

HONORING DR. JULIAN SEBASTIAN AS A MEMBER OF THE RWJ EXECUTIVE NURSE FELLOW PROGRAM

HON. ERNIE FLETCHER

OF KENTUCKY

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 3, 2000

Mr. FLETCHER. Mr. Speaker, it is my honor to recognize a distinguished member of the medical community of Central Kentucky. Dr. Juliann Sebastian is an Associate Professor and Assistant Dean for advanced practice nursing as well as the Director of Graduate Studies for the MSN degree program of the College of Nursing at the University of Kentucky. Dr. Sebastian is a dedicated medical professional who has educated countless students during their journey through nursing school.

Recently, Dr. Sebastian was honored by the Robert Wood Johnson Nurse Fellows Program at the Friends of the National Institute of Nursing Research's Annual Gala. This honor will allow Dr. Sebastian to embark on a three year self-study program while continuing her current duties at the University of Kentucky.

It is a pleasure to recognize Dr. Juliann Sebastian in the United States House of Representatives today, on her prestigious achievement. It is clear that the Fellows program recognized Dr. Sebastian's many talents and abilities to contribute so much to the medical community. As a fellow member of the medical community, I salute you, Dr. Sebastian.

RETIREMENT OF SANDY GOSS, DEPUTY CHIEF OF COBB COUNTY FIRE AND EMERGENCY SERVICES

HON. BOB BARR

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 3, 2000

Mr. BARR of Georgia. Mr. Speaker, I rise today to recognize Sandy Goss, Deputy Chief of Cobb County Fire and Emergency Services, for his dedication and commitment to the entire Cobb community, and to congratulate him on his retirement after 37 years of service.

Mr. Goss, who grew up around the fire department and following in his father's footsteps, joined the fire department full time immediately following his graduation from high school, in 1965.

Over the years, he worked his way through the ranks. In 1968, he was promoted to lieutenant; he made captain in 1983; he became the battalion chief in 1996; the following year he made colonel; and in 1998, he became deputy chief. While deputy chief, he was in charge of 85 percent of the department, with special operations, the HAZMAT team, technical rescue, vehicle maintenance, armored guards, and the fire suppression division all under his supervision.

He will be sorely missed, and will leave behind a legacy hard to match. I join many others in wishing Sandy and his family the very best.

SMALL BUSINESS INNOVATION RESEARCH PROGRAM REAUTHORIZATION ACT OF 2000

SPEECH OF

HON. CONSTANCE A. MORELLA

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Monday, September 25, 2000

Mrs. MORELLA. Mr. Speaker, today I ask my colleagues to join me in supporting the passage of H.R. 2392, a bill to reauthorize the Small Business Innovation Research Program, or SBIR.

Last year around this time, the House passed H.R. 2392. After months of work by the House and Senate, the Senate took action and passed H.R. 2392, with an amendment in July of this year. Their amendment incorporated both changes to the House provisions and new Senate provisions.

Now, H.R. 2392 is to go back to the Senate with additional Small Business provisions attached to the bill, but with the agreed-to provisions relating to SBIR untouched. These include: extending the program through fiscal year 2007; requiring small businesses to submit a concise commercialization plan with their proposals; requiring agencies participating in SBIR to provide an annual performance plan in accordance with the Government Performance and Results Act; requiring the collection and maintenance of data which will allow program evaluation; and a National Research Council report on how SBIR has used small businesses to stimulate technological innovation and how agencies have used SBIR in meeting their research and development needs.

The above are the main provisions that emanated from the House. The Senate has added provisions, including: a partnership grant program between small businesses and states (FAST, Federal and State Technology Partnership Program), and a mentoring network developed through the funds provided for in the FAST program.

Overall, the provisions contained in this bill improve upon the SBIR program and I am confident that we can again work with the Senate to reach an agreement allowing for the continuation of this excellent program. I urge my colleagues to support this important reauthorization.

NEW YORK'S MOST OUTSTANDING OLDER WORKER

HON. CAROLYN MCCARTHY

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 3, 2000

Mrs. MCCARTHY of New York. Mr. Speaker, today I name Bernard Tzall, a microbiologist at a research laboratory in Nassau County, as New York's Most Outstanding Older Worker for the year 2000.

I admire Bernard's dedication and commitment. At the age of 85, he is still working tirelessly to improve the lives of those around him through his research.

Bernard began working at the laboratory in the 1940s, after serving his country in the Army. Over his six decades of service, he has received awards from national, state, and local

organizations for his outstanding research and contributions to the community. In 1953, he was promoted to managing director of the Lab.

About ten years ago, Bernard was diagnosed with throat cancer and was forced to stop working. Miraculously, he was able to successfully fight off the cancer and he returned to work after his surgery.

Even with the handicap of using a voice-assisting prosthesis, he played an instrumental role in discovering the cure for an unknown virus in New York waters. Mr. Tzall is currently enrolled as a PhD. Candidate, becoming one of the oldest engineering students in the country. He continues to work at his laboratory, training new employees and managing its library.

The Prime Time 2000 award, sponsored by Green Thumb, was presented to an outstanding senior over the age of 65 from each state who works more than 20 hours per week. Mr. Tzall demonstrated excellence and commitment that put him in a class with a select few Prime Time recipients.

I commend Bernard for all he has overcome and all he has accomplished. I am honored to give him this recognition he well deserves.

PHARMACIA & UPJOHN ABUSE OF AVERAGE WHOLESALE PRICE SYSTEM: STARK CALLS FOR FDA INVESTIGATION

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 3, 2000

Mr. STARK. Mr. Speaker, I have today sent the following letter to Pharmacia & Upjohn, highlighting the extent to which this company has been inflating its drug prices and engaging in other deceptive business practices.

The evidence I have been provided shows that Pharmacia & Upjohn has knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

In doing so, Pharmacia & Upjohn is abusing the public trust, endangering patients by affecting physician prescribing practices, and exploiting America's seniors and disabled who are forced to pay 20% of these inflated drug costs. American taxpayers pick up the rest of the tab.

These findings are particularly timely as the Ways and Means Subcommittee on Health will today markup a Medicare bill that seeks to delay any administrative action by the Department of Health and Human Services (HHS) to alleviate this problem. This is bad policy. And I strongly oppose this provision of the bill. Reform of current Medicare drug reimbursement policy is needed now to protect taxpayer funds and public health.

To help bring an end to these harmful, misleading practices, I have today called on the FDA to conduct a full investigation into Pharmacia & Upjohn business practices.

These practices must stop and these companies must return the money that is owed to the public because of their abusive practices.

I would like to submit the following letter to Pharmacia & Upjohn into the RECORD.

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 AWP's and DP's 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 useful 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 Re-

duction 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 AWP's and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNER-SHIP 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. INTER-OFFICE 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