

October 12, 2000

and the Court, will continue for the foreseeable future. In addition, I am not aware of any suggestion or concern that the U.S. Supreme Court Police has misused its authority, or should not be entitled to such authority on a permanent basis.

In fact the evidence suggests that the U.S. Supreme Court Police has discharged its responsibilities in an efficient and cost effective manner. For example, the cost of the program has been minimal. The Supreme Court Police work closely with the U.S. Marshal's office to provide security for Supreme Court Justices when they travel outside the Washington, DC, metropolitan area. Over the past 4 years, there were 74 requests for Supreme Court Police protection beyond the D.C. metropolitan area at a total cost of \$16,855, or \$4,214 per year.

In light of continuing security concerns, and the Supreme Court Police's record of providing appropriate protection over the past 18 years for the Justices, Court employees, and official visitors, I support making the Supreme Court Polices authorization to provide security on and off Supreme court grounds permanent. As a result, I urge my colleagues to support the bill.

#### A TRIBUTE TO GAIL WEISS

**HON. BENJAMIN A. GILMAN**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 11, 2000

Mr. GILMAN. Mr. Speaker, I am pleased to join with my colleagues this evening to recognize the long, distinguished career of Gail Weiss. Gail, who serves so ably now as the Minority Staff Director on the Committee on Education and the Workforce, and before that as Staff Director of that Committee, had earlier served as Staff Director of our Committee on Post Office and Civil Service, chaired by my good colleague, the gentleman from Missouri, Mr. CLAY. Serving as the Ranking Minority Member of the Post Office Committee at that time, I had the opportunity to work closely with Gail. I found her to be a true professional and I appreciated the time she took to listen to our positions on various issues before our Committee.

We will surely miss having Gail's experience and institutional memory upon which to rely. Gail is one of a dwindling corps of staff who have the ability to put the measures before us into the perspective of earlier legislation enacted to address important issues. Her expertise on postal and civil service issues and those before the Committee on Education and the Workforce have helped us to develop legislative initiatives that address these issues in an effective manner.

I am certain that Gail will continue to be active in a number of areas that are of keen interest to her. I know that our colleagues will also continue to reach out to her for her thoughts on key matters that we deal with in the Congress. I've certainly become fond of both Gail and her husband Jack and wish them great success, happiness, and good health as they enter this new and rewarding time in their lives.

#### EXTENSIONS OF REMARKS

##### TRIBUTE TO ITALIAN GARDENS RESTAURANT

**HON. KAREN MCCARTHY**

OF MISSOURI

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 11, 2000

Ms. MCCARTHY of Missouri. Mr. Speaker, I rise today to pay tribute to a Kansas City, Missouri family tradition. Seventy-five years ago a small, family owned business established its roots in the heart of Kansas City. Today, the Italian Gardens Restaurant is a well established and celebrated Kansas City landmark and popular eatery.

The late John Bondon, Sr., first opened the Italian Gardens Restaurant in 1925 with his nephew Frank Lipari. It was a difficult time for the partners and most of the country as the economy collapsed and a world war became a reality. Despite these challenges Italian Gardens persevered and in 1933 the restaurant was able to move to its current location at 1110 Baltimore with the help of a \$1,500 loan from a waitress. John Bondon and Frank Lipari owned only one new pair of shoes worn by whomever was working with the public in the front of the restaurant. When America entered World War II, the Italian Gardens recognized the anti-Italian sentiments present at this time and was forced to temporarily change the name of the restaurant to "The Gardens." The restaurant was available for dinner only since many of the staff was working in the defense industry.

Over the past 75 years, the Italian Gardens has spanned five generations of family proprietorship and attracted a large and loyal following of patrons. The restaurant has attracted a diverse crowd of customers such as Joe Di Maggio, Katherine Hepburn, Frank Sinatra, Liberace, and the famed outlays Bonnie Parker and Clyde Barrow. For seventy-five years the Italian Gardens has been known by businessmen, artists, athletes, and neighbors to be a large community table and gathering place where everyone is made to feel welcome and part of the family.

Throughout their rich heritage the Italian Gardens Restaurant has been a significant charitable and civic contributor to our community, including lending the talents and expertise of its executives to critical boards and commissions benefitting the Greater Kansas City Area. The Italian Gardens family includes the now retired Carl DiCapo, John Bondon, president of the restaurant company, and great-nephew of the original co-founder, Bondon's mother, Carolyn Berbiglia, Bondon's wife, Vicki, and his daughter Bianca. The Italian Gardens is a Kansas City landmark that has served as a model of success in our community. It is one of the few longtime family owned operations still present in our region. This cherished local eatery has established a standard of excellence that will continue to be celebrated for years to come.

Mr. Speaker, please join me in congratulating the Italian Gardens Restaurant family as it celebrates seventy-five years of service to the Kansas City community.

22705

##### 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 threatening 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. aureus 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 generic 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 Medi-

care. 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 over-prescribed 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 Acquisition 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:

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% up-charge	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%).
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 al-

most 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 finan-

cial 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 came to challenging the Nazarbayev dictatorship.

Promises from Mr. Nazarbayev went unfulfilled. The administration failed to sup-

port 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 purpose for the visit of Mr. Nazarbayev to United States.

The issue at stake was Kazakhstan's MiG sales to North Korea and the failure of democracy. When Mr. Nazarbayev promised Mr. Gore the next election "would be better," the OSCE report on the 1999 elections in Kazakhstan were still pending. Mr. Fuerth said at the meeting, "We will adopt its [OSCE's] finding as leverage on Nazarbayev." Mr. Fuerth continued, "Our government has been saying repeatedly, and the vice president personally, pay attention to what the monitors are saying about your, i.e., Nazarbayev's, elections." Mr. Fuerth said Mr. Nazarbayev is "not your poster boy" for democracy and freedom. Mr. Fuerth said, "Gore sees his personal relationship as essential to prodding Nazarbayev toward democracy."

America's goals include, says Mr. Fuerth, "carrying Kazakhstan to a modern self-sustaining state at every level of societal concern. . . . We are into their affairs at an fantastic level of detail, and that is only possible with the political support of Nazarbayev and this [Gore-Nazarbayev] commission and the commitment of the United States to a face-to-face meeting with the vice president."

Mr. Fuerth continued to say the United States must persuade them to "more and more perfect democracy," and he is "perfectly aware of the imperfections." According to Mr. Fuerth, Mr. Gore's message is "Democracy is on the agenda. Democracy is not our idiosyncrasy." He describes Mr. Gore's agenda as follows: "Democracy and elections are essential parts of the relationship Nazarbayev wants with the U.S. Gore will explain why a valid election is indispensable if he [Mr. Nazarbayev] wants the relationship he seeks."

After meeting with the president, Mr. Nazarbayev went back home and continued in his oil-mired practices, human-rights violations and the creation of his position as president for life.

Since Mr. Gore was given the portfolio on Russia and the independent states of the former Soviet Union, the essential difference between what the Cox Report finds in the case of Russia and the administration policy toward Kazakhstan is that in the case of Russia it was mired with good intentions for reform that turned sour because of support for Boris Yeltsin's corrupt, undemocratic government. You cannot tell Russia, a major power, what to do, while the situation in Kazakhstan was totally different.

Not only was the United States in the position to help implement the recommendations for democracy and freedom in Kazakhstan, it coddled the dictator and made no impact whatsoever or follow up on the promises made my Mr. Nazarbayev to Mr. Gore to advance the democracy in Kazakhstan.

In the case of Kazakhstan, the United States was in a stronger position than in Russia, with the support of OSCE, multiple human rights organizations and NGOs, to impose upon the dictatorship to implement their promises made on human rights and free elections as a price for legitimacy in American eyes.

They did not do it. The administration tacitly accepted Mr. Nazarbayev's defense that there is an emergent democracy in Kazakhstan and it is a question of "time."

It seems the Clinton-Gore administration did not try very hard to institutionalize and implement their commitments to democracy, free elections, and an open press in the case of Kazakhstan.