those directly relating to care, safety and quality of life. These findings have been collaborated by the GAO and others. Yet, despite these findings and the clear personal and financial costs, as amply exemplified in the case of antipsychotic drug use, we continue to underfund and undermine oversight agencies on both the state and federal levels.

These are but a couple of the potential avenues by which we can begin to better address the widespread and pernicious issue of inappropriate antipsychotic drug use. We hope that the Committee will use these as a basis for continuing momentum and progress to combat this critical problem.



November 21, 2011

Donald Berwick, MD
 Administrator
 Centers for Medicare and Medicaid Services
 U.S. Department of Health and Human Services
 200 Independence Avenue, S.W., #314B
 Washington, DC 20002

Dear Dr. Berwick:

On behalf of the National Alliance on Mental Illness (NAMI), I am writing to follow-up on the meeting held in your office on October 27 on off-label prescribing of medications to residents in long-term care facilities. First NAMI would like to thank for including us in these important discussions. As our nation's largest organization representing people living with serious mental illnesses and their families, NAMI is committed to assisting the Centers for Medicare and Medicaid Services (CMS) in developing new policies that carefully balance the needs of nursing home residents living with mental illness to access the treatment they need, with the need to ensure that medications are not prescribed in clinically inappropriate ways.

NAMI Opposes Use of "Chemical Restraints" in Long-Term Care Settings

For more than a decade, NAMI has maintained a strong policy with respect to use of both mechanical and chemical restraints. NAMI's Policy Platform reads in part:

"Restraint and seclusion have no therapeutic value. They should never be used to 'educate patients about socially acceptable behavior,' for purposes of punishment, discipline, retaliation, coercion, and convenience; or to prevent the disruption of the therapeutic milieu." AND "Medication is typically important for the treatment of the symptoms of mental illness. However, medication should never be used for the purposes of discipline, staff convenience, immobilization, or reducing the ability to ambulate."

It is this policy that grounds NAMI's opposition to prescribing of antipsychotic medications for any purpose beyond clinical treatment for approved on-label usage or within the confines of accepted clinical treatment guidelines. This policy further places NAMI in opposition to prescribing of antipsychotic medications for the purpose of chemical restraints.

NAMI remains concerned about the findings of the May 2011 HHS Inspector General's report that found alarmingly high levels of prescribing of antipsychotic medications in the absence of an on-label indication or use of peer reviewed clinical treatment guidelines to guide off-label prescribing. It is critical that CMS moves forward to institute policies

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designed to curb inappropriate prescribing of all medications as chemical restraints in long-term care facilities and to work with a broad array of stakeholders to limit this practice. NAMI is committed to assisting CMS in this process and would like to offer a number of recommendations toward this shared goal.

Distinguishing Between Mental Illness and Dementia in Long-Term Care Settings

First, NAMI would like to note that in long-term care settings, it is often difficult for frontline staff to make clear distinctions between the symptoms of mental illness and dementia among frail elderly residents. In NAMI's experience it is not uncommon for frail elderly nursing home residents experiencing dementia to exhibit symptoms such as delirium, agitation, anxiety, psychosis, delusional thoughts or paranoia. These are the very symptoms that are central to schizophrenia, bipolar disorder, psychotic depression and severe anxiety disorders. These are symptoms squarely within the accepted on-label indications for every FDA-approved antipsychotic medication.

At the same time, NAMI recognizes that there are clear diagnostic parameters that separate these symptoms of serious mental illness from disorders such as vascular dementia and Alzheimers disease. Unfortunately, many of the staff in long-term care facilities lack the experience, expertise and clinical training to make such distinctions. NAMI therefore urges CMS to work with research organizations and professional societies to develop additional protocols, guidelines and training materials to help front-line staff in nursing homes to make the distinction between the symptoms of dementia and serious mental illness.

NAMI would also recommend the development of additional quality measures for nursing homes that promote the adoption and adherence to the use of such guidelines and training protocols. These quality measures can and should move providers toward ensuring that their staffs are better equipped with the tools to distinguish between serious mental illness and dementia.

Promoting Policies That Protect Access to On-Label and Clinically Appropriate Prescribing on Anti-Psychotic Medications

In moving forward to promote policies that limit inappropriate prescribing of antipsychotic medications, NAMI would recommend that CMS recognize that these medications are a critical and legitimate foundation for the treatment of serious mental illness and have a broad range of on-label indications and a robust body of evidence in various compendia and clinical treatment guidelines. Any policy designed to curb inappropriate prescribing of antipsychotics must take this reality into account.

It is also the case that a large number of non-elderly people living with serious mental illness currently reside in nursing homes, residential care facilities, board and care homes and other restrictive settings. NAMI is firmly committed to the promotion of policies that can significantly diminish use of these restrictive settings as a residential option for non-elderly people living with mental illness. As you know, CMS is helping states move

forward with policies that will further this goals of limiting use of restrictive housing settings and promoting community integration.

NAMI applauds these efforts, but also recognizes that the pace with which states are moving forward on implementing the US Supreme Court's Olmstead mandate and CMS initiatives such as Money Follows the Person and Medicaid rebalancing remains complex and slow. As recent studies have indicated, as many as 330,000 non-elderly people with disabilities remain in nursing homes, and far too many of them have a diagnosis of serious mental illness. For these nursing home residents that are living with serious mental illness, or experiencing the symptoms of a serious mental illness – both elderly and non-elderly – prescribing of an antipsychotic medication is essential to their ongoing treatment and recovery.

Any and all policies adopted by CMS to curb inappropriate prescribing of antipsychotics must take this reality into account. Additional quality metrics and standards developed by CMS must take into account the needs of nursing home residents living with serious mental illness and should not serve to interfere with their ongoing access to clinically appropriate on-label prescribing.

Any Changes to Medicare Part D Coverage Should Be Carefully Weighed

As you know, a large majority of residents in long-term care facilities are eligible for Medicare and receive prescription drug coverage through the Part D program. This includes both elderly residents, as well as non-elderly beneficiaries with disabilities. As a result, Medicare Part D plays a critical role in meeting the treatment needs of nursing home residents. Likewise, any effort to develop policies to address inappropriate off-label prescribing antipsychotic medications must take into account the role that Part D plays in offering prescription drug coverage for nursing home residents.

In moving forward to address the role of Medicare Part D, NAMI would urge CMS to take into account current policies that have been carefully designed to ensure broad access to antipsychotic medications for some of the most vulnerable beneficiaries in the program. As you know, antipsychotics are currently covered under subregulatory guidance developed by CMS requiring all Part D plans to include "all or substantially all" of the FDA-approved antipsychotics on plan formularies. NAMI has strongly supported this policy since its inception in 2005.

NAMI would recommend against CMS eroding this critical beneficiary access protection as part of any effort to use Part D as a means of denying coverage for antipsychotics prescribed in long-term care settings. Further, NAMI would urge CMS not use coverage policies or formulary guidelines for Part D plans as a blunt instrument to curb inappropriate prescribing of antipsychotics. In particular, NAMI would strongly recommend against any mandate or protocol by which Part D plan sponsors would impose an automatic step edit or prior authorization requirement for prescribing of an antipsychotic in a long-term care setting. NAMI is especially concerned that having

commercial Part D plans implement such as a policy will inevitably result in significant disruptions in continuity of care for beneficiaries living with serious mental illness.

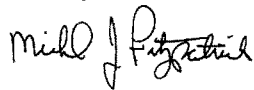
NAMI Recommendations to Promote Quality and Limit Use of Chemical Restraints

NAMI would make the following recommendations to CMS as part of efforts to make progress in curbing use of chemical restraints in long-term care settings:

- Institute additional protocols and guidelines that better define chemical restraints and clearly distinguish between clinically appropriate use of antipsychotics to treat mental illness and inappropriate off-label use that is beyond peer-reviewed guidelines and existing compendia.
- Develop staff training and education protocols and guidelines to assist front-line staff in long-term care facilities in distinguishing between the symptoms of mental illness and dementia. The CMS Center for Medicare and Medicaid Innovation can play a key role in providing technical assistance to providers to further this important goal.
- Implement new quality metrics and payment policies that reward providers for limiting use of chemical restraints.
- Invest in research and development of alternatives to prescribing of medications for nursing home residents with dementia experiencing symptoms such as delirium, wandering or agitation.

NAMI appreciates the opportunity to share our views and recommendations on this important issue. We look forward to working with you and your colleagues at CMS on minimizing the use of chemical restraints in long-term care settings. It is critical that we make progress toward our shared goal of quality improvement and protecting access to treatment for people living with serious mental illness.

Sincerely,



Michael J. Fitzpatrick, M.S.W.
Executive Director



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**Statement of the
National Community Pharmacists Association
United States Senate Special Committee on Aging
Hearing on "Overprescribed: The Human and Taxpayers'
Costs of Antipsychotics in Nursing Homes"
November 30, 2011**

The National Community Pharmacists Association (NCPA) appreciates this opportunity to provide comments to the Committee regarding costs associated with the use of antipsychotics in nursing homes. NCPA represents the pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines. Thirty-four percent of our members serve an LTC facility and forty-eight percent serve an Assisted Daily Living facility. In sum, approximately 40% of the long-term care market is serviced by an independent community pharmacy.

NCPA is committed to the appropriate prescribing and dispensing of all medications, including those for use by nursing home patients. Our members are focused on ensuring appropriate use of antipsychotic medications in long-term care facilities. We are pleased to work in partnership with all stakeholders to address the use of antipsychotic medications and share our ideas for possible ways to improve practice in this area.

NCPA Points of Clarification Regarding the May 2011 OIG Report "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents"

The May 2011 HHS OIG report focused on results of a 2007 survey on the prescribing of atypical antipsychotics for nursing home residents. OIG states that 51 percent of Medicare claims for atypical antipsychotic drugs were erroneous, amounting to \$116 million. Atypical antipsychotic drugs are only labeled to treat schizophrenia and bipolar disorder; however, up to 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions and 88 percent were associated with the condition specified in the Food and Drug Administration's (FDA) boxed warning (i.e. dementia).

THE VOICE OF THE COMMUNITY PHARMACIST

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It is important to note that medical review was conducted on only 600 of the 1.7 million claims, leading to a potential overestimation of erroneous prescriptions and estimated savings. This report is based on a 2007 survey, however prescribing patterns and the availability of atypical antipsychotic drugs in generic form have changed greatly since that time. Savings quoted in this study were likely overstated as the generic cliff and move to short-cycle dispensing in the long-term care setting is decreasing the amount of savings that can be realized by decreasing the cost of the products. Short cycle (14 days or less) dispensing for brand name medications prescribed for Part D nursing home residents will begin in 2013, actually leading to an increased potential for savings.

Of the 10 atypical antipsychotics approved by the FDA to treat schizophrenia and/or bipolar disorder, Clozaril (clozapine), Risperdal (risperidone) and Zyprexa (olanzapine) are currently available in generic form. There are only 7 drugs in this class that are currently brand-name only and by 2012 that number will drop to 4 drugs. In essence, cost savings that are based on data from 2007 in the OIG report are no longer valid and need updating.

NCPA believes that atypical antipsychotics should only be prescribed for elderly nursing home residents when clinically indicated, as determined by the prescriber and consulting pharmacist, and should be provided in the lowest effective dose to achieve the clinical outcomes desired. The pharmacist provides an initial review with all new prescriptions for allergies and/or drug interactions. A more in-depth review is provided every 30 days, including F Tag 329, which relates to unnecessary drugs. This includes gradual dose reduction of antipsychotics. An important role of consultant pharmacists is to ensure that survey guidelines are adhered to so that facilities can pass their state and federal surveys.

However, an off-label prescription may still be the best treatment for an individual patient. The LTC pharmacist works with the prescriber and the LTC facility to ensure the patient diagnosis and previous clinical indicators warrant the use of an atypical antipsychotic. Also, it is oftentimes the case that alternative drug side effects are too severe. In fact, a comprehensive review by the Agency for Healthcare Research and Quality, updated in September 2011, found that risperidone, an atypical antipsychotic, has the best evidence for efficacy in the management of psychosis and agitation in older adults with dementia.

Since much of the concern surrounding the use of antipsychotics in nursing home residents rests on off-label use, it is important to point out that the use of antipsychotics in nursing facilities are recognized in the CMS State Operations Manual (Appendix PP)¹ for three purposes:

1. Psychiatric diagnosis (e.g. schizophrenia)
2. Psychotic symptoms resulting from medical illnesses (including dementia) or delirium (e.g. hallucination or delusions that are distressing to the individual or present a risk of harm to the resident or others)
3. Dementia with behavioral symptoms, where the behaviors present a risk of harm to the individual or others

At the time of the HHS OIG report on atypical antipsychotic use in nursing facilities, no diagnosis code was available to identify individuals with dementia and behavioral symptoms. A

new ICD-9 code has been released for 2012 that will facilitate identification of these individuals on the Minimum Data Set:

- 294.20 Dementia, unspecified, without behavioral disturbance
- 294.21 Dementia, unspecified, with behavioral disturbance

NCPA will work to help ensure that these new ICD-9 codes are used appropriately to help identify these individuals. We will encourage consultant pharmacists to help educate facility staff, including assessment nurses, about these new codes.

NCPA Suggestions to Lower the Potential Overuse of Antipsychotics in Nursing Homes

NCPA respectfully requests that the May 2011 OIG Report “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” be re-conducted using more recent data as prescribing patterns and the availability of these drugs in generic form has changed dramatically since 2007. NCPA is committed to offering recommendations on how such an updated study should be structured.

We also suggest that a study be conducted to identify who initiates an antipsychotic medication prescription and under what circumstances. (i.e. patient is in a hospital, following admission to a LTCF, etc). Such a study to determine the extent of acute-care setting use of antipsychotics in older adults will identify the source of the medication regimen and pinpoint who is best served by improved education and communication to support appropriate pharmacotherapy.

The use of antipsychotic medications in older adults often begins in the hospital, before the person is transferred to the nursing facility. It is sometimes difficult to get an accurate medication history on newly admitted nursing facility residents, and physicians may be reluctant to reduce or discontinue these medicines until the history of use of the antipsychotic is determined. As CMS is responsible for the Conditions of Participation for hospitals, an effort could be made to focus on antipsychotic use in elderly hospital patients. Initiating these agents only when needed, and discontinuing prior to discharge may reduce the risk of adverse outcomes in these elderly patients, whether discharged to a nursing facility or back to the community.

Regarding potential studies surrounding the use of antipsychotics, NCPA also suggests that a study be conducted to identify how many residents in LTCFs have the diagnosis of schizophrenia, bipolar disorder, or other mental health disorder, for which antipsychotic medication use is appropriate. This will help determine if greater use of antipsychotic medications in LTCFs is due to a higher prevalence of mental health diagnoses in these facilities, for which antipsychotic medication use is appropriate. As many states have closed state-run mental health facilities, these patients are transferred to LTCFs, which may result in a disproportionately higher percentage of LTCF patients requiring this treatment. Understanding the patient mix in LTCFs is a first step to identifying opportunities for team communication and collaboration to support appropriate pharmacotherapy.

In addition to the studies recommended above, CMS should work with Medicare Part D plan sponsors to ensure that existing Drug Utilization Review (DUR) edits in place are improved.

NCPA has concerns with a letter sent from CMS to all Part D sponsors on September 28, 2011, regarding improving DUR controls in Medicare Part D. CMS is recommending plans implement an enhanced retrospective DUR process in which sponsors consider the drug classes and establish clinical upper thresholds through sponsor specific Pharmacy and Therapeutics (P&T) committees. NCPA contends this recommendation will add yet another inconsistent Part D policy. This recommendation has the probability of adding numerous disparate thresholds to the system that pharmacies would have to work with. CMS should focus on improving the current system before requiring new, beneficiary-level controls.

NCPA recommends that CMS establish consistent guidance in this area so network pharmacies are not left with multiple processes to contend with, thereby having the potential to distract from true patient care activities. As Pharmacy Benefit Managers (PBMs) do not have patient diagnosis information they are not in a position to determine at point of dispensing if clinically appropriate. Only the pharmacist working in conjunction with the prescriber can determine appropriateness. It is also important to note that a significant proportion of nursing facility residents are below the age of 65, and the FDA "black box" warning against use in the elderly with dementia would not apply to these individuals. There is a risk that interventions from Part D plans could have the unintended consequence of impeding access to antipsychotic medications for these younger individuals, many of whom have longstanding psychiatric conditions. Also, antipsychotic medications are sometimes needed in emergent situations in nursing facilities. Part D plans should not impose strategies that might prevent the timely dispensing of antipsychotics to individuals with acute delirium or other crises.

Lastly, the role that PBMs may play in the use of these medications should be examined. For example, there are currently two large national Medicare Part D Prescription Drug Plans that will only pay for the brand name version of Zyprexa, even though generic versions are on the market, based on rebates that the Part D plans are receiving from the brand drug manufacturer. Note that Zyprexa became available in generic form on October 24, 2011. Recent OIG reports have questioned the ways in which Medicare Part D plan sponsors allocate rebates. Some PBMs may be deliberately underestimating their rebates in order to increase their profits. CMS should closely scrutinize whether these presumed Zyprexa rebates being obtained by the plan sponsors are truly passed through to CMS and ultimately the beneficiary.

NCPA Concerns Regarding Efforts to Separate LTC Consultant Pharmacists from LTC Pharmacy

NCPA opposes recent proposals by CMS that would require a LTC facility to employ or directly or indirectly contract for the services of a licensed pharmacist who is independent of any affiliations with that LTC facility's LTC pharmacy, pharmaceutical manufacturers and distributors, or any affiliates of these entities. NCPA does not dispute that some large, chain LTC pharmacies participated in distasteful practices in the past. However, this practice was conducted by a small group of individuals; the entire industry should not be punished or completely changed for the actions of others.

NCPA contends that any manufacturer incentives to independent community pharmacies related to atypical antipsychotics were terminated based on the black-box warning from the FDA. Long

term care independent pharmacies do receive rebates on other products but they are small discounts amounting to less than 2% of their total drug purchases. These rebates are discounts that take into consideration the formularies within the Medicare Part D program and are designed to work with formularies to decrease costs.

It should be noted that in the six-year period from 2004 (\$50.96) to 2009 (\$70.92), the average cost per long-term care prescription dispensed by corporate-owned long-term care pharmacy providers climbed nearly 40%. By comparison, the average cost per long-term care prescription grew only 5% at independently-owned LTC pharmacy providers during this period, to \$62.84 in 2009 from \$59.60 back in 2004. These numbers signify that the large, chain pharmacies have certain incentives to move market share for more expensive products, unlike the small independents. Therefore, it should not be assumed that unscrupulous practices by some are being committed by the entire industry, nor should such a separation proposal be imposed on the entire industry.

Based on survey guidelines, the consultant pharmacist is the pharmacist of record and they are responsible for managing drugs and services within the facility. Separating the consultant from the pharmacy will lead to operational disconnect between the pharmacy and facility as well as disrupt the continuum of care. Also, forcing these pharmacists to start up their own consulting businesses could prove costly and discourage them from the profession as pharmacists have the security of knowing they have benefits like medical insurance, vacation time for someone else to assist with consulting, etc. If separation happens they must set up these benefits themselves or do without.

Separation will cause an undue hardship on rural providers, where an independent consultant may not be available. In a recent NCPA survey of our members, 57% of respondents stated that there is currently a shortage of independent consultant pharmacists in the area that their pharmacy subsidizes. In addition, 53% stated there is a shortage in the area their facilities reside. Another important factor is facilities may not be able to find pharmacists willing to travel to their location because of the distance to get there. A pharmacist working at a retail/LTC combination pharmacy may be the only pharmacist in the local area.

It is imperative that a study be conducted comparing medication use across 2 separate channels (facilities serviced by independent consultant pharmacists versus facilities serviced by consultant pharmacists employed by long-term care pharmacies). NCPA has information that several drug manufacturers report usage in New Jersey (where separation is required) is not any different than the national average for new and highly used drugs in the LTC setting.

Lastly, CMS is basing a proposal to separate consultant pharmacists from the LTC pharmacy on an OIG study from June 2008 titled "Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents." NCPA has severe concerns with this study forming the basis for such a major change in the LTC pharmacy industry. This study included only interviews, not scientific analysis of dispensing data, of staff and pharmacy directors from 144 nursing homes. Of note, not one consultant pharmacist was interviewed for the OIG study.

Conclusion

Thank you for your attention to these matters. We appreciate your consideration of the information above and look forward to working with all LTC industry stakeholders on these important issues.

¹ Appendix PP of State Operations Manual http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltc1.pdf



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Consumer Group Asks HHS for Policies to End Chemical Restraint of Nursing Home Residents

Resolutions Call for Action on Antipsychotic Drugs, Pharmacist Independence

Member organizations of The National Consumer Voice for Quality Long-Term Care this week approved resolutions calling for the Department of Health and Human Services to curb the widespread misuse of antipsychotic drugs in nursing homes as chemical restraints and ensure that long-term care consultant pharmacists are free from the influence of pharmacies and manufacturers that benefit from increasing drug sales.

Twenty-six percent of nursing home residents receive antipsychotic medications. The HHS Office of Inspector General found that 88 percent of residents who receive antipsychotics are elderly people with dementia—people whom the Food and Drug Administration says are at increased risk of death from their use.

Medicare and Medicaid prohibit physically or chemically restraining residents for staff convenience, but the government alleged that major pharmaceutical companies and the largest long-term care pharmacy illegally marketed antipsychotics to treat symptoms of dementia. Inspector General Daniel Levinson said “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged—and seek solutions” to the misuse of antipsychotic drugs as restraints.

The Consumer Voice resolutions call on HHS to take specific steps, including:

- (1) Prohibiting the use of psychoactive drugs without written informed consent;
- (2) Publishing facilities' rate of psychoactive drug use on Nursing Home Compare;
- (3) Strengthening enforcement of regulations on chemical restraints and unnecessary drugs;
- (4) Implementing procedures to prevent Medicare payment for non-therapeutic use of antipsychotics;
- (5) Excluding long-term care pharmacies from Medicare and Medicaid if they illegally promote antipsychotic drugs in long-term care facilities;
- (6) Sponsoring education programs about the dangers of antipsychotic drugs and alternative forms of care; and
- (7) Publishing regulations it is considering to prohibit consultant pharmacists from affiliation with drug manufacturers or long-term care pharmacies.

For more information, contact Janet Wells, Director of Public Policy, 202-332-2275, ext. 205.

The National Consumer Voice for Quality Long-Term Care (formerly NCCNHR) is a 501(c)(3) nonprofit membership organization founded in 1975 by Elma L. Holder that advocates for quality care and quality of life for consumers in all long-term care settings.

2001 Connecticut Ave., NW • Suite 425 • Washington, DC 20036

Resolution Requesting the Department of Health and Human Services to Address the Misuse of Antipsychotic Drugs in Nursing Homes

WHEREAS the chemical restraint of nursing home residents is a leading form of elder abuse that causes misery, loss of independence, over-sedation, confusion, falls, severe medical side effects and death;

WHEREAS many nursing homes commonly use antipsychotic drugs to chemically restrain elderly residents with dementia and as a substitute for needed care;

WHEREAS 26% of U.S. nursing home residents – more than 350,000 residents – are given antipsychotic drugs;

WHEREAS nearly 40% of U.S. nursing home residents who have cognitive impairments and behavioral symptoms are given antipsychotic drugs despite the absence of psychotic or related conditions;

WHEREAS the Centers for Medicare & Medicaid Services guidelines on unnecessary drugs state that analysis of antipsychotic drug use by 693,000 Medicare nursing home residents found that 28.5% of the doses received were excessive and 32.2% lacked appropriate indications for use;

WHEREAS the United States Food and Drug Administration (FDA) has not approved antipsychotic drugs for the treatment of dementia and has issued advisories and “black box” warnings that antipsychotic drugs greatly increase the risk of death for persons with dementia;

WHEREAS nursing home residents who receive antipsychotic drugs and their representatives are often not properly informed about the dangers of these drugs or of alternative forms of care and treatment;

WHEREAS the HHS Office of Inspector General issued a prominent report in May 2011 revealing that – despite FDA warnings on the greatly increased risk of death – 88 percent of the nursing home residents who are subjected to powerful antipsychotic drugs are elderly persons with dementia; and that Medicare overpaid \$116 million for erroneous nursing home claims for atypical antipsychotic drugs in a six-month period of 2007;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions” concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents;

WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors as a treatment for dementia; and whereas one large national long-term care pharmacy

has entered into agreements with the Department of Justice and several state governments to settle charges that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug it manufactures;

WHEREAS a large national long-term care pharmacy continues to provide drugs to residents of hundreds of long-term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS the Nursing Home Reform Law of 1987 and implementing regulations prohibit the unnecessary use of antipsychotic drugs and chemical restraints;

WHEREAS the Department of Health and Human Services (HHS) published proposed regulations on February 5, 1992 that would significantly strengthen the protections for nursing home residents against chemical restraint and prohibit the use of psychoactive drugs without written informed consent; and whereas, however, the proposed regulations have not been finalized:

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform a monthly drug regimen review for each resident and provide consultation on all aspects of pharmacy services within the facility; however, this requirement is not serving its purpose of independent analysis of nursing home drug use because most consultant pharmacists work for large long term care pharmacies that are the exclusive provider of drugs to the nursing homes, and the long term care pharmacies often subsidize the cost of consultant pharmacist services;

WHEREAS the Affordable Care Act of 2010 requires the Centers for Medicare & Medicaid Services to review and modify the Nursing Home Compare website to provide clear, timely and comprehensive information of value to consumers;

WHEREAS numerous studies have found that antipsychotic drugs are generally ineffective in treating behavioral symptoms of dementia, and that they are sometimes outperformed by placebos; studies also show that it is often a nursing home's drug use rate, not a resident's medical condition, which determines the likelihood of whether a resident will be given antipsychotic drugs and put at risk of serious harm and premature death;

WHEREAS, a growing number of nursing homes are proving there is a better way of caring for residents with dementia that focuses on ensuring their comfort and on timely assessment and response to the underlying causes of any behavioral symptoms;

THEREFORE BE IT RESOLVED that Congress hold hearings to address the rampant misuse of antipsychotic drugs to sedate and chemically restrain nursing home residents and that Congress enact legislation to ensure that antipsychotic drugs are not given to nursing home residents without medical justification and without the specific informed consent of residents and their representatives.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services publish up-to-date information on each nursing home's use of antipsychotic drugs on Nursing Home Compare and that it factor antipsychotic drug use into its Five-Star Rating System for nursing homes.

BE IT FURTHER RESOLVED that HHS adopt the 1992 proposed regulations on chemical restraint, subject to modifications that nursing homes be required to inform residents and their representatives in writing of the known risks of psychoactive drugs, including any black box warnings, and to advise them if the drugs are being prescribed for off-label purposes.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies strengthen enforcement of existing chemical restraint and unnecessary drug requirements by carefully examining antipsychotic drug use during surveys and complaint investigations, by consulting with consumer stakeholders on needed modifications to survey and enforcement procedures for this purpose, and by promulgating new regulatory methods to prevent or discourage the prescribing of antipsychotic drugs for residents in the absence of psychotic or related conditions (such as implementing computerized warning systems particularly related to the use of antipsychotic drugs).

BE IT FURTHER RESOLVED that HHS establish and implement effective procedures to prevent Medicare payment for non-therapeutic use of antipsychotic drugs and to recover erroneous payments for these drugs.

BE IT FURTHER RESOLVED that when the HHS Office of Inspector General and the Department of Justice find that a provider of pharmacy services is illegally engaged in marketing and promoting antipsychotic drugs to long-term care facilities, they exclude the long-term care pharmacy from Medicare and Medicaid.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies establish high-profile education campaigns to advise consumers, nursing home employees, and physicians about the dangers associated with the misuse of antipsychotic drugs and to inform them of alternative forms of care and treatment for symptoms of dementia.

Resolution Supporting a Federal Requirement for Long-Term Care Pharmacist Independence from Conflict of Interest

WHEREAS the health and safety of nursing home residents depends upon medication recommendations and reviews being conducted by long term care consulting pharmacists whose independence and clinical judgments are free from conflicts of interest;

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform drug regimen reviews for each resident at least monthly and to provide consultation on all aspects of pharmacy services within the facility;

WHEREAS CMS guidelines on unnecessary drugs and the findings in the May 2011 OIG Report, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), indicate that there exists in our nation's nursing homes a serious and ongoing problem of residents being given unnecessary, excessive, inappropriate drugs, and even potentially lethal drugs covered under FDA "Black Box" warnings;

WHEREAS financial arrangements between long term care facilities, long term care pharmacies, pharmaceutical manufacturers, and long term care consultant pharmacists may create misaligned incentives for long term care consulting pharmacists to put other interests ahead of what is the most appropriate medical care for residents;

WHEREAS the Office of Inspector General has raised concerns that pharmacists employed by long term care pharmacies inappropriately influence the drugs that are prescribed to residents in nursing homes, and that drug manufacturer rebates to long term care pharmacies may create undisclosed incentives for pharmacists and consultant pharmacists to recommend certain drugs over others based on financial considerations as opposed to clinical considerations;

WHEREAS many long term care consultant pharmacists work for large long term care pharmacies, a highly concentrated industry in which a few companies enjoy huge percentages of market share for the provision of drugs to nursing home residents, and the long term care pharmacies often provide consultant pharmacist services to nursing homes at a subsidized rate;

WHEREAS the Department of Justice announced in 2009 that the nation's largest nursing home pharmacy and drug manufacturer would pay \$112 million dollars to settle False Claims Act cases, including allegations of kick-backs which involved physicians prescribing antipsychotic medications to nursing home residents, illegal conduct which "can undermine the medical judgments of healthcare professionals, lead to patients being prescribed medications they do not need, and drive up the costs of health care," according to the Department of Justice's Assistant Attorney General;

WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors for "off-label" use as a treatment for dementia;

WHEREAS a large national long term care pharmacy continues to provide drugs to residents of hundreds of long term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that "government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions" concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents; and

WHEREAS concern over patient safety and quality of care has prompted the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services to publish proposed federal regulations CMS-4157-P, Federal Register Vol. 76, No. 196, Oct. 11, 2011, which would:

Require LTC consultant pharmacists to be independent of any affiliations with LTC facilities/pharmaceutical manufacturers, distributors or any affiliates of these entities; and

Require LTC facilities to use qualified professional pharmacists to conduct drug regimen reviews and make medication recommendations solely on the best interests of the resident; and

Define independent pharmacists as those who are not employed, under contract, or otherwise affiliated with the facility's pharmacy, pharmaceutical manufacturer or distributor, or any affiliate of these entities.

THEREFORE BE IT RESOLVED that The National Consumer Voice for Quality Long-Term Care urges the Department of Health and Human Services to adopt regulations to ensure the independence of long term care consultant pharmacists by prohibiting any affiliations between the long term care consultant pharmacists and the facility's long term care pharmacy, drug manufacturers, distributors, or any affiliates of these entities; and

BE IT FURTHER RESOLVED that The National Consumer Voice for Quality Long-Term Care urges the Centers for Medicare & Medicaid Services and state survey agencies to create strict enforcement mechanisms to ensure the independence of long term care consultant pharmacists, including imposition of lengthy exclusion from participation in Medicare and Medicaid for any non-compliance, and including CMS consultation with consumer stakeholders about data collection, modifications to survey and enforcement procedures, and other means for ensuring strict compliance with the independent consulting pharmacist requirement.

**Statement of Dr. Diana Zuckerman, President
National Research Center for Women & Families**

Senate Aging Committee Hearing on Atypical Antipsychotic Drugs

November 30, 2011

The Aging Committee has done the American people a great service today in holding this very important hearing. The IG's finding that about half of the 1.4 million atypical anti-psychotic drug claims for nursing home residents did not comply with Medicare criteria should be a wake-up call for CMS and for all of us who care about the humane care of our most vulnerable elderly citizens. The IG's determination of noncompliance is based on the fact that the drugs were not used for medically accepted indications. This means that patients are dying unnecessarily, and American taxpayers are paying for the drugs that are causing these deaths.

There is conclusive research evidence that atypical antipsychotics can kill elderly patients. **Sudden death is a "side effect" of the drugs.** If an elderly patient is schizophrenic, the benefits of these drugs in helping them function could certainly outweigh the risk of death. This is not true, however, if a dementia patient is given an antipsychotic drug as a chemical restraint to keep them sedated. In that case, there are safer alternatives to help quiet the patient, rather than knocking them out with a potentially fatal drug.

Our Center has been contacted by many family members of elderly patients who were given atypical antipsychotics as casually as you or I would take an aspirin. In some cases, the loved one died from the pills before the family even knew what they were taking. In other cases, family members were told that the antipsychotic pills were necessary and that taking them off the drugs would cause dangerous withdrawal symptoms, creating a classic "Catch-22": the patient should never have been put on the drug to begin with, no informed consent was provided, but now that he or she was on the drug, family members were told it was too risky to take them off.

It is no accident that these very expensive and very dangerous drugs are widely misused. The Department of Justice has investigated AstraZeneca, Eli Lilly, and Johnson & Johnson for promoting these drugs inappropriately, and in some cases providing kickbacks to nursing homes or pharmacies. The billions of dollars in fines may not be a strong enough disincentive against these practices, because the companies are making billions of dollars on these inappropriate uses.

In their testimony today, CMS states that the widespread use of atypical antipsychotics in nursing homes "may not be appropriate." **That is life-threatening understatement.** So far, CMS has done much too little to create incentives for doctors and nursing homes to reduce the unsafe and ineffective use of these drugs. We expect that today's hearing will give CMS a better understanding of the urgency of this issue, and we will work with public health experts across the country to make sure that CMS follows through. In addition, FDA decision-makers and physicians across the country should be aware of the research findings and the IG's report, and immediately find ways to reduce the misuse of atypical antipsychotics for children and adults.



**Statement of Omnicare, Inc.,: Senate Special Committee on Aging:
Overprescribed: The Human and Taxpayers' Cost of Antipsychotics in Nursing
Homes. November 30, 2011**

Omnicare is the nation's leading provider of comprehensive pharmacy services to residents of long term care facilities, including nursing homes and assisted living facilities. We appreciate the opportunity to provide testimony on the important issue of the use of antipsychotic medications in the nursing home setting.

Nursing Home Residents

Nursing home residents are a particularly vulnerable population, which motivated the passage of the Nursing Home Reform Act¹. The evolution of the long term care pharmacy industry is, in many respects, a result of the provisions of this landmark legislation. The requirement for a monthly drug regimen review performed by a consultant pharmacist and the general requirement that a resident be free from unnecessary drugs stimulated the evolution of the specialized practice of long term care pharmacy.

- The requirement that a qualified pharmacist regularly reviews the resident's drug regimen is intended to assist the facility achieve or maintain each resident's highest practicable level of functioning by helping to optimize medication therapy and to identify, prevent (or minimize), and resolve adverse consequences related to medication therapy to the extent possible.
- The opportunity for suboptimal medication therapy and adverse consequences is significantly higher for the frail elderly, because of the presence of multiple acute and chronic conditions and the associated 8-10 medications used to treat or managed those conditions.

The requirement that residents be free of unnecessary drugs is partly motivated by historical concerns that nursing home residents were often prescribed psychoactive medications in order to manage their behavior rather than to treat a specific illness.

Omnicare has attained a leadership position in the long term care pharmacy industry because of its demonstrated expertise in managing complex geriatric drug regimens and thus helping our client facilities to comply with state and federal standards of care.

¹ 42 USC 1396r

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A key element of that expertise is the publication of the industry standard reference for drug therapy management in the geriatric population: *The Omnicare Geriatric Pharmaceutical Care Guidelines*. This volume, now in its 16th edition, evaluates over 1,000 medications as to their acceptability for use in the geriatric population. The reference is compiled under the independent leadership of the University of the Sciences in Philadelphia, the nation's oldest college of pharmacy. It is also endorsed by the American Geriatrics Society.

Omnicare consultant pharmacists perform regular assessments of nursing home residents' drug regimens in conjunction with their medical records. The consultant makes recommendations to the attending physician on dosage changes of prescribed drugs, discontinuance of specific drugs or the addition of drugs in order to achieve the best clinical outcome with the lowest risk of unwelcome side effects.

In the past 5 years, Omnicare's consultant pharmacists have made over 700,000 recommendations to prescribers regarding antipsychotic use, 99.7% of which were to reduce a dose; discontinue the drug; question the reason the drugs are used; or monitor for potential, known side effects.

Physicians and other prescribers have the legal responsibility to respond to the consultant pharmacist recommendation, as the pharmacist does not have the authority to prescribe drugs.

OIG Report

A recent report by the Health and Human Services (HHS) Inspector General² (OIG) has refocused attention on the prevalence of what OIG defines as inappropriate prescribing of atypical antipsychotic drugs in nursing homes. The OIG's findings included the observation that in 2007, 14 percent of nursing home residents had Medicare claims for atypical antipsychotic medications. It also concluded that 83 percent of Medicare claims for atypical antipsychotics were for off-label indications (based on medical reviewer assessment). The extent of off-label use of certain drugs in nursing homes raises concern by the OIG.

The increased use of all mental health drugs, including atypical antipsychotics, across the US population suggests that this is part of a larger trend. A recent survey³ from a major pharmacy benefit management company shows that utilization of antipsychotic medications, antidepressants, anti-anxiety drugs and drugs treating attention deficit hyperactivity disorder are experiencing significantly wider use across all age demographics.

² Dept. of Health and Human Services; Office of the Inspector General: *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*. May 2011

³ "America's State of Mind." Medco MediaRoom - Welcome. Medco Health. <<http://medco.mediaroom.com/>>.

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CMS Notice of Proposed Rulemaking

The Centers for Medicare and Medicaid Services (CMS) issued a Notice of Proposed Rulemaking⁴ (NPRM) on October 11, 2011. In this document, CMS suggests that there is an inherent risk of unethical behavior when the consultant pharmacist for a nursing home is employed by the dispensing pharmacy. CMS fears that consultant pharmacists will recommend medications for addition to the resident's regimen that provide more profit to the dispensing pharmacy.

In response to this concern, CMS proposes that the Medicare Conditions of Participation be amended to require nursing facilities to employ or contract with pharmacists that are independent of the dispensing pharmacy. CMS goes to some length to project improvements in quality and cost as a result of this change, but fails to mention that a model currently exists to evaluate the result of implementing such a policy.

New Jersey has a long-standing requirement that nursing homes employ pharmacists that are independent of the dispensing pharmacy⁵. If CMS' proposed remedy were valid we would expect to see evidence of this in the Medicare experience in New Jersey in both a lower volume of prescriptions dispensed and a higher quality

Dispensing Data in New Jersey vs. Other States

An examination of Omnicare national dispensing data for residents of skilled nursing facilities (SNF) reveals no difference between average number of prescriptions dispensed to residents of New Jersey facilities (11.3 prescriptions per month) and the average for the rest of the United States (11.3 prescriptions per month).

Antipsychotic Use in New Jersey vs. Other States

If CMS is correct in its assumption that use of independent consultant pharmacists ensures a reduction in use of antipsychotic drugs, we would expect the data to demonstrate lower overall use of antipsychotic drug use among residents of New Jersey nursing homes and fewer nursing homes cited by surveyors for drug-related deficiencies.

The two data points that shed light on these points are:

Average percentage of facility residents currently prescribed antipsychotic medications⁶:

⁴ Medicare Program; Proposed changes to Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and other proposed changes; Considering changes to the Conditions of Participation for Long Term Care Facilities. Proposed Rule, Federal Register 76, 63018-63091 (October 11, 2011)

⁵ N.J. Admin. Code § 8:39-29.1(d)

⁶ Omnicare data: attached

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Lowest percentage:	Michigan	11.174% of residents (1)
Middle Percentage:	Nebraska	18.675% of residents (24)
New Jersey Percentage:	New Jersey	20.692% of residents (33)
Highest Percentage:	Vermont	25.624% of residents (48)

Percentage of Nursing Facilities Cited for Unnecessary Drugs/Excessive Dose⁷:

Using CMS's own CMS-Casper data as of September 2011, New Jersey ranks 19th nationwide, with 14.4% of facilities cited, for states with the fewest facilities cited for F329 [Unnecessary Drug: In Excessive Dose.

Coordinated Care

CMS has been a recent advocate of increasing coordination of care for Medicare beneficiaries. The recent experiments with Accountable Care Organizations through the Medicare Shared Savings Program seek to encourage providers to collaborate in order to improve quality and reduce cost.

However, when CMS considers nursing homes it moves in the opposite direction; preferring less coordination by suggesting that severing the relationship between the consultant pharmacist and the dispensing pharmacy.

While Omnicare believes a mandatory move to independence between consultants and dispensing pharmacies would not have a material financial impact to the Company, it does complicate our continuing efforts to implement quality improvements that would help ensure that nursing home residents receive the best possible pharmaceutical care.

Summary and Recommendations

Public concern about the potential for overuse of atypical antipsychotic drugs in the nursing home environment deserves careful scrutiny. Off-label uses of atypical antipsychotic drugs are controversial, but a recent Agency Healthcare for Research and Quality publication⁸ suggests that the accumulated evidence supports the use of certain of these drugs in diagnoses where they were previously considered unhelpful, such as dementia and depression.

As we gain more knowledge about the usefulness of these powerful medications it would seem prudent to avoid making generalizations that ultimately prove to be untrue. For example, the fact that there is a higher incidence of prescribing of atypical antipsychotic medications in SNFs does not automatically indicate poor medical judgment. Only a careful examination of the medical history, diagnosis and observation will provide reliable feedback on the usefulness of these drugs. We believe this approach is best achieved when the consultant pharmacist and the

⁷ American Health Care Association. LTC Stats. Nursing Facility Standard Health Survey Report, September, 2011 Update.

⁸ Agency for Healthcare Research and Quality: Off-label use of atypical antipsychotics: an update; Comparative Effectiveness Review number 43; September, 2011

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dispensing pharmacy work closely together with the nursing home professional staff, medical directors and attending physicians.

CMS has extensive data on the use of atypical antipsychotic medications in Medicare Part D. A careful examination of the millions of Prescription Drug Event (PDE) the Part D program has generated since 2006 should yield nearly definitive evidence as to whether independence between consultant pharmacists and dispensing pharmacies has the potential to yield improvements in quality and cost. The agency has the ability to segregate data from New Jersey nursing home residents and compare them to data from other states. We believe Omnicare's data will be substantiated by the data CMS has within its database.

If a thorough review of the data determines that nursing home residents are routinely subject to inappropriate prescribing of atypical antipsychotic medications the next step should be to concentrate on the most effective methods to ensure appropriate prescribing. Approaches that include academic detailing and prescriber education have shown promise and are perhaps more appropriate first steps than mandatory certification requirements in encouraging the adoption of best practices.

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Comparison of Scripts/Resident in New Jersey vs. Rest of United States: Omnicare data

State	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10	AVG
New Jersey Scripts/Resident	11.3	10.7	11.9	11.1	11.3	11.5	11.3	11.4	11.1	10.9	11.2	11.6	11.3
US Average (ex-NJ) Scripts/Resident	11.3	10.6	11.6	11.2	11.2	11.3	11.4	11.5	11.3	11.4	11.4	11.6	11.3

Comparison of Percentage of Residents Prescribed Antipsychotic Drugs
12-month average (October, 2010 through September, 2011) Omnicare data

State	Rank	Average
Illinois	#30	20.02%
New Jersey	#33	20.69%
Rhode Island	#35	21.42%
Texas	#37	22.15%
Massachusetts	#40	22.46%
Louisiana	#42	22.89%
Arkansas	#44	23.76%
Montana	#46	24.01%
Georgia	#47	24.24%
Vermont	#48	25.02%

Comparison of State Survey Results in Areas related to Medication Use

State	F329 Unnecessary Drug: In Excessive Dose	Rank Facilities Cited	F431 Labeling of Drugs and Biologicals	Rank Facilities Cited	F433 Rank [Fewest % Facilities Deficiency Free]
US	19.3%	25	16.4%	20	9.0%
AK	20.6%	4	13.8%	13	0.0%
AL	2.6%	4	7.9%	13	12.3%
AR	10.3%	15	3.0%	2	3.4%
AZ	43.6%	46	20.7%	32	6.4%
CA	28.7%	34	32.4%	44	1.2%
KS	61.7%	49	19.8%	30	5.6%
KY	1.4%	2	19.1%	29	6.7%
LA	34.3%	41	26.1%	41	7.1%
MA	11.5%	16	20.4%	8	0.0%
MD	28.4%	38	21.4%	35	5.2%
ME	28.4%	38	22.9%	36	9.2%
MI	10.2%	14	17.8%	28	20.1%
NC	20.3%	26	16.7%	26	3.6%
ND	20.3%	27	7.2%	11	6.3%
NE	6.4%	10	12.8%	18	15.4%
NH	14.1%	18	4.2%	4	12.7%
NJ	14.1%	18	21.8%	33	9.5%
NM	9.9%	13	14.5%	23	8.5%
PA	8.2%	12	0.0%	1	34.8%
RI	4.4%	5	1.1%	1	1.1%
SC	2.7%	5	15.3%	34	11.7%
SD	0.8%	1	23.1%	37	6.2%
TN	5.6%	8	16.7%	26	12.4%
TX	37.7%	44	20.2%	31	3.9%
VA	18.8%	23	4.6%	7	11.5%
WI	33.3%	39	23.9%	40	0.9%
WV	31.6%	38	23.7%	38	0.0%

Source: American Health Care Association; LTC State Nursing Facility Standard Health Survey Report, September, 2011 Update