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

M E M O R A N D U M

To: Reporters and Editors
Re: Pfizer, Inc. Settlement
Da: Thursday, May 13, 2004

Sen. Chuck Grassley, chairman of the Committee on Finance, today commented the announcement that Pfizer, Inc. has agreed to pay a Medicaid fraud settlement totaling $430 million, including a $240 million criminal fine and $190 million in civil settlements.

Based on today's development, Sen. Grassley has written to the Attorney General asking for a briefing on its ongoing drug company investigations, including whistleblower cases. The text of that letter follows Sen. Grassley's comment, along with the news release and text of a letter Sen. Grassley sent last month with Sen. Max Baucus to various drug companies about Medicaid drug pricing.

Sen. Grassley was the Senate author of the *qui tam* whistleblower amendments to the False Claims Act. Enforcement of the False Claims Act and its whistleblower provisions has returned more than $12 billion to the U.S. Treasury since it was updated in 1986. According to the Centers for Medicare and Medicaid Services, approximately 550 pharmaceutical companies participate in the Medicaid drug rebate program. Forty-nine states and the District of Columbia cover drugs under the program.

Grassley comment —

"We need to see continued aggressive investigation and pursuit of fraud against the taxpayers by pharmaceutical drug manufacturers. Whistleblowers can be a valuable part of that effort, as we've seen in this case, and the Justice Department obviously must stay committed and send a clear message of zero tolerance. Drug companies that illegally pad their profits with Medicaid dollars that should be going to help low-income people, including pregnant women and children, must be held accountable."

Grassley letter to Ashcroft —

May 13, 2004

The Honorable John Ashcroft
Attorney General
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Ashcroft:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs in the United States Senate. The Committee is presently reviewing some business practices among drug companies participating in the Medicaid drug rebate program. Thus, I noted with great interest today, that Pfizer, Inc. has reportedly agreed to pay a Medicaid fraud settlement with the Department of Justice (DOJ), totaling $430 million, including a $240 million criminal fine and $190 million in civil settlements.

As the Committee focuses on the numerous problems and challenges that confront the Medicaid program, it is no small concern that Medicaid spending continues to skyrocket each year. Medicaid spending for 2004 is projected to be over $300 billion and has surpassed Medicare as the largest government health program in the United States. Hundreds of billions of taxpayer dollars are at stake and oversight of the Medicaid program appears to be a decade or more behind oversight of the Medicare program. As Chairman of the Committee, among the issues that are most troubling to me is the extent to which the drug industry is profiting at the expense of America's taxpayers. According to the non-profit organization, Taxpayers Against Fraud (TAF)[1]:

> Since 2001, the Department of Justice (DOJ) has settled seven cases involving allegations of Medicare and Medicaid drug pricing and marketing fraud against six pharmaceutical manufacturers: AstraZeneca, Bayer, Dey, GlaxoSmithKline, Pfizer, and TAP Pharmaceuticals . . . [a]mong these are three of the top five companies (by sales volume) in the industry: Pfizer (#1), GlaxoSmithKline (#2), and AstraZeneca (#5). *The total paid out by these manufacturers to settle these cases is nearly $1.66 billion. ... Remarkably, these recoveries resulted from allegations involving just a handful of drug products...*
>
> (emphasis added).

Every one of these settlements involved Medicaid liability and likely represent just the tip of the proverbial iceberg. With astronomical profits at hand, it appears that some drug companies are not always abiding by the letter of the law, and in other cases not abiding by the spirit of the law. During the remainder of this session of Congress, this Committee will continue to look closely at drug companies' business practices with respect to federal programs and the exorbitant costs that America's taxpayers are paying for drugs. Any drug company that improperly lines its pockets with Medicaid dollars, which are intended to benefit low-income Americans, pregnant women and poor children, should know that America's taxpayers, myself included, expect that it should be held fully accountable.

In light of the Pfizer settlement announced today, coupled with the aforementioned settlements, there are a great many questions that demand answers and issues that merit review by this Committee. It is incomprehensible that settlements involving billions of dollars may be viewed within the pharmaceutical industry as the cost of doing business with government. Any company doing business with the United States must be disabused of the notion that it can wash its hands of a fraudulent business practice and move onto the next, while continuing with business as usual.

Accordingly, I request that the appropriate DOJ staff provide a confidential briefing to my staff about the scope and subject matter of all pending drug company investigations, including all whistleblower *qui tam* cases, whether DOJ has intervened or declined to intervene. Additionally, please fully brief my staff about the claims and allegations against drug companies that have resulted in settlements over the past five years. By this letter, I am also requesting that the Office of Inspector General, Department of Health and Human Services, provide a confidential briefing for my committee staff on its ongoing investigations with respect to drug companies' business practices.

Sincerely,

Charles E. Grassley
Chairman

cc: Dara Corrigan, Acting Principal Deputy Inspector General
William E. Moschella, Assistant Attorney General

For Immediate Release
Thursday, April 29, 2004

Grassley, Baucus ask drug manufacturers questions about how they price drugs for Medicaid

WASHINGTON - Sens. Chuck Grassley and Max Baucus are asking drug companies to provide information about how they price drugs because certain pricing practices may have a substantial impact on the cost to taxpayers of drugs purchased by the Medicaid program. Grassley is chairman and Baucus is ranking member of the Committee on Finance.

The senators made their request in letters to 19 drug companies about eight classes of pharmaceutical drugs. These companies were industry leaders in sales in 2003, and the eight drug classes included in the request were top sellers in 2003.

Grassley and Baucus said they want to know if drug companies are inappropriately using an exception to the best-price reporting requirements that apply to the Medicaid drug rebate program. To participate in the drug rebate program, a drug company must report to the

government its best price, which is the lowest price its drug was sold to any purchaser in the United States. Congress created an exception to best-price reporting to encourage drug companies to continue making drugs available to charitable organizations at cheaper than market rates.

Grassley said the question is, "are drug companies abiding by both the letter and spirit of the law with regard to that exception?"

Baucus said, "I am very concerned about Medicaid's continued ability to provide prescription drug coverage to the nation's neediest population. By making sure that drug companies are playing by the rules, we can help ensure that these folks have access to the medications they need to get and stay healthy."

Grassley and Baucus have been working to bring down the high costs of prescription drugs. The new Medicare prescription drug benefit program they successfully shepherded through the Senate last year encourages private plans to drive hard bargains in negotiations with drug makers so they can offer beneficiaries the lowest prices possible. It also speeds up the entry of generic drugs to the marketplace.

The drug makers who received a letter from Grassley and Baucus were Pfizer, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals Inc., Abbott Laboratories, Hoffmann-La Roche Inc., TAP Pharmaceutical Products Inc., Schering-Plough Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., Sanofi-Synthelabo and Eisai, Inc.

Variations of the following text comprised the Grassley-Baucus letter to the 19 drug makers.

April 29, 2004

Dear _____ :

The U.S. Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, and accordingly, a responsibility to oversee the proper administration of those programs which provide health care coverage to more than 80 million Americans. During this legislative session, the Committee intends to study issues relating to these programs' coverage of prescription drug benefits, including pricing practices that could have an impact on the cost to taxpayers of purchasing prescription drugs. As Chairman and Ranking Member of the Committee, we ask that _____ cooperate with the Committee and provide it with information regarding these matters as requested.

In recent years, the cost to Medicaid of purchasing prescription drugs is growing faster than any other single area of the program. As a result of this and tight fiscal constraints, states have been reducing prescription drug benefits; between 2001 and 2004, 45 states reduced drug benefits under Medicaid. Considering that prescription drugs are now an integral part of quality health

care, such reductions in benefits may be detrimental to the health of Medicaid beneficiaries.

Congress has revisited payment for prescription drugs under Medicaid several times to ensure that federal and state taxpayers are not generally paying more for drugs than hospital buying groups, health maintenance organizations, pharmaceutical benefit managers, or other purchasers. In 1990, Congress created the Medicaid drug rebate program, which requires any drug manufacturers seeking reimbursement for prescription drugs from state Medicaid programs to enter into a rebate agreement (Medicaid Rebate Agreement) with the Secretary of Health and Human Services (HHS) under which the manufacturer promises to pay a rebate for each covered outpatient drug paid for by Medicaid. The rebate formula is established in section 1927 of the Social Security Act (the Act) and, for single source drugs and innovator multiple source drugs, generally is either the difference between the average manufacturer's price (AMP) for that drug and the best price at which the drug was sold to a purchaser (Best Price), or a minimum percentage of AMP, whichever is greater. In determining and reporting the statutory Best Price, drug manufacturers must take into account all cash discounts, free goods contingent on a purchase requirement, volume discounts, and rebates provided to covered purchasers.

When the rebate requirement was enacted, Congress created an exception to determining the Best Price for drug sales involving prices that were merely nominal in amount (Nominal Price Exception/NPE). Congress was trying to address a particular concern in establishing the Nominal Price Exception; namely, to ensure that manufacturers did not have an incentive to terminate steep discounting practices designed with charitable intent to promote access to medication for low-income or other populations for which access might be limited. The Centers for Medicare and Medicaid Services (CMS) has defined the Nominal Price Exception to include prices that are 10 percent or less of AMP for the drug in the same quarter for which AMP was computed, as is included in your company's Medicaid Rebate Agreement. However, notwithstanding this Congressional intent, we understand that some drug manufacturers may be using the Nominal Price Exception as part of their commercial pricing practices. These practices could undermine the purposes of the Medicaid Best Price policy and may be costing taxpayers hundreds of millions of dollars through reduced Medicaid rebates.[1]

The Committee wants to assess how frequently the Nominal Price Exception to Best Price reporting is used, in what contexts, and for what purposes. This will assist us in determining whether and to what extent the exception has been used to promote access to prescription drugs as intended by Congress and whether refinements should be made to the existing statutory language to ensure that the Nominal Price Exception is not used for purposes other than those intended. In order to ensure that the Committee has sufficient information on which to base its determinations, we are inquiring about drugs in the eight most popular classes to those manufacturers that ranked among the top twenty according to sales in 2003. Therefore, as Chairman and Ranking Member of the Committee, we request that your company provide the following information and data to the Committee:

1. Provide an executed copy of your company's most recent Medicaid Rebate Agreement with the Secretary of Health and Human Services.

2. Provide a copy of the assumptions used by your company in determining Best Price, in accordance with the terms of manufacturer's responsibilities under section II of your Medicaid Rebate Agreement.

3. Identify the person(s) and/or agent(s) (including, name, title and contact information) within or affiliated with your company who is/are currently responsible for calculating, determining, generating, reporting and maintaining the quarterly Medicaid rebate program data for your company, including but not limited to AMP and Best Price.

4. Identify the person(s) and/or agent(s) (including, name, title and contact information) within or affiliated with your company who is/are currently responsible for ensuring compliance of reported quarterly data for the Medicaid rebate program with appropriate laws and program directives.

5. Identify the person(s) and/or agent(s) (including, name, title and contact information) within or affiliated with your company who is/are currently responsible for authorizing, developing, implementing, and/or monitoring any marketing or sales programs in which sales of covered outpatient pharmaceuticals are made at prices considered to be "merely nominal" under section 1927 of the Act.

6. State whether your company has a formal, written policy with respect to sales of covered outpatient drugs at prices considered to qualify for the Nominal Price Exception, or if your company relies on an unwritten policy. To the extent a written policy exists, attach copies, including all versions and revisions of the policy since its inception. To the extent an unwritten policy exists, describe it in detail, including but not limited to describing any criteria used in authorizing, developing, implementing and/or monitoring any marketing or sales programs in which sales of covered outpatient drugs are made at prices considered to qualify for NPE.

7. In accordance with your company's response to #6 above, describe the factors and circumstances your company takes into account when determining whether sales of covered outpatient drugs should be made at prices that are considered to fall within NPE. For example, what factors does your company take into account when determining who may purchase covered outpatient drugs at a "merely nominal" price? What type(s) of entities purchase drugs at prices that are "merely nominal?" Are not-for-profit entities the exclusive recipients of a "merely nominal" price? Under what circumstances may for-profit entities purchase covered outpatient drugs for a "merely nominal" price?

8. What types of contractual arrangements govern your company's drug sales that fall under NPE? For example, what contractual terms or conditions does your company typically and/or commonly include in transactions for drugs sold under NPE? Must a purchaser meet a certain market share percentage requirement for a drug or class of drug as a condition to obtaining a "merely nominal" price? Does your company ever make drug prices under NPE transactions available for only one quarter or do they typically have longer duration? Does your company ever condition the sale of any drug at a "merely nominal" price on an agreement to purchase more of that drug or other drugs? If so, explain the details and circumstances.

9. For each of the drugs listed below, provide the number of units sold at prices within NPE. For each single source and innovator multiple source drug, provide the requested information broken down by quarter, and by applicable 11-digit National

Drug Code (NDC), for the 12 most recently completed quarters as of the date of this request. In addition, provide the percentage of each drug that was sold under NPE for each of the same 12 quarters. For those drugs that are no longer single source as of the date of this request, also provide the requested information (both the number of units and the percentage) broken down by quarter, and by applicable NDC, for at least eight quarters prior to the drug status change from single source.

10. For each drug listed in #9 above, and for the same quarters, provide the total number of units sold at prices that were included in the determination of Best Price, i.e., at prices that were above "merely nominal" prices. In addition, provide the percentage of the drugs that were sold at prices that were included in the determination of Best Price for each of the quarters.

11. For each drug listed in #9 above, and for the same quarters, calculate the average unit price for all sales that were considered within NPE. Then calculate and report the percentage below Best Price that average unit price is.

12. For each drug listed in #9 above, and for the same quarters, identify each non-excluded purchaser that bought a drug at a price within NPE in one of the quarters and paid above NPE price for the same drug in another quarter(s) during the time period for which your company provided responses for that drug.

13. Identify any drug not previously identified in this request, that your company sold at a price within NPE, i.e., at a price that was "merely nominal," during the 12 most recently completed quarters as of the date of this request.

Please provide the information and documents requested in questions 1 through 8 by May 17, 2004. For questions 9 through 12, provide the requested information for the most recent four quarters by May 17th, and the remaining quarters by June 7, 2004, unless it is available sooner. In complying with this request, respond by repeating the enumerated request, followed by the accompanying response; attach and identify all relevant documents or data by title and the number(s) of the enumerated request(s) to which they are responsive. Finally, in complying with this request, _____ means its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which _____ entered into a partnership, joint venture or any other business agreement or arrangement.

1. The HHS Office of Inspector General has warned that drug pricing practices in the private sector may nonetheless have significant effects on federal programs:

> Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discounts to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however

characterized, should be carefully scrutinized.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (2003).

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Member