CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, DC, October 3, 2000.

MR. FRED HASSAN,
Chief Executive Officer, Pharmacia & Upjohn Co., Inc., Peapack, NJ.

DEAR MR. HASSAN: You should by now be aware of Congressional investigations suggesting that Pharmacia & Upjohn has for many years been reporting and publishing inflated and misleading price data and has engaged in other deceptive business practices in order to manipulate and inflate the prices of certain drugs. The price manipulation scheme is executed through Pharmacia & Upjohn's inflated representations of average wholesale price (''AWP'') and direct price (''DP''), which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true prices that providers pay is regularly referred to in your industry as ''the spread.'' In turn, this has caused the Medicare and Medicaid Programs to expend excessive amounts in paying claims for certain drugs. The evidence amassed by Congress clearly shows that Pharmacia & Upjohn has reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive a windfall profit from Medicare and Medicaid.

The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of $946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for $168.00 and to Comprehensive Cancer Center for $152.00 (Composite Exhibit 1''). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

Pharmacia & Upjohn's strategy of increasing the sales of its drugs by enriching with taxpayer dollars, the doctors and others who administer the drugs is reprehensible and a blatant abuse of the privileges that Pharmacia & Upjohn enjoys as a major pharmaceutical manufacturer in the United States. This is perhaps best illustrated by Pharmacia & Upjohn's own internal documents which reveal that the company abused its position as a drug innovator in an initial Phase III FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit ''2'').

''. . . Clinical Research Trials

Initial Phase III Protocol trial for ''Oral Idamycin'' in lymphomas. This trial will offer AOR $1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at $5,000 per patient. . . .

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect.''

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial. I am hopeful that the FDA will take immediate action to stop such behavior by your company. The FDA's inability to act to ensure the validity of drug trials will necessitate legislative action.

Doctors must be free to choose drugs based on what is medically best for their patients. It is highly unethical for drug companies to provide physicians with payments for FDA clinical trials and inflated price reports that financially induce doctors to administer Pharmacia & Upjohn's drugs to patients. In particular, Pharmacia & Upjohn's conduct, along with the conduct of other drug companies, is estimated to have cost taxpayers over a billion dollars. It also has a corrupting influence on the exercise of independent medical judgment both in the treatment of severely ill cancer patients and in the medical evaluation of new oncological drugs.

In addition to Pharmacia & Upjohn's action in the context of the Phase III FDA clinical trial, internal Pharmacia & Upjohn documents secured through Congressional investigations clearly establish that Pharmacia & Upjohn created and then exploited misleading information about its prices. Following is one example: ''Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over $8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit'' (Exhibit ''3'').

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from $292.43 to $309.98, while the price charged to industry insiders fell by $43.15 (Composite Exhibit ''4'').

Congress attempted to address the issue of inflated drug reimbursement, in part, in 1997 legislation requiring Medicare to reimburse drug costs at 95% of AWP.

Unfortunately, Congress was unaware that, while it intended to improve Medicare's solvency, Pharmacia & Upjohn was submitting false price reports to further inflate reimbursement amounts for both Medicare and Medicaid that would nullify the effects of Congressional action. Composite Exhibit ''5'' demonstrates that Pharmacia & Upjohn increased its price representations for its cancer drug Toposar by 5% in October 1997 while taking care to ensure customers that the change in reported prices would not have any impact on the lower, true prices being paid, but would increase government reimbursement.

The following excerpt, addressing Medicaid reimbursement, is illustrative of the steps Pharmacia & Upjohn took to ensure that government health programs paid the inflated reimbursement resulting from false price reports: ''FYI—Heads up. The following P&U price increases may create a spread between purchase price and Medicaid reimbursement that may create sales complaints if not resolved in reasonable time period by customary Medicaid updates. Therefore, your action may be required in some instances if over the next few months Medicaid does not automatically pick up the price changes'' (Exhibit ''6'').

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit ''7'' reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to $152.00 while reporting an AWP of $946.94: ''Dear Willie, A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition. . . .''

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including ''educational grants'' and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price—the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit ''8'' highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL: Medical Education Grants. A $55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including: Education/Disease Management, Research Task Force, AOR Annual Yearbook. A $40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997. . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO: If needed, you have a ''free goods'' program to support your efforts against other forms of generic doxorubicin. . . .

Use your ''free goods,'' wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

My reading of the Federal Food, Drug, and Cosmetic Act and the corresponding regulations suggests that the FDA should pay particular attention to Pharmacia & Upjohn's misleading price reports. Accordingly, I am today requesting that the Commissioner of the FDA, Dr. Jane Henney, conduct a full investigation into Pharmacia & Upjohn's business practices.

I urge Pharmacia & Upjohn to immediately cease these acts and make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

Please share this letter with your Board of Directors and in particular with the Board's Corporate Integrity Committee.

Sincerely,

PETE STARK,
Member of Congress.

INTRODUCTION OF H.R. 5361, THE PIPELINE SAFETY ACT OF 2000

HON. JAMES L. OBERSTAR

OF MINNESOTA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 3, 2000

Mr. OBERSTAR. Mr. Speaker, before we adjourn we need to pass legislation to improve pipeline safety. The recent explosions in Bellingham, Washington (three fatalities) and Carlsbad, New Mexico (12 fatalities) are the most visible indications of a serious, long-term

problem. Today I am introducing H.R. 5361, the Pipeline Safety Act of 2000, a bill that I believe will help us to go forward quickly and pass this badly needed legislation. The bill is cosponsored by Congressmen DINGELL, INSLEE, UDALL (NM), PASCRELL, LEWIS (GA), PALLONE, SMITH (WA), and TIERNEY; many of the cosponsors represent citizens in States that have had serious pipeline accidents.

Our Nation has 2.2 million miles of pipeline carrying 617 million ton-miles of oil and refined oil products, and 20 trillion cubic feet of natural gas. The pipeline system and the volume of products transported continue to grow. In the last ten years, pipeline mileage has grown by ten percent—at the same time that our Nation's suburbanization continues to bring more families near pipelines.

Regrettably, as the industry has grown, safety has declined. In the last decade, there were 2,241 major pipeline accidents resulting in death, serious injury, or substantial property damage. These explosions killed 226 people and caused more than $700 million of damage to property and the environment. And pipeline safety is deteriorating: the General Accounting Office (GAO) has found that the rate of pipeline accidents is increasing by four percent a year.

To exacerbate the problem, we are dealing with an aging pipeline system. About 24 percent of gas pipelines are now more than 50 years old. The section of pipeline involved in the recent Carlsbad, New Mexico tragedy was almost 50 years old and had suffered substantial internal corrosion.

Congress and the National Transportation Safety Board (NTSB) have long been aware of the unacceptable state of pipeline safety. A series of laws and NTSB recommendations have given the responsible federal agency, the Office of Pipeline Safety (OPS) of the Department of Transportation, direction as to the steps that need to be taken. Regrettably, OPS has not been responsive.

A recent GAO study found that OPS has failed to implement 22 statutory directives for regulations and studies. Twelve of these provisions date from 1992 or earlier. OPS has the lowest rate of any transportation agency for compliance with NTSB recommendations. In addition, GAO has challenged OPS'new policy of reduced reliance on enforcement fines.

During the past year, we have made progress in developing legislation to improve pipeline safety. The Senate has passed a bill, S. 2438, that includes some provisions that would enhance safety but, at the same time, the bill fails to deal satisfactorily with the most important safety issues. It is my judgment that it would be a serious mistake to adopt the Senate bill unchanged. The minimal contributions that the bill would make to safety are outweighed by the legislative reality that passage of this bill would make it extremely difficult to pass additional pipeline safety legislation during the period of the three-year authorization Provided by the bill.

The Senate bill, as passed, is opposed by the families of the victims of the Bellingham, Washington, pipeline explosion, and the following organizations: the National Pipeline Reform Coalition; League of Conservation Voters; Environmental Defense; Clean Water Action; National Environmental Trust; Natural Resources Defense Council; Physicians for Social Responsibility; U.S. Public Interest Research Group; AFL–CIO Transportation Trades Department; the International Brotherhood of Teamsters; and the AFL–CIO Building and Construction Trades Department.

I believe that the House should go forward with its own legislation and then work with the Senate to develop a joint product that would make an effective contribution to pipeline safety.

Until a few weeks ago, this was the path we were following in the House. Several good pipeline safety bills had been introduced, including H.R. 4792, a bill sponsored by Congressman INSLEE and 15 other Members. Within the Transportation and Infrastructure Committee, the Committee with primary jurisdiction over this issue, there had been extensive bipartisan discussions and staff work, and draft legislation had been prepared and was within days of being ready for a markup in early

I find the industries' assessment of the legislative situation to be obviously selfserving. When was the last time we heard an industry demand that a ''tough'' bill be passed to Improve its safety? How could anyone, three weeks ago, say with a straight face that the last five weeks, or the last two weeks, of this Congress provide insufficient time for negotiations on this relatively limited issue, when during the last two weeks the House and the Senate will have to resolve all the major issues associated with 11 of the 13 appropriation bills?

The bill I am introducing today does not include all the provisions that I would like to see included in a pipeline safety bill. In the interest of facilitating prompt House action on pipeline safety, my bill is based largely on the House bipartisan staff draft bill that had been developed for an early September markup.

I believe that this bill is a major improvement over the Senate product and can make important contributions to pipeline safety. In accordance with a joint statement of principles for improving pipeline safety endorsed by Congressman JOHN DINGELL, Ranking Democratic Member of the Committee on Commerce which also has jurisdiction over pipeline safety, and me, the bill requires pipeline integrity management programs; requires periodic pipeline inspections; ensures that pipeline employees are qualified, well trained, and certified; expands the public's right to know; provides environmental accountability and increases enforcement; expands States' role in pipeline safety; enables more citizen involvement; and increases funding to improve pipeline safety. A summary of the bill may be found at the end of this statement. Although the Senate bill includes provisions on some of these issues, in most cases they are not effective to deal with the problem.

Let me just focus on a couple of issues to illustrate the difference between my objectives and the Senate bill. I believe that any pipeline safety bill must require pipeline operators to adopt integrity management programs and must require periodic inspections of pipelines at least once every five years.

Why is that so important?—two reasons: First, required inspections will prevent tragedy. The need for regular inspections is particularly acute because of the age of our pipeline system. As I have already said, about 24 percent of gas pipelines are now more than 50 years old. The section of pipeline involved in the recent Carlsbad, New Mexico tragedy was almost 50 years old, and the National Transportation Safety Board (NTSB) has found that the failed sections had significant internal corrosion and pipe wall loss in some areas of more than 50 percent. The NTSB stated that, based on their initial investigation, the 50-year-old pipeline was never properly tested. The company never conducted an internal inspection of the pipeline involved in the explosion. I believe that inspections probably would have uncovered these corrosion problems before they led to a tragedy. Without requiring pipeline inspections, there will be more tragedies. We don't need another Carlsbad, New Mexico, Bellingham, Washington, Edison, New Jersey or Mounds View, Minnesota.

Second, a subtle, but important, distinction between this bill and the Senate bill is that the Senate bill does not require the pipeline companies to do anything. The Senate bill only requires the Office of Pipeline Safety to adopt regulations dealing with the issue. This approach has been tried and failed. In 1992, Congress passed legislation that directed OPS to adopt regulations requiring inspections by 1995. Now, 13 years after the NTSB recommended required periodic inspections and eight years after the statutory mandate, the Office of Pipeline Safety has not issued a single regulation imposing pipeline inspection requirements. For important parts of the industry NTSB has not even issued a Notice of Proposed Rulemaking.

The failure of the Office of Pipeline Safety's failure to comply with statutory inspections mandates is just one example of OPS' lack of responsiveness to Congressional directives and NTSB recommendations when it comes to pipeline safety. The GAO has found that the Office of Pipeline Safety has not complied with 22 existing statutory requirements regarding pipeline safety, many of which had statutory deadlines that have long since past. We should not pass a bill, like S. 2438, that imposes a 23rd statutory requirement telling OPS to do the right thing.

It is time for the House to lead; it is time for these needless pipeline tragedies to stop. The House should go forward with its own pipeline safety legislation and we should get a truly effective pipeline safety bill on the President's desk before we adjourn.

Summary of H.R. 5361, The Pipeline Safety Act of 2000

1. Requires pipeline integrity management programs

Statutorily requires that hazardous liquid and natural gas pipeline operators adopt integrity management programs, regardless of whether the Department of Transportation's Office of Pipeline Safety (OPS) completes pending and planned rulemakings to require these programs.

The Department of Transportation (DOT) must review each operator's integrity management program, and either accept it or require changes.

2. Requires Periodic Inspections (at least once every five years)

Statutorily requires periodic inspections of pipelines at least once every five years in areas of high population or environmental sensitivity; methods for monitoring cathodic protection on the operator's entire system; follow-up actions which will be taken if inspections reveal deficiencies; and programs for installing emergency flow restricting devices.

3. Ensures that pipeline employees are qualified, well trained, and certified

Statutorily requires that each pipeline operator develop and implement a program for ensuring that all employees performing safety sensitive functions are qualified.

Qualifications of employees must be established by testing and may not be established by observing on-the-job performance only (as would be permitted under a recent OPS regulation).

Requires DOT to review all pipeline operator programs, and either accept them or require changes.

Establishes a pilot program in which DOT will develop a test for certifying persons who operate computer-based systems which control pipeline operations. OPS will use its test to certify these employees at three companies.

4. Expands the public's right to know

Requires pipeline operators to establish programs to educate the public on the use of the one call program prior to excavation, and on how to identify and respond to a pipeline release.

Requires pipeline operators to make useful information available to state emergency response committee and local emergency planning committees, and to make maps of pipelines available to municipalities.

Requires pipeline operators to provide DOT, and DOT to provide the public, with pipeline segment reports including histories of incidents and inspection, enforcement actions affecting the segment, and the results of periodic testing of the segment.

5. Provides environmental accountability and increases enforcement

Establishes a new penalty with strict liability (no fault required) for oil spills, of $1,000 per barrel of hazardous liquid (e.g., oil) discharged. This is the same penalty as is currently imposed for oil spills in water.

Raises maximum civil penalties from the current law level of $25,000 per violation and $500,000 for a related series of violations to $100,000 per violation and $1,000,000 for a series of violations.

Expands the Attorney General's authority to pursue civil actions and get appropriate relief.

6. Expands States' role in pipeline

Authorizes the Department of Transportation to enter into agreements with states to enable the states to participate in pipeline safety inspections and oversight, and to comment on pipeline operators' integrity management programs.

7. Enables more citizen involvement

Establishes a pilot program to establish and fund nine Regional Advisory Councils to enable public and local government representatives to make substantive recommendations to the pipeline industry and regulators regarding improving pipeline safety.

8. Increases funding to improve pipeline safety

Significantly increases authorizations for pipeline safety programs to enable the Office of Pipeline Safety to carry out an active, aggressive inspection program.