

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 its 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