U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Thursday, August 26, 2004

Grassley works to protect taxpayers, beneficiaries from health care fraud

WASHINGTON — Sen. Chuck Grassley is defending the False Claims Act from criticisms leveled by the trade association representing pharmaceutical drug makers. The group known as PhRMA sent its unsolicited adverse comments to Grassley following a survey earlier this summer by Grassley of large drug makers about how they inform employees of the federal law that empowers whistleblowers to come forward with information about fraud against the taxpayers.

Grassley also has asked the Inspector General for the Department of Health and Human Services to help determine whether any drug companies are repeat pharmaceutical fraud offenders. Grassley expressed his concern that billion dollar fraud settlements are just part of the cost of doing business.

The text of Grassley's letters to PhRMA and the inspector general follow here, along with the text of PhRMA's letter to Grassley. Grassley is chairman of the Senate Committee on Finance, which has legislative jurisdiction over the Medicare program. He was also a principal Senate sponsor of the 1986 update of the False Claims Act. The amendments he sponsored have helped the Justice Department recover more than $12 billion for the federal Treasury that would otherwise have been lost to fraud.

August 26, 2004
Mr. Alan F. Holmer
President and Chief Executive Officer
Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW
Washington, DC 20005

Dear Mr. Holmer:

As chairman of the Committee on Finance (Committee), I am writing in response to your letter, dated August 13, 2004, on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). Your letter responded to my letter, dated July 30, 2004, which was sent to 19 of the top 20 drug companies by sales in 2003. Specifically, my letter asked whether or not drug companies would voluntarily provide basic information about the False Claims Act (FCA) to their employees.

I was pleased, and somewhat surprised, by those drug companies that responded positively to my letter. For example, one company responded, "while we are already providing information concerning the FCA to employees (for example, including information about the FCA in compliance training), we will, as you suggest, make additional FCA information available to all employees through our compliance program." Another responded, "[w]e intend to launch a course, which contains information about the False Claims Act in early 2005." However, PhRMA, as the representative of America's leading drug companies, responded by questioning the fairness of the FCA and of the Department of Health & Human Services, Office of Inspector General's exclusion authority. Based on the majority of favorable responses from PhRMA members, the tone of PhRMA's response appears to be out of tune with a number of its own members.

Without addressing your letter point-by-point, I am perplexed by your statement: "It is not my intent here to discuss the facts of any particular case, but only to point out that the deck is stacked so heavily against [drug] companies in FCA litigation...." It should come as no surprise to you that Congress explicitly recognized that the *government* is frequently overmatched in its fight against fraud. As the principal sponsor of the 1986 amendments to the FCA, I pointed out that the deck is in fact stacked against U.S. taxpayers, investigators and prosecutors, not corporate America. The lasting legacy of the FCA is its ability to discourage fraud and change the culture of corporate America. Corporations forced to focus on meaningful compliance programs are not encouraging a culture of deceit where anything goes in the pursuit of profits.

Your letter concludes with the assertion that "serious consideration should be given to leveling the playing field in those situations in which a complaint is filed in court." As you might expect, I keep close tabs on whether the FCA is effective and effectively enforced. Therefore, I am interested to hear from you about which specific pharmaceutical fraud lawsuits under the FCA did not "provide a fair opportunity for litigating factual and legal issues." Because, as you know, drug companies have paid out well over $2 billion to settle drug pricing and marketing fraud investigations in recent years. And numerous additional pharmaceutical fraud investigations are ongoing with more drug company settlements looming on the horizon. Furthermore, six top drug companies—AstraZeneca, Bayer, Pfizer, Schering-Plough, GlaxoSmithKline, and TAP—are presently operating under corporate integrity agreements. Drug companies seem to settle these cases and enter into corporate integrity agreements based on a simple cost-benefit analysis.

For example, a recent *USA Today* article, dated August 18, 2004, and entitled "Drugmaker admitted fraud, but sales flourish," reported on the $430 million settlement that Pfizer's Warner-Lambert division obtained in May. Pfizer's most recent settlement included a $240 million criminal fine and $190 million in civil settlements. According to the Department of Justice:

Warner-Lambert's tactics were part of a widespread, coordinated national effort to implement an off-label marketing plan. ... [T]he growth of off-label [Neurontin] sales was tremendous. While not all of these sales were the consequence of Warner-Lambert's illegal marketing, the marketing scheme was very successful in increasing Neurontin prescriptions for

unapproved uses. The state Medicaid programs were harmed by Warner-Lambert's aggressive promotion for off-label uses in numerous ways.

Pfizer's revenue on Neurontin was $2.7 billion last year. The *USA Today* article asked: "What happens to drug companies that commit federal crimes? For the nation's No. 1 drug company, the answer is: some pain, more gain." It appears the bottom line for the illegal marketing of Neurontin was a 32% increase in its sales.

Further, one state's office of the attorney general stated to my Committee staff emphatically that it did not want to settle a recent pharmaceutical fraud case, but rather wanted to pursue it in court. However, the drug company in question never obtained its "day in court" because it offered four times the damages that the state could prove legally in court. On behalf of taxpayers, the state's office of the attorney general felt it could not ethically litigate the matter and therefore accepted the drug company's settlement offer. Despite PhRMA's protestations about "leveling the playing field," it's America's taxpayers who can least afford to pay for fraud in the drug industry, not the drug companies.

In closing, PhRMA should abide by and embrace the example set by a number of its own members. Rather than taking the FCA to task, the drug industry would be better served if PhRMA took upon itself the challenge to educate its members about the importance of a zero tolerance policy on health care fraud. The role of the FCA has been integral—in fact indispensable—in fighting pharmaceutical fraud. Without the FCA, pharmaceutical fraud recoveries would undoubtedly be a fraction of the billions paid by drug companies to date. Every PhRMA member should follow the example of drug companies that have taken meaningful steps to provide basic information about the FCA to their employees. And PhRMA should be leading the way in providing that information to its members. I look forward to working with you and the drug companies that responded positively to my inquiry in developing appropriate and meaningful information for your other members.

Thank you in advance for your written response by September 8, 2004, unless it is available sooner.

Sincerely,

Charles E. Grassley
Chairman

August 26, 2004

Ms. Dara Corrigan
Acting Principal Deputy Inspector General
Department of Health & Human Services
330 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Corrigan:

As chairman of the Committee on Finance (Committee), I sent the attached letter, dated July 30, 2004, to Schering-Plough Corporation. The same letter was also sent to 18 of the top 20 drug companies by sales in 2003. Additionally, please find attached a response received from the Pharmaceutical Research and Manufacturers of America (PhRMA).

My letter to the drug companies discussed the need for the drug industry to articulate written standards of corporate conduct and to educate employees about health care fraud. Specifically, I asked whether or not drug companies would voluntarily provide basic information about the False Claims Act (FCA) to their employees. I was pleased, and somewhat surprised, by those drug companies that responded positively to my letter. For example, one company responded, "while we are already providing information concerning the FCA to employees (for example, including information about the FCA in compliance training), we will, as you suggest, make additional FCA information available to all employees through our compliance program." Another responded, "[w]e intend to launch a course, which contains information about the False Claims Act in early 2005." However, PhRMA, as the representative of America's leading drug companies, responded by questioning the fairness of the FCA and of the Department of Health & Human Services, Office of Inspector General's exclusion authority. Based on the majority of favorable responses from PhRMA members, the tone of PhRMA's response appeared to be out of tune with a number of its own members.

Among other issues, my letter also raised the OIG's draft model compliance program guidance for pharmaceutical manufacturers. The vast majority of companies—15 out of 19—responded that they relied on the OIG's guidance to some extent in drafting their compliance programs. It appears that the drug industry received the guidance positively and responded to it favorably.

Because PhRMA challenged the fairness of the FCA and specifically the OIG's exclusion authority in its letter, I am bringing the following statements to your attention directly:

[W]hile lawsuits under the FCA can play an important function, we would like to point out that they do not always provide a fair opportunity for litigating disputed factual and legal issues. Under regulations proposed in 1997 and adopted in 1998, the OIG changed its prior rules to take the position that pharmaceutical companies . . . are nonetheless subject to mandatory exclusion from governmental healthcare programs for certain convictions, including under the fraud and abuse laws. This corporate "death sentence," as it has been called, creates enormous pressures on companies to settle rather than to obtain their day in court. ... [T]he deck is stacked so heavily against these companies in FCA litigation that it can preclude meaningful access to the courts for fair and impartial decisions.

PhRMA's response on behalf of America's leading drug companies leads me to conclude that perhaps they just don't get it. In recent years drug companies have paid out well over $2 billion to settle drug pricing and marketing fraud investigations. My Committee staff informs me that six top drug companies—AstraZeneca, Bayer, Pfizer, Schering-Plough, GlaxoSmithKline, and TAP—are presently operating under corporate integrity agreements. I am also mindful that

numerous pharmaceutical fraud investigations are ongoing and that additional drug company settlements loom on the horizon. Despite PhRMA's protestations about "leveling the playing field," it's America's taxpayers who can least afford to pay for fraud in the drug industry, not the drug companies.

In closing, I am interested to know whether any drug companies are repeat offenders when it comes to corporate integrity agreements. Please advise me about any such companies and keep my staff informed if any drug companies join the ranks of repeat offenders in the future.

Thank you in advance for your written response by September 8, 2004, unless it is available sooner.

Sincerely,
Charles E. Grassley
Chairman

August 13, 2004

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing in response to your letters dated July 30, 2004, to 19 pharmaceutical companies regarding the False Claims Act (FCA). While each company may individually respond as well, we believe that it would be helpful to address certain of the issues collectively on behalf of PhRMA.

Representatives of PhRMA met with the Office of Inspector General (OIG) and filed comments in connection with the OIG's development of its Compliance Program Guidance for Pharmaceutical Manufacturers, issued in April 2003("Compliance Program Guidance").

We share your longstanding commitment to Medicare, Medicaid, and other governmental healthcare programs and to the importance of fair and effective enforcement of the laws against fraud and abuse in these programs. We also appreciate the role that private relators (so-called "whistleblowers") may play in certain cases alleging violations of the FCA.

We would also like to emphasize that effective programs against fraud and abuse must go well beyond reliance on whistleblower lawsuits under the FCA and, indeed, that the statutory scheme unfortunately at times may work at cross-purposes with the goal of advancing company efforts to detect and promptly stop potentially fraudulent activities.

The "fundamental" elements of an effective compliance program, as recognized in the

Compliance Program Guidance, are as follows:

Implementing written policies and procedures;
Designating a compliance officer and compliance committee;
Conducting effective training and education;
Developing effective lines of communication;
Conducting internal monitoring and auditing;
Enforcing standards through well-publicized disciplinary guidelines; and
Responding promptly to detected problems and undertaking corrective action.

68 Fed. Reg. 23731 (2003).

In its discussion of "effective lines of communication," the DIG emphasized the importance of communications among employees and their supervisors and the compliance officer "for reporting problems and initiating appropriate responsive action." Id. at 23741. The OIG's goal - which we share - is to prevent improper activity from occurring in the first place and, where such activity is initiated, to identify and put a stop to it as quickly as possible. The employee who initiates this process through discussions with a supervisor, use of a hotline to the compliance officer, or other forms of communication within a company thus plays a vital role in preventing and promptly stopping potentially fraudulent activity.

The FCA, however, inadvertently creates incentives for employees that can conflict with this vital role as internal whistleblower. Rather than communicating problems to supervisors who can respond promptly to ensure compliance, employees who choose to be qui tam relators go to court through a confidential process seeking damages and injunctive relief for past conduct. As you know, private complaints under the FCA are filed under seal and are not available to the companies involved, often for an extended period of time. This makes it difficult if not impossible for a company to take voluntary corrective action based on the individual's information, which should be the foundation for effective compliance.

As part of its emphasis on voluntary corrective action, the OIG's Compliance Program Guidance supports the "creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation." Id. at 23733. Indeed, the OIG assumes that FCA suits are brought "after a failure or apparent failure by the company to take action when the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials." Id. at 23743 n.18. We believe that it would be inconsistent with the OIG's guidance to place undue emphasis on FCA lawsuits at the expense of prompt notification through a company's lines of communication and an opportunity for voluntary corrective action.

Finally, while lawsuits under the FCA can play an important function, we would like to point out that they do not always provide a fair opportunity for litigating disputed factual and legal issues. Under regulations proposed in 1997 and adopted in 1998, the OIG changed its prior rules to take the position that pharmaceutical companies and other suppliers that are not direct

providers are nonetheless subject to mandatory exclusion from governmental healthcare programs for certain convictions, including under the fraud and abuse laws. This corporate "death sentence," as it has been called, creates enormous pressures on companies to settle rather than to obtain their day in court. Indeed, just recently a number of individual employees of a pharmaceutical company were acquitted following a jury trial in a case that their employer settled. It is not my intent here to discuss the facts of any particular case, but only to point out that the deck is stacked so heavily against these companies in FCA litigation that it can preclude meaningful access to the courts for fair and impartial decisions.

As our companies work diligently to establish and implement effective voluntary compliance programs, serious consideration should be given to leveling the playing field in those situations in which a complaint is filed in court.

I would be pleased to discuss the issues raised in this letter further with you or your staff.

Sincerely,
Alan F. Holmer