the Palestinian Authority with the clear understanding and expectation that the Palestinians would maintain order and security there;

Whereas the Palestinian Authority, with the assistance of Israel and the international community, created a strong police force, almost twice the number allowed under the Oslo Accords, specifically to maintain public order;

Whereas the Government of Israel made clear to the world its commitment to peace at Camp David, where it expressed its readiness to take wide-ranging and painful steps in order to bring an end to the conflict, but these proposals were rejected by Chairman Arafat;

Whereas perceived provocations must only be addressed at the negotiating table;

Whereas it is only through negotiations, and not through violence, that the Palestinians can hope to achieve their political aspirations;

Whereas even in the face of the desecration of Joseph's Tomb, a Jewish holy site in the West Bank, the Government of Israel has made it clear that it will withdraw forces from Palestinian areas if the Palestinian Authority maintains order in those areas; and

Whereas the Palestinian leadership not only did too little for far too long to control the violence, but in fact encouraged it: Now, therefore, be it

Resolved by the House of Representatives (the Senate concurring), That the Congress—

(1) expresses its solidarity with the state and people of Israel at this time of crisis;

(2) condemns the Palestinian leadership for encouraging the violence and doing so little for so long to stop it, resulting in the senseless loss of life;

(3) calls upon the Palestinian leadership to refrain from any exhortations to public incitement, urges the Palestinian leadership to vigorously use its security forces to act immediately to stop all violence, to show respect for all holy sites, and to settle all grievances through negotiations;

(4) commends successive Administrations on their continuing efforts to achieve peace in the Middle East;

(5) urges the current Administration to use its veto power at the United Nations Security Council to ensure that the Security Council does not again adopt unbalanced resolutions addressing the uncontrolled violence in the areas controlled by the Palestinian Authority; and

(6) calls on all parties involved in the Middle East conflict to make all possible efforts to reinvigorate the peace process in order to prevent further senseless loss of life by all sides.

CALLING FOR AN FDA INVESTIGATION INTO ABUSE OF AVERAGE WHOLESALE PRICE SYSTEM

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, October 12, 2000

Mr. STARK. Mr. Speaker, last week, I sent the following letter to the FDA, in support of an investigation concerning how some of the nation's leading drug manufacturers are using false pricing data to distort the practice of medicine in America.

The letter details what I believe to be the bilking of the Medicare system by a number of large, powerful drug companies. The evidence I have been provided shows that certain drug companies are making enormous profits available to many doctors on the "spread" between what Medicare and other payers reimburse for a drug (the average wholesale price), and what that drug is really available for.

These companies have increased their sales by abusing the public trust and exploiting America's seniors and disabled. It is my firm belief that these practices must stop and that these companies must return the money to the public that is owed because of their abusive practices.

The data in the letter is an indictment of the companies' abuse of the taxpayer and of the patient.

The letter follows:

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

Dr. JANE E. HENNEY,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. HENNEY: I would like to share with you concerns I have regarding the conduct of certain drug companies that are regulated by your agency. Internal drug company documents and other evidence from an industry insider, obtained through a Congressional investigation, have exposed deliberate price manipulation by some drug companies. I believe drug companies' misleading acts are exploiting the health care needs of our most seriously ill, poor, disabled and elderly citizens and taking money from the pockets of innocent Medicare beneficiaries who are required to pay 20% of Medicare's current limited drug benefit. These wrongful actions cost federal and state governments, private insurers, and others billions of dollars per year in excessive drug payments and corrupt the professional independence of medical decision makers.

The compelling evidence recently amassed by Congressional investigators reveals that certain drug companies have been reporting and publishing inflated and misleading price data and have engaged in other deceptive business practices in order to manipulate and inflate the prices of certain drugs. The drug manufacturers have perpetrated this fraudulent price manipulation scheme for the express purpose of causing the Medicare and Medicaid Programs to expend excessive amounts in paying claims for certain drugs. The inflated reimbursement arranged by certain drug companies is used to aggressively market the drugs in question, to influence physician prescribing practices, and to increase sales and market share.

The evidence I have seen indicates that the drug companies involved have knowingly, deliberately, and falsely inflated their representations of the average wholesale price ("AWP"), wholesaler acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The evidence also clearly establishes that, contrary to previous drug company representations, the initial source of the price data is the drug companies themselves and those acting in concert with them. I have learned that the difference between the inflated AWP and WAC versus the true prices paid by providers is regularly referred to by industry insiders as "the spread."

The Congressional investigation establishes that this "spread" has not occurred accidentally but is the product of conscious and fully-informed business decisions. Bristol-Myers Squibb (BMS) documents, for example, demonstrate drug company control over the spread and knowledge that the spread acts as a financial inducement that affects medical judgments. I am told that BMS, as the innovator of the cancer drug Etoposide, repeatedly published inflated prices of approximately $138 while the true market price fell to less than $10. BMS then developed Etopophos, a newer, therapeutically superior substitute for Etoposide. As the following excerpts from BMS' own documents reveal, BMS' earlier participation in the false price manipulation scheme with Etoposide interfered with physician medical decisions to use Etopophos:

"The Etopophos product profile is significantly superior to that of etoposide injection . . ." (Exhibit #1).

"Currently, physician practices can take advantage of the growing disparity between VePesid's [name brand for Etoposide] list price (and, subsequently, the Average Wholesale Price [AWP]) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished" (Exhibit #2).

BMS' control over the AWPs published for its drugs is revealed in the following excerpt from a letter to the national publisher of drug prices relied on by the Medicaid Program:

Bristol-Myers Squibb Company:

"Edward Edelstein, First Data Bank . . .

"DEAR MR. EDELSTEIN: Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not affect any other business of Bristol-Myers Squibb Company" (Exhibit #3).

As a result of BMS' instructions, I am told First Data Bank recalculated BMS' AWPs and reported them to the State Medicaid agencies and Medicare Carriers as a BMS price increase when in truth it was nothing more than a means of creating a greater "spread" for BMS drugs.

Additionally, the drug companies in question often falsely state that they have no control over the AWPs and other prices published for their drugs. Comparing the following excerpts from a 1996 *Barron's* article entitled, "Hooked On Drugs," and Immunex's own internal documents reveals that drug companies do indeed have control over their prices:

"But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. 'The drug manufacturers have no control over the AWPs published . . .,' says spokeswoman Valerie Dowell" (Exhibit #5).

"Kathleen Stamm, Immunex Corporation . . .

"DEAR KATHLEEN: This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system. The price changes that were effective January 3, 1996 were posted in our system on January 5, 1996. 1 have enclosed an updated copy or your Red Book listing for your files. If there is anything else I could help you with do not hesitate to call.

Sincerely, Lisa Brandt, Red Book Data Analyst" (Exhibit #6)

The drug companies involved are well aware of the destructive impact their price manipulation has on prescription drug costs, as stated in the following excerpt from a Glaxo internal document:

"Is the [pharmaceutical] industry helping to moderate health care costs when it implements policies that increase the cost of pharmaceuticals to government?" (Exhibit #4).

These examples of clear deception appear to be "only the tip of the iceberg" as demonstrated by the evidence reflected in composite Exhibit #5. This evidence indicates that an official of the state of Florida Medicaid pharmacy program contacted Hoechst

Marion Roussel directly requesting pricing information for Hoechst's new drug Anzemet. Exhibit #5 is a copy of the fax sent to the Florida Official by Hoechst containing Hoechst representations of its prices.

The following chart represents a comparison of Hoescht's fraudulent price representations for its injectable form of the drug versus the actual prices paid by the industry insider. The industry insider was aware that a 100 mg vial of Anzemet could be purchased from a wholesaler/distributer for $70.00. The chart compares Hoescht's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoescht did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses doctors for the injectable form of this drug and not the tablet form. And by providing doctors a profit, Hoescht can influence prescribing. The tablet form is usually dispensed by pharmacists who accept the doctor's order. This example reflects the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs. Likewise, it underscores that we cannot rely upon the drug companies to make honest and truthful representations of their prices, and that Congress may be left with no alternative other than to legislate price controls.

Some drug companies have also utilized a large array of other impermissible inducements to mask true prices and stimulate sales of their drugs. These inducements, including bogus ''educational grants,'' volume discounts, and rebates or free goods are designed to result in a lower net cost to the purchaser, while concealing the actual cost beneath a high invoice price. A product invoiced at $100 for ten units of a drug item might really only cost the purchaser half that amount. Given, for instance, a subsequent shipment of an additional ten units at no charge, or a ''grant,'' ''rebate'' or ''credit memo'' in the amount of $50, the transaction would truly cost a net of only $5.00 per unit. Through all of these ''off-invoice'' means, drug purchasers are provided substantial discounts in exchange for their patronage, while maintaining the fiction of a higher invoice price—the price that corresponds to reported AWPs and inflated reimbursement from the government (Composite Exhibit #6):

The above document is particularly disturbing as it indicates that at least one purpose of ''masking'' the final price with free goods is so that the Federal Supply Schedule (''FSS'') falsely appears to be less than that of the hospital price.

Such misleading statements about pharmaceutical products by drug companies clearly entails deliberate price manipulation and in my opinion appears to be directly contrary to the letter and spirit of FDA law. For example, in 1997 Pharmacia & Upjohn reported an AWP of $946.94 for 200 mg. of Adriamycin PFS while it was offering to sell it to doctor groups such as American Oncology Resources for $168.00 and to Comprehensive Cancer Center for $152.00 (Composite Exhibit #7). Pharmacia & Upjohn then aggressively marketed its cancer drugs to health care providers by touting the financial inducements created by the false price representations and other types of monetary payments. It is apparent that Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers.

Moreover, Pharmacia & Upjohn's strategy of increasing the sales of its drugs by enriching, with taxpayer dollars, the doctors and others who administer them 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 it actually abused its position as a drug innovator in an initial Phase III FDA clinical trial for a cancer drug used to treat lymphoma, as detailed in Composite Exhibit #8:

The linking of doctor participation in FDA clinical drug trials to the purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is vital to the integrity of the trial. I am hopeful that the FDA will take immediate action to stop such behavior. Such quid pro quo in connection with new drug trials cannot be tolerated.

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 their 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.

My reading of the Federal Food, Drug, and Cosmetic Act and the corresponding regulations suggests that the FDA should pay particular attention to these misleading drug company actions. Accordingly, I am requesting that the FDA conduct a comprehensive investigation into drug company business practices.

Notwithstanding potential prohibitions under the Food Drug and Cosmetic Act, it appears drug manufacturers purposely create confusion and make false and misleading statements about drug pricing in order to deceive the United States Government and the States' Medicaid Programs. Recently there has been much media coverage of this issue—an article entitled ''Drugmakers Accused of Price Scheme'' in the USA Today and one entitled ''How Drug Makers Influence Medicare Reimbursements to Doctors'' in the Wall Street Journal.

In the larger sense, this letter and its accompanying exhibits raise questions of drug companies' wrongful influence on physician prescribing behavior, which leads to unsafe medical practice in the U.S. In light of these findings, I urge you to undertake a comprehensive review to ensure Americans are prescribed pharmaceuticals that are safe and effective. Physician prescribing should be based on need, not greed. I am extremely concerned that profit may be causing the public to be prescribed drugs that are not safe and effective for patients.

I have referred this evidence to you so that you may take action against these fraudulent schemes and, if appropriate, enforce relevant law and FDA regulations. I hope that you will take any and all administrative actions to ensure the integrity of drug pricing on behalf of the safety of the American public. And I look forward to discussing with you any necessary legislative solutions.

Sincerely,

PETE STARK,
Member of Congress.

TRIBUTE TO ARTHUR MALAN TINKER ST. CLAIR, AN OUTSTANDING WEST VIRGINIAN, ON HIS RETIREMENT AS U.S. SENATE DOORKEEPER

HON. NICK J. RAHALL II

OF WEST VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, October 12, 2000

Mr. RAHALL. Mr. Speaker, two days ago our distinguished senior Senator from West Virginia, ROBERT C. BYRD, rose on the floor to pay tribute to ''Tinker'' St. Clair of McDowell County, West Virginia. At the end of this year, Tinker St. Clair will retire from his post as senior Doorkeeper in the U.S. Senate after 21 years of distinguished service to that body.

Mr. Speaker, that is but a small part of this man's remarkable contribution to his family, his community, his State and his Nation.

When Arthur St. Clair was a toddler, he was an active little boy which led his grandmother to call him a ''little stinker.'' His envious brother, who couldn't yet pronounce all his words, called him ''a little tinker,'' and the nickname ''Tinker'' has remained with Arthur to this day.

Arthur ''Tinker'' St. Clair, born on January 6, 1916, is today 84 years old, having lived a busy, varied life with his late wife of 56 years, Elnora Hall St. Clair, raising their children Patty Lee and Linda, now Linda St. Clair Pence, wife of Ed Pence. Tinker is looking forward to his retirement, so that he can spend some quality time with his three grandchildren, Kimberly George, and Edwin Bryan and Mack Malan Pence. Tinker also looks forward to his greatest love, spending time with his two great-grandchildren, Nicholas Paul George and Jonathan Malan George.

Being a West Virginian, Tinker is the descendant from his father William Woods St. Clair, coal miner, school board member, and small businessman, and his homemaker mother Etta Mae Cochran St. Clair. Tinker was brought up with a strong work ethic, family values, and more than a gentle nudge toward community service handed down by his parents and grandparents, in what has been called ''the free state of McDowell.''

Mr. Speaker, I have the honor to represent McDowell County, West Virginia, Tinker's homeplace. I just as importantly have the honor of calling Tinker a dear and true friend from day one. Over the years, this southernmost county has seen a decline in population from 100,000 coal miners and their families, to today's count of approximately 30,000 men, women and children. The population drop was brought about when coal mines began to mechanize, and during those years of decline, unemployment has remained higher than the national average for the people who remained in McDowell County. It was the good, strong, determined people like Tinker St. Clair who stayed in the county and who never stopped helping his people in good times and in bad, until his retirement there in 1979.

Upon graduating from Gary High School in 1937, his first job was driving a school bus for McDowell County Public Schools. That is when he first met his future wife, Elnora. Once he was married and raising his children, Tinker went to work in 1941 for the Consolidated Bus Lines (which later became Continental Trailways), where he worked until 1947. Realizing how important transportation was and is