HEARING ON GAINSHARING

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

OCTOBER 7, 2005

Serial No. 109–44

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PRINTING OFFICE

26–377 WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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FRIDAY, OCTOBER 7, 2005

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:40 a.m., in room 1100, Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee), presiding.

[The advisory, revised advisory, and revised advisory #2 announcing the hearing follow:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
September 29, 2005
No. HL–10

CONTACT: (202) 225–3943

Johnson Announces Hearing on Gainsharing

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on gainsharing to align the interests of health care providers. **The hearing will take place on Friday, October 7, 2005, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include representatives from groups affected by Medicare's payment policies. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Improvements in the quality and efficient delivery of health care in the Medicare system is of paramount importance to Congress. In order to achieve these goals, it is essential that physicians and hospitals work together in the delivery of medical services. However, certain impediments prevent full cooperation between physicians and hospitals. For example, Medicare maintains separate payment systems for physicians and hospitals, and statutory and regulatory constraints make it difficult for physicians and hospitals to work together.

The use of certain operational and financial incentive arrangements, commonly referred to as gainsharing arrangements, may assist in improving the alignment of physician and hospital interests. One type of gainsharing arrangement uses methodologies designed to enable hospitals to directly increase payments to physicians for measurable contributions to, and for improvements in, all areas of hospital operational and financial performance, while improving the quality of care.

In announcing the hearing, Chairman Johnson stated, "To ensure that fee-for-service Medicare continues to be a viable option for America's seniors and people with disabilities, it is imperative to implement system changes which include the creation of opportunities for skilled medical service professionals to work together to improve both health care quality and efficiency. Gainsharing arrangements, if designed properly, have the power to create fundamental changes to systems that can help integrate the delivery of medical services across different groups of providers to achieve higher quality care and improved efficiency. This hearing will provide the Subcommittee with the opportunity to hear from witnesses on this important issue."

FOCUS OF THE HEARING:

The hearing will focus on the current Medicare payment system, identification of legal and regulatory considerations associated with the ability of physicians and hospitals to engage in gainsharing arrangements, and an examination of potential solutions. On the first panel, CMS and the Office of Inspector General will present information on the Medicare payment structure and gainsharing demonstrations,

and the legal and regulatory considerations involved in gainsharing arrangements. The second panel will provide input from affected parties, including testimony from witnesses with experience in gainsharing arrangements, hospital and physician issues.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*109th Congress*" from the menu entitled, "*Hearing Archives*" (*http://waysandmeans.house.gov/Hearings.asp?congress=17*). Select the hearing for which you would like to submit, and click on the link entitled, "*Click here to provide a submission for the record.*" Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business Friday, October 21, 2005. **Finally,** please note thatdue to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below.Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
September 29, 2005
No. HL–10 Revised

CONTACT: (202) 225–3943

Witness Announcement for Hearing on Gainsharing

The witnesses at the Subcommittee on Health, Committee on Ways and Means, hearing on gainsharing to align the interests of health care providers, will include a representative from the U.S. Department of Health and Human Services, Office of Inspector General, not the Centers for Medicare and Medicaid Services.

All other details for the hearing remain the same. (See Health Advisory No. HL–10, dated September 29, 2005).

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
October 05, 2005
No. HL–10 Revised #2

CONTACT: (202) 225–3943

Change in Time for the Hearing on Gainsharing

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee hearing on gainsharing to align the interests of health care providers, previously scheduled for 10:00 a.m. on Friday, October 7, 2005, in the main Committee hearing room, 1100 Longworth House Office Building, **will now be held at 9:30 a.m.**

All other details for the hearing remain the same. (See Health Advisory No. HL–10, dated September 29, 2005).

Chairman JOHNSON. We do have a closing time certain. I am sorry to get us starting a little bit late, but to make up for it, I am not going to use my opening statement, which is rather long. Instead, I am just going to say that this is as important a hearing as I have chaired in my years in Congress. There isn't a sector of economy that has improved quality without people working together in a different way than our current silo system allows,

incentivizes, encourages, or even makes possible. So, we do need to think through the challenge that the gainsharing demonstrations that have already taken place pose to us. Because the next round of improvement in quality is going to come from the embedding of technology into the delivery system The inclusion of all actors in that system—the whole team—in the understanding of measurement, in the commitment to quality, in the transparency of the system. So, we have a real challenge before us, but it is one we cannot afford not to meet. So, we have a very good panel today that will both give us better understanding of some of the tools that we have at our disposal as well as some of the concerns that we also have to meet. So, I welcome all of you. I welcome the panel. I am very pleased to have Mr. Morris from the Inspector General's Office here. I yield to Mr. Stark.

Mr. STARK. Madam Chair, it is so seldom that I take exception to your approach to these problems, but with the other issues we have before us—implementing the new private drug coverage, which evidently the Centers for Medicare and Medicaid Services (CMS) has screwed up again in their latest booklet. I recall 20 years ago in this Subcommittee we examined this gainsharing. We called it "kickbacks" in those days. We decided that wasn't such a good idea, to encourage profit sharing at the expense of beneficiaries Taxpayers, because they suffered. When the hospital prospective payment system was implemented, hospitals began enlisting physicians through incentive plans to help contain costs. But this created inducements for the docs to withhold care or create early discharge. We enacted new penalties in Title 9 of the Social Security Act. Bluntly stated, what we are going to talk about today is whether to turn back time Allow kickbacks, which will benefit nobody but either the doctor or the hospital, but saves money. The taxpayers The beneficiaries will suffer.

I would like to insert in the record a New York Times article of September 22nd, which outlines some shyster doctor down in Louisiana who was collecting hundreds of thousands of dollars for getting kickbacks, The New York Times can say it more eloquently than can I. But we have heard from Dr. Kassirer, The New England Journal of Medicine, about financial relationships between physicians, the pharmaceutical Biotech Medical device industries that are adversely affecting the quality of care. I understand the U.S. Department of Justice has recently issued subpoenas in an investigation of orthopedic device manufacturers' relationships with surgeons. It is possible that at least some of these relationships include illegal kickbacks. We should be considering ways to curb these relationships, not propagate them. I believe that gainsharing is not only misguided, it is very dangerous. The overall direction of the program we may disagree with, but we should reduce fraud Abuse. This idea of kickbacks—which is the only thing that you can call gainsharing—is wrong. If there is money to be saved, the hospitals should give it back to Medicare. There is no reason on God's green Earth that they should give it to the doctors. It should go to the taxpayers, or back to Medicare to increase benefits for the beneficiaries. I look forward to the witnesses trying to explain why they should do otherwise.

Chairman JOHNSON. Thank you, Mr. Stark. I appreciate your comments. Because certainly, those are the concerns that are raised by what I consider to be the historic system. I don't think it will meet the challenges of the 21st century, That is what we need to work on. So, Mr. Morris, welcome.

STATEMENT OF LEWIS MORRIS, CHIEF COUNSEL TO THE INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MORRIS. Good morning, Madam Chair, Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG). I appreciate the opportunity to discuss the OIG's views on gainsharing programs offered by hospitals. While there is no fixed definition of "gainsharing," the term has typically referred to an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs attributable to the physicians' efforts. Although there are a number of different types of gainsharing arrangements, one purpose of gainsharing is to align physician incentives with those of the hospital, and thereby hospital cost reductions. The OIG recognizes the potential benefits of gainsharing arrangements That hospitals have a legitimate interest in enlisting physicians in efforts to reduce and eliminate unnecessary costs. Nonetheless, the OIG has historically been very wary of gainsharing arrangements because these arrangements implicate the fraud Abuse laws. With respect to the civil monetary penalty (CMP) law, the major concern is the impact of gainsharing on the quality of care provided to Medicare Medicaid beneficiaries. The CMP is an intentionally broad prohibition reflecting congressional concern that under the prospective payment system hospitals would have an economic incentive to pay physicians to discharge patients too soon—quicker Sicker—or otherwise stint on patient care.

Put simply, any hospital gainsharing plan that encourages physicians through direct or indirect payments to reduce or limit clinical services violates the law. Gainsharing arrangements may also implicate the Federal anti-kickback statute, if one of the purposes of the payments is to influence referrals of Federal health care program business. For example, gainsharing arrangements that encourage physicians to "cherry pick" healthier patients for hospitals offering gainsharing, while sending the sicker, more costly patients to hospitals not offering gainsharing, implicates the anti-kickback statute. Although the OIG has significant concerns about the risks posed by gainsharing, we have issued seven favorable advisory opinions on gainsharing arrangements. The cost-saving measures in the improved arrangements generally fall into one of the following categories: product standardizations, product substitution, opening packaged items only as needed, or limiting the use of certain supplies or devices. We understand that the Committee is considering legislation that would allow the CMS to conduct demonstration projects to test and evaluate gainsharing methodologies. When considering the structure and requirement of such projects, we would recommend the inclusion of criteria that focuses on three

aspects: accountability, quality controls, and safeguards against payments for referral.

To promote accountability, the actions that will result in cost-saving incentives should be clear and separately identified. By ensuring transparency and full disclosure to patients, the demonstration projects would foster accountability, as well as allow for meaningful assessment of the arrangement's potential effects on quality of care. Quality controls are a second key safeguard. It is critical that the cost-saving measures for which gainsharing payments are made do not adversely affect patients. For example, establishing baseline thresholds below which physicians do not receive any money for savings may protect against inappropriate reductions in service. A third category of safeguards is directed at preventing gainsharing payments from being used to reward or induce patient referrals in violation of the anti-kickback statute. In this regard, the demonstration projects should contain limitations on how the payments are calculated distributed to physicians, including caps on the scope Duration of arrangements. Finally, in establishing the authority for a gainsharing demonstration, we recommend a careful review of any waiver of fraud abuse authorities, to ensure that it is not overly broad or undercuts the integrity of the project. In conclusion, gainsharing arrangements may help reduce hospital costs by aligning the economic interests of the hospital Its physicians. However, gainsharing arrangements violate the civil monetary penalty law and, improperly structured, pose substantial risks under the Federal anti-kickback statute. The OIG has approved several arrangements that have been structured very carefully in order to minimize the risk to quality of care The abuses associated with kickbacks. These arrangements incorporate a number of safeguards to promote accountability, quality, and protections against payment for referrals. We recommend that any gainsharing demonstration project incorporate these safeguards. Thank you.

[The prepared statement of Mr. Morris follows:]

Statement of Lewis Morris, Chief Counsel to the Inspector General, Office of Inspector General, U.S. Department of Health and Human Services

Good morning Madam Chairman and Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to discuss OIG's views on gainsharing programs offered by hospitals.

While gainsharing promotes hospital cost reductions by aligning physician incentives with those of the hospital, these arrangements also implicate the fraud and abuse laws. When evaluating the risks posed by a gainsharing program, OIG looks for three types of safeguards: measures that promote accountability, adequate quality controls, and controls on payments that may change referral patterns. Properly structured, gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of Federal health care program patients. In a number of specific cases, OIG has concluded that the arrangement presents a low risk of abuse and, therefore, exercised its prosecutorial discretion not to impose sanctions. However, absent a change in law, it is not currently possible for gainsharing arrangements to be structured without implicating the fraud and abuse laws.

My testimony begins with a brief overview of gainsharing and a discussion of the Federal laws that are implicated by these types of arrangements. I will then describe some useful considerations in evaluating the risk of fraud and abuse posed by gainsharing arrangements.

Background on Gainsharing Arrangements

While there is no fixed definition of gainsharing, the term has typically referred to an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs attributable in part to the physicians' efforts. Gainsharing can take several forms. Some arrangements are narrowly targeted, giving the physician a financial incentive to reduce the use of specific medical devices and supplies, to switch to specific products that are less expensive, or to adopt specific clinical practices or protocols that reduce costs. Other more problematic arrangements are not targeted at utilization of specific supplies or specific clinical practices, but instead offer the physician payments to reduce total average costs per case below target amounts.

A purpose of gainsharing is to align physician incentives with those of the hospital and thereby promote hospital cost reductions. Under Medicare's prospective payment system, hospitals have a strong incentive to reduce per patient admission costs, because they receive a fixed amount for inpatient services without regard to actual costs. Physicians, on the other hand, are reimbursed separately based upon a fee schedule and may have little or no incentive to choose less costly supplies or devices, or to support hospital efforts to negotiate lower prices from suppliers of physician-chosen items and supplies, such as stents and cardiac and prosthetic devices. In fact, there are reports of medical device manufacturers having financial relationships with some physicians that create conflicts of interest and potentially reward the physician for loyalty to the device manufacturer at the expense of the hospital and the health care system in general.

Gainsharing arrangements are an attempt to bridge the gap between the hospital and physician payment systems. By giving the physician a share of any reduction in the hospital's costs attributable to his or her efforts, hospitals anticipate that the physician will practice more cost effective medicine. For example, gainsharing programs that include product standardization may provide a physician with an incentive to choose clinically equivalent and medically appropriate devices that are also less expensive. The hospital then shares with the physician a portion of the hospital's savings resulting from the physician's use of the standardized product.

Perspective on Gainsharing

OIG recognizes the potential benefits of gainsharing arrangements and that hospitals have a legitimate interest in enlisting physicians in efforts to reduce and eliminate unnecessary costs. Nonetheless, OIG has historically been very wary of gainsharing arrangements, because these arrangements implicate the Civil Monetary Penalty (CMP) and Federal anti-kickback statutes. There may also be physician self-referral or "Stark" law implications. However, the physician self-referral issues are more appropriately addressed by the Centers for Medicare & Medicaid Services (CMS) because the "Stark" law falls under the purview of that agency.

With respect to the CMP, the major concern is the impact of gainsharing on the quality of care provided to Medicare and Medicaid beneficiaries. The CMP, sections 1128A(b)(1) and (b)(2) of the Social Security Act, prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under a physician's direct care. The CMP is an intentionally broad prohibition,reflecting Congressional concern that under the inpatient prospective payment system hospitals would have an economic incentive to pay physicians to discharge patients too soon—quicker and sicker—or otherwise truncate patient care.

Any hospital gainsharing plan that encourages physicians, through direct or indirect payments, to reduce or limit clinical services violates the CMP. The payment need not be tied to an actual reduction in care or to a reduction in medically necessary services, so long as the hospital knows that the payment may influence the physician to reduce services to his or her patients. There may be limited cost-saving measures that do not have the potential to reduce services, such as not opening certain supplies until needed. Even then, the circumstances must be closely scrutinized to ensure that the delay in opening the supplies does not have the potential to cause a reduction in services.

Gainsharing arrangements may also implicate the Federal anti-kickback statute, section 1128B(b) of the Social Security Act, if one purpose of the cost-saving payments is to influence referrals of Federal health care program business. Examples of gainsharing arrangements that give rise to concerns under the anti-kickback statute include, without limitation: an arrangement intended to encourage physicians to "cherry pick" healthier patients for hospitals offering gainsharing while sending the sicker, more costly patients to other hospitals not offering gainsharing; an arrangement intended to foster loyalty and attract more physician referrals to the hospital; or an arrangement that allows a physician to continue for an extended period

of time to reap the benefits of previously-achieved savings or to receive cost-saving payments unrelated to anything done by the physician. Moreover, OIG is concerned that gainsharing arrangements may lead to unfair competition among hospitals competing for physician-generated business.

Guidance on Gainsharing Arrangements

OIG has expressed significant concerns about the risks posed by gainsharing. In 1999, OIG issued a Special Advisory Bulletin on Gainsharing outlining its analysis of arrangements call "black box" gainsharing. Black box gainsharing refers to arrangements that give physicians money for overall cost-savings without knowing what specific actions the physicians are taking to generate those savings. Under these types of arrangements, there is little accountability, insufficient safeguards against improper referral payments, and a lack of objective performance measures to ensure that quality of care is not adversely affected. For example, the drive for savings could motivate the physician to discharge a patient prematurely or otherwise inappropriately influence length of stay decisions, the very abuses that led to the enactment of the CMP law.

OIG also has issued seven favorable advisory opinions on gainsharing arrangements that are significantly different from the black box arrangements discussed in the 1999 Special Advisory Bulletin. The cost-saving measures in the approved arrangements generally fall into one of the following categories: product standardization; product substitution; opening packaged items only as needed; or limiting the use of certain supplies or devices. While each advisory opinion is limited to the specific facts presented by the requestor and cannot be relied upon by any other party, the considerations identified in the opinions are relevant when assessing gainsharing arrangements.

When evaluating a particular gainsharing program, OIG has generally focused on three aspects: accountability; quality controls; and safeguards against payments for referrals. With respect to accountability, a transparent arrangement that clearly and separately identifies the actions that will result in the cost-savings promotes accountability in several ways. First, it allows for a meaningful, objective assessment of the arrangement's potential effects on quality of care. By contrast, black box gainsharing involves payments based on overall cost-savings, without any way to identify what specific and measurable actions the physician has taken to generate the cost-savings. Second, full disclosure to the patient of his or her physician's participation in the gainsharing program promotes accountability. Finally, transparency permits scrutiny of the actions of physicians that are attributable to gainsharing payments, thus allowing the medical malpractice liability system to act as a further safeguard against inappropriate care.

Quality controls are a second key aspect OIG looks at when evaluating a gainsharing arrangement under the advisory opinion process. It is critical that the cost-saving measures for which gainsharing payments are made do not adversely affect patients. Accordingly, OIG looks for features that protect quality care. For example, OIG believes it is important to have a qualified, outside, independent party perform a medical expert review of each cost-savings measure to assess the potential impact on patient care. The hospitals that obtained favorable advisory opinions established baseline thresholds based upon historic utilization and national data to protect against inappropriate reductions in services and to ensure that physicians would not receive any money for savings that accrued beyond the baseline thresholds. This structure helped protect against the physicians receiving payments for savings resulting from limiting necessary items and services. The arrangements OIG approved also include ongoing monitoring of quality of care and compliance with the gainsharing program. This oversight allows for the detection and appropriate handling of any inappropriate variation in treatment or uses of supplies or devices.

A third category of safeguards is directed at preventing gainsharing payments from being used to reward or induce patient referrals in violation of the anti-kickback statute. In this regard, OIG focuses on how payments are calculated and distributed to the physicians. Examples of safeguards that minimize the risk of abuse include, but are not limited to: calculating savings based on the hospital's actual acquisition costs; limiting participation to physicians already on the hospital's medical staff (to prevent enticing other physicians to change referral patterns); limiting the amount, duration, and scope of the payments (there is less incentive for a physician to switch referral patterns for short-term dollars); and distributing the gainsharing profits on a *per capita* basis to all physicians in a single-specialty group practice (reducing the incentive for individual physicians to generate disproportionate cost-savings). In short, there need to be safeguards that minimize the physician's incentives to change referral patterns or cherry pick healthier patients for the hospitals offer-

ing gainsharing payments, while steering sicker, more costly patients to other facilities.

It must be stressed that any evaluation of the risks presented by a gainsharing arrangement is highly fact specific. For example, with respect to the product standardization cost-saving measures approved in the favorable advisory opinions, OIG knew the specific vendors and products at issue and were able to have a medical expert evaluate the impact on quality of care. Furthermore, the physicians participating in the gainsharing arrangements could make patient-by-patient determinations of the appropriate supply or device, because the hospital continued to stock the full range of supplies and devices, not just those that would result in cost-saving payments. It is important to note that OIG did not approve every cost-saving measure proposed by the requestors of the opinions. As noted in the opinions, some measures were rejected and withdrawn from the arrangements. As such, any broad reading of the opinions should be done with caution. Different cost-saving measures or different payment structures could have produced different results.

Conclusion

Gainsharing arrangements may help reduce hospital costs by aligning the economic interests of the hospital and its physicians. However, gainsharing arrangements violate the CMP and, improperly structured, pose substantial risk under the Federal anti-kickback statute. OIG has approved several arrangements that had been structured very carefully in order to minimize the risk to quality of care and the abuses associated with kickbacks. These arrangements incorporated a number of safeguards to promote accountability, quality, and protections against payments for referrals.

Chairman JOHNSON. Thank you very much, Mr. Morris. Let me just ask you a couple of things. You say in your testimony on page 2 that any hospital gainsharing plan that encourages physicians through direct or indirect payments to reduce or limit clinical service violates CMP. To me, it is an example of how backward-thinking our law is, because there is nothing in this statute that talks about medical necessity or quality. I mean, if the same device is on the market for about $1,000 differential in payment, why isn't that kind of limit a reasonable limit? You see, to reduce or limit clinical services violates the CMP: that is what we used to think. Now there is such a plethora of services that medical necessity and quality care really should be the drivers of service determination. So, if we have a Federal law, it is kind of like defensive medicine. If courts are going to require you to be exposed on all fronts, well, then you are going to do every test under the sun. If they are going to hold you accountable for appropriate treatment of that disease, then you can look at the protocols of your specialty organization and the specific information about that patient, You can provide appropriate, high-quality care, without doing inappropriate and unnecessary tests, which we have seen a plethora of. So, doesn't it concern you that the civil monetary penalty law, as well as the anti-kickback law, really don't look at quality?

Mr. MORRIS. You are correct that the CMP law is very broad Would sanction a hospital or a physician that receives payments to reduce care, regardless of whether that care was medically unnecessary or otherwise. The anti-kickback statute also addresses incentives that could potentially distort physician decision-making. The concern in both cases is that those incentives to physicians could adversely affect care. The CMP, however, does not distinguish between reduction of services that are medically unnecessary from those that are medically necessary.

Chairman JOHNSON. Certainly, we are going to hear later from the next panel from a company that you actually have worked quite a bit with, I understand, Joane Goodroe's company—"Something Solutions," I have kind of forgotten its name. But anyway, would you say that the technology of measurement has advanced in recent years? Could we have benchmarked physicians 10 years ago the way we can benchmark them now? Could we have tracked specific actions of physicians that committed to gainsharing arrangements 10 years ago the way we could now?

Mr. MORRIS. I think I would defer to Ms. Goodroe on that question. I would tell you that in the advisory opinions we have issued we relied heavily on the ability of both experts within HHS as well as the quality measures that the particular arrangements provided, to give us those sorts of assurances. I think, frankly, that much of this would turn on the specific arrangement, the particular sorts of services under the gainsharing arrangement, and the measures that would be available. But I think Ms. Goodroe could probably tell you more about what specific measures are available.

Chairman JOHNSON. I did want to make that point early; that you really couldn't have overseen a system like this in the old days. Now that we have learned so much about chronic disease management, we have also learned a lot about measuring, a lot about oversight, that we didn't know even five years ago. You do have to have that kind of system capability or, you are right, you really expose the system to those who would most criminally manipulate it. Mr. Stark.

Mr. STARK. Thank you. Mr. Morris, in your testimony you used the word "share." As you think of that "share," you mean sharing money, I suspect.

Mr. MORRIS. In the context of the gainsharing arrangement?

Mr. STARK. Yes.

Mr. MORRIS. Yes, it would be sharing some of the proceeds that result from savings.

Mr. STARK. Could those not be synonymous with—the financial words, I suppose, would be "commission," "profit sharing," even "kickback" if one wanted to use the vernacular. All of those things similar; would they not?

Mr. MORRIS. Yes, they would. I think we always have a concern when sharing, commissions, or call them what you will, occurs between anyone who has the ability to control referrals and anyone who would benefit from those referrals.

Mr. STARK. Now, you mentioned just a minute or two ago that this idea of paying physicians might, I think you said, distort the doctors' decision-making process. You are a lawyer?

Mr. MORRIS. Yes, sir.

Mr. STARK. If a doctor—I am not, but I wanted to think this through, and perhaps you could help me. But if a doctor were routinely taking money for using a particular device or a particular drug or a particular procedure—say, earlier discharge—the patient was subsequently harmed, wouldn't that information to be detrimental to the physician in a malpractice case, in your opinion as a lawyer?

Mr. MORRIS. If I understand the question, if physicians inappropriately changed practice as a result of gainsharing or commissions

or kickbacks, that resulted in harm, that would seem to be highly relevant to both the government's law enforcement efforts—because we would pursue that as a kickback—Also, certainly in the private sector, as a malpractice variable.

Mr. STARK. Okay. Now, let me tell you what the VA does. The only reason I want to go through this is just to see, off the top of your head, whether you think there would be any problems with current law if we assumed for the minute that the VA was a state hospital association, or a single hospital or a chain. They bring together the clinicians, the docs—I suppose, maybe some other people, but the doctors principally who are involved in a procedure. The VA hospital people say, "Look, we would like to standardize. We would like to use one drug or piece of equipment, or whatever. Doctors, as a group, can you all agree on one item that we would agree is the right one to use?" Guess what? Generally, they can. So, they usually get somewhere between one and three items that are acceptable. They can define these in language so you could measure whether or not a piece of equipment or a drug met the standards. Then they go out to the manufacturers and say, "Do any of you make or provide equipment that meets these standards?" The ones that do are then allowed to submit a bid. They pick the lowest price, and that is how they proceed to buy those. I am not sure. I was talking with the VA; I forgot to ask whether somebody who wasn't the lowest price could also sell at that lower price that was established. Now, if that were set up, obviously, it would be a good thing for CMS to do that, and that would solve all of the problems. That would get us better results than this. But if a hospital did that, let's say, a large hospital, do you see anything in that kind of a procedure that would be considered a kickback or violating any current laws that you can think of?

Mr. MORRIS. Under the hypothetical you have offered, there would not be any money or remuneration going back to the doctors who participated both in that decision and who then conformed their clinical practice. There would not likely be a kickback, based on the scenario as you have described it. Although we would need to know an awful lot about the particular docs.

Mr. STARK. The doctors would just be helping the hospital save some money, They would be practicing good medicine.

Mr. MORRIS. I think a distinction—I don't profess to have a full understanding of how the VA system works, but my understanding is most of the physicians working in the VA system are employees of the VA; Therefore, under the direction and control of the hospital.

Mr. STARK. No. I mean, physicians are allowed to practice medicine in their own best judgment, so that they are no more under "the control." I suppose, if they were lousy and goofed up or weren't productive, they could be fired. Any more than a lawyer who works for a salary would give an opinion that was any less valid than a lawyer who was working by the hour. I mean, they have a code of ethics—even as government employees.

Mr. MORRIS. Well, as the New York Times article you referenced at the beginning indicates, one of the challenges that faces private-sector hospitals is having physicians order services or de-

vices consistent with the procurement interests of the hospital. Device manufacturers can use various incentives.

Mr. STARK. I suspect we would have to do that. I think you are right. I don't think they would have a lot of trouble. But there is always the CMS—could not follow a procedure like this. Then that would solve the problem. Thank you very much.

Mr. MORRIS. Yes, sir.

Mr. STARK. Mr. McCrery.

Mr. MCCRERY. I will be very short, Madam Chair. Mr. Morris, you are from the Inspector General's Office with HHS; is that right?

Mr. MORRIS. Yes, sir.

Mr. MCCRERY. So, your focus is on enforcement of current laws, with respect to kickbacks and all those kinds of considerations; is that right?

Mr. MORRIS. That is correct.

Mr. MCCRERY. So, you are not here in a policy position with HHS to comment on potential changes to the law which might vary the scope of your examinations in the Inspector General's Office, right?

Mr. MORRIS. That is correct.

Mr. MCCRERY. But even working with the current set of laws that are in place, your office has found some of these kinds of arrangements to be acceptable under the laws we have right now; is that right?

Mr. MORRIS. We have found the arrangements we looked at to, in each case, implicate the civil monetary penalty law. They violate the law by providing incentives to physicians to reduce care. They also implicate the kickback statute. But because our advisory opinion authority allows us in the specific instance to indicate that we will exercise prosecutorial discretion and not pursue a particular arrangement, provided there are adequate safeguards, in these instances we found that there were specific safeguards that would warrant us not pursuing a sanction or other action against these particular requesters.

Mr. MCCRERY. Okay. Thank you. Madam Chair, it might be interesting to have HHS testify at another time as to any ideas they have for curtailing the increases in costs that we are seeing in the system. Obviously, we are looking at a very dangerous, I think, result of current law at the end of this year, when physicians' payments are going to be reduced dramatically because of the current law. If we don't find some way to curtail the increase in these costs, I am afraid we are going to be stuck with some of the old ways of living within our means; which is just to cut reimbursement rates. So, I am hopeful that HHS will bring us some positive ideas as to how to accomplish our task.

Chairman JOHNSON. Thank you. I hope the Inspector General will work with us, from his experience in this regard, because we are just in a different world. The plethora of possibilities is just simply too great for the law not to notice the difference between necessary and unnecessary, or appropriate Inappropriate, care. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Madam Chair. Mr. Morris, a study published in yesterday's New England Journal of Medicine con-

cluded that innovative new implantable cardiac defibrillators represent good value to the Medicare Program. I could have offered that voluntarily, but the empirical data don't lie. It was, as I said, a study released yesterday. This study's authors, as I read the article, noted that a key contributor to improved outcomes for patients, including heart patients, is the flexibility—I am quoting now from the study, "A key contributor to improved outcomes is the flexibility to change systems of care to incorporate new knowledge into practice." My question is this: How specifically would gainsharing recognize and reward important new medical breakthroughs, new medical knowledge such as the technology that led to the development of implantable defibrillators?

Mr. MORRIS. I believe Ms. Goodroe could give you more specifics. I think the general answer would be this. Gainsharing, if properly structured, would provide for sufficient quality controls and accountability so that if physicians received incentives to try new devices or take into account savings that would result from certain cost-effective measures, we could both ensure that patient care was secured and cost savings were realized.

Mr. RAMSTAD. I am sure you are aware, Mr. Morris, speaking of empirical data, of the studies in the field that show overall, if you look at the macro picture, health care, medical technology saves dollars for the system. There is ample research to support that assertion that conclusion. My concern is that we are going to provide an incentive for doctors and providers to do it in the cheap, to coin a phrase, to avoid the use of life-saving, life-enhancing medical technology—which at the time for that patient might cost more, but, if you look at that patient's longer view, could save his or her life or enhance their lifestyle, enhance their very life—it is, again looking at the macro picture, going to save the system money. So, don't you share that concern that perhaps we are going to provide incentive for providers to do it on the cheap?

Mr. MORRIS. That is one of the concerns that we have, It was taken into account when we looked at these particular arrangements. As I mentioned, one of the reasons that these particular arrangements were approved was because we felt that there were adequate safeguards to ensure quality. For example, in the arrangements we looked at, the physicians, although they would receive incentives if they used some of the standardized cardiac devices, were all still able to get any device they wanted to use. So, their ability to provide the best device for a particular patient was preserved.

Mr. RAMSTAD. What do you base that on, that the access has not been thwarted?

Mr. MORRIS. Because as part of analyzing these particular arrangements, the requesters laid out in great detail the specific measures and both the accountability and quality control measures that were in place. They certified that those measures will be in place. We also relied on clinicians, experts within the department, to review all of the safeguards to ensure that patient care would not be compromised. So, we basically relied on both experts as well as the representations of the requester.

Mr. RAMSTAD. Well, you know, they always say the proof is in the pudding. I don't think we know enough, the experience of

gainsharing is not that long in terms of time span. But I am really concerned about access and quality, I think we need to keep those. I am glad you share those concerns as we work together on this legislation.

Mr. MORRIS. Thank you.

Mr. RAMSTAD. Thank you. Yield back, Madam Chair.

Chairman JOHNSON. Thank you very much. Mr. Lewis.

Mr. LEWIS. Thank you very much, Madam Chair. Thank you, Mr. Morris, for being here. Madam Chair, before I ask my questions, I would just like to say that I am very concerned about the mistake in the Medicare new handbooks that have been sent out to seniors. The mistake is in the table that helps beneficiaries compare plans. The mistake is in the column that tells beneficiaries whether they will have to pay extra premiums. So, beneficiaries choose a plan, think there are no extra costs; when in fact, they will be hit with extra premiums. I understand that CMS does not plan to correct this handbook. Instead of correcting the handbook and sending out new ones, CMS suggests that people can go to the Medicare website. Well, most seniors do not use computers. The CMS also says you can call the organization offering the drug plan, or call CMS. This prescription drug plan is already complicated enough. Seniors should not have the burden of making sure the information is accurate. People need to make informed choices. If the seniors see this information in print, they should be able to depend on it. The CMS should reprint the handbook. Otherwise, CMS should cover the costs of additional premiums for people who are surprised by additional costs. Madam Chair, I renew again my call for oversight hearings for Medicare part B. Now, Mr. Morris, what are the potential dangers for patients under gainsharing arrangements? Do you support codifying the safeguards that were in the OIG advisory opinion? If not, why not?

Mr. MORRIS. The potential risks to patients posed by poorly designed gainsharing arrangements would include giving physicians incentives to reduce the length of stay, get the patient out of the hospital quicker and sicker; to skimp on devices or supplies that would be necessary to care for the patient; or otherwise cut costs in such a way that would compromise care. The particular arrangements that we looked at, and the many cost-saving measures that would be recognized as part of a gainsharing program, were carefully scrutinized by us, experts within the department, as well as outside consultants. Because each of those arrangements is very fact determinative, and there were many of the cost-saving measures which we did not find sufficiently safeguarded for quality, I think it would be dangerous to take any of the advisory opinions and codify a gainsharing standard based on those. The approach that we have recommended in our testimony is to take into account three general principles—accountability, quality controls, and measures to ensure kickbacks are not in play—and use those principles to oversee a demonstration project and the arrangements that would come out of it.

Mr. LEWIS. When the OIG issued its advisory opinion on the six gainsharing arrangements earlier this year, what steps did you take to ensure that incentive was not included in arrangements to encourage physicians to reduce care to Medicare patients?

Mr. MORRIS. What incentives were in place?

Mr. LEWIS. Yes.

Mr. MORRIS. There are a number of incentives we took into account. There were caps on the amount of money that a physician could realize. There were baselines established, so that a physician could not reduce the level of services he or she was providing based on historic baselines. There were quality oversight measurements. There is an ongoing monitoring of the arrangement itself to ensure that quality is preserved. So, there is a wide range of safeguards, both in terms of specific caps and ceilings, structural safeguards, as well as ongoing oversight. We believe that those in combination adequately protected the interests of the patient as well as the program.

Mr. LEWIS. Thank you. Mr. Morris, why do you limit approval of a gainsharing program to just 1 year? What was the rationale?

Mr. MORRIS. The rationale was that we did not want the payout coming from gainsharing savings to be spread out over multiple years, because it could implicate remuneration for kickbacks. We wanted to have a fairly tight, focused return to the physician for specific acts done within a tight timeframe. We thought a 1-year timeframe was appropriate.

Mr. LEWIS. You think it would work?

Mr. MORRIS. Well, I think we will be interested to see what the results are. We are going to be watching this area very carefully, to see whether gainsharing actually does successfully align the incentives of hospitals and physicians without compromising quality of care.

Mr. LEWIS. Thank you very much. Madam Chair, yield back.

Chairman JOHNSON. Thank you, Mr. Lewis. Mr. English. Oh, sorry. Mr. Johnson.

Mr. JOHNSON. Mr. Morris, do you believe in gainsharing that doctors will place financial incentives above patient care if given the opportunity?

Mr. MORRIS. I can't say as to any particular arrangement. I will say that our experience has been, as a law enforcement agency, that physicians respond to economic incentives. We have seen, both in their opportunity to invest in imaging centers and laboratories and the like, that if they can enhance their financial position by making referrals to a particular entity, they will do so. We have also seen at times that that results in both inappropriate costs to our program also can implicate quality of care. So, I think the short answer would be I think that some physicians may inappropriately allow financial incentives to affect their medical judgment.

Mr. JOHNSON. Depends on the guy, is what you are saying.

Mr. MORRIS. Or lady, yes.

Mr. JOHNSON. Or lady. You know, since 1999, you only approved seven arrangements for gainsharing. It seems like it is exceedingly difficult to implement a meaningful program. Could you comment?

Mr. MORRIS. I think that is a fair perception. We have worked very hard to ensure that any gainsharing arrangement has sufficient controls to assure accountability, quality controls, Inhibit kickbacks or referrals. We have scrutinized each one very carefully.

A lot of the arrangements we have looked at did not pass the bar and were not deemed acceptable.

Mr. JOHNSON. Well, you must have some criteria set up. What is it? Let me ask you this question. If you do approve a gainsharing operation in some hospitals, do they continue to have access to all of, let's say, the medical devices, for example? Or do they go to one company and try to cut costs? Have you run into that?

Mr. MORRIS. In the arrangements that we approved, physicians continued to have access and were able to use devices that they felt, on a patient-by-patient basis, were in the best interests of the patient. They would realize the gainsharing benefits if they picked one of the products which had been standardized. In the arrangements we looked at, there was more than one vendor who was providing the devices that were standardized. But even so, physicians continue to have the ability to select particular devices or equipment that they felt was in the best interests——

Mr. JOHNSON. But they wouldn't participate in gainsharing if they did that, according to you.

Mr. MORRIS. They would not realize the gainsharing benefits from that particular decision. But most of these gainsharing arrangements had multiple—19, 20 different cost-saving measures. If they conformed their clinical practice to those measures, they would realize the benefit of gainsharing as to those measures. So, for example, they might choose not to pick a particular device, although it was part of the list of standardized products; but they might agree to use other cost-saving measures that were part of the gainsharing arrangement.

Mr. JOHNSON. I can't see much difference in that and specialty hospitals, for example, in which the docs get together and try to form their own gainsharing, if you will. Do you consider that a difference?

Mr. MORRIS. Well, specialty hospitals are different. I mean, a gainsharing arrangement exists between a hospital and physicians who are not its owners, generally, and for whom it is trying to align their interests. Obviously, if the physicians own the hospital you have a very different matrix.

Mr. JOHNSON. Okay. Thank you very much. Thank you, Madam Chairman.

Chairman JOHNSON. Thank you. Mr. Camp.

Mr. CAMP. Thank you very much. I, too, am interested in these pilot programs that OIG implemented. I just wonder if you could elaborate a little bit more on why OIG selected the sites that it did.

Mr. MORRIS. Oh, let me clarify. We did not implement any pilot projects. The Inspector General's Office does not engage in any programmatic functions. What we did was, consistent with our advisory opinion authority, tell entitles that were setting up arrangements whether we felt there were adequate safeguards to warrant not pursuing our enforcement authorities. So, we did not pick the arrangements, and we did not pick the entities that came in and requested advisory opinions from us.

Mr. CAMP. Thank you. Do you think there are adequate safeguards for further implementation of the gainsharing agreements for a wider-scale implementation or a larger-scale implementation of these agreements?

Mr. MORRIS. It would really depend on the specific facts of the specific arrangement.

Mr. CAMP. Are you satisfied, then, with the safeguards that were in place for those pilot programs that did occur?

Mr. MORRIS. For the seven arrangements that we reviewed, we believe there were adequate safeguards to ensure accountability, quality control, and protections against kickbacks. We articulated those in the advisory opinions. So, as to those specific arrangements, we indicated that we would not use our enforcement authorities.

Mr. CAMP. Does that allow you to make any judgment on a broader or a larger-scale implementation of the gainsharing programs in other places? I mean, you are satisfied with what occurred? Do you think that protections are in place? Are they adequate for larger implementations of the gainsharing agreements?

Mr. MORRIS. It would depend on the agreement. It is, you know, the old adage: if you have seen one gainsharing agreement, you have seen one gainsharing agreement. It would have to be a case-specific analysis. If there was to be a demonstration whereby there were a larger number of gainsharing arrangements underway, we would urge that there be a range of safeguards put in place so that all of those arrangements conform to the three touchstones that we have touched upon: quality, insurance against referrals, and accountability.

Mr. CAMP. Some have said that these agreements could lead to a lessening of the quality of care. What do you think about that?

Mr. MORRIS. I think that is a real risk. I think it is one of the reasons why it is so important that there be a great number of safeguards and ongoing monitoring, to assure that patient care is not compromised through gainsharing. We do believe, based at least on the arrangements that we have reviewed and approved of, that it is possible, at least in the context of those arrangements, to structure a gainsharing arrangement so that patient care and the interests of the program are safeguarded. But vigilance is critical.

Mr. CAMP. So, if there were a broader implementation of these agreements, you see that that could happen if the proper safeguards were put in place on a case-by-case basis?

Mr. MORRIS. On a case-by-case basis.

Mr. CAMP. All right. Thank you. Thank you.

Chairman JOHNSON. You know, I am stunned at your comments. I want my colleagues on the Committee to think about this. You are saying only on a case-by-case basis, under a law that doesn't discriminate between medical necessity and non-medical necessity. Now, we have hip devices that are plastic, that are $3,000, that are good for 3 years. We have titanium hips that are good for 40 years, that are $8,000. Now, should a health care system that is getting increasingly unaffordable to the people of America have no ability to look at appropriateness of when to use the plastic and when to use titanium? Is that really what you are saying; that on their own they should have no ability to do this; that only if the government gets in there and approves this relationship, that only then should they have that ability? Because remember, the CMP law doesn't allow any consideration for anything other

than access. Device numbers. They are all lined up on the shelf; you have to have access to every one. Now, are we nuts?

Mr. MORRIS. I won't answer the second question, for lack of competence.

[Laughter.]

Chairman JOHNSON. Okay. Let me ask you—I do know the answer to that one. Let me ask you one other thing. The way you describe this, are you aware that hospitals and device manufacturers currently—currently—negotiate agreements that involve price and volume usage, just like the pharmaceutical companies do?

Mr. MORRIS. Yes, I am aware of that.

Chairman JOHNSON. Do you oversee those contracts?

Mr. MORRIS. No.

Chairman JOHNSON. No. You don't know in how many hospitals people have access. I have heard that there are some community hospitals that provide one device. I think our gainsharing bill will guarantee a far better selection than that, and a far more doctor-centered, doctor-controlled situation than that. I also know that there are contracts that are based on getting 70, 80 percent of your business. Now, you are not looking at that. The government either can't see it, or doesn't want to see it. We are acting as if the gainsharing agreements are in a vacuum. The world is changing. If you don't think the big guys with big devices aren't negotiating in a way that keeps little guys out, you aren't noticing.

Mr. MORRIS. The distinction I think I would make is that we certainly are very much in favor of volume discounts; provided that they are passed on to our program so we realize savings on behalf of the Medicare program. The concern that I think gainsharing raises is that if a physician shares in those savings, agrees to change his or her clinical practice so as to only use the less expensive hip, to use your analogy, and realizes profit or part of the revenues of it, and it doesn't go back to the program, the risk is that that may—may—affect his or her medical judgment. So, it is not a question of being in favor of discounts being passed on to our program. We strongly favor that. The question is ensuring that the decisions are made in a way that ensures quality of care.

Chairman JOHNSON. But we are not overseeing that now. In a transparent gainsharing agreement we will actually know much more about that. There will be measurements; there will be parameters. What is going on now is happening, and we do not know how much it is happening, and we can't see it if it does happen. The money isn't going back to Medicare. It is keeping the hospital alive, and there is some value in that. But we don't know the interaction of the savings there with subsidizing hospital services that we don't recognize in Medicare and don't pay for, that Medicaid doesn't pay for, and the private sector no longer subsidizes. So, it is not quite as easy as: the money all has to flow back to Medicare. So, I don't want to put you in an awkward position, but I just want to point out that I agree with everything you said about gainsharing and how important it is to have a structure over it so that we can measure and hold people accountable. But I don't want the Members of the Committee to think that we have this structure in place now. Because I think gainsharing will give us more ability to assure that hospital care is physician-patient-centered and account-

able than we are seeing develop now, whether it is in the boutique hospital sector, the specialty hospital sector, or whether it is in some of the arrangements that the market of course is very ingenious at developing. So, I will conclude the comments of the panel, then, because we want to hear the other panel, and we are under a time constraint. Thank you very much, Mr. Morris, for your good answers to the questions and for your excellent testimony. We look forward to working with you.

Mr. MORRIS. Thank you very much.

Chairman JOHNSON. As the next panel assembles at the dais, let me recognize Mr. Ferguson of New Jersey to introduce one of the participants. Also, let me recognize Mr. Gingrey, who is a Member of Congress but also a physician, and has taken a great interest in the work of this Subcommittee because he understands the nature of what we are doing and its importance to the evolution of the medical community. We thank you for being here. Mr. Ramstad, did you wish to speak?

Mr. RAMSTAD. Yes. Madam Chair, I would also like the privilege of introducing one of the witnesses from my district.

Chairman JOHNSON. Well, why don't you start, Mr. Ramstad? Sorry, I was unaware of that.

Mr. RAMSTAD. Not at all. Madam Chair, Members of the Committee, thank you for the privilege of introducing an outstanding chief executive officer, a great corporate citizen, and a personal friend, Martin Emerson, who is Chief Executive Officer of American Medical Systems in Minnetonka Minnesota, my hometown. So, it is great to have you here, Marty, as well as the other witnesses. Thank you, Madam, Chair.

Chairman JOHNSON. Mr. Ferguson.

Mr. FERGUSON. Thank you, Madam Chair. I very much appreciate your graciousness in allowing me to introduce a friend and constituent; I certainly appreciate your interest in this gainsharing issue. I serve as Vice Chair of the Health Subcommittee on the Energy Commerce Committee, and have a great deal of admiration for your work and the work of this Subcommittee. I also appreciate the fact that you have come to New Jersey to review and get a better understanding for our New Jersey demonstration project that is the topic of this conversation today. I am particularly pleased to be able to support something as creative as the New Jersey Physician Hospital Demonstration Project, and am very pleased to be able to welcome a friend Constituent, Gary Carter, who is President and CEO of the New Jersey Hospital Association (NJHA). Gary has been advocating for hospitals and improving health care for many years; the last 11 spent leading the health care advocacy group, the NJHA. Prior to coming to my home state of New Jersey, Gary was the President of the New Hampshire Hospital Association for 8 years. Before coming east, he had a number of executive management posts with Intermountain Health Care, which is a system of hospitals in Utah, Idaho, and wyoming, and Nevada. He is known as an association leader who builds consensus, who fosters cooperation. He is certainly dedicated to working in New Jersey to improve hospital-physician relations and broader advocacy on behalf of the NJHA's member hospitals; Certainly, I think, will have some great

insights for your Subcommittee with regard to gainsharing. So, thank you very much.

Chairman JOHNSON. Thank you for that nice introduction. I would say, I say this to all of you, it was a very important experience for us to go sit with the New Jersey people. I am going to invite all Members of the Subcommittee to repeat that experience. Because we got to talk to doctors; we got some sense of how the relationships changed as they got into this, and what it means to move to a patient-centered hospital system, which is not exactly what I believe we have now. So, I agree with you: he is a consensus builder. We are delighted to have him here. I consider his testimony, his contribution today, very crucial to our ability to move forward. I do think all Members need to do that. I think we need to go to other sites where people are doing creative things, and we need to understand how the current law is a barrier, actually, to deeper, more powerful relationships within the caring community. That much said, Ms. Goodroe?

STATEMENT OF JOANE GOODROE, PRESIDENT CHIEF EXECUTIVE OFFICER, GOODROE HEALTHCARE SOLUTIONS, NORCROSS, GEORGIA

Ms. GOODROE. Chairman Johnson Distinguished Members of the Committee, I want to thank you for the opportunity to appear before you today to share my thoughts on the topic of gainsharing. My name is Joane Goodroe. I received a bachelor of science in nursing and a masters in business administration, and have extensive clinical and administrative background in hospitals.

Chairman JOHNSON. Excuse me, Ms. Goodroe. I did forget to mention that the timer gives you 5 minutes. This goes for everybody. Your whole statement will be included in the record, but you will have only 5 minutes. Now, the bells have rung for two votes: a 15-minute vote, followed by a 5-minute vote. I have read all the testimony. While I regret that I won't be here to hear your statement, I am going to leave immediately. Then I will come back Chair the hearing up until the point I have to go for the second vote. I would urge some of the members of the panel to go now, and come back and question, so that we can keep the panel moving through these two votes. So, know that I have read your testimony, Ms. Goodroe and Mr. Emerson, I will be back as promptly as possible. Meanwhile, Mr. McCrery will take the chair.

Mr. MCCRERY. [Presiding.] Please continue, Ms. Goodroe.

Ms. GOODROE. I am currently the CEO of Goodroe Healthcare Solutions, which was acquired this week by VHA, Inc. Goodroe Healthcare is the company that developed the gainsharing model which has received seven separate approvals from the OIG. These approvals were obtained only after our gainsharing methodology was highly scrutinized to assure that any decrease in cost would not negatively impact patients. As part of the gainsharing plan, there are safeguards to protect the patient, including that any technology a physician requests must be available. My first experience with gainsharing started in 1989, when I was an administrator at Saint Joseph's Hospital of Atlanta, which was one of the hospitals that worked with CMS on the Medicare Coronary Artery Bypass Demonstration Project. In this well-studied project, we created a

gainsharing model that aligned incentives to decrease costs while maintaining quality. As you consider legislation, I want to comment on three important aspects of gainsharing. The first: Gainsharing is important because it is the physicians who are the ones who can control costs. This has been well documented, and once again validated in the February 2005 Boston University School of Public Health study that was recently released. The summary was simple: Health care costs are soaring unsustainably.

Their solution to the problem is economic alignment of physicians with these thoughts: physicians control 87 percent of spending; very important, physicians know where the waste exists; also, it is the individual doctor's decision that is the best way to assure that patient care is not compromised when saving money. The physician is the one with the ultimate responsibility of the patient. It is the physician who takes personal risk when caring for patients. It is the physician who has the knowledge to decrease costs without compromising quality. In our current system, the hospital pays for the products Services that are utilized, even though it is the physician who determines how to use them. Most people do not realize that each physician delivers care to the same type of patient in a unique manner. For example, in any procedure performed, each physician will have a preference card outlining the way he wants the procedure done. You can use the comparisons of a chef or an artist who wants to create the best possible product. Each takes pride in their individual process, because physicians believe they are delivering the best care to their patients.

Yet each of these practices have not been studied to assure quality care to the patients. In gainsharing, cost-saving practices are analyzed before implementation, with safeguards in place to protect the patient. The second point: Gainsharing targets the waste of resources in the health care system, in order to improve quality. Physicians practicing with a unique preference is a waste of resources. More importantly, there is no way that so many different methodologies result in the best quality for patients. This diversity in patient practice begins in training. Physicians may have three different professors who teach them the same procedure three different ways. Each physician then takes all of these practices, and develops an additional methodology specific to their practice. There are as many ways to perform a procedure in this country as there are physicians performing that procedure. For the physician there has been no incentive for them to change their practice. Matter of fact, changing a way a physician practices is hard work, and requires a substantial amount of effort. From the physician's point of view, why take the risk of changing the way you perform a procedure, if you feel good about the outcomes?

It is important to understand that no other industry could remain competitive on quality and cost without key engineers—which are the physicians—determining how to maintain quality while decreasing costs. Physicians reengineering the care of patients is the best way to save billions of dollars, while assuring that quality is maintained. The final point: There are many misconceptions of gainsharing; most importantly, the idea that quality of patient care may be harmed. In order for gainsharing programs to work, you must make sure that quality of care is maintained by looking at

quality, predetermining changes, and measuring data. If you look at 50 physicians performing the same procedure, you will see 50 different ways the procedure is formed. Gainsharing is a process where the physicians study how colleagues perform their procedures and determine the best processes to adopt in order to increase efficiency while assuring quality. In addition to a body of knowledge being created where physicians will constantly invent more efficient ways of delivering care to their patients, the best way to think of this is to look at how other industries operate. They look at not just quality, but also cost. That is what we must do in health care today, because we do not have the dollars to continue to just think that quality is the only thing that will be delivered to these patients. Quality will be withheld from patients if we can't afford to give patients quality. Thank you for your time.

[The prepared statement of Ms. Goodroe follows:]

Statement of Joane Goodroe, President and Chief Executive Officer, Goodroe Healthcare Solutions, Norcross, Georgia

Chairman Johnson and distinguished members of the Committee, I want to thank you for the opportunity to appear before you today to share my thoughts on the topic of gainsharing. My name is Joane Goodroe. I received a bachelor of science in nursing and a masters in business administration and have an extensive clinical and administrative background.

I am currently CEO of Goodroe Healthcare Solutions, LLC, the company that developed the gainsharing model which has received seven separate approvals from the Office of Inspector General. These approvals were obtained only after our gainsharing methodology was highly scrutinized to assure that any decrease in cost would not negatively impact quality. As part of the gainsharing plan, there are safeguards to protect the patient including that any technology a physician requests must be made available.

My first experience with gainsharing started in 1989, when I was an administrator at Saint Joseph's Hospital of Atlanta, one of the hospitals that worked with CMS on the Medicare Coronary Artery Bypass Demonstration Project. In this well studied project, we created a gainsharing model that aligned incentives to decrease costs while maintaining quality.

As you consider legislation, I would like to comment on three important aspects of gainsharing.

One: Gainsharing is important because the physicians are the ones who can control costs.

This has been documented many times and again validated in the February 2005, Boston University School of Public Health study on Health Care Costs from 2000–2005. The summary was simple: Healthcare costs are soaring unsustainably. Their solution to the problem is economic alignment of physicians with these thoughts.

- Physicians control 87% of spending.
- Physicians know where the waste exists.
- An individual doctor's decision is the best way to assure that patient care is not compromised when saving money.

The physician is the one with the ultimate responsibility for the patient. It is the physician who takes personal risk when caring for patients, and it is the physician who has the knowledge to decrease costs without compromising quality.

In our current system, the hospital pays for the products and services that are utilized even though it is the physician who determines the products and services for each patient. Most people do not realize that each physician delivers care to the same type of patient in a unique manner. For example, in any procedure performed, each physician will have a preference card outlining the way he wants the procedure done. You can use the comparisons of a "chef" or an "artist" who wants to create the best possible product. Each takes pride in their individual process because physicians believe they are delivering the best care to their patients. Yet, each of these practices has not been studied to assure quality care for patients. In gainsharing, cost saving practices are analyzed before implementation with safeguards in place to protect the patient.

Two: Gainsharing targets the "waste" of resources in the healthcare system in order to improve quality.

Physicians practicing with a unique preference is a waste of resources and more importantly there is no way that so many different methodologies result in the best quality for patients. This diversity in physician practice begins in training. Physicians may have three different professors who teach them to perform the same procedure three different ways. Each physician then takes all of these practices and develops an additional methodology specific for their practice.

There are as many ways to perform a procedure in this country as there are physicians performing a procedure. For the physicians, there has been no incentive for them to change their practices.

Matter of fact, changing the way a physician practices is hard work and requires a substantial amount of effort. From the physician's point of view, "why take the risk of changing the way you perform a procedure if you feel good about the outcomes?"

It is important to understand that no other industry could remain competitive on quality and cost without the key "engineers" (this would be the physicians) determining how to maintain quality while decreasing overall costs. Physicians reengineering the care of patients is the best way to save billions of dollars while assuring that quality is maintained.

Three: There are many misconceptions of gainsharing, most importantly the idea that quality of patient care may be harmed.

In order for gainsharing programs to work, there must be careful measurement of existing quality, pre-determination of where changes may be appropriate, and data to measure outcomes of changes. These simple tasks assure that quality patient care is maintained while cost are decreased.

If you look at 50 physicians performing the same procedures, you will see 50 different ways the procedure is performed. Gainsharing is a process where the physicians study how colleagues perform their procedures and determine to best which processes to adopt in order to increase efficiency while assuring quality.

Our gainsharing model was designed for complex cardiac procedures. With appropriate safeguards to assure quality, gainsharing concepts can be applied throughout all services.

If physicians first make changes based on best practice outcomes, followed by eliminating unnecessary costs, then quality will actually improve.

In addition, a body of knowledge is created where physicians constantly invent more efficient ways of delivering care to their patients. Again, the best way to think about this is to look at how any other industry operates today. For example, if you are making washing machines, you will not be able to produce the best product at an affordable product unless the engineer is considering both quality and cost of the products being made. No one but the engineers of this product are qualified to make the decisions of how changes will affect quality. In health care, the physician is the engineer.

The physician has been concerned about quality but has never been concerned about costs. Today, healthcare is not affordable. This means that all patients are not currently receiving the care that they need. Physicians working with hospitals to assure that resources are available to pay for needed technology and services is the best to guarantee quality care.

Gainsharing is simply:

Physicians assuring that patients have access to all needed technology in order to deliver the best quality care while eliminating waste in the system.

Mr. MCCRERY. Thank you, Ms. Goodroe. Mr. Emerson.

STATEMENT OF MARTIN J. EMERSON, CHIEF EXECUTIVE OFFICER, AMERICAN MEDICAL SYSTEMS, WEST MINNETONKA, MINNESOTA

Mr. EMERSON. Thank you, Mr. Chairman, Ranking Member Stark, other Members of the Committee. My name is Marty Emerson. I am President CEO of American Medical Systems, a leading innovator today in the field of urology and gynecology. I am here today on behalf of the Advanced Medical Technology Association,

AdvaMed. I ask that my full written statement be entered into the record. AdvaMed would like to thank the Subcommittee for holding this important hearing today to begin discussions on gainsharing. We strongly believe that significant changes to Medicare law require a thorough review of all potential impacts on patients. You will hear some things today that may sound appealing about gainsharing, but this is a complex issue. You are considering rolling back some basic provisions for protecting patients. We have two primary concerns about gainsharing. The first is setting up a system that incentivizes delivering cheaper care, versus delivering quality care. The second is creating a system that could limit patient access to beneficial technologies. We are entering an era of technological advance that is revolutionizing patient care. In the last few years, patients have benefited from new technologies like drug-eluting stents that open up clogged arteries without major surgery, and diagnostic tests that identify which patients will benefit from new cancer drugs.

As I mentioned earlier, we are concerned that a policy like gainsharing will have a negative effect on these advances. This policy might reward short-term savings, not better treatments, and might impact patients' access to those better treatment options. My company recently introduced an innovative device, "Perigee," which is designed to significantly improve the treatment of bladder prolapse, a painful condition in which a woman's pelvic muscles become weak or damaged and the bladder shifts out of its normal position. Our Perigee product replaces the current procedure which requires significant recovery times and has a one-year failure rate of 30 to 50 percent. Our new technology provides consistent successful results that significantly reduce recovery times and prevent the need for further surgery. I ask you, what would have happened to thousands of patients who have already benefited from our new technology under gainsharing? Currently, a healthy tension exists between physicians who advocate for patient care via advanced medical treatments, and the hospital administrators who actively work to manage costs. Under a gainsharing program, this balance between patient care and cost cutting might be skewed, and access to innovative approaches, approaches like my company introduces, could be compromised, as hospitals might choose to focus on short-term savings over technologies that may cost more up front, but will also generate larger savings for our health care system in the long run.

This is especially concerning to small company innovators. As you know, small companies create most of our new technologies. At least two-thirds of AdvaMed's membership is comprised of companies that are classified as small businesses. These companies already must overcome real hurdles to make our technologies available to Medicare beneficiaries. Gainsharing would create yet another hurdle within a marketplace where the largest manufacturers would have a significant advantage. Gainsharing could also negatively impact patient choice among current technologies. Medical devices are not always interchangeable commodities. For example, physicians are now able to choose between mechanical, porcine, and different heart valves made from the pericardium of a cow. The physician and patient together select a heart valve based on the as-

sessment of the benefits and risks of each valve, and the lifestyle, age, and medical condition of the patient. Choosing the cheaper porcine valve would save money today, but would require another costly and painful surgery down the road. Even in situations where average results from two devices would be expected to be similar, factors unique to the patient—such as patient size, or the configuration of the patient's anatomy where an implantable device will be placed—may indicate that one brand of a device is superior for that patient.

We are concerned that gainsharing arrangements would lack adequate safeguards to prevent these concerning situations for patients. We share the Subcommittee's desire to eliminate excess cost and waste from our health care system. We believe that there are a number of steps that can be taken to reduce costs without compromising quality care, such as: additional efforts to prevent and treat diseases early; reduction in medical errors; improvements to the management of chronic diseases; and advances to the infrastructure and organization of care through the adoption of information technology. Should the Committee choose to move forward on gainsharing, we welcome the opportunity to work with you on achieving mutual objectives, if we can find a carefully targeted and limited approach that does not create incentives to cut back on patient care, limit the therapeutic choices available to doctors and the patients, or slow the development and diffusion of medical innovation. Thank you.

[The prepared statement of Mr. Emerson follows:]

Statement of Martin Emerson, Chief Executive Officer, American Medical Systems, West Minnetonka, Minnesota

AdvaMed and its member companies would like to thank the Chairwoman, Ranking Member, and Members of the Subcommittee for holding this important hearing today to begin the discussion on the topic of gainsharing. We strongly believe that significant changes like this to Medicare law require thorough review of any and all potential impacts on the people the program is designed to serve, Medicare beneficiaries.

The Medical Technology Industry

AdvaMed represents over 1300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our companies produce approximately 90% of the medical technology products used in the United States. AdvaMed is proud to represent an industry that brings new hope to patients around the world, and U.S. companies that are benchmark manufacturing leaders in terms of total production, innovation and highest quality products. The medical technology industry directly employs about 350,000 workers in the U.S.

Our industry is fueled by innovative energy and competition, which drives very rapid product development cycles that, in many cases, can lead to new technology iterations every 18 months. Two-thirds of AdvaMed's membership is comprised of companies with sales of under $30 million annually.

Innovative medical technology saves and enhances peoples' lives. Our products enrich patients' productivity and quality of life, thereby improving living standards and benefiting society overall. Medical technology also contributes substantially to economic growth. Our products increase productivity by allowing workers to recover from illness faster, remain longer in the workforce, and thrive without expensive long-term care. Studies show that funds invested in health care yield far greater benefits than costs to a nation's economy over the long term.

The role of medical technology will become even more important as our nation's population ages. According to the 2002 Commission on Global Aging, medical advances will bring "longer, healthier, more productive lives with declining rates of disability for the elderly." Innovative medical technologies offer an important solu-

tion for nations that face the challenges of balancing serious budget constraints and the demands of serving aging populations.

To deliver value to patients, our industry invests heavily in research and development (R&D). The level of R&D spending in the medical devices and diagnostic industry, as a percent of sales, more than doubled during the 1990s, increasing from 5.4% in 1990 to 8.4% in 1995 and over 11% last year. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. Our industry's R&D spending is over three times the overall U.S. average.

The Potential Impact on Patient Care

As the Members of the Subcommittee know, gainsharing is an arrangement between a hospital and a physician to share in any savings as a result of specific actions taken by the physician in directing the use of items or services for patient care. These arrangements have been considered to be in violation of the federal anti-kickback provisions, physician self-referral laws, and the civil monetary penalty (CMP) prohibition on hospital payments to physicians. Under the CMP rules, a hospital cannot pay a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician's direct care.

The greatest concern about relaxing these existing laws designed to protect patients is the potential negative impact on patient care. Patients deserve the best treatment options and technologies available for their unique circumstances. They deserve to reap the fruits of this new century of the life sciences, unhindered by policies that will slow the progress of medical knowledge from the lab bench to the bedside. They expect government policies that support providing the most appropriate and highest quality care.

American Medical Systems, Inc. (AMS) and the medical technology industry are very concerned about proposals to relax these laws and legalize gainsharing. We believe gainsharing should be carefully studied by Congress before any decision is made to move forward with relaxing the existing rules that prohibit gainsharing. We believe that gainsharing would have an immediate and significant negative effect on public health by encouraging the use of the least expensive option without consideration of long-term effects or overall health economics. It would be a severe impediment to the development and rapid diffusion of beneficial new technology, could have an especially negative impact on small companies, and could eliminate important therapeutic and diagnostic choices for doctors and patients. We are concerned that, in the end, patients could suffer most.

At the same time, we share this Subcommittee's desire to reduce excess cost and waste in our health care system, and we want to work with you on ways to achieve this goal in a way that truly protects patients and medical innovation.

The Potential Impact on Technology Development and Diffusion

We are entering an era of technological advance that has the potential to revolutionize patient care. In just the last few years, we have seen such remarkable new technologies as drug-eluting stents to open up clogged arteries and prevent heart attack without major surgery, new artificial hips and knees that may never need to be replaced, electrical implants to treat Parkinson's disease and epilepsy, and diagnostic tests to identify which patients will benefit from a new cancer drug and which will not.

We are concerned that a policy like gainsharing will have a negative impact on these advances in technology development and diffusion. If not designed with adequate safeguards for patients, gainsharing could easily reward cheaper treatments, not better treatments. It could be based solely on the short-term cost of a hospital stay, not the longer term cost of treatment over the course of an illness. It is primarily focused on the issue of cost, not value.

AMS is a medical device company that develops and markets minimally-invasive, life-restoring therapies. Recently, we introduced an innovative device, Perigeë, which is designed to significantly improve the treatment of bladder prolapse in women. Bladder prolapse is a painful and distressing condition in which a woman's pelvic muscles become weak or damaged, and the bladder shifts out of its normal position. Our device integrates a specialty surgical mesh with a set of delivery tools to deliver superior efficacy in correcting the condition. This device replaces the current "gold standard" procedure for bladder prolapse in which the physician plicates (or pulls together) the patient's existing tissue to resupport the bladder. Plication procedures demonstrate a one-year failure rate of 30–50%, while our technology provides consistent, successful results that reduce and prevent the need for further surgeries.

Despite the failure rates of the current plication procedure and the success rate of our technology, some patients do not have access to the technology when hospitals

are reluctant to make them available for use. Currently, a healthy tension exists between the physician advocates for patient care and the use of advanced and new technologies and the hospital administration that seeks to manage costs. This is a good balance between patient care and efficient use of resources. Under a gainsharing program, the balance between patient care and cost-cutting will be skewed. Patient access to the best care could be compromised and virtually insurmountable hurdles for adoption of beneficial new technologies could be created.

Our company is also evaluating a number of innovative and minimally invasive techniques to treat benign uterine fibroids and their debilitating symptoms. The current standard of care for treating fibroids is a hysterectomy, an invasive procedure in which the uterus and offending fibroids are removed. While efficient for the healthcare system, the recovery period for a hysterectomy is long and there are significant risks associated with surgery. In addition, many women and physicians believe it is critical to leave the healthy uterus intact and treat this condition with the least invasive procedure possible.

If gainsharing were implemented, our company would be forced to re-evaluate our decision to invest in the design and development of new minimally invasive technologies in this area. We believe we would face overwhelming obstacles in the adoption of this new technology since, even though it offers the potential for improved patient care, it would not provide hospitals and physicians with the short-term savings that would be rewarded under gainsharing.

A significant amount of new technologies are created by small companies. These companies already confront significant hurdles to bring technologies to market and have them accepted into the Medicare system. Gainsharing would place an additional barrier to the adoption of their advanced devices. Patients currently face notable barriers in accessing several innovative technologies made by AMS, even thought they offer clearly beneficial outcomes for patients. We are concerned that gainsharing would exacerbate this problem, especially since AMS does not have vast resources to overcome the additional market adoption hurdles that could be presented by gainsharing. Gainsharing's standardization measures would create an anti-competitive marketplace where the largest manufacturers would have a significant advantage.

The Potential Impact on Therapeutic and Diagnostic Choices

Gainsharing could negatively impact patient access to new technologies as well as choice among current technologies. Advanced medical devices are not always interchangeable commodities. For example, physicians are now able to choose between mechanical heart valves, porcine heart valves, and valves made from the pericardium of a cow. The physician and patient select a prosthetic heart valve based on an individual assessment of the benefits and risks of each valve and the lifestyle, age and medical condition of the patient. When considering the use of a tissue valve, the porcine heart valve is cheaper, but may not last as long as the more expensive alternatives. For some patients, choosing the cheaper porcine valve would save money today, but could require another costly and painful surgery down the road. Plastic, metal, and ceramic replacement hips all have different characteristics that could affect their durability for individual patients and the likelihood that they would need to be replaced.

Even when the choice is between two brands of devices made from similar materials, the best choice for an individual patient is not always obvious. In situations when average results from two devices would be expected to be similar, factors unique to the patient, such as the patient's size and the configuration of the area where an implantable device will be placed, may suggest that one brand of device is superior for that patient. Physician familiarity and comfort with a particular device is also critical. Typically, it is the match between a physician's skills, training, and familiarity with a specific device which produces the best outcome for a patient.

Physician use is also important in medical device innovation. Physicians help generate the next generation of devices by coming up with new ideas in the clinical setting. Removing the choices available to physicians will only hinder the industry in device innovation.

Oversight of Quality and Accountability

As you may know, the OIG issued advisory opinions in February 2005 on six different requests by hospitals proposing gainsharing arrangements. In *all six* advisory opinions, the OIG noted that the gainsharing arrangements could violate the CMP statute, but the OIG wrote that it would not impose sanctions against the hospitals if several protections were included in the arrangements. The protection from sanctions was not granted for any other arrangements beyond these six specific requests,

and under current law, the OIG will continue to scrutinize any gainsharing arrangement requests on a case-by-case basis.

The tailored patient safeguards delineated by the OIG in the advisory opinions addressed maintaining patient access to quality care, designing quality controls with the input of credible medical experts, limiting the scope of the arrangements, ensuring public awareness and accountability on the details of the arrangements, and restricting actions allowed for yielding savings and methods of distributing the savings. The OIG required these elaborate and extensive safeguards to ensure that hospitals would not stint on care because it recognized that gainsharing could result in economic incentives undermining clinically appropriate decisions by physicians.

Since we do not have feedback from the six arrangements to review and little experience with gainsharing, it seems premature to push ahead without careful study. For example, the several hospitals that have received advisory opinions are blinded to the public and stakeholders. We are concerned about how the quality will be measured given the difficulty of risk adjustment, lags in data, and the pervasive lack of measurement of value as opposed to cost across our whole system. It will also be hard to assess quality in the short term since different patient outcomes for some technologies will not be apparent for years after the procedure is performed, and it may be impossible to account for lost quality from failure to adopt new technology.

The Impact on Long-Term and Overall Program Costs

We are strongly concerned that when gainsharing is permitted to occur, arrangements will be designed to find savings by limiting the range of medical technologies. While these approaches may yield short-term savings to an individual hospital and the physicians working there, they may well be eclipsed by far greater overall health system costs in the long-run.

Current contracting patterns at the hospital, regional, and ownership level already drive down the cost of devices without jeopardizing the physician or the patient in the quality of care provided. The medical technology industry is highly competitive and under immense market pressure to keep costs down. According to figures from the Bureau of Labor Statistics, price increases for medical devices have consistently been below the increases in the consumer price index for the last five years. According to Department of Commerce and CMS figures, medical devices as a share of national health spending have remained constant at about 5%. When the American Hospital Association (AHA) studied the increase in hospital costs over the last five years, it found that the cost of purchasing medical devices as a component of the increase was not even large enough to warrant breaking it out as a separate item.

Conclusion

We share the Subcommittee's desire to eliminate excess cost and waste from our health care system and we strongly support evidence-based medicine. We believe that there are a number of steps that can be taken to achieve the objective of reducing costs without compromising quality care, such as additional efforts to prevent and treat diseases early, reduction in medical errors, improvements to the management of chronic diseases, and advances to the infrastructure and organization of care through the adoption of information technology. Incentives should also be adopted to encourage treatments and innovations that focus on improved patient outcomes and overall savings to the health care system.

As you know, Congress passed laws to prohibit gainsharing out of concern about conflicts of interest that could influence a physicians' ability to exercise independent professional judgment about the best interests of his or her patients. Congress did not want hospitals paying physicians to reduce or limit services to Medicare patients. Congress must continue to ensure that high-quality patient care is not jeopardized by financial incentives to cut costs.

Thank you again for providing us the opportunity to submit the views of our industry on this important topic. We welcome the opportunity to work with this Subcommittee on achieving mutual objectives if we can find a carefully targeted and limited approach that does not create incentives to cut back on patient care, limit the therapeutic choices available to doctors and patients, or slow the development and diffusion of medical innovation.

Mr. MCCRERY. Thank you, Mr. Emerson. There are only about 3 minutes left on the vote. Mrs. Johnson obviously got tied up on the floor. So, I am going to recess the Subcommittee hearing until

such time as Mrs. Johnson returns. It shouldn't be but just a few minutes. So, the Subcommittee is in recess.

[Recess.]

Chairman JOHNSON. The hearing will reconvene. While Members are on their way back from the floor, since some in our audience are fairly new to Washington, I do want to just take a point of personal privilege and say, if you haven't walked through the tunnel between Longworth and the Capitol, you owe it to the children of America. Every year, we have an artist from every district, through competition. We bring their work to Washington and we hang it in that tunnel. This year, it is just exceptional. There are some pieces there that will knock your socks off. You owe it to yourself, as well as to the youth in our high schools, to go by and look at it.

Mr. STARK. Will the gentlelady yield?

Chairman JOHNSON. Yes, I will be happy to yield.

Mr. STARK. You weren't here at the time, but guess which elderly Member of the House of Representatives walked through that tunnel for years, looking at those stupid bare walls, and went to Architect White and said, "Why can't we hang state posters or something in this hallway?" Guess who that Member was who found the place to hang that art?

Chairman JOHNSON. Outstanding! Pete, you have always been high on my list of creative thinkers and real contributors to this process, and you are now the best. Okay. Now, it rained. When I realized how hard it was raining, we all have to go around, and it takes longer. The best laid plans don't work. So, I understand that Ms. Goodroe concluded. I am not sure that Mr. Emerson concluded.

Mr. STARK. Concluded, yes.

Chairman JOHNSON. You concluded? Okay.

Mr. EMERSON. I have concluded.

Chairman JOHNSON. Mr. Carter.

STATEMENT OF GARY S. CARTER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NEW JERSEY HOSPITAL ASSOCIATION AND AFFILIATES, PRINCETON, NEW JERSEY

Mr. CARTER. Good morning. I am Gary Carter, President and CEO of the New Jersey Hospital Association. I would like to thank Chairwoman Nancy Johnson and the Members of the Committee for allowing me the opportunity to meet with you today. In particular, I would like to thank Mrs. Johnson and the members of her staff for their visit to New Jersey to get a better understanding of what we were trying to accomplish with our demonstration project; and I would let you know that, if you would like, we would be happy to bring physicians and CEOs to visit with you here to talk about what we were doing. Aligning the performance incentives of physicians, hospitals, and the Medicare Program is an efficient and practical way to encourage optimal quality of care decisions. Although it was stalled by a few hospitals that wanted to be included but were precluded by a CMS cap on participation, I feel that the New Jersey Demonstration experience I am about to describe held the promise to achieve this goal. If reimplemented in some form, hospital participation in this project should remain voluntary, with opportunities to opt out at the end of years one and two of the

project if the participating hospital is not achieving an appropriate level of physician participation, quality improvement, or cost savings.

Prior to granting New Jersey a waiver, CMS originally required participating hospitals to guarantee a savings to the Medicare Program of not less than 2 percent of a hospital's Medicare payments beginning in the second year of the demonstration. While participating hospitals would prefer a project without the guarantee, I believe it is critical that any guaranteed savings requirement begin no sooner than the second year. Also, a guarantee that is lower than 2 percent will stimulate greater hospital participation, and should be considered moving forward. Finally, while specialty hospitals do not exist in New Jersey, NJHA does not view the implementation of this project as a reason to lift or ease current efforts to implement a moratorium on specialty hospitals. They are very separate issues. Now I would like to provide a brief overview of our project. Traditionally, hospitals and physicians operate with different economic incentives. For the last 20 years, hospitals have been paid on a per-case basis, while physicians are paid on a fee-for-service basis. Long lengths of stay, by default, tend to consume more services and accumulate additional costs and create potential quality problems. In order to guarantee proper oversight, a rigorous structure was created to ensure that everyone stayed focused on physician-hospital collaboration and quality performance. The NJHA created its own demonstration steering committee; each hospital also required to form its own internal oversight committee staffed by not less than 50 percent physicians.

In September of 2003, the CMS awarded to the New Jersey Hospital Association a waiver to demonstrate what is commonly referred to as gainsharing. The incentives were structured as follows: The objective of the demonstration was to reempower physicians, under a rational economic structure, to partner with hospitals in patient care; Physician participation is strictly volunteer; The project provided a bonus only for physicians; therefore, no risks or penalties; the purpose is to incentivize improvement and reward achievement, not to punish; The incentives are based on individual physician performance, adjusted for severity of illness; The demonstration was designed to place no additional paperwork demands on physicians; there are no changes in claims processing or payment routines; Quality and responsibility for quality are the project's highest priorities. It is the hospitals themselves who provide sources of funds for demonstration. I have been asked why hospitals would be willing to take on this responsibility. The obvious answer is that improved operational performance can lead to improved quality and financial performance. Quality monitoring is a key component of this demonstration. Process measures selected to evaluate performance were associated with acute myocardial infarction, heart failure, and community acquired pneumonia. These quality measures were chosen based on their relevance to the Medicare population. Participating hospitals also integrated their own individual quality programs into the project.

Hospitals were given the power to condition participation in the demonstration by individual physicians on participation in institution-specific quality programs, including clinical quality protocols.

As physician interest in the demonstration grew, interest also grew in promoting its success by utilizing the demonstration framework as a tool to further improve quality. In conclusion, I am here today to support legislation that would allow New Jersey and other states to participate in a program where we could align incentives of physicians and hospitals. We appreciate your efforts in this regard, and look forward to continuing our work with the Subcommittee in developing gainsharing policies. Thank you.

[The prepared statement of Mr. Carter follows:]

Statement of Gary S. Carter, President and Chief Executive Officer, New Jersey Hospital Association and Affiliates, Princeton, New Jersey

Good morning. I am Gary Carter, President and CEO of the New Jersey Hospital Association. I'd like to thank Chairwoman Nancy Johnson and members of the committee for allowing me the opportunity to meet with you today. In particular I would like to thank Mrs. Johnson and members of her staff for their visit to New Jersey to get a better understanding of what we were trying to accomplish with our Demonstration project.

Aligning the performance incentives of physicians, hospitals and the Medicare program is an efficient and practical way to encourage optimal quality of care decisions. Although it was stalled by a few hospitals that wanted to be included, but were precluded by a CMS cap on participation, I feel that the New Jersey Demonstration experience that I am about to describe held the promise to achieve this goal. If re-implemented in some form, hospital participation in this project should remain voluntary with opportunities to opt-out at the end of year's one and two of the project, if the participating hospital is unhappy for any reason, is not achieving an appropriate level of physician buy-in, quality improvement or cost saving success.

Prior to granting New Jersey a waiver, CMS originally required participating hospitals to guarantee savings to the Medicare program of not less than 2 percent of a hospital's Medicare payments beginning in the second year of the demonstration. While participating hospitals would prefer a project without the guarantee, I believe it is critical that any guaranteed savings requirement begin no sooner than the second year. Also, a guarantee that is lower than 2 percent will stimulate greater hospital participation and should be considered moving forward.

Finally, while specialty hospitals do not exist in New Jersey, NJHA does not view the implementation of this project as a reason to lift or ease current efforts to implement a moratorium on specialty hospitals. These are separate issues.

Now I would like to provide a brief overview of our project. Traditionally, hospitals and physicians operate with different economic incentives. For the last twenty years hospitals have been paid on a per-case basis while physicians are paid on a fee-for-service basis. Long lengths of stay, by default, tend to consume more services and accumulate additional cost for which the hospital receives no additional reimbursement from Medicare. This has the potential to create an adversarial atmosphere between hospitals and physicians.

New Jersey's Medicare Demonstration of Performance Based Incentives project was designed as an attempt to identify, pilot test and evaluate a specific methodology to better align current payment methods with quality improvement goals. Almost half of the hospitals in the state of New Jersey expressed interest in participating in the project.

In order to guarantee proper oversight, a rigorous structure was created to ensure that everyone stayed focused on physician/hospital collaboration and quality performance. NJHA created its own Demonstration Steering committee staffed by participating hospital CEOs, CFOs and Medical Directors, as well as Quality Oversight and Finance sub-committees. Each hospital was also required to form its own internal Oversight Committee staffed with not less than 50 percent physicians. Hospital specific internal Quality and Finance sub-committees were also a required component of participation.

In September of 2003, the Centers for Medicare and Medicaid Services (CMS) awarded to the New Jersey Hospital Association a waiver to demonstrate what is commonly referred to as gainsharing. By properly aligning physician and hospital incentives the New Jersey demonstration held the promise to achieve several objectives:

1. Facilitate collaboration between physicians and hospitals;
2. Infuse efficiency through greater access to needed services, quicker turn around time on procedure scheduling and test results;

3. Provide a new source of funds to support quality initiatives;
4. Add incremental payments to augment depleted physician fee schedules;
5. Return patient care decisions to physicians in consultation with their patients;
6. Improve the financial health of hospitals;
7. Improve the long-term viability of the Medicare Trust Fund.

Physician and hospital economic incentives are, at best, inconsistent. This means that there will be a significant amount of inefficiency in the delivery system so long as this situation persists. Real progress cannot be made on the challenge of improving performance—both quality and operational—without returning responsibility to the doctors and making them partners.

The way in which physicians in the field perceive this program is critical to its success. The incentives were structured as follows:

- The objective of the Demonstration was to re-empower physicians—under a rational economic structure, to partner with hospitals in patient care.
- Physician participation is strictly voluntary.
- The project is bonus only for physicians; therefore, no risks or penalties. The purpose is to incent improvement and reward achievement; not to punish.
- Incentives are based on individual physician performance, adjusted for severity of illness.
- The Demonstration was designed to place no added paperwork demands on physicians; there are no changes in claims processing or payment routines.
- Quality, and responsibility for quality, are the project's highest priorities.

It is the hospitals themselves who provide the source of funds for the Demonstration. I have been asked why hospitals would be willing to take on this responsibility. The obvious answer is that improved operational performance can lead to improved financial performance. This, in turn, creates a source of funds for important needs including quality of care initiatives, care to the uninsured and capital improvement.

For the hospital, aligning incentives can result in:

- Shorter inpatient stays;
- Improved quality of patient care;
- Fewer marginal but costly diagnostic tests;
- Reductions in pharmacy expense;
- Efficient use of operating rooms;Cost effective use of critical care and telemetry units;
- Evidence-based selection and purchase of medical devices and hardware;
- Improved discharge planning.

In addition, if the Demonstration were to be implemented and successful, it should:

- Improve the financial health of hospitals;
- Augment physician fee schedules;
- Provide a new source of funds to Medicare and its beneficiaries; and
- Provide a model that could improve the performance of the Prospective Payment System (PPS).

Quality monitoring is a key component of this demonstration. Process measures selected to evaluate performance were associated with Acute Myocardial Infarction (AMI), Heart Failure, and Community Acquired Pneumonia. These quality measures were chosen based on their relevance to the Medicare population. Participating hospitals also integrated their own individual quality programs into the project.

Hospitals were given the power to condition participation in the demonstration by individual physicians on participation in institution-specific quality programs, including clinical quality protocols. As physician interest in the Demonstration grew, interest also grew in promoting its success by utilizing the Demonstration framework as a tool to improve quality.

In conclusion, I am here today in support of legislation that would allow New Jersey and other states to participate in a program where we could align incentives of physicians and hospitals. We appreciate your efforts in this regard and look forward to continuing our work with the Subcommittee in developing gainsharing policies.

I would now be happy to answer any questions.

Chairman JOHNSON. Thank you, Mr. Carter. Mr. Fine.

STATEMENT OF STUART H. FINE, CHIEF EXECUTIVE OFFICER, GRAND VIEW HOSPITAL, SELLERSVILLE, PENNSYLVANIA, ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. FINE. Good morning. My name is Stuart Fine, I am the CEO of Grand View Hospital in Pennsylvania. I am here today on behalf of the American Hospital Association, its 4,800 member hospitals and health systems. Part of Grand View's mission is to provide and coordinate the appropriate utilization of quality, cost-effective health care and related services for our community. There are approximately 300 full- and part-time physicians on our medical staff and more than 1,500 employees of Grand View who help us to accomplish our mission. Madam Chairman, we commend your leadership, and thank the Committee for its work in seeking public policy changes that can help hospitals and doctors work together to improve the quality and efficiency of patient care delivery. But we believe very strongly that gainsharing can do the most good for the most people if we move beyond thinking of it only as a way to achieve cost savings. We need to be able to use incentives in working with physicians to improve quality of care and patient safety and to ensure that our communities have access to the care and services that they require. We believe it is time to move beyond demonstration projects. Such projects benefit only a limited number of communities, but doctors and hospitals everywhere need help. We need to clear away the underbrush of what are confusing laws and regulations that prevent doctors and hospitals from focusing on the bigger picture: providing quality care at an affordable price.

Hospitals and doctors currently have only a few ways in which they can share incentives to come together. Hospitals can employ doctors, or they can spend large sums of money and years of time to take advantage of remarkably limited and confusing case-specific gainsharing opportunities. We urge you to amend Federal law and regulation. Many changes are desperately needed. The CMP law prohibition against any incentive to reduce care, regardless of medical necessity, is far too all-encompassing. It prohibits inducements to reduce services even when such services may be unnecessary or duplicative. The HHS Secretary should be authorized to create safe harbors to foster this broader range of care improvement initiatives with proper safeguards. Those safe harbors should apply across all Federal that restrict them. The current Federal focus on limiting incentives to the sharing of cost savings feeds consumer fears. This causes folks to worry that this could result in stinting on care or delaying adoption of new technologies and treatments. For providers, gainsharing is often not a realistic option, because such collaborative programs have generally been limited to a year's duration. That simply does not support the needed investment, both in time and money, for either hospitals or physicians.

Any proposal that would seek to guarantee up-front savings to the Medicare Program would likely stifle most providers' incentive to participate. For example, an initiative to adopt technologies that improve patient safety might require significant capital investment to purchase hardware and software, as well as to train hospital staff, physicians, and physician support staff in their use. That investment could reduce medical errors and complications, but might

not yield monetary savings for the hospital. Yet it is the right thing to do for patients and for the Medicare Program. Hospitals should not be penalized or have impediments put in their way to making such investments on behalf of their communities. Because physician-owned limited-service providers can offer incentives without the same constraints that apply to facilities not owned by physicians, requiring payments to Medicare would be an unfair penalty against community hospitals. Importantly, patient safeguards could govern the incentive arrangements we are recommending. However, there are no patient safeguards covering the incentives allowed by physician-owned limited-service providers. The financial rewards associated with our recommended approaches would never equal those of ownership. Therefore, we strongly urge that action to remove barriers to the use of incentives must not be considered a substitute for the needed ban on physician self-referral to limited-service providers.

The actions we have recommended will help create productive working relationships with physicians. They can do nothing, however, to change the conflict of interest inherent in physician ownership under the physician self-referral prohibition. In conclusion, while the roles of hospitals and physicians are different, each needs the other, and our patients need us both. Too many legal and legislative barriers still in the way of hospital and physician efforts to collaborate in making health care better. Congress can help by modernizing law and regulations so that hospitals and physicians can work together in ways that benefit everyone having a stake in providing, or in receiving, high-quality care. Thank you very much for this opportunity to participate in today's hearing, I remain available to respond to your questions.

[The prepared statement of Mr. Fine follows:]

Statement of Stuart H. Fine, Chief Executive Officer, Grand View Hospital, Sellersville, Pennsylvania

I am Stuart Fine, CEO at Grand View Hospital in Sellersville, Pennsylvania. I am here today on behalf of the American Hospital Association (AHA) and our 4,800 member hospitals, health systems and other health care organizations, and our 33,000 individual members. We appreciate the opportunity to share with you our thoughts on the potential of gain sharing to help patients, physicians, hospitals, and the Medicare program itself.

Formed in 1913 as Bucks County's first hospital, Grand View Hospital is in most ways a typical community, not-for-profit hospital. We provide a broad array of patient services, from obstetrics to orthopedics, and from hospice/home care to oncology. Our mission, in brief, calls for us to "provide and coordinate the appropriate utilization of quality, cost-effective health care and related services" for the people of our community. More than 250 physicians comprise our medical staff.

Madam Chairman, all health care is about teamwork. It involves the talent and dedication of a wide range of very special people—from doctors and nurses to technicians and nutritionists and many, many more. Hospital care is especially dependent on the ability of hospital leaders to work with physicians to make sure they have the resources needed to get patients the right care, at the right time, and in the right setting.

We therefore commend your consideration of public policy changes that could improve the ability of hospitals and physicians to work together to improve the efficiency of hospital care delivered to Medicare patients. When we talk about gain sharing as a way to improve the efficiency of our health care system, we are talking about much more than just *cost* efficiency—gain sharing can also bring gains in quality, patient safety and community access.

For this reason, we urge the committee to revise various federal laws that affect hospital-physician working relationships, so that they can foster the teamwork need-

ed to address the many challenges facing the delivery of health care today and in the future.

Currently, federal laws are focused on prohibiting or limiting interactions between hospitals and physicians that might have monetary value to either party. While the intent is honorable—to avoid conflicts of interest—the effect is to impede the ability of hospitals and physicians to work together using incentives to improve quality, patient safety and community access to services. The current federal focus on sharing "cost savings" gives rise to a fear among beneficiaries and consumers that such efficiency-only incentives would result in things like curtailed care and slower adoption of new technologies and treatments. We believe Congress should modernize the current concept of gain sharing and focus on the broader goal of fostering hospital-physician arrangements that provide incentives for care improvement.

At the same time, we also urge that Congress not view action in this area to be a substitute for a permanent ban on the use of the whole hospital exception under the Ethics in Patient Care Referrals Act by physician-owned limited-service hospitals.

Gain Sharing in Today's Environment

Gain sharing is currently understood to be the sharing between hospitals and physicians of cost savings that stem from specific actions to improve the efficiency of care delivery. Very little gain sharing is currently allowed. The Department of Health and Human Services (HHS) Office of Inspector General (OIG), which is charged with enforcing some of the laws that affect hospital-physician relationships, in 1999 issued a ruling that effectively banned gain-sharing arrangements. In that ruling, the OIG noted that well-designed arrangements could result in better care at lower cost by, for example, encouraging physicians to reduce the use of unnecessary ancillary services and inpatient days. Nevertheless, the OIG concluded that the Civil Money Penalties Law prohibited gain sharing, and that the OIG lacked the statutory authority to impose safeguards to ensure that cost-saving measures do not reduce quality.

Earlier this year, the OIG issued several advisory opinions that allowed a very narrow approach to reducing costs of cardiac procedures. The opinions allowed a specific arrangement to provide incentives for physicians to adhere to clinical best practices and reduce the inappropriate use of supplies. Though judged illegal under current law, the OIG elected not to challenge those arrangements at present because they included multiple safeguards to protect quality of care for beneficiaries and to guard against inappropriate use of Medicare funds. This slight alteration in the OIG's position on gain sharing may have been stimulated by recommendations from the Medicare Payment Advisory Commission (MedPAC) in March 2005. MedPAC urged that Congress provide HHS with the authority to allow a much broader use of hospital-physician gain sharing arrangements, as long as they are regulated to protect the quality of care and minimize financial incentives that could affect physician referrals.

A Broader Approach

The AHA believes that broadening gain sharing to focus not just on cost reduction but also on care improvement initiatives would benefit patients, hospitals and physicians. Specifically, we believe federal laws that affect hospital-physician relationships should be amended to:

Foster hospital-physician incentive arrangements designed to improve or maintain community access to services, or to achieve one or more of the six aims for health care delivery articulated by the Institute for Medicine (IOM) in its report, *Crossing the Quality Chasm*. The six aims are that health care be safe, effective, patient-centered, timely, efficient, and equitable.

Foster hospital-physician incentive arrangements that are designed to:

- Achieve needed improvements in the health care delivery system even if they do not produce an immediate cost savings.
- Sustain community access to services that are essential. With physicians less dependent on hospitals as a place to practice, new incentives should be allowed in order to maintain community access to services (such as trauma and emergency department services), support community outreach efforts, care for the uninsured, and other aspects of hospital operations that require physician support.
- Promote the integration of clinical care across providers, across settings, and over time.
- Adopt and integrate information technology (IT) systems and technology. IT linking hospitals, physicians, and other providers together is essential to im-

proving patient safety, productivity, quality monitoring, and coordination across care settings.
- Enhance institutional or practitioner productivity or achieve other efficiencies.

Establish a simpler, consistent set of rules for how hospitals and physicians construct their working relationships. The complexity, inconsistency and sometimes-conflicting interpretations of federal laws and regulations affecting hospital-physician arrangements is a significant barrier. Few arrangements can be structured without very significant legal expense. Even then, it is often unclear whether the arrangements might be challenged in the future.

Enable hospital-physician contracting with health plans and purchasers as a single unit, especially when pay-for-performance provisions are utilized. Health plans and purchasers often adopt different approaches to payment for hospitals and physicians that in turn create different and sometimes-conflicting incentives. As more purchasers move toward pay-for-performance methods, the need to align hospital and physician payment incentives becomes critical.

More specifically, AHA believes that the following types of arrangements should be allowed if they are designed to achieve an acceptable purpose, there are mechanisms in place to protect the quality of care provided to beneficiaries and avoid inappropriate influence on physician referrals, and the incentive arrangements are transparent to patients. These arrangements may not yield tangible savings to a *hospital*, but they may yield savings to the health care system overall and can improve the care we provide.

- Sharing of cost savings from efficiencies
- Incentives to meet quality indicators (even when savings do not accrue to the hospital)
- Incentives to clinically integrate services and coordinate care across settings
- Sharing of pay-for-performance bonuses from payers
- Joint recruitment of physicians by hospitals and physician practices
- Joint hospital and physician contracting with payers to ensure aligned performance incentives
- Service contracts with physicians to build new service capacities
- Management contracts with physicians
- IT and other technology sharing to enable communication across settings
- Ability to purchase or operationally support IT for other providers to increase IT adoption and integration
- Hospital assistance to physicians in obtaining malpractice insurance

Moving from Gain Sharing to Incentives for Care Improvement Initiatives

Federal law affecting hospital-physician relationships is extremely complex and comes from multiple sources. These are the most-relevant federal laws:

- Medicare's Civil Money Penalty Law (CMPL) prohibits any direct or indirect hospital payments to physicians that are aimed at reducing or limiting services, regardless of medical necessity.
- Focusing this prohibition on preventing incentives to reduce medically necessary services would spawn many care-improvement initiatives, including those that would significantly improve the quality and safety of patient care both in the short and long terms. It also would allow hospitals to share with physicians the result of reduced costs.
- Medicare's Ethics in Patient Care Referrals Law prohibits physician self-referrals to any entity in which he/she has an ownership or financial interest for any of a lengthy list of designated health services, one of which is hospital inpatient and outpatient care. These provisions basically prevent any financial relationship between a hospital and a referring physician unless that relationship satisfies an exception. There are few exceptions that apply to non-ownership relationships between hospitals and physicians and the exceptions that do apply are very rigid.
- Medicare's Anti-kickback Law prohibits any payment for referrals, or inducement or reward for, the purchase, order, or lease of any covered item or service. The effect of these provisions is to limit arrangements to those that share verifiable cost savings. In many respects these provisions clash with those of the CMPL.
- Tax Exemption Law prohibits private benefit or inurement. These provisions prohibit payments to physicians that are based on a portion of gross or net revenues, or any payments that violate physician self-referral or anti-kickback laws.

Development of a Legislative Proposal

We applaud the Chairman's leadership in examining how to modify current law to foster productive relationships between hospitals and physicians that also benefit Medicare beneficiaries and the Medicare program itself. As you develop your legislative proposal, we have several recommendations:

Allow incentive relationships between hospitals and physiciansto support care improvement initiatives affecting quality, patient safety, and access to services, in addition to cost efficiency. Quality of care for beneficiaries, and cost savings to the Medicare program, will be the likely result in the form of reduced medical complication rates, reduced readmissions, reduced duplication of services by different providers, reduced admissions, and improved operational efficiency.

Reach beyond demonstration projects and amend current federal laws to eliminate inconsistent and counterproductive provisions. Clearly there are some changes that must be made. For example, the CMPL prohibition on any incentive to reduce care, regardless of medical necessity, should be limited so that it only prevents incentives to reduce medically necessary care. We also believe that the imperative to systematically address health care delivery issues calls for immediate change in the complex maze of federal requirements governing hospital-physician relationships. The HHS Secretary should be authorized to create safe harbors to foster care improvement initiatives with proper safeguards, and those safe harbors should be applied across all the federal laws that currently restrict them.

Do not require that hospitals guarantee savings to the Medicare program as a condition for incentive arrangements. Such a requirement would have an overwhelmingly chilling effect on the development of care improvement initiatives for several reasons:

- Hospitals would be taking the risk of upfront investment in incentive approaches that might or might not yield cost savings to the hospital. For example, an initiative focused on adopting technologies that improve patient safety would require significant upfront investment. That investment could bring increased patient safety and fewer complications, which might prevent readmissions. Most of those gains would not yield operating cost savings for the hospital, and in fact might reduce revenues to the extent that admissions are reduced. But it is the right thing to do for patient care, and the hospital should not be penalized by a requirement to pay Medicare for the right to do it.
- The viability of incentive arrangements would be limited to those hospitals or areas where costs and/or length of stay (LOS) are high. Per-case costs and LOS are the primary areas where reductions would yield savings to the hospital under Medicare's inpatient prospective payment system. Hospitals that already are very efficient, or are in areas where they are historically very efficient, might achieve limited or no savings. They would have to generate enough savings or other funds to cover the payment to the program, the investment cost of the incentive arrangement, and the cost of incentive payments to physicians.
- The long-term viability of the approach would be limited. We question whether the savings each year would cover a payment to the program, as well as the cost of investments and physician incentives. This is especially the case when any productivity gains might generate MedPAC recommendations for further reductions in the update factor.
- Any required payments to the Medicare program would be an unfair penalty against community hospitals compared to physician-owned hospitals. Physician-owned hospitals are able to provide incentives without the same constraints as hospitals not owned by physicians, and they would not be subject to the same payment requirement. MedPAC has demonstrated that physician-owned specialty hospitals do not provide care at lower cost, even though they have shorter lengths of stay. Such differences under the program would not be appropriate.

Do not substitute action in this area for the much-needed ban on physician self-referral to limited-service hospitals. The actions we have recommended will help create productive working relationships with physicians without entering into joint ownership arrangements. They can reshape hospital-physician relationships at a time when physicians depend much less on hospitals as a place to practice. They can do nothing, however, to change the conflict of interest inherent in allowing physician-owned limited service hospitals access to the whole hospital exception under the physician self-referral prohibition. Safeguards would govern the incentive arrangements we are recommending; the incentives allowed under the whole hospital exception have no patient safeguards. Further, the rewards associated with our recommended approach would never equal those associated with physician ownership.

Conclusion

The relationship between hospitals and the physicians who practice in them has always been central to quality care. Hospital managers and governing boards are responsible for providing the facilities, equipment, and staff required to deliver health care services, but it is the physicians who provide or direct the delivery of those services. While the roles of hospitals and physicians are different, they are highly interdependent—we need each other, and patients need both of us.

But in today's environment, too many legal and legislative barriers stand in the way of hospital and physician efforts to make health care better for all they serve. The major delivery system changes called for by the IOM and others are within reach. Congress can help us reach those goals by easing federal law so that hospitals and physicians can work together in ways that will benefit everyone with a stake in high quality health care.

Chairman JOHNSON. Thank you very much, Mr. Fine. Mr. Imparato.

STATEMENT OF ANDREW J. IMPARATO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES

Mr. IMPARATO. Good morning, Madam Chair and Members of the Subcommittee. My name is Andy Imparato. I am the President and CEO of the American Association of People With Disabilities (AAPD). We have about 120,000 members around the country, and our mission is political and economic empowerment for children Adults with all types of disabilities. I wanted to start by thanking all three of you for your leadership on disability issues. I know Congressman Ramstad is the Co-Chair of the Bipartisan Disabilities Caucus, and we really appreciate your raising the issues that you raised at this hearing today that are particularly important for folks with disabilities. This year, we celebrated the 15th anniversary of the Americans With Disabilities Act. The goals for that law is how we evaluate public policy: equality of opportunity, full participation, independent living, and economic self-sufficiency. We hold those goals up against the Medicare Program as it currently exists. Oftentimes, the program is not meeting the needs of people with disabilities who want to participate fully in their communities. We have had big fights with Medicare about getting coverage for a wheelchair for people who are able to take one step when they get out of their bed. So, there are a lot of real basic things that people need that Medicare oftentimes fights in terms of being willing to pay for them.

That is the backdrop that we look at as we evaluate the practice of gainsharing. The AAPD is part of a coalition with seniors and health advocates who have some serious concerns regarding gainsharing, many of which have been mentioned; concerns that have to do with the potential of this practice to exacerbate preexisting problems with how Medicare meets the needs of beneficiaries with disabilities. It may harm the physician-patient relationship. It may produce illusory short-term cost savings at the expense of long-term health. It may punish physicians who have developed a specialty practice with an emphasis on higher-cost patients with disabilities and chronic health conditions. In my written testimony I cite two studies that were done recently that document how Medicare is inadequately serving patients currently. There

was a 2004 RAND report on quality of care received by older adults that found that vulnerable and disabled seniors receive about half of the care that would be recommended for people with their conditions. Also, a 2003 Kaiser Family Foundation survey of health experience of people with disabilities found that Medicare beneficiaries had the biggest cost-related problems of all of the respondents who had health insurance. Within this population, almost 70 percent reported going without needed items, such as equipment and eyeglasses. So, that is the backdrop that we look at this new practice of gainsharing.

On the physician-patient relationship, I think we all want our doctor to be our advocate. When a doctor is evaluating what treatment to prescribe, we want the doctor to be using their medical training and making a medical decision that is in the best interests of the patient. Anything that gives the doctor a financial incentive around what they are going to prescribe raises a red flag. I know one of the things that the Inspector General has recommended is disclosure forms, so that patients know if there is a practice like this going on. But I really worry about how that is going to operate in practice. If you are getting that disclosure form as you are checking in for a procedure to a hospital, are you really in a good position to say, "No, I don't like this gainsharing relationship"? Our fear is that it is going to be fine print that a lot of people won't notice. Again, it may affect the trust that the patient has for the physician. On the short-term versus long-term costs, just a basic example is the type of seating that somebody gets prescribed for their wheelchair. It may be cheaper to prescribe a seating system that may result in pressure sores, which could result in longer-term costs down the road. So, really, taking that into account is important.

Last, on this issue of penalizing doctors, there was a reference by the Inspector General to "cherry picking," where patients that are higher cost might get referred to hospitals that don't have gainsharing. We are also concerned about physicians who develop specialties and have a high-cost patient base. We don't want them to be penalized in a gainsharing context. So, I would like to close just by asking questions for the Subcommittee to consider as you look at this issue: Will patients be able to benefit from the latest technology, as Congressman Ramstad raised? What will be the impact on research, development, and innovation, if physicians aren't prescribing the latest technologies? Will people be able to get treatment or devices that are best suited to their individual needs, or will they be forced to select from a pre-approved list from the hospital that may not meet their individual needs? Will people with hard-to-diagnose conditions be obstructed from seeing an experienced specialist because of cost concerns? Thank you again for the opportunity to be here.

[The prepared statement of Mr. Imparato follows:]

Statement of Andrew J. Imparato, President and Chief Executive Officer, American Association of People with Disabilities

Madame Chair, Ranking Member Stark, and Members of the Subcommittee:

Thank you for inviting me to testify at this important hearing. My name is Andrew J. Imparato, and I am the President and CEO of the American Association of People with Disabilities (AAPD), the largest membership organization rep-

resenting children and adults with all types of disabilities in the U.S. AAPD's pursues its mission of political and economic empowerment through programs in the area of public policy advocacy and research, leadership development, civic participation, and mentoring and career exploration.

Prior to joining AAPD, I was general counsel and director of policy at the National Council on Disability, an independent agency advising the President and the Congress on public policy issues affecting people with disabilities. I have also worked as an attorney with the U.S. Equal Employment Opportunity Commission, the U.S. Senate Subcommittee on Disability Policy, and the Disability Law Center in Boston, Massachusetts.

AAPD was founded on the fifth anniversary of the signing of the Americans with Disabilities Act (ADA), and we promote public policies that are consistent with that law's important goals for people with disabilities: equality of opportunity, full participation, independent living, and economic self-sufficiency. As we look at the potential impact of "gainsharing"—the topic of today's hearing—on Medicare beneficiaries with disabilities, we will want to know whether or not this practice will lead to greater opportunity, participation, independence and self-sufficiency for the consumer population.

Based on our preliminary analysis of the potential impact of this new practice on beneficiaries with disabilities and chronic health conditions, we have some important questions for the Subcommittee to consider.

Will patients be able to benefit from the latest technology if doctors feel pressure to use older, less costly options? What impact will changes in physician behavior brought about by gainsharing have on research and development and innovation? Will people be able to get the treatment or device best suited to their individual needs, or will they be forced to settle for whatever the hospital decides to include in its inventory of low-cost options? Will people with hard-to-diagnose conditions be obstructed from seeing an experienced specialist because of cost concerns?

As you know, Medicare is a critical program that serves millions of people with disabilities across the lifespan. Approximately 6 million current Medicare beneficiaries are people with significant disabilities who are under 65. Unfortunately, when Medicare was created, society's expectations for people with disabilities were not as robust as they are today. These artificially low expectations created restrictions in the Medicare program like the requirement that disabled beneficiaries with mobility impairments can only be covered for items they need to get around their home or apartment.

AAPD has worked with other disability and seniors organizations to modernize Medicare so that it is made more consistent with the goals of the ADA. We welcome creative approaches to improve the Medicare program so that it works better for beneficiaries, including efforts to eliminate wasteful health care costs. We believe it is important that reform proposals be assessed so that they do not inadvertently harm patients or jeopardize quality care.

The Wrong Incentives Can Take a Bad Situation and Make it Worse

Last year, RAND issued a report examining the quality of care received by older adults.[1] In their report, the researchers found that vulnerable and disabled seniors receive about half the care that would be recommended for people with their health condition, and that care for geriatric conditions, such as incontinence or falls, is poorer than care for general medical conditions. They also found that physicians often fail to prescribe recommended medications for older adults.

These findings are particularly significant as the Subcommittee examines whether physicians should be given an incentive to reduce the costs of providing care to their Medicare patients. If patients are already being under-treated, do we really want to reward doctors financially for doing even less?

In seeking to explain the reasons why geriatric conditions may get inadequate attention in primary care settings, the RAND researchers noted that medical schools and primary care residency programs may not emphasize the skills needed to diagnose and treat diseases limited largely to the geriatric population. This same concern applies in the diagnosis and treatment of many disabling conditions for people under 65.

When the Kaiser Family Foundation (KFF) did a survey looking at the health care experience of people with disabilities in 2003, they found that nearly half of those surveyed reported that they go without medically necessary equipment and other items due to cost; more than one-third postponed care because of cost; and more than one-third spent less on basics such as food, heat, and other services in

[1] "The Quality of Health Care Received by Older Adults," RAND 2004, available at www.rand.org.

order to pay for health care.[2] Focusing in on the Medicare beneficiaries, the KFF researchers found that among the survey respondents with any type of health insurance, those with Medicare alone reported the highest rates of serious cost-related problems. Within this population, nearly seven in ten reported going without needed items, such as equipment and eyeglasses; 60 percent said they had put off or postponed care due to cost; and more than half said they spent less on basic needs, such as food or heat, in order to pay for health care.

Many of the problems experienced by people with disabilities and chronic health conditions stem from the inadequacy of the Medicare benefits package. When the incentives associated with gainsharing are superimposed on this already problematic situation, my concern is that disabled Medicare beneficiaries will have even greater difficulty getting the health care services that they need.

Harming the Physician-Patient Relationship

In addition to the concerns about gainsharing exacerbating preexisting problems with the quality and adequacy of care being delivered to Medicare beneficiaries with disabilities, I have a parallel concern about what these kinds of financial incentives will do to the physician-patient relationship. People with disabilities and chronic health conditions often have a difficult time finding a physician with the skills and experience necessary to help them manage what are often complex and highly individualized medical conditions. Once a patient finds the right physician, s/he expects that physician to be an advocate for the patient when there are disputes with insurers about what is medically necessary and whether a particular course of treatment is justified over other, potentially less costly, alternatives. If a patient knows that his or her physician has a financial incentive to keep costs down, that knowledge is likely to make it more difficult for the patient to trust that s/he is getting objective medical advice. We should be very cautious about setting up a health care system where the physician comes to be viewed as an agent of the insurer and not as an advocate for providing the best possible care for the patient. Gainsharing raises many of the same issues for disabled consumers as the earlier proliferation of managed care. People with disabilities often ran into serious barriers in getting the right care from the right provider in the managed care environment. The difference in the gainsharing context is that the doctor now has a financial stake in limiting a patient's options.

Short-term Savings can Harm Long-term Outcomes

For consumers with long-term disabilities and chronic health conditions, it is important for the health care system to take a long-term view of how best to help the patient manage their condition. In a gainsharing system that rewards physicians for producing short-term savings, it is unclear that doctors will have the right incentives to take a long-term view about what equipment and procedures will produce the best long-term outcomes for a particular patient. In such an environment, savings may be short-lived and patient health and quality of life are likely to suffer. For example, if a patient with quadriplegia is prescribed a low-cost seating system, that might create short-term savings over a more expensive product, but it can also result in costly future emergency room visits to deal with the ensuing pressure sores.

As AAPD noted in a letter from a range of patient advocacy groups sent to members of Congress earlier this week (a copy of the letter is attached to this testimony), we have a range of other concerns related to how the physician incentives associated with gainsharing will play out for patients.

The letter raises several specific examples of how gainsharing might affect the quality of care patients receive in the context of artificial hips or heart valves, spinal fusions, heart monitoring devices, female Alzheimer's patients, and cancer detection and treatment. And once again, all of these concerns should be viewed in the context of a Medicare program that is already proving to be inadequate in meeting the health needs of disabled and vulnerable Medicare beneficiaries.

There are currently powerful economic forces within the Medicare payment system, which are designed to drive costs down. Moreover, market competition and entities such as group purchasing organizations also force economies. We believe that additional efforts to contain costs should be focused on measuring and rewarding improved quality of care and outcomes as well as efforts to improve system efficiency through electronic medical records and greater use of health information technology. Also, if there are really savings to be realized from changing physician

[2] "New Survey Shows People with Disabilities Face Major Barriers," Kaiser Family Foundation 2003, available at www.kff.org/newsroom/Disability-Health-Coverage.cfm.

behavior, why not allow the Medicare program, as opposed to individual physicians, to benefit from these savings?

Penalizing Physicians Who Serve Difficult-to-Treat Patients

A final concern that I would like to raise regarding gainsharing has to do with how it will affect physician decisions about which patients to treat. Physicians who have developed highly specialized skills and experience may find themselves penalized for having a practice that produces high per-patient costs associated with more expensive diagnostics and care. Although hospitals may attempt to risk adjust in these situations, there is no guarantee that the risk adjustment will be adequate to create a level playing field for physicians that have a particular expertise resulting in consistently high expenditures because of the complex nature of their patients' disabilities. Ultimately, this can create disincentives for doctors to go into certain specialties, and it can create disincentives for general practitioners to agree to treat patients who have unusually complex or chronic health conditions.

Given the concerns that I and other patient advocates have raised regarding gainsharing, I strongly encourage the members of this subcommittee to proceed with great caution as you evaluate whether to encourage the use of this practice in the Medicare program. It is my understanding that limited use of the practice has been authorized by the Office of the Inspector General at the Department of Health and Human Services. I am hopeful that we will study how the practice is affecting patient care in these approved programs, paying particular attention to the quality of care being received by patients with disabilities and chronic health conditions, before taking up the issue of whether the practice should be expanded through new legislation.

Thank you for the opportunity to testify on this important topic.

Dear Member of Congress:

We, the undersigned consumer, patient and health care organizations are aware of various legislative proposals aimed at reducing waste and unnecessary costs in the health care system through the use of "gainsharing" arrangements and by rewarding physicians for their "efficiency."

While we strongly support the need to eliminate wasteful health care costs, we are very concerned about the policies that create incentives to achieve short term savings at the expense of patients and quality care. These reforms could result in the following:

- The doctor-patient relationship could be undermined by creating a potential conflict between physicians' responsibility to provide the best possible care for patients and physicians' economic interests.
- Gainsharing could cause physicians both to forgo a more long-term, holistic approach to patient care in favor of short-term savings, and to view patients as data points.
- Patients may be denied the latest technology as physicians feel pressure to use older, less costly options.
- Research and development innovation could be severely impacted due to lack of physician adoption based on cost, making it even more difficult to bring new research that could benefit patients to market.
- Patients may not have access to the most appropriate treatment or device for their individual needs, due to the hospitals' inventory of lowest cost options.
- Patients with particularly hard to diagnose conditions may be obstructed from seeing an experienced specialist who would provide more extensive (and costly, but essential) tests, procedures and/or care.
- Groups that already suffer from undertreatment of their conditions—women, minorities, and people with disabilities or chronic conditions—may find their situation worsened.
- When translated into actual patient care, we are worried that the following kinds of examples may occur:
- Physicians may choose short-term savings solutions, such as less-expensive artificial hips or heart valves with a 5 year life expectancy versus a 10 year life expectancy, to receive a financial incentive.
- Patients requiring spinal fusion may only have access to the low-cost option of Allograft Bone products (which offer a limited choice of shapes and sizes), even though alternative, albeit more expensive, products offer an extensive range of sizes, angles, shapes and strengths to meet individual patient needs.
- For patients with Congestive Heart Failure, new medical devices are available which measure fluid levels in patients' chests, helping to prevent or minimize edema. However, these devices are more expensive than traditional devices and

specialized implanting physicians have no incentive (in fact, they have disincentive) to implant the newer, improved, and more expensive devices.
- Female patients may be disproportionately impacted, as much of the new research and technology focused specifically on women has occurred in recent years. New information about the role gender plays in Alzheimer's disease may never reach patients if physicians are unable to justify the cost of understanding the differences of the disease in men and women.
- Cancer patients may be negatively affected from initial discovery of their disease thru treatment. Improved technology allowing oncologists to provide earlier, unequivocal cancer diagnoses could have a major impact on individual patient outcomes, but only if the medical environment continues to encourage research and development. Treatment breakthroughs in radiation therapy, such as brachytherapy and IMRT (allowing for more targeted radiation therapy) may be overlooked for older, less-expensive options.
- Highly specialized, experienced physicians may be most negatively impacted by physician profiling, as they are more likely to be involved with high risk or special needs patients, who require more expensive diagnostics and care. A specialist certainly couldn't compete with the "cost-savings" score of, for example, a family physician.

We are deeply concerned about the consequences of legislation establishing gainsharing or "efficiency" standards for physicians. Before any legislation is enacted in this area, there should be a full and open consultation process with patient advocacy organizations, as well as experts in the field.

Sincerely,

American Association of People with Disabilities
Alliance for Aging Research
Families USA
Family Voices
Kidney Cancer Association
National Association For Continence
National Disability Rights Network
National Mental Health Association
National Spinal Cord Injury Association
Parkinson's Action Network
Prevent Blindness America
Society for Women's Health Research
United Spinal Association
WomenHeart

Chairman JOHNSON. Thank you, Mr. Imparato. Dr. Rich.

STATEMENT OF JEFFREY RICH, M.D., CHAIRMAN, THE SOCIETY OF THORACIC SURGEON'S TASK FORCE ON PAY FOR PERFORMANCE, NORFOLK, VIRGINIA

Dr. RICH. Thank you, Madam Chairman Johnson, Ranking Member Stark, and Members of the Subcommittee, for inviting me to testify on behalf of the cardiac surgeons about gainsharing and aligning incentives for quality improvement and cost savings. I am the Chair of the Virginia Cardiac Surgery Quality Initiative, an organization that has been restricted by current laws in our attempt to advance quality improvement. We support the intent of these laws, but believe their broad interpretation has led to the stifling of innovation in health care delivery and payment. Finding a balance between these two goals will be critical as we move forward with value-based purchasing; for in this difficult budget environment, incentives for these programs can come from the sharing of savings between hospitals and physicians that stem from improvements in quality. It is critical that we make a key distinction between two types of gainsharing. The common model of gainsharing that many are discussing today occurs through the coordination of

supply-based purchasing to manage resources and create cost savings that are shared with physicians. This model can be appropriate with routine items used in care delivery where quality is not significantly impacted by the choice of supplies. We must be careful, however, not to impede access to advanced technology and devices where clinical indication and quality are critical.

The other model for gainsharing is very different. We believe this is the model on which the future of value-based purchasing will be built. This is the model that I will refer to as "quality sharing," because improved quality is the primary factor that drives cost containment. While there is debate regarding the benefit of purchasing decisions, there is no question that reducing complications is best for patients, can lower costs, and can be fostered through quality sharing. Quality sharing does not create incentives to use inexpensive but sub-optimal supplies. It refers to the savings that accrue from improving quality of care. The Virginia Initiative has tested this model, and we believe we can now achieve and quantify cost savings associated with quality improvement, as I noted in my testimony before you in March. In 2002, we proposed the CMS demonstration that would achieve savings by the sharing of data between hospitals and physicians on outcomes, costs, and best practices. The purpose was to show how we could simultaneously improve quality and reduce costs in cardiac surgery by aligning incentives for physicians and hospitals. Payments to surgeons were to be adjusted based upon the outcome of their patients. A portion of the savings was to be returned to CMS. Secretary Thompson announced approval of our project in 2003. The CMS issued strong statements in support of it. In July 2004, CMS advised us that our quality improvement demo was in violation of Federal law. The OIG maintained that a redistribution of a global payment by the hospital with incentives for performance violated "Stark" regulations and civil monetary penalty laws, despite quality controls, accountability through public reporting, and monitoring of referral patterns.

The project was effectively terminated due to broad interpretation of the current statutes. Our work in Virginia now forms the basis for a proposed Medicare pilot program yet to be approved by Congress. The STS seeks to establish a national program whereby we reduce complications from cardiac surgery for all Medicare beneficiaries, while potentially saving the program hundreds of millions of dollars annually. We will accomplish this by combining our National cardiac clinical database with the Medicare part A claims database, to determine exactly the level of quality that is being delivered at each site, and at what cost. We will improve outcomes, reduce costly complications, Achieve savings. Under our pilot program, cost savings will occur from improved outcomes. The majority of these savings accrue to the hospital, but some is also returned to CMS. However, without changes in existing laws, none of the savings will go to the surgeons who bear the responsibility for achieving them. This is why restrictions such as the "Stark" CMP laws must be reexamined to allow and encourage quality-focused cost containment. The laws should allow the sharing of Parts A and B savings with the hospital and the physicians who create these savings, as long as quality improvement is demonstrated.

Shared savings are one way to help finance value-based purchasing programs.

Can quality sharing offer a solution to the health care financing crisis? Most definitely, but it will require the approval of the shared savings models that are quality-focused, patient-centered, and safe. Current laws have stifled innovation in health care reform and prevented the implementation of some of these more unique programs. Perhaps it is time for a change. Physicians, hospitals, and device manufacturers are striving for ways to simultaneously protect beneficiaries, improve quality, and reduce costs. I am here to tell you that we have shown that it is possible. All we need is trust granted us by the government, to allow us to create these models of care delivery and realize these shared goals. Thank you for your time this morning.

[The prepared statement of Dr. Rich follows:]

Statement of Jeffery Rich, M.D., Chairman, The Society for Thoracic Surgeon's Task Force on Pay for Performance, Norfolk, Virginia

Good morning Madam Chairman Johnson, Ranking Member Stark, and members of the Subcommittee. Thank you for inviting me to this hearing on gainsharing and to discuss our experience with sharing incentives between Medicare parts A and B to improve the quality of care for Medicare Beneficiaries. My name is Jeffrey Rich. I am Chairman of the Society of Thoracic Surgery (STS) Taskforce on Pay for Performance. I am also the Chair of the Board of Directors of the Virginia Cardiac Surgery Quality Initiative (VCSQI) an organization that has felt the implications of current laws in attempting to advance quality improvement.

The term gainsharing can carry a negative connotation to patients, providers, industry and even some in Congress. This has occurred as a result of the perception that gainsharing works explicitly to reduce choice and services to patients in an effort to save money through the sharing of these dollars with physicians. Congress enacted legislation to protect populations at risk against some gainsharing activities, and we support the intent of these laws. As we will discuss, the broad interpretation of these laws, however, has led to the stifling of innovation in healthcare delivery and payment reform. We fear that this may continue. In the current healthcare financing crisis as stakeholders attempt to craft potential solutions, it has become apparent that Pay for Performance leading to Value-Based Purchasing has ascended to the option of choice. It has also become apparent that these proposals, including the Chariman's H.R. 3617, the Medicare Value-Based Purchasing for Physician Services Act of 2005, will utilize incentives for achieving measures of economic efficiency, translated as cost savings. Money to finance these programs will almost certainly come in part from the sharing of Part A/B savings that result from physician's improving quality. These incentives may first be shared between CMS and physicians and ultimately between physicians and hospitals as the savings potential is greatest on the Part A side. Proper interpretation and application of current Stark and CMP laws or modifications of them will be decisive in their success.

Gainsharing—or Qualitysharing

It is critical that we make a key distinction in our discussions of "gainsharing" arrangements. Much like Pay for Performance, which is in a rapid evolutionary phase, gainsharing can have a variety of meanings to different people and we must be certain that we understand the intended definition as we discuss health policy and legislative action. Two types of gainsharing need to be understood and considered *separately* in order for us to move rapidly towards innovative payment reform. The first is perhaps the most commonly understood which is coordination of supply-based purchasing to manage resources and create reduction in costs. This model can be appropriate with routine items used in care delivery such as gloves, masks, intravenous tubing, and other medical supplies where clinical indication and outcomes are not significantly impacted by the choice of supplies. This model, however, can impede a very critical component of high quality care, and that is access to advanced technology and devices such as heart valves and artificial joints. It is essential that gainsharing arrangements not restrict the physician's choice of the most beneficial clinical device or treatment solely on the basis of cost. Additionally, gainsharing agreements that promote buying consortia for advanced technologies are acceptable but must provide equivalency in outcomes related to the use of the

product and include the proviso that providers continue to have access to clinically appropriate alternate products which may be considered superior.

The other model for gainsharing is very different, and we believe this is the model for the future of P4P with the potential for savings of a much larger magnitude. This is a model that I will refer to as "Qualitysharing" because quality must be the primary factor that drives resource utilization management and cost containment in healthcare through the development of cost savings models.

We know that medical complications lead to a higher cost of care because complications are linked to prolonged hospitalization and increased use of diagnostic and therapeutic interventions. As I demonstrated in my testimony here in March, the highest quality hospitals in our project were also those with the lowest costs. As quality increases, complications—and therefore costs—are decreased. Qualitysharing refers to the savings that accrue from improving quality of care.

Qualitysharing does not create incentives to use inexpensive but suboptimal resources. The quality of care is ensured through careful development of the models and is measured prior to the sharing of savings. We believe that qualitysharing can appropriately align incentives between physicians, hospitals, and CMS to improve the quality of care for all Medicare beneficiaries leading to reductions in costly complications, the creation of quality guided resource utilization, and the achievement of sustained savings. This should be the "Holy Grail" of Value-Based purchasing. It will, however, require the development of physician incentive programs that allow in the sharing of savings generated by these QI efforts, a concept quite different from the currently perceived gainsharing arrangements.

VCSQI Demo

I'd like to explain how "Qualitysharing" would have worked through our experience, and why it ultimately was prevented from moving forward by the Civil Monetary Penalty Laws and, with no offense to the Ranking member, "Stark" laws.

In 2000, we had proposed a demonstration program that would achieve savings through hospitals and physicians sharing data on outcomes, cost, and best practices. The purpose was to increase quality and contain costs in cardiac surgery statewide in the Commonwealth of Virginia through an initiative called the Virginia Cardiac Surgery Quality Initiative (VCSQI).

The VCSQI is a voluntary consortium of 16 hospitals and 10 cardiac surgery practices providing open-heart surgery in Virginia. Hospitals include four multi-hospital systems (one for-profit), two state university medical centers, and 6 regional medical centers and community hospitals. They perform 99% of Virginia's open-heart procedures. The VCSQI was established through a grass roots, self funded effort in 1996 with a mission to improve the quality of cardiac surgical care on a statewide basis, contain healthcare costs, and test reimbursement methodologies that reward quality improvement. It sought to demonstrate that an inclusive collaboration between hospitals and physicians would improve clinical outcomes across an entire state in programs of all size through the sharing of data, outcomes analysis, and process improvement driven by use of the Society of Thoracic Surgeons (STS) National Cardiac Database. Its cost containment goals were to occur through the creation of a unique IT platform, a database linking clinical and financial outcomes. The VCSQI's intent was to demonstrate that through a focus on quality, cost containment in cardiac surgical care could be achieved through a reduction in complications, improved efficiencies of care and reduced resource utilization driven by explicitly defined savings models.

The VCSQI in conjunction with ARMUS Corporation developed a unique clinical/financial IT platform. Clinical data from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery database was mapped with financial data from standardized hospital (Medicare Part A "UB–92") claims files. These Part A, UB–92 files were further refined by organization of 239 ICD 9 revenue codes into 21 Revenue Categories to allow more definable hospital-to-hospital comparisons. Hospital specific Medicare defined Ratio of Cost-to-Charges (RCCs) were then applied to the charge driven UB–92 record to normalize charges and create applicable cost profiles. Tracking of the financial impact of quality improvement was, and currently is possible and forms the cornerstone of many current VCSQI QI initiatives. A business case for quality has been developed within the state.

In March 2000 an application to CMS for a demonstration project (Demo) entitled "Statewide Quality Focused Global Pricing for Cardiac Surgery" was submitted. The 3 year project was to combine Part A and B payments into a single hospital specific global payment for cardiac surgical DGRs, and would allow payment redistribution at the local level based on physician performance as measured by quality metrics. The intent was to create financial incentives for meeting quality goals tied to clinical performance in open-heart surgery. The demonstration was designed to align

clinical and financial incentives between hospitals and physicians while elevating the standard of care and reducing costs. On the physician side, it provided a method for physicians to remove themselves from the much-maligned Resource-Based Relative Value System (RBRVS) through the use of Pay for Performance models. For CMS, there was potential to reduce financial risk (outliers included), stabilize payments for costly procedures, and reduce administrative costs (simplified billing). On the hospital side there was the potential to increase profitability by the application of explicit savings models aimed at reducing resource utilization while always maintaining a focus on quality. Patients benefited from statewide access to high quality care and a single co-pay.

In early 2001, the VCSQI Demo application was introduced to Secretary of Health and Human Services (HHS) Thompson who immediately was in support of the project. Subsequent meetings with CMS Administrator Scully and the Division of Demonstration Projects at CMS occurred. Concurrent with these efforts the Institute of Medicine (IOM) had issued its report on "Crossing the Quality Chasm" which described exactly the VCSQI efforts to improve quality and "better align current payment methods with quality improvement". Additionally on April 12, 2001 Reuters Health announced "upcoming White House efforts to reform Medicare are likely to include financial incentives to hospitals and doctors who successfully—improve the quality of care".

The VCSQI project gained tentative approval at CMS in March 2002 and final approval in November. Secretary Thompson announced approval of the project to a standing ovation at the STS annual meeting in January 2003. The project was temporarily derailed when budget neutrality as defined by the Office of Management and Budget included a post-acute care component that placed hospitals at-risk for financial losses occurring beyond the hospitalization discharge DRG. An acceptable risk model was eventually developed and the VCSQI hospitals and physicians began an intense implementation design for the project while the project was under review at the Office of the Inspector General (OIG). Simultaneously, CMS was describing this project's ability to "achieve savings for the Medicare program through increased efficiencies and, in the longer term, reductions in complications" and stating that "the global payment will align financial incentives of hospitals and physicians and give providers flexibility to allocate resources as they determine appropriate". In July 2004 CMS advised the VCSQI that the Demo payment incentive plans would be a violation of federal law. The Department of Justice maintained that redistribution of a global payment by the hospital with incentives for performance violated Stark Regulations and Civil Monetary Penalty laws. Although told to proceed if desired, it was in the context of the statement that the VCSQI "would be in violation of the law but the department would not prosecute". Furthermore, we were simultaneously advised that any other entity could file civil suit. This was occurring in the same timeframe that a group of hospitals in New Jersey followed similar advice and had their project halted by court order. This directly led to the VCSQI hospitals and physicians collectively deciding not to pursue any further efforts to implement the project. Despite widespread support from HHS, CMS, and the entire state of Virginia, and in line with IOM directives, a project that appeared to have "all the right stuff" was dismantled by a federal agency.

Since that time additional voices have weighed in about the value and efficiency of reducing the artificial barrier between Parts A and B for some services. In a letter dated December 30, 2004 from MedPAC Chairman Hackbarth to Vice President Cheney, he described the global payment model as a solution to payment reform whereby "the quality of a surgery and its related pre—and post-surgical care could be measured as a whole; and the hospital and surgeon would be held jointly accountable. Combining hospital and physician payments would make it possible for Medicare to reward good quality outcomes directly, and leave it to the participants in the care to divide the reward among themselves." The VCSQI model exactly!

Since the undoing of the VCSQI demo, Dr. David Brailer at the then newly formed Office of the National Coordinator for Health Information Technology had a high profile IT projected in metropolitan Chicago halted by OIG on grounds of violation of Stark Regulations. At this point red flags should be flying high for any private or government agency wishing to embark on Pay for Performance or any other payment reform methodology. An important solution, I believe, will be for Congress to create carefully crafted leeway in the Stark and CMP rules to remove barriers to implementation for similar projects. Exceptions are needed that protect patient choice and quality of care, yet still align incentives to accelerate quality improvement, reduce costly complications, and develop patient centered, safe cost savings models, all of which will work to achieve significant savings in healthcare costs.

Future STS and VCSQI Initiatives

Where does that leave the VCSQI? VCSQI remains a collaborative effort actively improving quality on a regional basis. In fact we are leading the private P4P effort. We have entered into agreements with the largest private insurer in the state, Anthem BC/BS of Virginia, to utilize our STS quality data in a private P4P program. We hope to continue to be a test bed for policy formulation/ payment reform in cardiac surgery with a model that can be replicated nationally. Our collaborative will continue to address the quality/ cost relationship in an attempt to achieve cost containment through a focus on quality.

In fact, the VCSQI is the basis for a national pilot program that the STS has submitted to Congress entitled "Quality Focused Cost Containment in Cardiac Surgery for Medicare Beneficiaries". It is a national program designed on the Virginia model with a blended STS clinical and Medicare UB–92 financial database. It will focus on quality improvement through the creation of regional collaborations that will share data and develop and share national best practices. Clinical performance will be based on the National Quality Forum National Voluntary Consensus Standards for Cardiac Surgery, a project that the STS was instrumental in bringing to fruition. Cost containment will occur through the reduction of costly complications and the development of cost savings models using quality guided resource utilization management and measures of efficiency that are patient centered and quality focused. Through this mechanism we hope to achieve significant and sustainable reductions in Medicare healthcare spending. Implicit will be the need to provide performance-based incentives to physicians that are meaningful and can drive change. This will require the sharing of Part A/B savings with CMS and hopefully between hospitals and physicians consistent with the principles outlined previously for "QualitySharing". We hope that CMS and Congress will join us in another attempt to improve quality for Medicare beneficiaries while reducing costs and ask respectfully for relief of the legislative and regulatory barriers that we have encountered previously.

The Future of quality improvement without incentives

This debate is really about where to locate incentives to accelerate quality improvement in health care delivery. However, it is impossible to have this debate without some suggesting that physicians ought to improve quality without incentives, but rather because it is what they do. I agree with those sentiments. I think the same ought to be true of hospitals and device manufacturers and purchasing consultants, but that is not the reality that we are living in today. The STS has some strong feelings on this central topic that I must share with you.

Through our STS National Cardiac Database cardiac surgeons have improved quality by dramatically reducing mortality in open-heart surgery. These reductions in operative mortality were achieved in the face of dramatic progressive increases in the risk and acuity of our patient population.

In the last two decades, the STS has taken the lead in objective, data-centered quality improvement on a national level. We will continue to do so with the resources available, but I must emphasize that:

1. **Quality Improvement requires significant investments in time and money.** The much sicker patient population mandates increased resources to provide safe care. The well-recognized quality improvements associated with IT require significant capital investments. The STS Database itself is an unfunded financial burden on an already strained system. We can improve quality and we can reduce costs, but we can not continue to do while the government continues reduce our payments and undervalue our services.
2. **Our financial resources are greatly diminished.** We improved quality over a period during which our Medicare payment rates were cut by over 50%, and while our practice costs skyrocketed. Unfortunately, a major consequence of these payment cuts has been an unsustainable reduction in applicants to our specialty and the early retirement of a large portion of our workforce. One third of our residency programs did not fill this year. This is occurring at a time when the population ages and the potential pool of Medicare beneficiaries in need of cardiac surgery is expanding rapidly. By our estimates, we are on the verge of an access crisis in cardiothoracic surgery—the specialty that treats the top six causes of death in the country. Under the current payment system you may witness the slow death of a specialty that quite literally none of us can live without. The STS believes that under "QualitySharing" agreements meaningful incentives can and should be provided to reverse this trend.

Furthermore, there is a related problem that now serves to prevent cardiothoracic surgeons from continuing to improve quality and achieve cost savings. As the IOM

has pointed out, in high-risk surgery such as open-heart surgery, having a consistent team in place in the OR is a key to quality. Cardiothoracic surgeons currently employ such a team and bring those team members to the hospital to give clinical assistance. In 1999 CMS decided to remove the payment for these clinical staff from the practice expense calculations. Very rarely do hospitals pay for such a skilled team, and Medicare no longer will. In fact, we have recently seen examples of hospitals charging the surgeons to bring clinical staff to the hospital! This is a direct barrier to our ability to improve patient outcomes, is counter to the IOM recommendations, and more to the point, is directly in violation of the BBA '97 language on practice expense.

Rather than compromise the quality of care, most CT surgeons continue to employ these clinical staff at their own expense, and again the costs are borne not by Medicare, not by hospitals, but by the surgeons—who have no opportunity to share in the savings these staff generate. For most, the improvement in lives saved is enough compensation, but the cost of $50 to $100 million per year of uncompensated expense in this specialty has further decreased reimbursement making the specialty less attractive to trainees and has furthered the reduction in applicants. "Quality Sharing" would allow incentives that may once again maintain consistent teams for high quality care in cardiothoracic surgery.

Current and future implementation potential

It is important to highlight that not all physician groups can presently achieve quality-based savings. It requires the development of a set of the most clinically relevant specialty performance measures that must be vetted through the consensus development process at the NQF as we have done with our NQF approved cardiac measure set. It requires a database of clinical data mapped into Medicare claims data with a high match rate. It requires not only process measures but also outcome measures that use scientifically validated risk adjustment. And it requires the will and determination of physicians, hospitals, data managers, and Government. Most importantly, it requires the creation of shared savings models that provide meaningful incentives to create change. I must say CMS has been a tremendous asset to us, with intelligent and well motivated people sharing our goals of striving for ways to improve quality and simultaneously reduce costs. I am here to tell you that it is possible, all we need is trust granted us by government to create these models of care delivery and realize these shared goals.

Since it is the goal of the Congress and CMS to one day have all physicians electronically submit clinical data on their patient encounters through EMRs, it is important that we undertake pilot programs now with those who are prepared. Credible models must be developed prior to implementing these payment systems for all physicians in the future.

QualitySharing: the New Metric

In conclusion, the STS and its regional collaborations such as the VCSQI have been involved in QI for the past 15 years. These improvements have occurred in an era of declining reimbursements and without incentive payments primarily because we feel that this is our professional responsibility. I personally feel that the greatest privilege society has given us as physicians is the ability to care for patients. But on behalf of all physicians, as perhaps the primary drivers of quality improvement, and hence health care savings, I must ask a central question about gainsharing. Why should physicians, who drive much of the "gain," be the only group excluded from the "sharing"?

In the current healthcare financing crisis, the STS now realizes that our next greatest responsibility is the delivery of high quality care in a fiscally responsible manner. Is traditional gainsharing a partial solution? Possibly, if done properly. Is "QualitySharing" a more complete solution? Most definitely, but it will require the development of shared savings models that are quality focused, patient centered and safe and that will hopefully lead to reductions in healthcare expenditures and the stabilization of the Medicare Trust Fund. To date, current laws have stifled innovation in healthcare reform and prevented the implementation of some of these more unique programs. Perhaps it is time for a change. "QualitySharing" appears to be the right thing to do, at the right time, and for the right reasons.

Thank you for this opportunity and your attention this morning.

Chairman JOHNSON. Thank you very much, Dr. Rich. I have basically two questions that I want to bring to people's attention. Mr. Emerson, in your testimony you clearly state what others have

raised concerns about; that gainsharing could have an especially negative impact on small companies and could eliminate important choices for doctors and patients. You go on to state that gainsharing would place an additional barrier to the adoption of smaller companies' devices, and would create an anti-competitive marketplace where the largest manufacturers would have a significant advantage. Now, isn't it true that in today's world hospitals negotiate with device manufacturers and agree and develop purchasing contracts where larger device companies provide reduced prices to hospitals that promise 70 to 80 percent of annual revenue from device-related procedures; that 70 to 80 percent of the annual revenues will go directly to that company's devices? Aren't there a lot of things going on right now between device manufacturers and hospitals that are clearly barriers to smaller companies getting their devices onto the market, clearly barriers to competition?

Mr. EMERSON. Madam Chairman, I would agree with your statement. But I would draw one clear distinction between an era of gainsharing as it is currently being discussed, and the era that we live in today. What we live in today as a small company is, yes, we have significant hurdles in front of us; but when we bring innovation to the market, we always know that we can count on physicians to be an advocate for that technology. The concern I would have in an era of gainsharing is that we have put the physician on the other side of that advocacy equation. As we move forward as a small company trying to bring innovation to market, who at a hospital will we find that we can hope to look for a friendly ear, who will be looking to advocate for patient care and new technologies? Certainly, we have competitive issues today; but the competition, in and of itself, is not bad.

Chairman JOHNSON. Well, it is these controlling contracts that I think are very concerning. If 80 percent of the revenues from device-related procedures will be directly tied to the use of that company's devices, you have really closed a lot of the market to any other competitor, large or small. But the other thing I wanted to mention, too, is in terms of the doctor being an advocate, unfortunately, we are seeing more and more evidence that the doctor is an advocate because the doctor gets a cut. So, we can't answer this one way or another. I know you don't condone that, but I think to notice that the way devices are marketed now does not assure either physician choice or patient choice—nor does it assure easy access for small, innovative companies—is important. You know, the heart of this matter is exactly what Mr. Imparato said. The heart of this matter: Is this going to be a more doctor-centered system, or a less doctor-centered system? Is it going to increase the voice of physicians in the running of hospitals? Now, when I sat with Mr. Carter's people, doctors and others, at first the doctors didn't believe this was going to give them any more. So, I want you to talk about—those of you who have tried it, Dr. Rich Mr. Carter Ms. Goodroe, who have had experience—at first, doctors are suspicious. At least, that has been my experience.

You have been in this a long time, Dr. Rich, over many years now. What happens? Why is it doctors change their attitude? What happens afterward? What are the systems consequences of the attitudinal changes that take place, when you really can work together

for quality Cost, but cost is secondary to the quality changes that take place? Now, that is my impression. So, I want you to either affirm or deny. Don't feel uncomfortable denying. Remember, my knowledge is about as big as a thimble. So, why don't we start from the left. Ms. Goodroe, would you comment on this issue of systems change in quality and doctor control? Because that is at the heart of this whole thing.

Ms. GOODROE. There is a lot of misunderstanding when people think that the technology is going to be withheld. If anything, the opposite happens. What you have are physicians finally, under these economic arrangements, physicians working together to look to see what is the best quality. Then, how do you apply costs to that? How do you figure out how to get the physicians all going in the same direction to get the best quality? That turns around to be less cost. So, it is not about not putting in something. Matter of fact, there is no reward if you don't put in an internal defibrillator that we heard earlier. A defibrillator would be that you would look at the options of the types of defibrillators you would put in. Is it right to put in a single chamber versus a dual chamber that has a huge price difference? Then, you have a lot of different vendors. So, it is not about ever the technology not being available. There is no reward for that, whatsoever.

Chairman JOHNSON. Mr. Carter?

Mr. CARTER. Madam Chairman, we actually have seen a tremendous amount of collaboration between the physicians and the administration. I think what happened, as you found when you visited our State, there was a concern: what was the agenda? But once we explain we are trying to improve the quality of care through discussion about the way in which we are doing it—as Ms. Goodroe said, at the beginning, your physicians are trained by a variety of different teachers; have different techniques of doing things. The whole staff could be trained by different physicians and all have a unique way of doing it. Once we got together and talked about a better way of doing it from a scientific standpoint, there was great collaboration. We weren't allowed to proceed, because of litigation, but there is still interest in improving this by working together.

Chairman JOHNSON. How did you select medical devices? You say in your testimony that it was an evidence-based selection and purchasing process.

Mr. CARTER. What we did was, we brought together the physicians and asked them what was the best approach to this. It wasn't a CEO-driven issue or a CFO-driven issue. It was the physicians talking about what they thought was the best technique for the patient.

Chairman JOHNSON. Could they have a range of choices?

Mr. CARTER. Yes.

Chairman JOHNSON. If they decided they wanted something that wasn't on the shelf, could they get that?

Mr. CARTER. Yes.

Chairman JOHNSON. They were not in any way dinged, in terms of their payment, if they used devices that were not part of the original plan?

Mr. CARTER. Well, again, it was all outcome basis. So, with the patient, if there were no complications and they were discharged in a timely fashion, then there was no ding, as you call it.

Chairman JOHNSON. Yes. I meant to bring this up earlier, because a big point was made of how voluntary this is, both on the institution's part and on the doctor's part; that is very important; That you can come in or you can go out, You have control over that. But in terms of payment, are the doctors all paid the same?

Mr. CARTER. I honestly cannot remember how they were done. I think it was individual-based, but I can't remember for sure. Can I just turn around and look at somebody?

Chairman JOHNSON. Yes.

[Pause.]

Mr. CARTER. It was individual-based.

Chairman JOHNSON. Okay. Dr. Rich?

Dr. RICH. For us, collaboration with the hospital has been incredibly important. I will speak from my own personal experience at Sentara Health Care, where we put together collaborative arrangements between cardiologists, cardiac surgeons, The hospital administrators a decade ago. The focus of those collaborations was, and always will be, quality improvement. It was designed to bring people together to continue to improve quality, with the realization that by improving quality we could reduce complications and potentially save money for the system. We used that model in the private sector, and had enormous benefit from it. We had no restriction to any technologies. The determinations of the results of the program on quality and on the financial side were all done at the programmatic level, so no physician was ever stopped from using any technology. Every technology was available. There were, of course, groups put together that looked at perhaps picking three valves, or three devices that would be the preferred devices; but never any restriction beyond that in terms of being able to obtain technologies.

Chairman JOHNSON. But what you were able to do in the private sector, you were not able to do in the public sector?

Dr. RICH. No. This is just a model that we used for our demonstration project. Basically, the restrictions were put on us through these current laws that said that any redistribution of payments—in our payment mechanism, there was a pay-for-performance mechanism that we developed with variable payment rates to physicians Surgeons. We went at-risk as well as at-benefit, so we could potentially reduce our payments on any annual basis. The problem was that the interpretation of the law said that one penny above our medical allowable charge in an incentive program violated these laws.

Chairman JOHNSON. Right.

Dr. RICH. Despite focusing on quality, providing absolute improvement in quality, monitoring of quality, and accountability through public reporting.

Chairman JOHNSON. Okay. Those of you who have had experience in this, we have a premiere hospital demonstration that is electing to meet a far greater number of quality criteria—I think it is 62, or something—than the 12 required under the law. We are looking to see what are the consequences of this. What we are find-

ing is that there is a dynamic that happens when you reach the 62 that doesn't happen when you reach the 50. A dynamic that results from closer collaboration, mutual respect, broadening of the team, so on. So, are you seeing that? Can you measure that, Ms Goodroe?

Ms. GOODROE. That is exactly what you are seeing, is a collaboration between hospital and all the different physician colleagues. Right now, everybody is working very independently, on their own. These types of economic alignments bring all physicians together, and the hospital together with the physicians. It is all based on data, looking, discussing things; instead of people doing the things they think work best, which may get a quality outcome but you are going to have a huge cost differentiation, and that is why there is so much waste in the system right now.

Chairman JOHNSON. So, you actually can measure specifically what they are doing? For instance, if they get together and discuss the way one person is working, another person, what the protocols are in that discipline?

Ms. GOODROE. Yes. I will give you an example. Every surgeon sutures differently. They use different lengths, types, everything. Now, those are $1, $5, $10 items that can cost millions of dollars at the end of the year. They will sit down and discuss, "Well, why do you suture that way? Why do you suture this way? What is good about this? What is the best way?"

Chairman JOHNSON. They never did that before?

Ms. GOODROE. Never. It is not in the literature. They have never discussed it. It is truly in this very artistic way the physicians have practiced.

Chairman JOHNSON. Yes, Dr. Rich?

Dr. RICH. Yes. We did exactly that. I would say, you know, we talk about standardized treatment protocols; we developed within the system standardized practice protocols. Those are exactly as Ms. Goodroe described. Tracking quality and tracking outcomes is important, and we do this through the Society of Thoracic Surgery database. We blended it with the UB-92 database, the Medicare claims database, so that we can actually look at the impact on quality.

Chairman JOHNSON. Let me call myself to a halt, because I am over my time I want the others to have a chance before we have to adjourn at 12:00. But both of you have databases. I think I have to point out from your testimony that the burden of these databases is almost greater than any one organization can bear. That is another reason why you really have to have collaborative efforts. But technology and measurement are at the heart of what you have been able to do. Mr. Stark.

Mr. STARK. Thank you, Madam Chair. Dr. Rich, have you ever opened a bag of charcoal briquettes?

Dr. RICH. Yes, sir.

Mr. STARK. You know if you pull that string, sometimes, if you get the right string, the whole top comes right off, and if you don't get the right string, you sit there and pull? Can you assure me—I can't look at my latest wound here in public, but can you assure me that they never used those stitches on me?

Dr. RICH. Yes.

Mr. STARK. Okay. I feel much better. I will pull on this string.
[Laughter.]
Mr. STARK. Actually, I want congratulate the thoracic surgeons.
Dr. RICH. Thank you.
Mr. STARK. In pedestrian parlance, you were back here in March, suggesting to us that, while you thought pay-for-performance had its good qualities, we weren't ready for it yet. I think I am going to hark back to your testimony. This excludes the thoracic surgeons, but for the most part, most specialties don't have the database, the outcomes research that your specialty has built up, I think over the last 5 or 6 years—which may be long enough or not. But I think what you indicated is that we need more information More database to effectively do pay-for-performance. I am further advised, or guess, that the anesthesiologists may be the one other specialty besides the thoracic surgeons. This was to defend themselves from malpractice, but I don't care why. But at any rate, they have gathered a great database on anesthesia procedures that they have found have saved lives and been more efficient as they worked on this. Is it fair to suggest that there aren't any—at least, I am unaware—specialties, procedural specialties, that have done as advanced research and building a database as you and the anesthesiologists?
Dr. RICH. Actually, the cardiologists have a very sophisticated database.
Mr. STARK. That is separate? That is different from thoracic?
Dr. RICH. Yes.
Mr. STARK. Okay. But don't we need that across the procedural specialties to really accomplish any kind of measuring of quality? Don't we need to collect more and more sophisticated and detailed databases and outcomes research?
Dr. RICH. Yes. Absolutely.
Mr. STARK. Thank you. That, I think, is key. Also, I want to congratulate you. Again, in your testimony, slipped in here someplace, you suggest that you think that it is impossible to have this debate that we are having today without some suggesting that physicians ought to improve quality without incentives, but rather because it is what they do. I think that is a very good statement, because I notice that Ms. Goodroe suggests that there is no incentive for physicians to change their practices. I just go down the list, other than dollars: professional recognition; pride; successful treatment of patients; psychic remuneration; for those of you who care, under this faith-based Administration you get brownie points from Saint Peter. All kinds of incentives out there.
[Laughter.]
Mr. STARK. So, I would just like to suggest that there are incentives other than dollars. Then I would like to talk with Mr. Carter and Mr. Fine. I was up early this morning reading "Pig Will and Pig Won't." I suspect, unless your children are very small like mine, you haven't read "Pig Will and Pig Won't" lately. You can skip it. But you guys remind me of that, because both of you in your testimony say—Mr. Carter says, "Finally, while specialty hospitals don't exist in New Jersey, the New Jersey Hospital Association does not view the implementation of this project as a reason to lift or ease current efforts to implement a moratorium on spe-

cialty hospitals." Mr. Fine, you suggest that you don't substitute action in this area for the much-needed ban on physician self-referral to limited-service hospitals. Gentlemen, we don't have time in my allotted time, but I am going to submit to you that there is no difference; that this gainsharing is just the camel's head going into the tent of specialty hospitals. The only difference is a matter of degree. Some legal basis to make that statement is that if we allowed the gainsharing, we would just open the doors to specialty hospitals, and for general acute care hospitals this could be financially disrupting. I am one to say that is up to what the hospitals want to do. I am not going to tell you how best to organize. But I just want you to think carefully. I mean, I would want to get the savings back for Medicare that you guys think you would get, and not let you give it to the doctors. You don't like that idea. But the other side of it is, you may just open the floodgates to specialty hospitals, because there isn't much difference. It is only in degree Intensity. So, go back and think about that with your members and colleagues, Think how much you really want to share all these savings with the docs. I yield back.

Mr. FINE. Well, may I offer a comment concerning that?

Mr. STARK. Oh, sure. I would love to hear it.

Mr. FINE. I believe my comments spoke not only about limited-service hospitals, but limited-service providers. In my region in southeastern Pennsylvania, we have a vast number of private endoscopy centers, private imaging centers, things of that ilk. We, like in Mr. Carter's state, do not have specialty hospitals of the types referred to.

Mr. STARK. Right.

Mr. FINE. We certainly have rehab hospitals like Children's Hospital.

Mr. STARK. But Mr. Fine, it is the same thing. It takes the high-profit, high-margin services out of your members' hospitals, and sets them over here where there is more profit to be made. That is profit that you have to use in cost shifting to pay for the emergency room or whatever is the least profitable part of your members' services.

Mr. FINE. We have no ability to work with members of our medical staff to try to come out with something that addresses both of our needs. They are now incented to construct these freestanding facilities and skim the cream and leave us dealing with the more complicated higher——

Mr. STARK. To the credit of the physicians, most of those things are promoted by the "Shylocks" of the medical care promotion industry, who are neither hospital administrators nor physicians, but people out there creating a good—they are entrepreneurs of a sort. It is something you guys have to deal with. I don't have any answers. But I mean, the question I am only saying is, do you really want to cannibalize the whole hospital, and put the emergency room here and the birthing center there and the acute care center there? Traditionally, you have kept it together for cost shifting. That is a discussion I think needs to go on before we just open the gates to letting people cannibalize the various procedures within.

Mr. FINE. Yes, we would certainly enjoy working with you and your staff to pursue that further.

Mr. STARK. Great. Talk to the Chairman. She is the one in charge around here.

Chairman JOHNSON. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Madam Chair. Mr. Imparato, first of all, I want to thank you for your kind words and for the privilege, really, of working with you and your group, the American Association of People With Disabilities. Both Jim Langevin, my colleague and friend from Rhode Island, I, and the rest of our bipartisan Disabilities Caucus really enjoyed it and appreciated working with you and your group. My first question for you, Mr. Emerson, if you will, please, as all of you know, the Committee is considering proposals to ensure, really, that Medicare genuinely receives value for the physicians' services that it purchases. Hardly an Earth-shattering concept, and certainly a worthy one, an important one. But again, the devil is in the details. In determining value, these proposals must rely on quality and efficiency measures selected through a careful consensus-based review process based on recommendations of physician specialty services—or societies, rather. Various societies determine the standards. Now, if gainsharing were implemented, wouldn't it be problematic—or irresponsible, really—to subject patients to possible cuts in services that haven't been similarly reviewed; that is, that haven't gone through the same careful review and selection process based on the judgments of national specialty societies or a consensus of the peer-reviewed literature? Is that a different standard?

Mr. EMERSON. Yes, Mr. Ramstad, it would be difficult. One of the challenges facing the health care system today is the disparity of data across different disease states and different specialties. There are clearly some disease states and some specialties where the data is well understood and the dataset is very solid; which can lead to a fruitful conversation as to the ultimate goal of delivering better patient outcomes. Across different specialties, and quite honestly in areas where we are talking about introducing new technologies, by definition, the dataset isn't as robust. So, one of the challenges then in a gainsharing environment would be, how would those new technologies be assessed from a perspective of being able to deliver the innovations that we believe they will deliver? I think the outcome of that would be patients running the risk, again, of not having a physician advocate on their side, in terms of trying to bring forward new technologies as a way of bettering outcomes.

Mr. RAMSTAD. Well, those are pretty important caveats, and certainly my concerns, as well. The other question I have is for you, Ms. Goodroe, if you please. You have publicly talked about the rise in acquisition costs of devices in coronary stenting procedures, and the increase in total costs per procedure. This is a little bit puzzling to me, and perhaps you can help me understand. My understanding is that the newer drug-eluting stent products have resulted not in increases, but in substantial reductions in the need for retreatment and hospital readmissions caused by rhestinosis. In addition, according to the literature I have read and the studies that I have seen, the newer devices have really become more sophisticated. Doctors are dealing with more complex cases that previously would have required more invasive, and therefore more expensive procedures; more expensive, more invasive surgeries. For

example, people like my dad, who had a blockage in the left main artery, or multiple arteries, and require more stents per procedure. Diabetics is another example, with multiple problems; and others. Do you, when you make those statements, acknowledge those factors?

Ms. GOODROE. Yes, sir. Our technology measures cost, quality, and utilization. You are referring to studies that were very small studies that were to the approval of those devices. Our technology actually captures data on every patient that had a stent procedure. We look at how those stents were used What happened. An example is when drug-eluting stents were released about a year and a half ago, the cost of the stents was very, very high for drug-eluting. They actually came down when another stent came on the market that offered the same thing. But the cost per case went up immensely over the last year and a half, even though the price came down. Our database can show that the physicians started utilizing more devices per patient; that right now, out of our database—and we are hoping now to get these studies published; we are working with Stanford University and others on it—it is showing that you can't measure a benefit from that increase in cost. That is our problem right now. It is that we use technologies without evaluating where we are getting the benefits. I am the first one that is for new technology. We need the best technology for patients. But we have got to make sure that we put an incentive in there that people study how these technologies are really being utilized. The initial studies that look at the effectiveness of this are not enough. Because the effectiveness has nothing to do with how those devices are really used once they come into the market.

Mr. RAMSTAD. Well, I think your assertion that you cannot quantify—not to use your words, but to use my words—cannot quantify a benefit from the increase in costs, I am not sure all the literature, all the studies would support that.

Ms. GOODROE. We are working on studies right now that there has been a $4 billion increase in costs based on drug-eluting stents, alone. We are working on studies right now—that have not been accepted yet, but we are looking at it—that will look at what kind of benefit there has been.

Mr. RAMSTAD. How many people's lives have been saved, like my dad's life, in that expenditure? How many people's lives have been enhanced so they can function?

Ms. GOODROE. It is interesting because it——

Mr. RAMSTAD. I hope your studies measure——

Ms. GOODROE. Yes, that is what we——

Mr. RAMSTAD. —the human value, as well.

Ms. GOODROE. Yes. We are looking at that. Rhestinosis—and the cardiac surgeon probably could answer this the best—but rhestinosis does not often result in death. Rhestinosis does send you for another procedure, but not often in death.

Mr. RAMSTAD. I see my time is up. Thank you, Ms. Goodroe, and thank you to the rest of the panelists, too. We appreciate your input counsel.

Chairman JOHNSON. I certainly take my colleague from Minnesota, Mr. Ramstad's, concerns very seriously. I do think if we had more time for dialog around this issue we could get a clearer

public understanding of what has to be done to assure that physician choices aren't limited and that patients aren't denied access to the technology they need; while at the same time hospitals aren't compelled to stock devices that are roughly similar. I mean, there are now in the device group, like there are in the pharma area, medications that are very, very similar. It doesn't mean you might not want a different prescription drug than the one covered by your plan. You have to have access to that. But I think we are losing sight of the degree to which the environment of technology has changed, like the environment of pharmaceutical therapeutics has changed in the last five to 10 years. We do have to get a physician-controlled process, just like in the physician payment system; the physicians control the clinical data that may be selected for their quality standards.

So, this is a new world. We hope to work this in a way that you all are going to be at least relatively comfortable with the outcome. But it is a time of change. My point in asking the question of Mr. Emerson is that the change has happened. It is going on. We can't even see it, It is having some of the very effects that Mr. Ramstad is concerned about. So, to do nothing is to let it all happen pell-mell. To do something is to give some form and structure that results in public accountability and quality. This is actually not about money. It is about quality. It is about relationships. It is about a dynamic of quality that is parallel to what happens in continuous improvement in other parts of the economy and cannot by law happen in health care. So, we look forward to working with all of you, as well as Mr. Stark and his staff. He does have a different point of view. He certainly has legitimate concerns. But it is true, the world has changed. My hope is that we can help Medicare keep pace with the quality changes that the delivery system now has an opportunity to realize, for the sake of the patients. Thank you.

[Whereupon, at 11:58 a.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of Joane Goodroe, Goodroe Healthcare Solutions, Norcross, Georgia

Presentation Summary

Drug-eluting stents quickly replaced bare-metal stents as the arterial revascularization device of choice because trials show that in-stent restenosis is markedly reduced with the new device. Most of the available data comparing drug-eluting stent (DES) to bare-metal stents (BMS) arises from randomized trials designed for the purposes of gaining FDA approval.[1]

In our current outcomes analysis of nearly 17,000 bare-metal stent patients we found that, prior to DES release, population-level stent outcomes were markedly better than those reported in the control arms of the FDA-oriented randomized trials. Consequently, reliance on the trials results substantially overstates the magnitude of the clinical problem that DES are designed to reduce. The potential for improvement in post-stent outcomes with widespread DES use in our population is markedly smaller than reported by the randomized trials. We expect that the cost-effectiveness of new stent technology adoption in this population is much less attractive than the FDA-oriented trials would suggest.

Reimbursement and policy decisions for technology adoption based on the outcomes reported in the FDA-oriented trials of emerging therapies may not align with decisions that would be made if population-level analyses were used to assess the opportunity for outcomes improvement.

Our goal is to provide information and analyses that are useful to policy-makers and to both clinical and reimbursement decision makers. We welcome your feedback and questions.

Background

The major health and economic consequence of in-stent restenosis is symptom-driven repeat revascularization, usually treated with additional percutaneous coronary intervention (PCI).[2] Rapid acceptance of drug-eluting stents (DES) was based on evidence that they reduce bare-metal stent restenosis by as much as 75%.[3,4]

However, in-stent restenosis is just one cause of recurrent angina after stenting, and the proportion of all subsequent procedures that might be averted with restenosis prevention is uncertain. Because coronary artery disease is progressive in nature, many patients require additional procedures to relieve symptoms caused by newly symptomatic lesions even when the initially-stented segment remains fully patent. Cutlip et al analyzed 5-year follow-up data for 1,288 randomized stent trial patients and observed that after the first follow-up year the hazard rate for target lesion events (including death, infarction, and revascularization) was 1.7% while that related to non-target lesions was 6.3%.[5] Accordingly, we examined bare-metal stent outcomes in unselected patients during a period immediately prior to the market release of DES to identify the relative clinical importance of stented-segment lesion recurrence (restenosis) and development of other arterial lesions.

Methods

The data analyses described herein were conducted in compliance with the Privacy Rule contained in the Health Insurance Portability and Accountability Act of 1996, and with approval from the Stanford University Panel for Human Subjects in Medical Research.

We examined combined data from 17 hospitals that use CathSource™ Enterprise software (Goodroe Healthcare Solutions, LLC, Norcross Georgia) for cardiac catheterization laboratory data management. Contributing hospitals were geographically distributed throughout the United States and submitted all their cardiac catheterization records to the Goodroe Data Warehouse every 3 months. To ensure accuracy, an automated rules engine validated the clinical and device usage data. We were able to observe patients who returned to the catheterization laboratory for any reason after initial stenting and the details for the procedures they received after the index procedure. The database does *not* include information about clinical events that occur outside of the catheterization laboratory, and so we cannot report the rates of stroke, out-of-lab mortality. Nor are we able to observe subsequent procedures done in laboratories that do not submit data to the Goodroe Healthcare Solutions Warehouse.

Analysts at the Warehouse reviewed the procedural data collected for all patients who underwent PCI to identify patients who received bare-metal stents between December 1, 1998 and March 31, 2003. Patients who underwent atherectomy or brachytherapy were excluded. Patients whose PCI records did not include physician-entered data describing the stented arterial segment, or lesion type and severity were also excluded. We reviewed the data-harvesting pattern from all sites to ensure that the Warehouse received data from that site for at least 9 months subsequent to each index procedure date. Unique patient identifiers were employed to search the database for evidence of repeat PCI or diagnostic catheterization up to 365 days following the index bare-metal stent procedure. Angiographic data from any subsequent catheterization laboratory procedures were examined to determine the anatomical targets of repeat PCI, or diagnostic catheterization results that advised coronary artery bypass surgery (CABG) referral.

Angiographic data were collected in accordance with guidelines set forth by the American College of Cardiology National Cardiovascular Data Registry (ACC–NCDR).[6] Recurrent coronary artery lesions were defined as those with ≥ 50% lumen diameter reduction at the time of subsequent diagnostic catheterization, or those in which repeat PCI was performed regardless of percent stenosis. The arterial segment in which a bare-metal stent was placed is called the target segment, or stented segment.

The records for all stent procedures subsequent to the market release of DES were examined to illustrate the dissemination pattern of the new technology. We calculated the average device acquisition cost for single-vessel stent procedures in aid of observing the economic effect of DES adoption.

Results

Of 16,950 patients, 63.5% were male and the average age was 64.3 (± 12.2 years). Previously untreated (denovo) lesions were the sole therapeutic target of the index stent procedure in 94% of the patients, and 87% of the procedures were single-vessel treatments.

Diagnostic catheterization was performed on 3,623 (21.4%) of the patients between 9- and 12-months follow up follow-up year, Table 1. One third of those

angiograms resulted in medical management recommendations without further revascularization. Subsequent PCI was performed in 2,070 and CABG was recommended for 209, for a total of 2,158 patients (12.7% of the cohort), including 144 patients who had both repeat PCI and subsequent CABG referral. The average time from the index stent procedure to the first (or only) repeat PCI was 114 ± 91 days.

Table 1. Follow-up diagnostic catheterization recommendations

	n	% of cohort
Diagnostic catheterization within—365 days	3,623	21.4
Unique patients with repeat PCI		
Subsequent PCI performed	2,070	12.2
PCI referral but procedure not observed in databank	118	0.7
Unique patients with any CABG recommendation	209	1.2
Medical management or non-cardiac recommendation	1,253	7.4

Diabetes (28.1%) and hypercholesterolemia (with or without statins, 47.3%) were more common, and the average number of lesions ≥ 50% was higher (2.24) in patients who required follow-up PCI than in patients for whom we observed only one stent procedure (23.2% diabetes, 44.3% hypercholesterolemia, 1.78 lesions ≥ 50%). The rate of subsequent PCI was lowest, 8.2%, for patients with single-segment disease who underwent single-segment stenting at the initial procedure and highest, 15.3%, for patients with multi-segment disease and who underwent initial multi-segment stenting, Table 2.

Table 2. Subsequent PCI rate by disease burden and extent of index stenting

	Disease burden at time of index procedure	
	Single-segment	Multi-segment
Segments stented		
Single	8.2%	14.4%
Multiple	13.9%	15.3%

Patient-level analysis of follow-up procedures

We examined the anatomical target of repeat revascularization for 2,158 patients with observed follow-up PCI or diagnostic catheterization that resulted in CABG referral, Table 3. Target vessel revascularization (TVR) was documented in 1,584 patients (9.3% of the cohort). However, 624 (39.3%) of the patients who required TVR also underwent PCI to relieve lesions in previously unstented arteries or had other lesions identified for CABG. Stented-*segment* (stent plus peri-stent margins) revascularization, with or without treatment of other lesions, was documented in 1,194 patients (7.0% of the cohort). Of the patients who required target-segment revascularization 65.7% also underwent either PCI or were referred to CABG with lesions (≥ 50%) in previously untreated arterial segments. Target-segment revascularization was the sole indication for repeat revascularization in 409 patients, or 2.4% of the cohort. Almost half (964, or 44.7%) of the patients who required subsequent revascularization did not have recurrent lesions within previously-stented segments at the time of their follow-up procedure.

Table 3. Anatomical site of subsequent revascularization, patient level

	n	%
Patients with repeat PCI data or CABG recommendation	2,158	12.7
Patients with any target-vessel revascularization	1,584	9.3
PCI	1,375	8.1
CABG	209	1.2
Revascularization limited to target vessel	960	5.7
Combined target and non-target vessel revascularization	624	3.7
Revascularization limited to non-target vessel	574	3.4
Patients with any target-segment revascularization	1,194	7.0
PCI	1,037	6.1
CABG	157	1.0
Revascularization limited to target segment	409	2.4
Combined target and non-target segment revascularization	785	4.6
Revascularization limited to non-target segment	964	5.7

Anatomical analysis of follow-up PCI procedures

Within 1-year follow up after index stenting 2,070 (12.2% of the cohort) patients underwent further PCI. One additional PCI procedure was observed for the majority of the returning patients (1,741, 84%), while 329 patients returned to the catheterization laboratory for further intervention more than once (2x 255 patients, 3x 58 patients, 4x 11 patients, 5x 5 patients). In sum, we observed 2,494 subsequent PCI for the 2,070 returning patients. For the 2,494 subsequent PCI procedures, the anatomical revascularization target was the initially stented segment in 31%, other arterial segments not treated at the index procedure in 54%, and both the stented segment and other arterial segments in 15%. Hence, 46% of the follow-up PCI procedures included any intervention to the initially stented arterial segment.

We observed a concentration of non-stented segment PCI within 8 weeks after the index stent procedure, constituting 18% of all follow-up procedures, Figure 1. Same segment PCI within the first follow-up month accounted for 3.4% of all comeback procedures and 10.9% of all same-segment reinterventions.

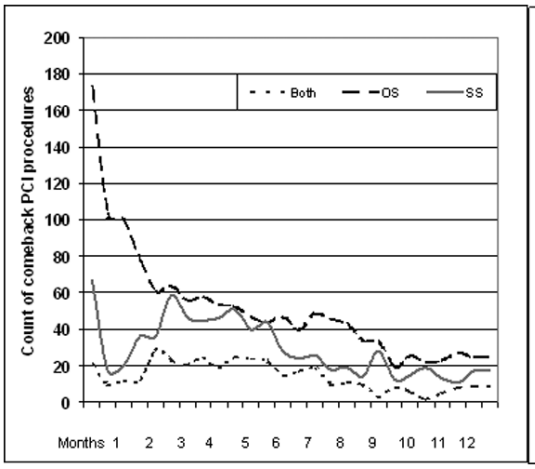

Figure 1. Distribution of days-to-comeback PCI by anatomical target of the follow-up PCI compared to the arterial segment stented at index procedure.

The rate of follow-up PCI is highest within 4 weeks of the index procedure (2.3% of the cohort), and swells again between 1 ½ and 7 months after index stenting. After the 7th month, the rate of follow-up PCI continues to decline. Less than 1% of the cohort underwent additional PCI in each of months 10, 11 and 12.

OS = arterial segment other than that stented at the index admission

SS = the same arterial segment that was stented at the index admission

Both = both the stented segment and other arterial segments treated at comeback PCI

In April of 2003, the first DES was FDA approved and within a few weeks 50% of all stent procedures performed in the Goodroe network involved DES. With approval of a second brand of DES in March of 2004 the dissemination of this technology proceeded further. In this network more than 90% of all stent procedures currently involve DES use and approximately 80% of all stent devices used are DES, Figure 2.

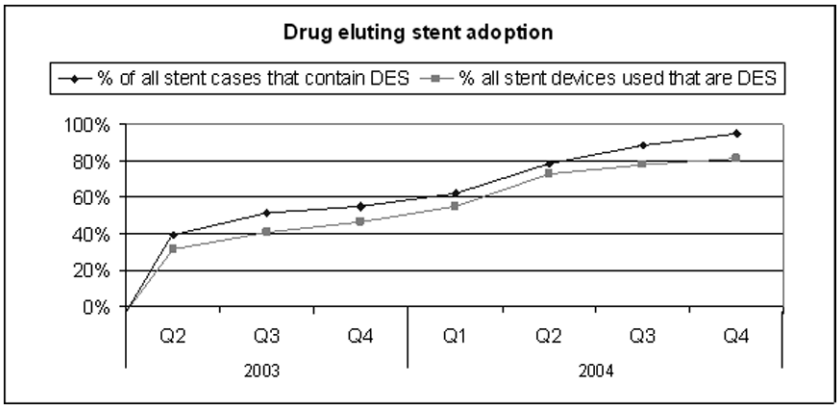

Figure 2. Drug eluting stent adoption from March 31, 2003 to December 31, 2004.

For patients who underwent elective single-segment stenting (as seen in 82% of this cohort), the catheterization laboratory acquisition costs for devices used in single-segment stent procedures (including guidewires, catheters and stents) increased 27% between the second quarter of 2003 and the end of 2004, Figure 3.

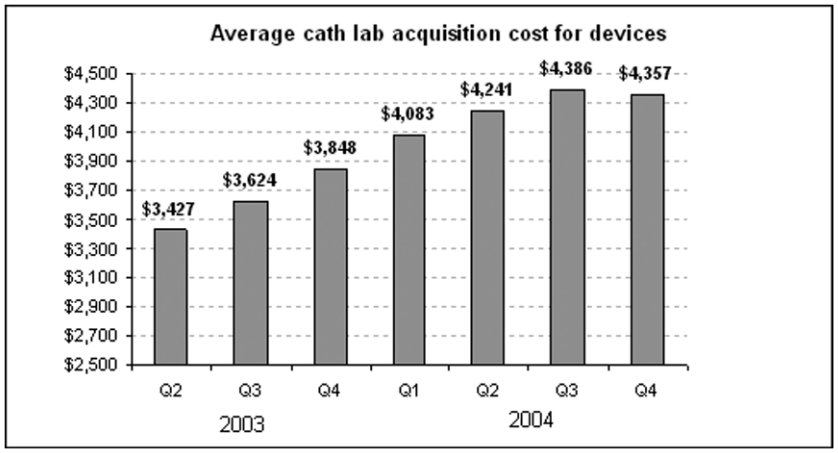

Figure 3. Device acquisition costs for single-segment, non AMI setting stent procedures

Stented segment revascularization was indicated in 55% of the patients who underwent additional PCI or who were referred to CABG. However, improved restenosis prevention with use of DES would have averted only some of those repeat procedures because 65.7% of the patients who required target-segment revascularization also had intervention in lesions in non-stented arterial segments. Just 7% of this bare-metal stent population returned to the catheterization laboratory for any repeat PCI to treat an arterial segment that had been previously stented with a bare-metal stent.

The randomized DES trials report substantially higher event rates subsequent to bare-metal stenting than those in this longitudinal study. In the Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions (SIRIUS) trial, the target-lesion revascularization (TLR) rate for the bare-metal stent subset was 20.0%,[4] compared with 7% target-segment revascularization in our bare-metal stent cohort. In one of Boston Scientific's paclitaxel-eluting stent trials, TAXUS IV, the one-year TLR rate was 15.1%.[5] This rate is also substantially higher than the rate for observed target-segment reinter-

vention in our series. Routine angiography is known to result in higher follow-up PCI rates than are observed in patient cohorts without angiographic follow-up assessment.[7] Because the DES trials performed for FDA approval incorporated mandatory angiographic follow up, we would logically expect the subsequent PCI rates to be higher than would be the case in practice settings in which follow-up events are symptom driven.

Kimmel reported a 6-month repeat PCI rate of 9.9% in 1,240 consecutive patients who received stents in the later part of 1995.[8] Based on chart review, Kimmel estimated that 85% of those follow-up PCI procedures were performed to treat restenosis. Recently Clark et al reviewed 1998 Medicare claims data in 9,868 PCI patients predominantly treated with stents, but including other forms of PCI. Compared to the Goodroe cohort, the Medicare patients were older (73.4 versus 64.3 years)[9] and contained a larger proportion of diabetics (33.8% versus 24.1%). The one-year repeat revascularization rate in the Medicare population was 16.9%, compared to 12.7% for the stent patients described here. Clark applied the 85% finding from Kimmel's work to their observed revascularization rate to derive an estimated clinical restenosis rate of 14.4%. However, since 1998 stent design evolution has resulted in improved stent patency rates, and those improvements could be reflected in the lower follow-up event rates in our study. In two trials of bare-metal stents, Baim et al[10] reported 9-month TLR rate of 7.7% and Serruys et al[11] observed that 7.0% of the patients underwent 9-month TVR. Our angiographically based findings are more aligned with these more recent stent trials: The one-year target-segment revascularization rate was 7.0% and the TVR rate was 9.3% in our cohort.

Clinical progression of coronary lesions accounted for repeat procedures in 5.8% of the PCI patients studied in a recently published report from the National Heart, Lung, and Blood Institute Dynamic Registry.[13] We observed that 5.7% of the patients in this series underwent subsequent PCI solely to treat lesions other than those stented at the time of the initial PCI. Additionally, 4.6% of the cohort received subsequent PCI to treat both the initially stented segment and lesions in other portions of the coronary anatomy and 69% of the follow-up PCI procedures included treatment of arterial segments not treated during the index stent admission.

Conversely, only 2.4% of the cohort returned for subsequent PCI solely to relieve symptoms related to the initially-stented segment.

Notably, 34% of all subsequent PCI procedures were performed on non-stented arterial segments within the first 8 weeks of follow-up after index stenting. These procedures reflect either intentionally staged treatment for multi-segment coronary disease or rapid clinical progression of lesions that were not responsible for symptoms at the time of index stenting.

Within the first follow-up month 20% of all comeback procedures were performed on non-stented lesions.

In another recently published study, Aegma et al reported on a series of 3,146 bare-metal stent patients with 9-month follow up.[12] The TVR rate was 10.3%, which compares favorably to 9.3% in this Goodroe patient cohort. An additional 66 patients (2.1%) in the Aegma study suffered cardiac death or acute myocardial infarction that may be attributable to clinical restenosis (events that we were unable to observe in the databank). These authors also reported that same-segment reintervention within one month of successful stenting was due to sub acute thrombosis and other sub-acute stent placement issues.[13] Of the same-segment reinterventions in this cohort, 10% occurred within the first month which would indicate a sub-acute in-stent event rate of less than one percent. Once we exclude all one-month reinterventions and any subsequent PCI procedures that solely targeted non-stented segments, 1,049 follow-up PCI procedures remain that included any same-segment reintervention and could potentially be restenosis-related. Hence we estimate that, at most, 42% of the PCI procedures done in follow-up could be associated with in-stent restenosis, and that these events affected 6.2% of the cohort.

The majority of repeat PCI procedures in this population were performed to treat lesions other than those stented in the index procedure, and so would have been required even if drug-eluting stents had been used as the initial therapy. The opportunity to improve stent outcomes by reducing in-stent restenosis in this group of unselected stent patients would be much smaller than is suggested by results of the randomized DES trials. Because the cost-effectiveness of any new therapy depends on its effectiveness relative to the existing therapy and the in-stent clinical restenosis rate in this cohort is considerably less than the control arms of the DES trials, we would expect that DES use in this cohort would be substantially less cost effective than is suggested by analysis of the DES trial results.[2]

Drug-eluting stents are intended to reduce in-stent restenosis, and while a small proportion of all stent patients suffer events related to restenosis we observe that DES are currently used in more than 90% of the stent procedures done in Goodroe

participating hospitals. This new technology disseminated quickly after its market release and the costs related to stent procedures grew. The global market for drug-eluting stents is estimated at $5 billion and there is intense competition for market share among stent manufacturers. However, one effect of the promotion of drug-eluting stents may be costly overuse of this new technology in low clinical value situations. Concerns persist about the sub-acute complications related to DES use, and more study is required to see if widespread dissemination of this new therapy includes a tradeoff between restenosis-related events and stent-related complications.

Limitations

The stent-related clinical event rate in this study population may be affected by a variety of factors that we did not study and are unable to observe given the nature of the databank. Stent patients who suffered out-of-lab death, stroke, or recurrent cardiac symptoms may have returned to cardiologists or hospitals other than their original provider, and those subsequent events would not have been captured in the Data Warehouse. We did not survey the contributing hospitals to see how their interventional case complexity and volume compares to other centers.

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Medical Device Manufacturers Association
Washington, DC 20006
October 7, 2005

The Medical Device Manufacturers Association (MDMA) and its member companies would like to thank the Subcommittee for holding this hearing on Gainsharing and for beginning the discussion on this critical public policy debate. It is important that all stakeholders (patients, hospitals, physicians and manufacturers) engage in a broad discussion and that a thorough review of all the possible ramifications is assessed before Congress enacts legislation.

MDMA is a national trade association representing the innovative and entrepreneurial sector of the medical device industry. Our membership is comprised of over 200 device manufacturers, including makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

Attempting to make the health care system more effective and efficient is a worthwhile goal shared by many and there has been much progress made in the area of "pay for performance" (P4P) initiatives. P4P initiatives are programs that create financial incentives for physicians to collect better data or deliver better outcomes and they are consistent with the evidence-based medicine movement that has generated broad-based support in the medical community as well as in Washington. However, "device contract gainsharing" (DCG) is separate and distinct from P4P initiatives. DCG provides physicians with incentives to limit care by using the cheapest alternative or through using only one device vendor.

Because the term gainsharing does not have a uniform definition there is much confusion surrounding the term. The U.S. Department of Health and Human Services' Office of the Inspector General (OIG) has defined the term as "an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs attributable in part to the physicians' efforts." This aligning of incentives can include giving a physician a financial incentive to "reduce the use of specific medical devices and supplies and to switch to specific products that are less expensive." Gainsharing, as defined by the OIG, is very concerning to many in the medical device industry as it is inferred to mean that a physician will receive a kickback for using cheaper and less advanced medical technology.

Currently illegal, gainsharing arrangements violate the Civil Monetary Penalty (CMP) law, federal anti-kickback statutes; and the Stark, physician self-referral law. Legalizing gainsharing could have long lasting ramifications that are detrimental to patient care, medical device innovation and the long term cost of health care.

MDMA defines DCG, one element within the broader discussion of gainsharing, as an attempt to cut health care costs by offering financial incentives to doctors who reduce expenditures through using cheaper medical devices or by limiting physician choice for clinical preference products. Device contract gainsharing forces doctors to make unacceptable choices between patient care and larger paychecks. MDMA believes that in order to protect patient quality of care and medical technology innovation, it is essential that doctors do not have a conflict of interest in providing patient care.

DCG Conflicts With Personalized Patient Care

Proponents of DCG argue that hospitals may achieve cost savings by offering "different" forms of care. Certainly, reducing hospital over-treatment, if it exists, by more carefully examining medical necessity and lowering supply costs through simple administrative changes are worthwhile goals. However, these cost-saving mechanisms do not justify the implementation of DCG arrangements.

- Any hospital may make adjustments to protocol, such as changing the packaging of surgical tools, in order to reduce costs. Hospital administrators and doctors can and should look for creative ways to make health care more efficient. However, offering financial incentives to doctors to "create efficiencies" presents a troubling conflict of interest; doctors are forced to choose between personal financial gain and a potential reduction in patient care. The personal financial conflict undermines a physician's responsibility to focus exclusively on patient outcomes.

- ADMA supports attempts to better align physician payments with improved data collection and better outcomes. These types of "pay for performance" initiatives are worthwhile since they focus on financial incentives for enhanced clinical practices that improve patient outcomes. However, MDMA is opposed to any programs that would create a financial incentive for doctors to limit patient access to medical technologies. These device contract gainsharing arrangements will negatively affect personalized patient care, stifle medical device innovation and may ultimately result in higher long-term costs to the health care system.

DCG arrangements threaten personalized patient care initiatives by creating a "one size fits all" approach to medicine. The Centers for Medicare and Medicaid Services (CMS) has recognized the value of moving towards patient centered care as the best way to improve the quality of care and reduce costs. Gainsharing will prevent this goal from being realized because it penalizes physician choice.

- No single brand of medical device is superior for all patients and physicians, as each device has unique features and functionalities. An artificial hip or pacemaker that produces an optimal clinical outcome for one person may pose a serious health risk to another patient. Similarly, a device that one physician may use with complete confidence and familiarity may pose serious concerns for another doctor. Many companies produce an array of devices that accommodate the hand size, eyesight, and individual preference of surgeons. Proposed DCG arrangements, by demanding a "one size fits all" approach to medicine, would jeopardize patient safety by denying patients and physicians access to necessary technologies.
- In Iowa, doctors constrained by a hospital's agreement have reported having to transfer patients to other hospitals in order to get them the brand of medical device that they need. In Pennsylvania, a physician has sued his hospital for using a standardization contract as a facade for receiving illegal kickbacks from a major manufacturer. This type of financial pressure to standardize medical devices can reduce a physician's ability to offer the most effective and appropriate medical care.
- DCG will require doctors to undergo a retraining and education period to learn how to properly use and monitor devices they are required to use. This training period will be costly, and medical mistakes and patient injuries are inevitable during this learning period. Any possible efficiency benefits of DCG may be substantially offset by the costs, in terms of money, patient safety, and device innovation that standardization of medical devices entails.

DCG Standardization Stifles Innovation:

Standardization of medical devices, in addition to posing immediate concerns regarding patient care, also may have the unintended effect of reducing medical device innovation. Exclusive contracts and the incentive structure of DCG discourage medical device innovation, hurt small businesses, and create anticompetitive market forces.

- DCG offers doctors strong financial incentives to maintain the status quo and avoid upgrading to those new and innovative medical technologies that could enhance patient outcomes. Doctors in DCG arrangements are encouraged to cut costs by using the cheapest medical devices, not to improve care by using the newest and most effective medical devices.
- DCG encourages doctors to ignore or reject the medical benefits of new technologies in exchange for personal income. DCG encourages doctors to purchase exclusively from large companies, which negotiate with GPOs to provide low-priced, exclusive and bundled contracts. However, innovation in the medical device market is driven by small and new companies; entrepreneurial companies are responsible for the overwhelming majority of medical device breakthroughs. They have revolutionized patient care, but they cannot be expected to compete and innovate if doctors are offered substantial financial incentive to accept exclusive contracts from large producers.
- Important and lifesaving medical devices such as the drug-eluting stent may never have been developed if DCG had been in place ten years ago. DCG arrangements encourage stagnation in the medical device industry by financially penalizing doctors for buying new and innovative medical devices.

The Potential for Overall Cost-reduction Under DCG is Small and Uncertain:

Doctors and health care professionals have expressed concern that DCG may not offer substantial and sustainable health care cost reductions. Current profit-sharing hospital models have failed to produce tangible cost savings, and the potential for

increased long-term costs reduces the feasibility of controlling health care expenses through DCG.

- Over the last three years, the Senate, the New York Times, Los Angeles Times, Government Accountability Office, the OIG, and Department of Justice all have launched investigations about the potential inefficiencies of GPOs and their drive to standardize devices within their member hospitals. Evidence does not support the assertion that standardization reduces contract prices, and GPOs, in many cases, increase health care costs. The financial justification for standardization, therefore, is based primarily on the suspect assertions of GPOs.
- MedPAC has indicated that physician owned hospitals, for-profit ventures that specialize in cutting costs to increase physician payments, have not succeeded in reducing per-procedure health care costs. Despite that fact that the interests of physicians and the hospital are perfectly aligned in the physician-owned hospital model, cost savings have not been achieved. The success of DCG arrangements, which are predicated on the same incentive-based theory as physician-owned hospitals, thus is substantially in doubt.
- The long-term cost-effectiveness of DCG agreements is also mitigated by the possibility that cheaper medical devices and fewer medical procedures will result in higher rates of medical complications, malpractice liability, and hospital re-admittance. While these decisions may result in reductions in immediate health care costs, the decreased durability of lower-cost medical devices may cause higher rates of medical complications and follow-up surgeries. Cheaper devices and cheaper medical procedures may cut short-term costs, but the likelihood of hospital re-admittance make DCG an unstable mechanism for producing long-term health care price reductions.

MDMA urges Congress to prohibit DCG

MDMA recognizes that rising hospital costs are a drain on health care resources, and reducing health care costs is necessary to ensure that health care is affordable. However, DCG is not an effective or adequate way to achieve these results. Containing the rising cost of health care by better aligning incentives of physicians and hospitals should be a priority and we hope Congress will recognize that the P4P model rewarding quality and appropriate care is the correct approach. Device contract gainsharing will simply create a race to the bottom, adversely impacting patient care, innovation, and the long-term cost of health care. MDMA urges Congress to oppose any legislation which would legalize DCG agreements.

Again, we thank Chairman Johnson and the Subcommittee for providing us the opportunity to express the gainsharing perspective of the entrepreneurial, innovative medical technology sector. We are encouraged by the prospect of working together to achieve reductions in the cost of health care without jeopardizing patient safety, curtailing device innovation or limiting physician choice.

Thank you.

Sincerely,

Mark Leahey
Executive Director