United States Senate Committee on Finance

M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, Grassley, 202/224-1308
Carol Guthrie, Baucus, 202/224-6769
C. Stuart Chapman, Rockefeller, 202/224-6101
RE: Inspector General Guidance on Patient Assistance Programs
DA: Friday, June 30, 2006

Today the Inspector General for the Department of Health and Human Services issued and Advisory Opinion for a clinic in West Virginia regarding its practice of dispensing drugs on behalf of the patient assistance programs sponsored by drug manufacturers. The Inspector General said that the clinic's practice would not constitute grounds for civil monetary penalties or administrative sanctions under federal anti-kickback statutes.

Statements from Sens. Chuck Grassley, Max Baucus and Jay Rockefeller are below. These senators have been working to see that drug-company sponsored patient assistance programs continue alongside Medicare's new Part D prescription drug benefit. They have sought legal guidance from the Inspector General and personally urged drug makers to continue these valuable programs.

Comments -

"I appreciate the initiative demonstrated by the clinic in West Virginia in asking for this important opinion. The Inspector General's advisory should help everyone involved in this clinic's program to distribute medicines on behalf of patient assistance programs know that their work doesn't violate the federal anti-kickback statute. Patient assistance programs help millions of Americans get the medicine they need. I also very much appreciate the Inspector General's continued diligent review of other similar requests regarding these valuable programs," said Sen. Chuck Grassley of Iowa, Chairman of the Senate Committee on Finance.

"Free clinics are a valuable way to get low-cost and no-cost drugs to Americans in need. This opinion from the Inspector General's office lets clinics know this service is not only laudable, but still legal under the new Medicare drug benefit. The Inspector General is working hard to harmonize patient assistance programs with the new Medicare law, and his opinion is a good step toward keeping these programs going and keeping seniors well," said Sen. Max Baucus of Montana, Ranking Member of the Senate Committee on Finance.

"I applaud this most recent guidance from the HHS Inspector General regarding free clinic participation in pharmaceutical patient assistance programs. This opinion will allow West Virginia Health Right and other free clinics around the country to continue providing vital prescription assistance to people who need it, including individuals enrolled in the Medicare

prescription drug program," said Sen. John D. (Jay) Rockefeller IV of West Virginia, Ranking Member of the Senate Finance Subcommittee on Health.

Information about the senators' efforts on this issue follows in these news releases:

For Immediate Release
Thursday, May 11, 2006

Senators call on drug company leaders to continue drug assistance programs

WASHINGTON — Members of the Senate Finance Committee met today with top executives from eight pharmaceutical drug companies as part of an effort by senators to see that drug assistance programs continue alongside the new Medicare prescription drug benefit.

Finance Committee Chairman Chuck Grassley chaired the meeting, which was also attended by Sen. Max Baucus, the Committee's Ranking Member, and Sen. Orrin Hatch, who is Chairman of the Subcommittee on Health. Sens. Mike Crapo, Jeff Bingaman, and Gordon Smith also attended the meeting. Sen. John D. (Jay) Rockefeller IV was unable to be at today's meeting, though he has been a leader in trying to secure the patient assistance programs that provide prescription medicines to lower-income Medicare beneficiaries. Rockefeller is Ranking Member of the Finance Subcommittee on Health.

The drug companies were represented at today's meeting by the following individuals:

- Mr. David Brennan, CEO, AstraZeneca Pharmaceuticals PLC
- Mr. Peter R. Dolan, CEO, Bristol-Myers Squibb Company
- Mr. Sidney Taurel, Chairman of the Board and CEO, Eli Lilly & Company
- Mr. David Stout, President of Pharmaceutical Operations, GlaxoSmithKline
- Mr. Seth H.Z. Fischer, Company Group Chairman, North America Pharmaceuticals, Johnson & Johnson
- Mr. Ian Spatz, Vice President, Merck & Co., Inc.
- Ms. Karen Katen, Vice Chairman, Pfizer, Inc.
- Dr. Fred Hassan, Ph.D., Chairman of the Board and CEO, Schering-Plough Corporation
- The Honorable Wilbert J. "Billy" Tauzin, Jr., President and CEO, PhRMA

Comments from Grassley, Baucus and Rockefeller follow here, along with previous news releases describing the work of these four senators on the drug company-sponsored benefit.

May 11th Statement of Senator Chuck Grassley of Iowa
Chairman, Committee on Finance

"The purpose of today's meeting was to say to the drug companies that the new Medicare drug benefit does not and should not prevent them from continuing to offer patient assistance programs to Medicare beneficiaries who enroll in Part D. It's not a legitimate excuse for dropping the assistance programs. Out-of-pocket costs for hyper-expensive drugs can be an insurmountable barrier for many beneficiaries even with the new Medicare benefit. Drug

companies should not penalize people who sign up for the Medicare drug benefit. I appreciate statements made in recent days by some pharmaceutical companies about continuing their programs or parts of their programs. There's more to do. I'm not going to let up. Beneficiaries need these programs."

May 11th Statement of Senator Max Baucus of Montana
Ranking Member, Committee on Finance

"The Medicare drug benefit is making drugs more affordable for many seniors, but some still need extra help. There's absolutely no reason drug companies can't keep serving people in need. The drug benefit must not be used as an excuse for ending patient assistance programs. Many manufacturers have already agreed to continue their programs, and I'd like to see the rest promise by next week to do the same."

May 11th Statement of Senator John D. (Jay) Rockefeller IV of West Virginia
Ranking Member, Subcommittee on Health

"Patient Assistance Programs (PAP) are vital to those Medicare recipients who cannot afford the prescription drugs they need even with the help of the Medicare prescription drug plan. Some pharmaceutical companies in recent days have announced that they will continue their PAP programs for Medicare beneficiaries, and I hope more companies will follow suit. But more needs to be done. Many subsidy-eligible Americans will need additional assistance meeting their Medicare drug benefit co-insurance obligations, and I want to make sure that free clinics around the country do not lose access to the drugs they currently receive through PAPs. We are at a critical juncture in the decision-making process, and the decisions made by these companies over the next few days will directly affect the health and well-being of thousands of people in West Virginia and throughout the nation."

For Immediate Release
Monday, May 8, 2006

Senators invite drug company execs to discuss prescription drug assistance programs

WASHINGTON — Pharmaceutical drug makers have been asked to meet with members of the Senate Finance Committee about the future of drug company-sponsored programs that help individuals with high prescription drug costs.

The meeting scheduled for May 11 is part of an effort by Sens. Chuck Grassley, Max Baucus, Orrin Hatch, and John D. (Jay) Rockefeller IV to see these assistance programs continue alongside the new Medicare prescription drug benefit. Grassley is chairman and Baucus is ranking member of the Finance Committee, which is responsible for health care policy. Hatch is chairman and Rockefeller is ranking member of the Subcommittee on Health Care.

The following companies have been invited to attend the meeting:

- Mr. David Brennan, CEO, AstraZeneca Pharmaceuticals PLC
- Mr. Peter R. Dolan, CEO, Bristol-Myers Squibb Company
- Mr. Sidney Taurel, Chairman and CEO, Eli Lilly & Company
- Dr. Jean-Pierre Garnier, Ph.D., CEO, GlaxoSmithKline
- Mr. William C. Weldon, Chairman and CEO, Johnson & Johnson
- Mr. Richard T. Clark, President and CEO, Merck & Co., Inc.
- Dr. Hank A. McKinnell, Ph.D., CEO, Pfizer, Inc.
- Mr. Fred Hassan, Chairman and CEO, Schering-Plough Corporation
- The Honorable Wilbert J. "Billy" Tauzin, Jr., President and CEO, PhRMA

The meeting – which will be held in SD-215 at 11:30 a.m., and be closed-door -- will follow other recent initiatives by Grassley, Baucus, Hatch and Rockefeller to secure the patient assistance programs for Medicare beneficiaries. Those efforts are described in the news releases below.

For Immediate Request
Friday, April 21, 2006

Senators keep focus on keeping drug assistance for Medicare beneficiaries

WASHINGTON — Leading senators are urging pharmaceutical drug makers to continue offering prescription drugs to Medicare beneficiaries through programs designed to help individuals with high prescription drug costs.

Sens. Chuck Grassley, Max Baucus, Orrin Hatch, and John D. (Jay) Rockefeller IV also have pressed for the Inspector General for the Department of Health and Human Services to issue clear guidance addressing the legal concerns of pharmaceutical manufacturers about offering drug assistance programs after May 15, when the first sign-up period ends for Medicare's new prescription drug benefit.

"We've got a situation where it looks like the May 15 date has become an excuse for dropping the assistance that many Medicare beneficiaries rely on, and that's not right," Grassley said. The Inspector General issued more guidance earlier this week, and some companies have announced that they'll continue their programs, so legal avenues do exist."

"Pharmacy assistance programs provide invaluable assistance to people working hard to get by," said Baucus. "The Medicare prescription drug benefit does not prevent drug companies from continuing to provide this help to those in need, and the Inspector General has made that clear. I hope that drug companies resolve their concerns and continue to provide this much needed help."

"Drug companies now have the green light to complement the new Medicare

program with their assistance programs, and I encourage them to continue giving generously to help our seniors," Hatch said.

"Now that the Inspector General has provided some concrete guidance, it's time for pharmaceutical companies to fulfill their obligation," said Rockefeller. "Simply put, these companies should not halt this vital assistance to Americans who cannot afford the prohibitively expensive prescription drugs they need in order to survive. The lives of many Americans depend on these companies being good citizens."

The text of the Senators' letter to PhRMA, the association representing the nation's leading pharmaceutical research and biotechnology companies, follows here, along with statements made earlier this week about an advisory from the Inspector General, and the text of a letter sent on Monday from Grassley, Baucus, Hatch and Rockefeller to the Inspector General.

April 21, 2006

The Honorable Wilbert J. Tauzin, Jr.
President and CEO
PhRMA
950 F Street, NW
Washington, DC 20004

Dear Mr. Tauzin:

We are writing to express our concern about the recent announcements made by some pharmaceutical manufacturers that they plan to curtail their patient assistance programs (PAPs) because of the perceived lack of clear federal guidance on operating a PAP now that Medicare's prescription drug benefit has become available. Millions of Americans, including Medicare beneficiaries, receive invaluable assistance in getting their prescription drugs through patient assistance programs offered by several PhRMA member companies. Many of these medications are extremely costly and without assistance from a PAP, some Medicare beneficiaries are not otherwise able to afford them, even if they are enrolled in the new Medicare prescription drug benefit.

Last November, the Department of Health and Human Services Office of the Inspector General (OIG) issued guidance regarding potential approaches for operating a PAP in the new Medicare prescription drug benefit environment. We understand that, for some pharmaceutical manufacturers, the OIG's November guidance did not provide enough clarity regarding the legality of PAPs in relation to the new Medicare prescription drug benefit. However, we believe the PAP model approved by the OIG earlier this week provides substantial clarification regarding the ways pharmaceutical manufacturers can structure their PAPs around the Medicare prescription drug benefit. Moreover, the OIG issued a statement in the November guidance indicating the OIG would exercise discretion in taking enforcement actions against pharmaceutical

manufacturers operating PAPs this year -- the initial year of the Part D benefit. These facts make a company's decision to end its PAP as of May 15 seem rather arbitrary.

We are happy that some companies have already announced that they will continue their PAPs. Merck, Schering-Plough, and AstraZeneca have all announced they will continue their patient assistance programs, which indicates that legal and feasible avenues for operating a PAP alongside the Medicare prescription drug benefit do exist. While Schering-Plough is the only company that has received an OIG advisory opinion to date, we are aware that other pharmaceutical companies have made such requests. The Schering-Plough model provides a workable roadmap for how a PAP can be operated going forward. It is, however, a floor and not a ceiling of possible options. A company that wants to pursue an alternative structure for its PAP could request an individual Advisory Opinion from the OIG.

We applaud Merck, Schering-Plough, and AstraZeneca for their commitment to their patient assistance recipients, who rely on their products to maintain their health. We wholeheartedly agree with PhRMA's statement that the OIG opinion on Schering-Plough's PAP, "can provide useful guidance to other companies." In your capacity as President and CEO of PhRMA, we implore you to call on other member companies to expeditiously develop approaches – as Merck, Schering-Plough, and AstraZeneca did – to continue their PAPs. It is simply unacceptable for any pharmaceutical company to use the launch of the new Medicare prescription drug benefit as an excuse to limit their PAPs as of May 15, particularly since there is now clear legal guidance from the OIG on ways to operate these programs.

If there are outstanding legal concerns about the ability of pharmaceutical companies to continue to operate PAPs, then we would like to know about them. Otherwise, we strongly encourage your member companies to find legal avenues for continuing these vital patient assistance programs, and we would appreciate your informing us about the actions PhRMA is taking to educate it members about such avenues.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Minority Member

Orrin G. Hatch
Chairman
Health Care Subcommittee

John D. Rockefeller IV

Ranking Minority Member
Health Care Subcommittee

M E M O R A N D U M

TO: Reporters and Editors
RE: IG Advisory Opinion
On Pharmaceutical Manufacturer Patient Assistance Programs
DA: April 18, 2006

Yesterday, Sens. Chuck Grassley, Max Baucus, Orrin Hatch, and John D. (Jay Rockefeller) asked the Inspector General for the Department of Health and Human Services for guidance to address the legal concerns of drug makers who participate in patient assistance programs. The Inspector General issued an opinion today. Comments from individual senators follow here.

"It's good to finally have this advisory opinion from the Inspector General. The company who made the request now knows that its program to help Medicare beneficiaries meets federal rules and requirements. I urge the Inspector General to provide similar assurance to other companies quickly as the May 15 deadline is fast approaching. Those companies also need to provide any additional information requested by the Inspector General in a timely way." -- Senator Chuck Grassley

"I'm glad the HHS Inspector General was able to advise one drug manufacturer on how to continue its patient assistance program properly in conjunction with the Medicare drug benefit. I trust that other companies seeking advice and assistance will get timely help from the IG, so they can keep their programs going. It's good that the pharmaceutical manufacturer involved has found a way to continue providing this much-needed assistance, and I hope that others in the industry can do the same so that financially needy Medicare beneficiaries can get the drugs they need." -- Senator Max Baucus

"The Inspector General's office made a good start today by clarifying for one company the legal parameters for operating a PAP. But more needs to be done. In the coming days, the Inspector General must give clear guidance to other drug manufacturers and to the free clinics also awaiting a decision. Hundreds of thousands of Medicare recipients are scared that they will not be able to afford the prescription drugs they need. We must make sure that these programs are still there to help our seniors." -- Senator John D. (Jay) Rockefeller IV

For Immediate Release
Monday, April 17, 2006

Senators seek continued assistance from drug companies for Medicare beneficiaries

WASHINGTON - Top health care policy makers in the U.S. Senate have asked for prompt and definitive guidance from the government to help ensure that Medicare beneficiaries with extraordinary needs can continue to access additional assistance from pharmaceutical drug makers even after signing up for the new Medicare prescription drug benefit.

At issue is the continued availability of pharmaceutical manufacturer patient assistance programs, known as PAPs. Sens. Chuck Grassley, Max Baucus, Orrin Hatch and John D. (Jay) Rockefeller IV have urged the Inspector General for the Department of Health and Human Services to make a clear statement as soon as possible addressing the legal concerns of drug manufacturers so that the additional drug assistance that helps so many individuals through these PAPs is not discontinued after May 15, the deadline for Medicare beneficiaries to sign up for the new Medicare drug benefit.

“Clear-cut guidance is needed to help maintain the drug assistance that many older Americans rely on, and we've been working to get that guidance for several months,” Grassley said. “These Medicare beneficiaries have extraordinary health care needs.”

“Many seniors simply wouldn't get the drugs they need without patient assistance programs, so it's important that the government quickly provide appropriate advice on how these programs can mesh with the new Medicare drug benefit,” said Baucus. “I believe it's possible to discourage Medicare fraud without discouraging drug manufacturers from providing these vital programs, and I know the Inspector General will seek to strike a balance that works.”

“We have been pushing for a resolution on this issue since November,” said Rockefeller. “We are less than a month away from having some drug companies terminate these vital programs, and yet our seniors still have no assurance that they will be able to get the prescription drugs they need from these programs. Nothing short of an immediate and complete clarification of these rules is acceptable.”

The text of the Senators' letter to the Inspector General follows here.

April 17, 2006

Mr. Daniel R. Levinson, Inspector General
Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Levinson,

We are writing to express our support for the continued availability of pharmaceutical manufacturer patient assistance programs (PAPs). As you know, manufacturer PAPs provide free or subsidized medications to thousands of individuals, including Medicare beneficiaries, who might not otherwise be able to afford their prescription drugs. Many seniors and individuals with disabilities who participate in manufacturer PAPs have chronic conditions. These beneficiaries must take very expensive prescription drugs - which often do not have generic drug equivalents - to manage those conditions and to maintain their quality of life. Without assistance from a PAP, some Medicare beneficiaries may not otherwise be able to afford their prescription drugs, even if they are enrolled in the new Medicare prescription drug benefit.

We appreciate that your office issued the Special Advisory Bulletin on Patient Assistance Programs last November. The goal of this Bulletin was to clarify the applicability of the federal anti-kickback statute to all PAPs, including those offered by pharmaceutical manufacturers. Unfortunately, it is our understanding that the Bulletin may have had the opposite effect. As a result, several pharmaceutical manufacturers have indicated that they will discontinue their prescription assistance to Medicare beneficiaries as of May 15.

Your office has achieved significant accomplishments in reducing waste, fraud and abuse in the Medicare Part A and Part B programs. We applaud the OIG's efforts in assisting, developing and implementing a comprehensive strategy to identify and prevent fraud, waste and abuse under Medicare Part D. Working with the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Investigation (FBI) and prosecuting attorneys at the Department of Justice (DOJ), the OIG has recognized the importance of protecting Medicare beneficiaries and taxpayers' dollars. That said, we are troubled that the OIG's Guidance may limit-albeit unintentionally-beneficiary access to necessary medications. We are particularly concerned about the ongoing availability of manufacturer PAPs for three groups of Medicare beneficiaries: 1) low-income beneficiaries of limited means who do not qualify for the low-income subsidy; 2) low-income beneficiaries between 135 percent and 150 percent of poverty who qualify for the low-income subsidy, but pay 15 percent coinsurance for their prescriptions; and 3) higher-income beneficiaries with catastrophic prescription drug needs who currently derive a significant benefit from participation in pharmaceutical manufacturer PAPs.

It is our understanding that some companies have requested advisory opinions from the OIG regarding the legality of the specific design of their PAPs. We understand that this process is iterative and that the OIG often must ask the requester for additional information. We hope, though, that the OIG will continue to work as expeditiously as possible in responding to these requests, which may help mitigate this situation. Again, we urge you to work to further clarify the legal guidance on the manufacturer PAPs as expeditiously as possible. We believe a resolution can be achieved that allows pharmaceutical manufacturers to continue providing much needed

assistance to certain groups of Medicare beneficiaries in a manner that does not violate the integrity of the Medicare program.

We thank you for your prompt attention to and consideration of this request. Because of the seriousness of this matter, we are instructing our staff to contact your office Monday to discuss this issue further.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Minority Member

Orrin G. Hatch
Chairman
Health Care Subcommittee

John D. Rockefeller IV
Ranking Minority Member
Health Care Subcommittee

cc: Michael Leavitt, Secretary, Health & Human Services