

The Neighborhood Social Club and Archives was founded by Rose A. Zitiello in 1993 to preserve the Italian American history of the neighborhood. Association President Sherri Scarpina DeLeva has presided over the last three annual award presentations to Joseph T. Fiocca, Yolanda Craciun, and Father Vincent Caruso, who served as the parish's first pastor in 1926.

Mr. Speaker, I ask my fellow colleagues in the U.S. House of Representatives to join me in honoring Michael Zone, Mary Zone, and the Zone family who have contributed so much to Cleveland's Mount Carmel West neighborhood and the city as a whole. Please also join me in acknowledging the contribution that the Neighborhood Social Club and Archives is making toward preserving the great heritage that the Zones and the Italian American community of Cleveland has made and continues to make.

DRUG COMPANY ABUSE OF AVERAGE WHOLESALE PRICE SYSTEM: PUBLIC DESERVES RETURN OF BILLIONS OF DOLLARS

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, September 28, 2000

Mr. STARK. Mr. Speaker, I have today sent the following letter to the Pharmaceutical Research Manufacturers of America (PhRMA), the chief trade association representing U.S. pharmaceutical companies.

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 letter follows:

COMMITTEE ON WAYS AND MEANS,

SUBCOMMITTEE ON HEALTH,

Washington, DC, September 28, 2000.

ALAN F. HOLMER,

President, Pharmaceutical Research and Manufacturers of America, Washington, DC.

DEAR MR. HOLMER. I am writing to share with you evidence and concerns I have, that certain PhRMA members, are employing false and fraudulent marketing schemes and other deceptive business practices in order to manipulate and inflate the prices of their drugs. Drug company deception costs federal and state governments, private insurers and others billions of dollars per year in excessive drug costs. This corruptive scheme is perverting the financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit. Furthermore, these deceptive, unlawful practices have a devastating financial impact upon the states' Medicaid Program.

As you may be aware, some state Medicaid administrators have been placed in the unenviable position of having to ration needed health care services to the poor due to a lack of funds. For example, major newspapers such as the Washington Post reported that the Administration abandoned its effort to extend Medicaid coverage for AIDS therapies due to the high cost of drugs needed to treat HIV patients (December 5, 1997).

The national media continues to report on the staggering cost of prescription drugs in the United States. By way of example, the shared Federal/State cost of providing a California Medicaid prescription drug benefit alone is now approximately \$2.4 billion dollars a year and that cost has risen by approximately 100% in the past four years. Through a Congressional subpoena, I have recently obtained internal drug company documents, together with documents from an industry insider, that explicitly expose the deliberate fraud that some of your PhRMA members are perpetrating on our nation's health care delivery system.

The evidence I have obtained indicates that at least some of your members have knowingly and deliberately 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 clearly establishes and exposes the drug manufacturers themselves that were the direct and sometimes indirect sources of the fraudulent misrepresentation of prices. Moreover, this unscrupulous "cartel" of companies has gone to extreme lengths to "mask" their drugs' true prices and their fraudulent conduct from federal and state authorities. I have learned that the difference between the falsely inflated representations of AWP and WAC verses the true prices providers are paying is regularly referred to in your industry as "the spread". The fraudulently manipulated discrepancies are staggering—for example in 1997 Pharmacia & Upjohn reported an AWP for its chemotherapy drug Vincasar of \$741.50, when in truth, its list price was \$593.20 (Exhibit #1 PHARMACIA 000867).

Exhibit #2 is a chart provided by an industry insider that lists a number of Medicare covered drugs where the Medicare beneficiaries' 20% co-payment exceeds the entire costs of the drug. These rogue drug companies then market their drugs to physicians and pharmacies based on this windfall profit which in reality is nothing more than a government funded kick-back to the provider.

The evidence is overwhelming that this "spread" did not occur accidentally but is the product of conscious and fully informed business decisions by certain PhRMA members. The following examples excerpted from the subpoenaed documents clearly indicate the companies' fraudulent efforts to manipulate Medicare and Medicaid reimbursements as contained in Composite Exhibit #3.

Pharmacia: "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 multisource products offered on the contract give AOR a wide margin for profit." (000025)

Bayer: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the

HHC. It is a very simple process to increase our AWP, and can be done overnight". (BAY003101)

Alpha: "Pharmacy billing and management services can bill for product based on the published AWP and thereby net incremental margin with Venoglobulin S usage. Margin for the pharmacy is the difference between AWP and acquisition cost. (\$76.15/g-\$30.00/g=\$46.15/g margin)." (AA000529)

Fujisawa: "Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business . . . I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we will still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is 162 we will have to be at least \$29 to have the same spread. Follow?" (F13206 & F13207)

Baxter: "Increasing AWP's was a large part of our negotiations with the large homecare companies" (0003153)

And the implications of the fraudulent manipulation of prices were clearly recognized by your member manufacturers who participated in this false pricing scheme. A series of memos from a pricing committee concerned with Glaxo's antiemetic, Zofran, show the committee's development of an enhanced spread for Zofran through increases in AWP and decreases in net purchase price (Exhibit #4).

Glaxo: "If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters . . . If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share. Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of government? How will this new pricing structure compare with costs in other countries? Is the [pharmaceutical] industry helping to moderate healthcare costs when it implements policies that increase the cost of pharmaceuticals to government?" (GWIG/7:00014 & 00015)

Internal documents from a contractor of SmithKline, (Glaxo's competitor) likewise reveal its recognition of the inflationary effect on government reimbursement of these pricing practices and the potential for an adverse counter-offensive (Exhibit #5):

". . . highlighting the difference between the actual acquisition cost and the published AWP may not only increase attention to Glaxo's pricing practices, but may provide the impetus for HCFA to implement a system that could impact not only reimbursement of anti-emetics, but all pharmaceutical and biological products. The ramifications could extend well past Medicare to include Medicaid programs. . ." (SB01915)

Perhaps the most striking example of the manufacturers' recognition of the spread and the companies' fraudulent abuse it represents is found in a revealing exchange of

correspondence between corporate counsel from Glaxo and SmithKline Beecham in which each accuse the other's company of Medicaid fraud and abuse (Exhibit #6).

Glaxo: ". . . In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their "profits" from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate." (SB04075) And SmithKline's response was (Exhibit #7):

SmithKline: "In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate . . . The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP. Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors." (SB044277) (In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.)

Some drug companies have also utilized a large array of other impermissible inducements to stimulate sales of their drugs. These inducements, including bogus "educational grants", volume discounts, rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price 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 these "off-invoice" means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price—the price that corresponded to reported AWP's and inflated reimbursement from the government composite Exhibit #8.

Bayer: "I have been told that our present Kogennate price, \$.66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest

a price of \$.60 to \$.62 to secure this volume. From Quantum's stand point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources." (BAY005241)

Baxter: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction of Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction." (0003632)

Gensia: "Hospital—Concentrate field reps on the top 40 AIDS hospitals using a \$54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of \$48.60 per vial." (G00888)

Gensia: "FSS—Establish a price of \$52.00/vial for Q1 and Q2."

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 it falsely appears that the Federal Supply Schedule ("FSS") is less than that of the Hospital Price.

This insidious behavior by some PhRMA members has a profound and dangerous additional effect by influencing some medical practitioners' judgements. This is acknowledged by Bristol-Myers Squibb ("BMS") who developed a second generation etoposide, namely, Etopophos (Composite Exhibit #9).

BMS: "The Etopophos product profile is significantly superior to that of etoposide for injection . . ." (BMS: 3: 000013)

"Currently, physician practices can take advantage of the growing disparity between VePesid's list price (and, subsequently, the Average Wholesale Price [AWP]) and the actual acquisition cost when obtaining reimbursement for etoposide purchase. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished." (BMS: 3: 000014)

This influence is further demonstrated by SmithKline Beecham and TAP:

SmithKline: "In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP. . . . Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of \$50.27 for the medication alone. . . . From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens." (SB00878)

TAP: "As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would

stop if the allowable issue was taken care of. NWI Urology has 180 patients on Lupron". (TAP-BL10036469)

The documents further expose the fact that certain of your members deliberately concealed and misrepresented the source of AWP's:

In a 1996 Barron's article entitled "Hooked On Drugs", the following quote from Immunex appeared (Composite Exhibit #11):

Immunex: "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 AWP's published . . ." says spokeswoman, Valerie Dowell. (IMNX003079)

However, Immunex's own internal documents indisputably establish the knowledge of the origin of their AWP's and their active concealment:

Letter from Red Book to Immunex: "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. I have enclosed an updated copy of 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." (IMNX 002262)

These examples of deception appear to be "only the tip of the iceberg" as demonstrated by the evidence contained in Composite Exhibit #12. Exhibit #12 contains the following:

1. Copy of advertisement sent to the insider from Oncology Therapeutics Network ("OTN") representing the true wholesale prices to the industry insider for Anzemet.

2. A copy of a fax sent to a Florida Medicaid pharmacy official by Hoechst containing Hoechst representations of its prices.

The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is also 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 by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores 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 and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

	NDC NO.	Unit size/type	Quantity	Net price as represented to Florida Medicaid	True wholesale price	Variance
Price Representations for:						
Anzemet injection	0088-1206-32	100 mg/5ml injectable	1	\$124.90	\$70.00	Represented price 78% higher than true wholesale price.
Anzemet tablets	0088-1203-05	100 mg tablets	5	275.00	289.75	Represented price 5% less than true wholesale price.

Hoescht thus falsely inflated the reported price of its Anzemet to create an improper financial incentive and thus capture market share. The following excerpt from an internal Glaxo document reveals that Hoescht directly benefitted from this diversion of tax dollars:

(Exhibit #13) Glaxo: "There is a decline in Zofran usage at Louisiana Oncology in Baton Rouge, Louisiana. Kevin Turner (H1JCO2) has seen a drastic decline in Zofran usage at this clinic over the last few months. The reason for this decline is strictly a reimbursement issue. This clinic has started using Anzemet because it is more profitable. Kevin has learned that this clinic is buying Anzemet for \$58.00 for a 100mg vial, which gives them a \$84.29 profit from Medicare. They are buying a 40mg vial of Zofran for \$145.28. If they use 32 mg of Zofran, which is \$3.63 per mg, this will net this clinic \$69.60 from Medicare reimbursement. Clearly Anzemet has a reimbursement advantage over Zofran. . . ." (GWZ 085003)

The above evidence leads to some shocking conclusions.

First—Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kick-back for their customers.

Second—Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physician and other healthcare provider customers.

Third—Certain drug manufacturers engage in fraudulent price manipulation for the express purpose of causing federally funded healthcare programs to expend scarce tax dollars in order to arrange de facto kick-backs for the drug manufacturers' customers at a cost of billions of dollars.

Fourth—Certain drug manufacturers arrange kick-backs to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive affect upon the physician/patient relationship and the exercise of independent medical judgement.

Fifth—Certain drug manufacturers engage in illegal price manipulation in order to increase the utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

As the principal association representing the pharmaceutical manufacturing industry, I believe you owe it to the citizens of the United States to advise Congress as to whether the above evidence reflects the standards of the pharmaceutical industry in this country. If it does, then explicit price regulation will clearly be necessary to counter your industry's inability to report prices will integrity and its propensity to engage in price manipulation. If, on the other hand, the above evidence does not reflect the standards in the pharmaceutical industry, then your association owes it to the American people to support and assist with the efforts of the federal and state enforcement authorities, including the U.S. Department of Justice, to correct the actions of the drug manufacturers engaging in this conduct and to require them to compensate Medicare, Medicaid and other federally funded programs for the damages they have caused.

Sincerely,

PETE STARK,
Ranking Member,
Subcommittee on Health.

EXTENSIONS OF REMARKS

RECOGNIZING IRONWORKERS LOCAL #395

HON. PETER J. VISCLOSKY

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Thursday, September 28, 2000

Mr. VISCLOSKY. Mr. Speaker, it is my distinct honor to congratulate some of the most dedicated and skilled workers in Northwest Indiana. On September 30, 2000, the Ironworkers Local #395, of Hammond, Indiana, will honor their newly retired members as well as their members with fifty, forty, thirty-five and twenty-five years of continued service. These individuals, in addition to the other Local #395 members who have served Northwest Indiana so diligently throughout the years, are a testament to the American worker: loyal, dedicated, and hardworking.

The men and women of Local #395 are a fine representation of America's working families. I am proud to represent such dedicated men and women in Congress. Those members who recently retired from Ironworkers #395 include: Anthony Bobrowski, Steve Bodak, Bruce Brown, Jack Bullard, Howard Cassidy, Jimmy Chandler, Nicholas Danko, Stanley Downs, LeRoy Garmany, Frank Hall, Richard Haynes, James Hendon, Harvey Hollifield, Peter Leon, Jr., Robert Morton, Harold Mowry, William Rathjen, Joe Rumble, Jacob Stoyakovich, Fred Strayer, George Ward, Dallas Woodall, and Austin Yale. The members who will be honored for fifty years of service include: Glen Bacon, Norman Barnhouse, Robert Bird, Alfred Bruce, Charles Coleman, Paul Condry, Joe Demo, Harold Eason, Floyd Evans, Herbert Goodrich, Wilbur Kissinger, Willard Lail, George Rosich, Russell Thomas, and Van Walker. Those members who will be recognized for their forty years of service include: Gerald Black, John Bowman, Howard Cassidy, Jimmy Chandler, Nicholas Danko, Jr., Donald Eagen, Arthur Erickson, Jr., Wayne Fiscus, Lowell T. Hannah, James P. Harrison, Richard Haynes, Donald Hendrix, Robert Jackson, Edgar Johnson, Karl Langbeen, Jerry Lee, William Libich, Roger Long, Gerald McBride, Robert C. McDonald, William McNorton, Richard Ogle, John Peyton, Joseph Quaglia, Ace Robertson, Richard Samplawski, Larry J. Sausman, Charles Schwartz, Louis D. Sewell, John Spicer, Larry M. Strayer, Joseph Sullivan, Robert D. Swanson, Ned Toneff, Gerald Trimble, Donald Vick, Lawrence D. Watson, Frank Wheeler, and Gerald Wilson. The members who will be honored for thirty-five years of service include: Thomas Anderson, Tony Bobrowski, Michael Cary, Ed Corrie, Joseph Dado, James E. Davis, James Eagen, Terry Evans, Arthur Gass, Jr., Arthur Gaynor, Franklin Gerwing, Donald E. Goodrich, Kenneth Hamilton, John Haugh, Dennis Hummel, Dennis Hutchens, Richard Jemenko, Barney Kerr, Michael Klaker, Kenneth Kollasch, Max Korte, Charles Langston, Robert Langston, Eugene Lemons, William Lundy, William Okeley, Jr., James Penix, Ronald Penix, Wilbert Risch, Terry D. Sausman, Tim Skertich, Daniel Stevens, Gerald Vasko, John Ward, William Weigus, Gerald Wheeler, David Wilmeth, Dallas Woodall. The members who will be honored for their

September 28, 2000

twenty-five years of dedicated service include: Henry Abegg, Donald Barringer, Paul Beck, Robert Brunner, Jr., Lenard Campbell, Everett Cleveland, Jr., James A. Curry, Clint Denault, John Grube, James Guzikowski, John Hillier, Timothy Jones, Sr., Thomas Kintz, Gary Komacko, Jack Kramarzewski, Dennis Quinn, William Robertson, John Schuljak, Stanley Siwinski, Douglas Splitgerber, John Williams. I would also like to congratulate those individuals that graduated from the apprenticeship program. These individuals include: James Anderson, John Anderson, Eric Blevins, Robert Brazeal, Jeremy Camplan, Steven Elliott, Thomas Franciski, Jr., Geno George, Anthony Gutierrez, Michael Hamilton, Anthony Hammerstein, Benjamin Lauper, David Maday, George Martinez, Brian McClain, David Ross, John Sechrest, Brian Swisher, Robert Thomas, Timothy Tinsley, Corey Weiland, and James Wilkie.

Mr. Speaker, I ask that you and my distinguished colleagues join me in congratulating these admirable and outstanding members of the Ironworkers Local #395 for their efforts in fulfilling the American ideal of success through hard work and determination. I offer my heartfelt congratulations to these individuals, as they have worked arduously to make this dream possible for others. They have proven themselves to be distinguished advocates for the labor movement, and they have made Northwest Indiana a better place to live, work, and raise a family.

HONORING A DEDICATED HUSBAND, FATHER, GRANDFATHER, VETERAN AND PHYSICIAN—JOHN CHARLES LUNGREN, M.D. (APRIL 27, 1916—FEBRUARY 28, 2000)

HON. JAMES E. ROGAN

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, September 28, 2000

Mr. ROGAN. Mr. Speaker, today, it is my distinct honor to pay tribute to an American who gave of himself during his 83 years of life—John Charles Lungren, M.D.

Dr. Lungren was born in Sioux City, Iowa on April 27, 1916. He attended the University of Notre Dame, graduating with a Bachelor's Degree in Science in 1938. Dr. Lungren subsequently received his Medical Degree in 1942 from the University of Pennsylvania.

During World War II, Dr. Lungren served with the United States as a Battalion Surgeon and Captain, 30th Infantry Division receiving four Battle Stars and a Purple Heart. This included participating in the pivotal battles of St. Lo and Mortain and in the Normandy Invasion in June of 1944.

After World War II, Dr. Lungren returned to his wife, Lorain Kathleen Lungren and, at that time, their first child. He settled in Long Beach, California specializing in internal medicine and cardiology which included various positions in the medical profession, including chief of staff for Long Beach Memorial Medical Center, member of the California State Board of Medical Quality Assurance and an emeritus associate clinical professor of medicine, UCLA School of Medicine, 1960–1977.