STARK CALLS FOR FURTHER FDA INVESTIGATION INTO ABUSE OF AVERAGE WHOLESALE PRICE SYSTEM

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 11, 2000

Mr. STARK. Mr. Speaker, I today sent the following letter to the FDA, in support of an investigation of how some of the nation's leading drug manufacturers are using false pricing data to distort the practice of medicine in America. The data in the letter is an indictment of the companies' abuse of the taxpayer and of the patient.

I submit the following letter into the RECORD:

HOUSE OF REPRESENTATIVES,
Washington, DC, October 10, 2000.

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

DEAR DR. HENNEY: I am writing you to supplement my recent letter of October 3, 2000. I would request that any FDA investigation into whether certain drug companies have engaged in conduct that violates FDA rules or regulations take into account the following:

1. *The findings contained in the HHS–OIG report entitled Infusion Therapy Services Provided in Skilled Nursing Facilities (December 1999 A–06–99–00058) Exhibit #1.* The OIG's independent findings provide compelling evidence of the magnitude, cost and public health issues resulting from drug price manipulation of the Medicare program.

The following excerpts from the above referenced OIG report are particularly noteworthy:

''Our review of three infusion suppliers, for the period 1995 through 1998, showed they provided infusion therapy services to Medicare-reimbursed SNFs that were excessively priced and unnecessary.'' (Page #1)

''At the 22 SNFs, $4.8 million out of $9 million in claims reviewed (53 percent) were not medically necessary.'' (Page #1)

''In addition to the financial effects we noted above, overutilization and overpricing were potentially harmful to the patients. Medical reviewers who were part of our audit concluded that patients receiving unnecessary infusion therapy services were placed at undue risk for complications, including increased risk of infection, fluid and electrolyte imbalance, and medical reactions. Furthermore, in addition, infusion services are invasive procedures that are painful and, when unnecessary, reduce the quality of life.''

''Based on a survey of infusion suppliers in Texas, we found that charges for infusion drugs varied widely, from as little as Average Wholesale Price (AWP), which is generally considered a reference price for drugs by the pharmaceutical industry, to more than 20 times AWP.'' (Page #6)

2. *The public health consequences of the drug pricing manipulation by certain companies for the IV antibiotic Vancomycin, the drug of last resort for many life theratening infections.* Exhibit #2 features an article from Hospital Pharmacist Report entitled Under Attack Vancomycin-resistant S. Aureus Hits U.S. Shores. ''The widespread, and often unwarranted, use of antimicrobial agents, particularly vancomycin is a major contributing factor in the emergence of S. aureau with diminished susceptibility to vancomycin.'' Indeed, as stated in the article, the problem has reached the level where the CDC has called for strict limits on the use of this vital drug. ''Published in the MMWR, detailed recommendations for preventing and controlling S. aureus with diminished susceptibility to vancomycin emphasize strict adherence to contact isolation precautions and their recommended infection control practices, *judicious use of vancomycin . . .*'' (emphasis added).

Enclosed as composite Exhibit #3 (provided by the industry insider pursuant to a congressional subpoena) is:

1. Listings from the 1995, 1996 & 1999 Red Book for Abbott's generic Vancomycin.

2. Copies of advertisements from Florida Infusion for the years '95, '96 and '99 for Abbott's genreic Vancomycin.

The following chart summarizes Exhibit 3:

ABBOTT'S VANCOMYCIN

[1 gm. 10s NDC#00074–6533–01]

Year	Red Book AWP	Red Book DP	Florida infusion true wholesale price	Difference between AWP & true price ''The Spread''
1995	604.44 (60.44/1 gm.)		$8.40/1 gm	$52.04
1996	628.66 (62.86/1 gm.)		$7.95/1 gm	$54.91
1999	727.82 (72.78/1 gm.)	612.90	74.00 ($7.40/1 gm.)	$65.38

As the above chart also demonstrates, Abbott actually raised its representations of AWP from 1996 to 1999 while the true wholesale price to providers fell from $7.95 to $7.40. Abbott's price manipulation, creating a financial incentive for doctors to increase their usage of Vancomycin at a time when America is experiencing a health crisis, is reprehensible conduct and clearly warrants an FDA investigation.

You may question why a major drug company would engage in this deplorable conduct? Abbott's direct benefit from its false price manipulation is demonstrated by data (enclosed as Exhibit #4 provided by the industry insider pursuant to a congressional subpoena) for calendar year 1996 from the State of Florida's Medicaid Pharmacy Program. The data outline Florida Medicaid's reimbursements paid to the customers of Abbott and utilization of Abbott's generic Vancomycin. Abbott maximized sales volume and captured the Florida medicaid pharmacy market for Vancomycin by causing the Florida Medicaid program to substantially inflate reimbursement to the detriment of Florida's Medicaid Program. As you know, drug companies capture market share and maximize sales volume by concealing true drug prices while falsely representing grossly inflated prices which in turn creates a spread between the providers' costs and the amount of reimbursement paid by Medicaid or Medicare. As a result, Abbott has captured the majority of the market (at least for Medicaid) by creating a financial incentive for doctors to increase their usage of the overprescribed drug (Exhibit #5—prepared by the National Association of Medicaid Fraud Control Units in conjunction with their ongoing investigation).

The insider's evidence demonstrates that providers will purchase and utilize the pharmaceutical manufacturer's product that has the widest spread between the provider's true cost and the reimbursement paid by third parties (including the States' Medicaid Programs and Medicare). For example, 1996 reimbursement demonstrates that the manufacturer which causes the widest spread, benefits from the highest utilization. The pharmaceutical manufacturers Abbott, Fujisawa, Lederle Lilly and Schein all made representations of Wholesaler Acquisiton Cost (''WAC'') to the State of Florida as illustrated in the chart below. The chart further sets out the number of reimbursed claims, the insider's cost and ''the spread'' between Medicaid reimbursement and true cost. A review of the chart clearly demonstrates that the vast majority of providers utilize the manufacturer's pharmaceutical with the greatest spread between the true Wholesale Acquisition Cost and the inflated false WAC reported by Abbott.

1996 FLORIDA MEDICAID UTILIZATION FOR VANCOMYCIN HCL 1 GRAM

Company/NDC	True cost $	Florida Medicaid Reimbursement	The spread	Reimbursement paid by Florida Medicaid	% of market share
Abbott/00074–6533–01	$7.95	$58.75	$50.80	$381,480.78	83.37
Fujisawa/00469–2840–40	6.42	13.91	7.49	19,023.54	4.16
Lederle/00205–3154–15	3.98	9.36	5.38	21,297.64	4.65
Lilly/00002–7321–10	14.30	13.35	(0.95)	19,096.96	4.17
Schein/00364–2473–91	6.05	12.52	6.47	16,672.18	3.64

It is important to note that Abbott publishes and reports truthful prices for many of its drugs when it does not seek to create a financial incentive to the provider. The following attached as composite Exhibit #6 is a chart specifying numerous drugs for which Abbott reports truthful prices:

ABBOTT LABS 1999 REPRESENTATIONS OF PRICES AND COST AND STATES' MEDICAID REIMBURSEMENT

Drug Strength & Size, NDC# 00074–	Red Book AWP	Bergen Brunswig cost (WAC*)	Provider cost with 7% upcharge	Florida Medicaid WAC + 7%	New York Medicaid AWP–10%
Biaxin 500 MG, 60S NDC#2586–60	$195.59	$164.13	$175.62	175.62 Spread $0.00	$176.04 Spread $0.42 (0.2%).
Cartol 5mg, 100s NDC#166–13	106.18	88.76	94.97	94.97 Spread $0.00	$95.57 Spread $0.60 (0.6%).
Cylert Tablets 37.5mg, 100s NDC# 6057–13	144.84	121.67	130.18	130.18 Spread $0.00	$130.36 Spread $0.18 (0.1%).

ABBOTT LABS 1999 REPRESENTATIONS OF PRICES AND COST AND STATES' MEDICAID REIMBURSEMENT—Continued

Drug Strength & Size, NDC# 00074–	Red Book AWP	Bergen Brunswig cost (WAC*)	Provider cost with 7% up-charge	Florida Medicaid WAC + 7%	New York Medicaid AWP–10%
Depakote 250mg, 100s NDC# 6214–11	82.66	69.30	74.15	$74.15 Spread $0.00	$74.40 Spread $0.25 (0.3%).

* WAC—Wholesaler Acquisition Cost (7 states use WAC for reimbursement).

3. *Examination of another Medicare reimbursed drug further confirms that the drug manufacturers engaging in the price manipulation are correct when they assume that the financial incentives they arrange will increase the usage of their drugs.* Atrovent (Ipratropium Bromide) is an inhalant medication that had almost no Medicare utilization while it was under patent and not subject to any generic competition. Sometime in 1997, Atrovent came off patent and became subject to generic competition. Certain manufacturers of the generic form of the drug began to make false price representations to create a financial inducement. As the chart below indicates, Medicare utilization has gone from $14,426,108.00 in 1995 to $253,400,414.00 in 1998. The spread has gone from virtually zero to over 100%!

Year	Medicare Reimbursement amount per unit*	True cost per Medicare unit**	Spread $	Spread %	Medicare expenditures
1995	$3.11 ($0.62/ml)	$3.11	0.00	0	$14,416,108
1996	3.75 (0.75/ml)	3.26	0.49	15	47,388,622
1997	3.50 ($0.70/ml)	2.15	1.35	63	96,204,639
1998	3.34	1.70	1.64	96	176,887,868
1999	3.34	1.60	1.74	108	253,400,424

* Medicare Units were converted from ml's to mg's for the years 1995, 1996 & 1997 (5 ml=1 milligram).

Would you please advise me if the FDA since 1995 has approved any other additional indications that might explain the dramatic increase in the utilization of Ipratropium Bromide. Is there any medical reason for these noted utilization increases?

It is essential that the Health Care Financing Administration and other government reimbursement authorities receive truthful and accurate information from drug manufacturers regarding drugs for which the government reimburses. The evidence uncovered by the Congressional investigation to date reveals a conscious, concerted and successful effort by some drug makers to actively mislead the Health Care Financing Administration and others about the price of their drugs. As the federal agency possessing primary regulatory responsibility with respect to drug makers' representations about their products, I urge the Food and Drug Administration to take immediate action before the present fiscal and public health consequences reach a catastrophic level.

Sincerely,

PETE STARK,
Member of Congress.

WRONG ON KAZAKHSTAN

HON. DAN BURTON

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 11, 2000

Mr. BURTON of Indiana. Mr. Speaker, I would like to draw the attention of my colleagues to a very disturbing Op Ed article by Professor Amos Perlmutter ("More words than deeds on Kazakhstan?" in the Washington Times of October 4, 2000), detailing how the Clinton-Gore Administration has dropped the ball in promoting democracy and respect for human rights in Kazakhstan.

Time after time, Kazakhstan's ruthless and corrupt President, Nursultan Nazarbayev, has made promises to Vice President Gore and others in the Administration and has then failed to deliver on those promises. And so as Professor Perlmutter puts it, the Nazarbayev regime continues its campaign of "relentlessly destroying the opposition, closing the free press and involving itself in corrupt schemes."

It should have been possible for the United States, which has had the support of the Organization for Security and Cooperation in Europe as well as numerous non-governmental human rights organizations, to insist that Nazarbayev fulfill the promises he made on human rights and free elections as a price for legitimacy in American eyes. Sadly, however, it seems clear that Clinton-Gore Administration has pulled its punches, because it wants oil rich Kazakhstan's support for an oil pipeline that does not go through Russia. What is particularly troublesome in this regard is that the United States should not be turning a blind eye to repression and corruption in order to persuade Kazakhstan to do something that is in its interest in any event.

Mr. Speaker, I would like to submit Professor Perlmutter's article for the RECORD.

MORE WORDS THAN DEEDS ON KAZAKHSTAN?

(By Amos Perlmutter)

The Clinton-Gore administration relationship with Nursultan Nazarbayev's corrupt dictatorship in Kazakhstan is, once again, making news. Not without reason.

The case is that the administration failed to defend political freedom and free enterprise in Kazakhstan. They talked the talk without walking the walk when it come to challenging the Nazarbayev dictatorship.

Promises from Mr. Nazarbayev went unfulfilled. The administration failed to support the claims of human rights organizations, non-government organizations (NGOs), and the OSCE that the Nazarbayev government is not only failing to undergo democratic changes as a price for support from the United States, but also is relentlessly destroying the opposition, closing the free press and involving itself in corrupt schemes.

The effort to support this regime was conceived in conformity with the American national interest. After all, there are three reasons for U.S. strategic interest in Kazakhstan: oil, nukes and independence. Kazakhstan has been one of the Soviet Union's major oil reserves, and continues to be a most significant oil reserve and also a Caspian littoral state. Josef Stalin made Kazakhstan a Soviet nuclear arsenal.

Independence was the goal of both the Bush and Clinton administrations, to strengthen Central Asia non-Russian Muslim states, and to move them in the direction of democracy and free enterprise. There was a tacit strategic purpose in separating Kazakhstan from Russia's historical imperial linkages (an exercise in futility). Kazakhstan is the most Russified Central Asian state, with close to 30 percent of its population Russians who serve as the main scientific industrial and business elite.

However, the Clinton administration sank into the pool of oil that inadvertently led to the most serious corruption of the Nazarbayev dictatorship by failing to resist the dictatorship. One of the administration's major foreign policy goals was humanitarian intervention to help bring an end to former communist dictatorships in the former Soviet Union and the Balkans.

In fact, the administration conducted a "humanitarian war" in Kosovo. The idea of a humanitarian and exemplary intervention, i.e. support of opposition groups in Kazakhstan, free press, and democracy was sacrificed, unfortunately, to the pool of oil.

The administration was not directly involved in support of the dictatorship. But it failed to vigorously resist the Nazarbayev violation of human rights, dissolution of the Kazakh parliament on two occasions, and above all the closing the only two opposition papers and the rigging of the 1999 elections.

In defense of the administration you could say diplomatic gobbledygook and securing unfulfilled promises form Mr. Nazarbayev was unfortunately subordinated to oil and nuclear strategic policies. The embassy in Kazakhstan continuously reported to the U.S. State Department on Mr. Nazarbayev's violations of human rights.

In fact, the OSCE, human rights groups, non-government organizations (NGOs), and other groups have warned the administration and continuously protested Mr. Nazarbayev's dictatorship and suppression of freedom in Kazakhstan. Leon Fuerth, Vice President Al Gore's national security adviser, and his assistant, Richard Brody, met on Sept. 15, 1999, at the Old Executive Office Building to discuss Nazarbayev to the United States. Attending were several people from the State Department, regional and human rights bureaus, as well as the Human Rights Foundation, and the Kazakhstan 21st Century Foundation.

Mr. Fuerth was on the defensive throughout the meeting, as the various representatives pressed hard the argument that the meeting was a mistake at that time, since Mr. Nazarbayev would interpret it as an endorsement of his behavior. According to one of the participants, Mr. Fuerth was unpersuasive and ineffective in defending the