

January 11, 2007

Senator Max Baucus
511 Hart Senate Office Building
Washington D.C. 20510

Dear Senator Baucus:

On May 11, 2006, you and members of the Senate Finance Committee invited top officials from major pharmaceutical companies to discuss the pharmaceutical company Patient Assistance Programs and their continuing assistance to Medicare Part D beneficiaries. Leaders from AstraZeneca, Bristol-Myers Squibb, Eli Lilly & Company, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, and Schering-Plough attended the meeting. Statements from you, Senator Grassley, Senator Hatch and Senator Rockefeller made it clear that Medicare Part D enrollment should not preclude any Medicare beneficiary from seeking assistance from these free drug programs. Three of those companies in attendance, AstraZeneca, GlaxoSmithKline and Schering-Plough, now allow Medicare Part D beneficiaries to apply for assistance with all of their Patient Assistance Program products, a decision we applaud. However, the others present do not. **Overall, the majority of pharmaceutical companies will not assist Medicare Part D beneficiaries through their Patient Assistance Programs at all.**

Prior to implementation of Medicare Part D, there was a significant population of Medicare beneficiaries who relied upon the pharmaceutical company Patient Assistance Programs. These programs provided reduced or no cost medications to individuals who could not otherwise afford them. Or, companies donated money to foundations that then provided assistance in purchasing the medication. All of these programs were a critical lifeline to many Medicare beneficiaries.

Since the implementation of Medicare Part D, many individuals who formerly relied on the Patient Assistance Programs were able to qualify for the Medicare Part D low-income subsidy. This significantly reduced the number of individuals in need of assistance from the Patient Assistance Programs. However, there are still substantial numbers of Medicare beneficiaries whose income or assets are too high for the low-income subsidy but not high enough to afford their medications under Part D. This population includes Medicare beneficiaries with serious medical conditions such as multiple sclerosis, cancer and AIDS, where drug cost can be prohibitively expensive. In addition, many older adults who have relied on *multiple* medications to support their health are struggling under Part D cost-sharing. For these individuals, the Patient Assistance Programs still must play an important role in their medical care.

Many pharmaceutical companies have claimed that they cannot assist Medicare beneficiaries through their Patient Assistance Program because of a November of 2005 opinion from the Health & Human Services Office of Inspector General (“OIG”). However, that opinion and subsequent opinions never prohibited assisting Medicare Part D enrollees through Patient Assistance Programs. In fact, several companies have had the OIG review and, in effect, approve their Patient Assistance Programs and its assistance to Medicare Part D enrollees. In general, the OIG opinions clearly laid out two low-risk options to the drug companies: assisting Part D enrollees outside of Part D and assuring that no assistance counts toward Part D cost-sharing or donating to cash for drug purchasing to charities or foundations that meet certain guidelines.

Given this, there is no compelling reason why any pharmaceutical company should continue to deny assistance to Medicare beneficiaries in need. Drug manufacturers have had varied responses, including:

- not assisting Medicare beneficiaries at all;
- only assisting Medicare beneficiaries who do not sign up for Medicare Part D;
- only offering assistance to Medicare beneficiaries with a limited number of medications that they manufacture – not all; or finally,
- referring all Medicare beneficiaries to foundations that might help with co-payments, but have historically long waiting lists.

Medicare Part D was supposed to provide greater access to medications for seniors and people with disabilities. Ironically, for Medicare beneficiaries who have been barred from Patient Assistance Programs and who do not qualify for the low-income subsidy, Medicare Part D has had the opposite effect. Rather than obtaining these medications for free or little cost, they now must attempt to access these drugs through the Medicare Part D plans that will, at some point in the year, charge them unaffordable co-payments or full price for these medications.

Attached is a chart outlining the current policies of each of the major pharmaceutical companies. We hope that you will join us in urging all of the pharmaceutical manufacturers to allow Medicare beneficiaries with limited incomes to enroll in their Patient Assistance Programs. Without this industry-wide shift and participation, Medicare Part D will be a barrier to medication access for many of our most vulnerable seniors and people with disabilities.

Sincerely,

WV Health Right, Inc.
CHAMP--Community HIV/AIDS Mobilization Project
Health & Disability Advocates
MEDBANK of Maryland, Inc.

Medicine for People in Need (Medpin)
National Association of Community Health Centers
National Association of Free Clinics
National Multiple Sclerosis Society—Greater Illinois Chapter
New York AIDS Coalition
Safety Net Hospitals for Pharmaceutical Access
Senior PHARMA*ssist*
Volunteers in Health Care/RxAssist

PAP Eligibility Criteria and Medicare Part D

No Medicare patients may apply for PAPs		
American Regent Axcan Biogen Boehringer Ingleheim Cangene Celgene Centocor (If diagnosis is for off-label use, Medicare beneficiaries may still apply.)	Cephalon Chiron/Proleukin Dermik Eisai First Horizon IVAX MedImmune Millenium Mylan	Novo-Nordisk PKL Biopharm Purdue Savient Scios Takeda Teva/Gate
Medicare patients w/o a Part D plan may apply for PAPs		
Alcon Allergan Amylin Astellas Bayer Berlex Biovail Bradley Pharmaceuticals Bristol Myer Squibb Chiron/TOBI (Part D see below) Daiichi Sankyo Duramed Endo	Enzon ESP Forest Galderma Genentech Gilead (Part D see below) Graceway (Formerly 3M) Intermune King Ligand (Part D see below) MedPointe MGI NitroMed Ortho-Biotech (Part D see below)	Reliant Roche (Part D see below) Sanofi-Aventis Serono Shire (Part D see below) Sigma-Tau (Part D see below) Solvay TAP (Part D see below) UCB Upsher-Smith Valeant (Infergen excluded) Vistakon Xcel
All Medicare patients may apply		
Abbott * Alpharma AstraZeneca --Part D enrollees use AZ Medicines & Me program Berlex/Beta Seron Found. (Cannot be LIS eligible) Digestive Care Eytech	GlaxoSmithKline --Part D enrollees use GSK Access program Johnson & Johnson* Kos Merck* Merck/Schering Plough* NABI (Cannot be LIS eligible) Novartis*	Pfizer* (Some medications may be not be available to Part D enrollees) Procter & Gamble (Cannot be LIS eligible) Schering-Plough Wyeth (Part D enrollees must submit hardship letter or LIS denial letter)
Medicare Part D patients may apply for selected medications		
Amgen --Sensipar and Enbrel only Chiron/TOBI --only if drugs not in patient's Part D plan Eli Lilly --Zyprexa, Forteo and Humatrope only Genzyme --Renagel only through Renagel Part D Assistance Program	Gilead --only if drugs not in patient's Part D plan Ligand --only if drugs not in patient's Part D plan Ortho-Biotech --only if drugs not in patient's Part D plan Roche --only if drugs not in patient's Part D plan	Shire --only if drugs not in patient's Part D plan Sigma-Tau --only if drugs not in patient's Part D plan TAP --Prevacid only Valeant -- only if drugs not in patient's Part D plan

LIS = Low Income Subsidy within Part D

*Will consider allowing some Part D enrollees to apply for PAPs; contact the company for more information