

USTR docket # USTR-2013-0040, Special 301

Reply Comments of Claire Cassedy¹, regarding drug company patient assistance programs

1. The USTR needs better data on patient assistance programs, particularly for patients with cancer living in developing countries.

An oft-cited claim by pharmaceutical companies and those lobbying on their behalf is that donations and patient assistance programs fully provide for those that cannot afford the high priced medications offered by the companies. During the hearing for the Special 301 Report process as well as the US International Trade Commission hearing on Indian trade policy, industry speakers repeated this claim as the response to how companies are ensuring access to life-saving drugs for poor patients who cannot afford drug prices that are sometimes several times their total annual incomes.

The question then naturally arises, what is the extent of these programs? In which countries do the pharmaceutical companies have patient assistance programs? How many people receive drugs through the programs, and which drugs do they receive? What are the eligibility criteria? In order to gather this information, KEI contacted the patient assistance programs for eight of the top oncology drug-producing pharmaceutical companies: Roche, Novartis, Sanofi, AstraZeneca, GlaxoSmithKline, Merck, Bayer, and Pfizer. The questions above were posed to each company, in hopes of garnering a more complete picture of the global impact of these programs.

For each of the companies I called the consumer contact telephone number for their patient assistance programs, to varying results. Not one of the companies offered me any of the information I requested over the phone. Half of companies simply told me that they did not have that information or that I should check their website. The other half of the companies called (Roche, AstraZeneca, Merck, and Bayer) recorded my questions and contact information and informed me that they would pass them along and would try to provide a response (promised response times varied from unspecified to a week). After explaining my purpose for calling, Bayer, Pfizer, and Roche transferred me to corporate relations contacts (to varying degrees of helpfulness). Sanofi, after providing me with the website for the US patient assistance program application process suggested that in order to find which other countries in which Sanofi has assistance programs, I would need to call Sanofi's phone number in each country globally to ask, or "look on the website."

Checking the websites for the companies (both the sites that I could readily find as well as the sites suggested by the patient assistance helplines) yielded mixed but ultimately unhelpful results. Roche routes to the Genentech patient access website where monetary amounts of medicines donated are cited (\$3.5 billion in 'free medicine to uninsured patients' since 1985)

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though it neglects to state how many patients were helped, where those patients are located, or which drugs are received. It does include one sentence stating that in 2012, Genentech helped “more than 100,000* fully insured, underinsured, and uninsured patients with access issues.”² The asterisk refers to a footnote that states, ‘patients must meet certain criteria.’ Other pharmaceutical companies’ websites survey yield similar results, either no data is given on the patients helped by the program at all, or there is a very brief mention of general information. AstraZeneca, for example, states that in 2012 it helped 562,000 fill 4.5 million prescriptions, only providing general information for one year of the patient assistance program.³ On its website, Merck states that it has provided medicines free of charge to “millions of eligible individuals” over the fifty years that it has operated the program.⁴ The critical caveat to this very miniscule amount of information available on the company websites is that all of the information on the patient assistance programs found is only applicable to US residents. A requirement for all of the patient assistance programs touted on the companies’ websites was that the patients who receive the free or low cost medicines must be US residents (among other eligibility criteria).

On the global front, there are a couple of minor exceptions. Novartis, although incredibly unhelpful on the phone, has one well advertized international donation program for Glivec, presumably in response to campaigns for access to the drug in several countries, as well as a patent case in India. In fact, the page on Novartis’ website highlighting the Glivec program provides a link to Novartis’ extensive webpage chronicling their perspective on the Glivec patent case in India.⁵ Facilitated through the MAX Foundation, the Glivec International Patient Assistance Program (GIPAP) website states that it has helped 61,512 people in 81 countries, though it does not list which companies it operates in.⁶ The GIPAP is the only international cancer drug assistance program I was able to readily identify. Pfizer does have two international assistance programs, donating Diflucan for fungal infections and Zithromax for trachoma and provides some bullets on program statistics, but I could not find detailed information on which specifically which countries and how many people have received the medicines.⁷

Overall, the search for information and statistics on the impact of pharmaceutical companies’ global patient assistance programs revealed a dearth of information. When attacking countries

² Genentech: “Patient Access.” <http://www.gene.com/patients/patient-access>

³ AstraZeneca. “AZ&Me Assistance Programs.”

<http://www.astrazeneca-us.com/medicines/help-affording-your-medicines>

⁴ Merck. “Patient Assistance Program.”

<https://www.merckresponsibility.com/focus-areas/access-to-health/community-investment/patient-assistance-program/>

⁵ Novartis. “Glivec International Patient Assistance Program.”

<http://www.novartis.com/corporate-responsibility/access-to-healthcare/our-key-initiatives/oncology-patient-assistance-programs.shtml>. For Novartis’ webpage on the patent case in India, see

<http://www.novartis.com/newsroom/product-related-info-center/glivec.shtml>.

⁶ The MAX Foundation. “Glivec International Patient Assistance Program.”

<http://www.themaxfoundation.org/GIPAP/Default.aspx>

⁷ Pfizer. “Global Health Initiatives: Enabling Global Access.”

http://www.pfizer.com/health/global_health/enabling_global_access

like India for their policies which seek to ensure access to medicines for their populations, pharmaceutical companies continually assert that there is no need for these policies. The companies or industry trade associations acting on their behalf often state that donation and patient assistance programs provide access to those who need the drugs. If that is true, why will these companies not provide the information about how many patients are helped worldwide by the programs? One company contacted told me that they thought that data might be proprietary and could not be given out. For what reason would that information be proprietary? One would think that if pharmaceutical companies are able to fill in access gaps with these programs that they would want to inform the public of the extent of their charitable efforts and 'commitment to access.'

If the US government is going to accept pharmaceutical companies' statement that India and other countries' policies are not needed to ensure access to medicines, and that the companies' assistance programs fully provide the drugs needed by their populations, then the government should have full data on these programs. If the US government wants to accept that donation programs solve all the access problems in developing countries, then it needs to know the actual number of patients that need the drugs and are then able to have access to it. This information needs to be available in order for them to make informed and accurate decisions. If not, the government will be making trade policy decisions that will impact the life and death of scores of patients worldwide, based on an industry soundbite rather than actual facts.

2. The US government subsidizes patient assistance programs, by providing special tax write-offs under the IRS Enhanced deduction provisions in federal income tax code.

When considering drug donations and patient assistance, one must not forget that these programs are not without benefit to the pharmaceutical companies. Besides the public relations opportunity afforded them by announcing their charitable donations or including a reassuring phrase at the close of their drug commercials, there is significant tax benefit as well. In 1985, the enhanced deduction provision was enacted in the Internal Revenue Code. Under IRC 170(e)(3), "when a corporation donates products to a charitable organization...the amount allowable as a charitable deduction is equal to the unrealized appreciation, not to exceed twice the taxpayer's basis in such property."⁸ Prior to the rule being put into place, companies could only deduct an amount equal to their cost for an item donated, whereas under the enhanced deduction provision that deduction for the item donated is equal to fair market value (up to twice the cost/basis of the item), this can be significantly higher than the cost of the item.⁹

The question then arises, what is the cost in tax subsidies to US consumers for these 'charitable' programs? For example, Merck's patient assistance program page states that over the last decade, they have made donations "representing a total value (wholesale acquisition

⁸ IRS. "Pharmaceutical Industry Overview."

<http://www.irs.gov/Businesses/Pharmaceutical-Industry-Overview---Complete-Version>

⁹ Fowler, R. and Henchly, A. "E. In-Kind Contributions." <http://www.irs.gov/pub/irs-tege/eotopice94.pdf>

cost) of more than \$2.67 billion.” This large donation was not purely altruistic then, Merck would have seen considerable tax deductions over this ten year period under the enhanced deduction provision. To what extent are US taxpayers subsidizing multi-billion dollar pharmaceutical companies through these charitable donation programs?

3. Bayer does not have patient assistance programs for most countries, and the program has been highly criticized in the countries where it operates.

Throughout the Special 301 Report hearing on February 24, 2014, pharmaceutical industry and trade association representatives continually highlighted the case of Nexavar in India, whereby the Indian government issued a compulsory license on Bayer’s liver and kidney cancer drug, Nexavar. The industry voices asserted that the compulsory license was simply a policy move by the Indian government to promote the generic pharmaceutical industry in India rather than a decision to facilitate access to the cancer drug in India. Bayer’s patient assistance programs were touted as sufficient to ensure access to Nexavar in India and other countries. In fact, Bayer does not have patient assistance programs for most countries.

One example of a major access gap not addressed by Bayer, is the availability of Nexavar in Egypt. Nina Mahmud, a US citizen, has been working to get affordable access to Nexavar for her father-in-law, Fathi Aboseada, who lives in Egypt. Aboseada has liver cancer, and his treatment of Nexavar costs him about \$115 a day, all while he earns approximately \$300 per month.¹⁰ He has used up all his life savings to purchase Nexavar, which has had a significant positive impact on his health, and has now run out of the drug. He is considering selling his small shop (a longtime family business) in order to purchase a mere seven more months of the drug.¹¹ Aboseada and Mahmud’s family cannot afford to sustain Aboseada’s treatment on Nexavar. Bayer does not have a patient assistance program in Egypt and there is a clear gap in ensuring access to this medicine. In fact, Egypt is the country with the fourth highest rate of liver cancer in the entire world,¹² and yet Bayer does not have a program in place to address this prevalent health problem.

4. Patient assistance programs do not address access to medicines issues in the United States, much less in developing countries.

Patient assistance programs do not even fully ensure affordable access to medicines in the United States. In an article covering the skyrocketing price of cancer drugs in the US, ABC News highlight the story of Patricia Thompson, a cancer patient whose life-saving drug, Sprycel,

¹⁰ Martin, Andres. “Life-Saving Medicine, High Costs, and the Intractable Patent Puzzle.” 05 March 2014. <http://www.businessweek.com/articles/2014-03-05/life-saving-medicine-high-costs-and-the-intractable-patent-puzzle#r=hp-ls>

¹¹ For more information on Nina Mahmud’s efforts to get access to Nexavar for her family, please visit http://www.youtube.com/playlist?list=PLLw9jWaZPEpzj9_OW4LKlxD5pvPto71xO.

¹² World Cancer Research Fund International. “Liver Cancer.” http://www.wcrf.org/cancer_statistics/data_specific_cancers/liver_cancer_statistics.php.

is priced at \$106,000 per year.¹³ Even with Medicare coverage, this represents a \$10,000 out-of-pocket cost for Thompson. In response to Thompson's case, Bristol-Myers Squibb, which produces Sprycel, stated that they base pricing on the cost to develop them and that "for Sprycel, we have robust patient assistance programs in place."¹⁴ Thompson applied to the Bristol-Myers Squibb reimbursement support program and was rejected. At the time of the story, Thompson had 30 pills of Sprycel left and no way to purchase any more of the life-saving medication. If patient assistance programs are not sufficient to address access gaps in the US, is it reasonable to accept that the programs fully address the problem in the developing world?

As noted by David Pfister in an article on the growing cost of cancer drugs,

"While there are drug-company sponsored programs to facilitate access to drugs for patients, of which the Merck-sponsored one to treat river blindness is a heroic example, overall such mechanisms are not a comprehensive solution for most cancer patients or scenarios. There is a need for better solutions, although the best strategy moving forward is controversial. Others have previously expressed concerns regarding the impact and sustainability of the growing cost of cancer care—of which the high price of related treatment and supportive care drugs is part of the picture—and similarly called for new strategies to contain costs without adversely affecting quality, safety or other outcomes."¹⁵

In seeking to address these growing costs for cancer drugs, India and other developing countries are looking to new strategies for their populations. Drug-company sponsored programs are not a comprehensive or sustainable solution, and nations such as India should not be placed on the Priority Watch List for using WTO-compliant policies to find long-term solutions for access to medicines in their countries.

¹³ Besser, Richard. "Outrage at the Increasingly High Cost of Cancer Drugs." 18 Dec 2013.

<http://abcnews.go.com/blogs/health/2013/12/18/outrage-at-the-increasingly-high-cost-of-cancer-drugs/>

¹⁴ Besser, Richard. "Outrage at the Increasingly High Cost of Cancer Drugs." 18 Dec 2013.

<http://abcnews.go.com/blogs/health/2013/12/18/outrage-at-the-increasingly-high-cost-of-cancer-drugs/>

¹⁵ Pfister, David. "The Just Price of Cancer Drugs and the Growing Cost of Cancer Care: Oncologists Need to Be Part of the Solution." *Journal of Clinical Oncology*. 01 Oct 2013. Vol. 31, No. 28. Pg. 3487-3489.

<http://jco.ascopubs.org/content/31/28/3487.short?rss=1>