

KEI's Additional Comments Special 301

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These comments supplement KEI's February 7, 2014 written submission (Also available here: <http://www.keionline.org/ustr/special301>, and <http://keionline.org/node/1927>), and our February 24, 2014 oral testimony, and provide also comment or reply to the written or oral submissions by others.

1. India is an important source of affordable medicines.

If the United States does anything to reduce the availability of low cost generic drugs from India, it will have huge consequences around the world. There effectively is no other country that can supply a range of low cost affordable generic drugs, at this point in time. If the US shuts down India as a source of generic drugs, the US shuts off the entire developing world.¹

2. US and Europe do more compulsory licensing of patents than India, by far.

While a large number of trade associations have expressed alarm over the decision by India to grant a single compulsory license on one cancer drug, since 2004, the United State has vastly expanded its uses of compulsory licenses, and the European Union is moving in the same direction.

- The state practice for the United States is described in Annex A.
- The state practice for the European Union is described in Annex B.

3. Cancer drugs are too expensive, everywhere.

This year's Special 301 list is about cancer, and whether or not India will be providing affordable generic cancer drugs. The fact is, prices for cancer drugs have soared, and are unsustainable and unaffordable, everywhere. If USTR imposes trade rules around the world that make cancer

¹ The United States itself has considered purchases of generic medicines from India or other countries when faced with a variety of crises, shortages of other challenges, including for example, the cancer drug doxil from India. President Obama Executive Order 13588 -- Reducing Prescription Drug Shortages October 31, 2011. See also: Roni Caryn Rabin, "Drug Scarcity's Dire Cost, and Some Ways to Cope," *the New York Times*, December 12, 2011, and FDA press release on drug shortage, Feb 21, 2012.

drug monopolies stronger, it will be ignoring a growing and deepening crisis in access to cancer drugs.

Annex C provides details of the 29 New Molecular Entity (NME) cancer drugs approved by the US FDA from 2011 to 2013. The unweighted average price for the 29 products was \$100 thousand. The median price was \$92.8 thousand.

I would like to add to the record the following articles:

2009, June 29. Tito Fojo and Christine Grady, How Much Is Life Worth: Cetuximab, Non–Small Cell Lung Cancer, and the \$440 Billion Question, *JNCI J Natl Cancer Inst* (2009) 101 (15): 1033 doi:10.1093/jnci/djp234 first published online June 29, 2009.

In some sense, every life is of infinite value, and we naturally avoid confronting the tension between not wanting to put a value on a life and having limited resources. But the spiraling cost of cancer care in particular makes this dilemma inescapable. We, the oncology community, cannot continue to ignore it. Such expensive therapies impose substantial burdens on patients and providers of health insurance. We must stop deluding ourselves into thinking that prescribing cetuximab, bevacizumab, erlotinib, or any of the other expensive chemotherapies and tests are an aberration, a temporary deviation from an otherwise reasonable cost trajectory.

2012. January 23. Merrill Goozer. High Cost Of New Cancer Drugs Sparks New Care Struggle, *Kaiser Health News*. Also published in *the Fiscal Times*.

"In the real world of private practice where most care is delivered, it would be a mistake to say rising costs haven't affected care," said Eric Nadler, a head, neck and lung cancer specialist at Baylor University Medical Center. A recent survey published in *Health Affairs* found a stunning 84 percent of oncologists say their patients' out-of-pocket spending influences treatment recommendations.

2012, Oct. Mustaqeem Siddiquia and S. Vincent Rajkumarb. The High Cost of Cancer Drugs and What We Can Do About It. *Mayo Clin Proc*. Oct 2012; 87(10): 935–943. doi: 10.1016/j.mayocp.2012.07.007

2012, Oct 14. Peter B. Bach, Leonard B. Saltz And Robert E. Wittes, In Cancer Care, Cost Matters, *The New York Times*.

Ignoring the cost of care, though, is no longer tenable. Soaring spending has presented the medical community with a new obligation. When choosing treatments for a patient, we have to consider the financial strains they may cause alongside the benefits they might deliver.

This is particularly the case with cancer, where the cost of drugs, and of care over all, has risen precipitously. The typical new cancer drug coming on the market a decade ago cost about \$4,500 per month (in 2012 dollars); since 2010 the median price has been around \$10,000. Two of the new cancer drugs cost more than \$35,000 each per month of treatment.

2013, Apr 23. More than 100 Experts in chronic myeloid leukemia. Price of drugs for chronic myeloid leukemia (CML), reflection of the unsustainable cancer drug prices: perspective of CML Experts. *Blood*. Journal of the American Society of Hematology. Published online before print April 25, 2013, doi: 10.1182/blood-2013-03-490003, *Blood* April 25, 2013 blood-2013-03-490003.

While cancer drug prices have been discussed recently by some financial analysts, and whenever new cancer drugs are approved, this Perspective reflects the views of a large group of CML experts, who believe the current prices of CML drugs are too high, unsustainable, may compromise access of needy patients to highly effective therapy, and are harmful to the sustainability of our national healthcare systems. These reflect the spiraling prices of cancer drugs in general. Of the 12 drugs approved by the FDA for various cancer indications in 2012, 11 were priced above \$100,000 per year. Cancer drug prices have almost doubled from a decade ago, from an average of \$5,000 per month to more than \$10,000 per month (2).. .

Imatinib was developed as a “goodwill gesture” by Novartis, and became a blockbuster, with annual revenues of about \$4.7 billion in 2012. Being one of the most successful cancer targeted therapies, imatinib may have set the pace for the rising cost of cancer drugs. Initially priced at nearly \$30,000 per year when it was released in 2001, its price has now increased to \$92,000 in 2012 (1), despite the fact that all research costs were accounted for in the original proposed price (5), that new indications were developed and FDA approved, and that the prevalence of the CML population continuing to take imatinib was dramatically increasing (14). This resulted in numerous appeals by patients and advocates to lower the price of imatinib, but to no avail so far (15, 16).

2013. Apr 25. Andrew Pollack, Doctors Denounce Cancer Drug Prices of \$100,000 a Year, *The New York Times*.

2013, May 23. Zosia Chustecka, High Price of Cancer Drugs 'One of Biggest Issues in Healthcare', *Medscape Medical News, Oncology*.

The high cost of cancer drugs "has been the elephant in the room when we have been discussing treatment," Dr. Kantarjian told *Medscape Medical News*.

It needs to be brought out into the spotlight, because this is currently one of the most important issues in healthcare, he said, pointing out that "cancer drug prices are going to be the number 1 discussed healthcare issue in the next 2 years."

2013, June 5. Tracy Staton, Sky-high drug prices will force change in cancer care, experts say. Fierce Pharma.Com FiercePharma:²

Patients are shouldering more of the cost burden, with 20% co-pays amounting to tens of thousands in some cases. And as one oncologist told Reuters, patients may soon be required to pay a higher share for drugs whose proven survival benefits are on the low end. "There will be increased cost-sharing for patients based on the relative value of a particular therapy," Dr. Neal Meropol of the University Hospitals Case Medical Center in Cleveland told Reuters.

2013, Aug 14. Mike Mitka, MSJ, High-Cost Drugs Account for Most of Medicare Part B Spending, *JAMA*. 2013;310(6):572. doi:10.1001/jama.2013.192555.

The 10 highest-expenditure drugs accounted for almost half of all Medicare Part B drug spending in 2010, according to testimony by the Government Accountability Office (GAO) (<http://tinyurl.com/mju652s>). Furthermore, the 55 highest-expenditure drugs represented 85% of the \$16.9 billion spent by Medicare in the Part B program. The GAO submitted its report during a June 28 hearing of the House Subcommittee on Health, which is considering reforms to improve the Medicare Part B drug program.

2013, Sep 3. David G. Pfister. The Just Price of Cancer Drugs and the Growing Cost of Cancer Care: Oncologists Need to Be Part of the Solution. *American Society of Clinical Oncology*. Published online before print September 3, 2013, doi: 10.1200/JCO.2013.50.3466 JCO October 1, 2013 vol. 31 no. 28 3487-3489.

2013, Sep 6. Zosia Chustecka, Cancer Drug Costs: Oncologists Must Be 'Part of the Solution', *Medscape Medical News, Oncology*.

2013, Oct 2. Brian P. O'Sullivan, MD; David M. Orenstein, MD, MA; Carlos E. Milla, MD, Pricing for Orphan Drugs. Will the Market Bear What Society Cannot? *JAMA*. 2013;310(13):1343-1344. doi:10.1001/jama.2013.278129.

The excitement for ivacaftor was tempered, however, with Vertex's decision to set a price of \$294,000 per year for this drug, a price that has increased to \$311,00 per year -- a charge to an individual patient as high as \$373,000. As opposed to some other short-term, high-cost therapies, ivacaftor likely will need to be taken for decades by individual patients, with the potential cost of many millions of dollars. . . . Ironically, the patients who assumed the risks of participating in the clinical trials necessary to bring this drug to market and who devoted countless hours to raising money for the CF Foundation to underwrite early work are now being asked to pay, most often through their

² <http://www.fiercepharma.com/story/sky-high-drug-prices-will-force-change-cancer-care-experts-say/2013-06-05>

insurers, and exorbitant price for the product that resulted from their efforts. . . .
Pharmaceutical companies need to be more transparent about how the price of a new drug is determined.

2013, Oct 20. Stephen S. Hall, The Cost of Living: New drugs could extend cancer patients' lives—by days. At a cost of thousands and thousands of dollars. Prompting some doctors to refuse to use them. *New York Magazine*.³

“Everybody agrees: The prices are unsustainable,” Saltz said. “And I often try to invite myself or people having these discussions to complete the thought: If it’s unsustainable, what happens when it’s unsustainable? Do we have an adjusted, steady correction? Or do we have an implosion and a crash?”

2013, Oct 30. Laura Watermeyer, Costs Keep Cancer Drugs Out of Developing Countries. AllAfrica.com.⁴

Lopes described cancer as a forgotten disease in the developing world, often overshadowed by the high number of deaths caused by malaria, AIDS and tuberculosis. Cancer, however, is taking more lives than these three killers combined. Cancer kills 7.1 million people every year, and 80 percent of these deaths occur in LMICs. In South Africa, more than 100,000 people are diagnosed with cancer every year. One in four South Africans will either be diagnosed with cancer themselves or know someone who is each year. “The cost of medication may drop by as much as 80 percent after the introduction of generics,” explained Lopes. “India, for example, is estimated to save around 800 million dollars by using generic medicines.”

2013, Dec 18. Richard Besser, "Outrage at the Increasingly High Cost of Cancer Drugs," *ABC News*.⁵

2014. Jan 4. The new drug war: Hard pills to swallow, Drug firms have new medicines and patients are desperate for them. But the arguments over cost are growing. *The Economist*.⁶

LOUIS MACHOGU, the owner of a pharmacy near Nairobi, has noticed a change. In the past decade Kenya, like much of Africa, has seen a surge in foreign aid to fight infectious diseases. Thanks to antiretroviral treatments, HIV is no longer a death sentence. But the decline of one scourge means that people are living long enough to fall sick in other ways. “The same way we had HIV killing people,” Dr Machogu says, “we now have hypertension and cancer.”

³ <http://nymag.com/news/features/cancer-drugs-2013-10/>

⁴ <http://allafrica.com/stories/201310301406.html>

⁵ <http://abcnews.go.com/blogs/health/2013/12/18/outrage-at-the-increasingly-high-cost-of-cancer-drugs/>

⁶ <http://www.economist.com/news/international/21592655-drug-firms-have-new-medicines-and-patients-are-desperate-them-arguments-over>

Treatment often depends on the whim of pharmaceutical firms' philanthropic programmes. Cancer drugs are particularly lacking. The Kenya Medical Supplies Agency buys medicines for public hospitals, but not those for cancer.

2014, Feb 14. Ronan J Kelly MD and Professor Thomas J Smith MD, Delivering maximum clinical benefit at an affordable price: engaging stakeholders in cancer care, *The Lancet Oncology*, Volume 15, Issue 3, Pages e112 - e118, doi:10.1016/S1470-2045(13)70578-3

Cancer costs continue to increase alarmingly despite much debate about how they can be reduced. The oncology community needs to take greater responsibility for our own practice patterns, especially when using expensive tests and treatments with marginal value: we cannot continue to accept novel therapeutics with very small benefits for exorbitant prices.

Andrew Martin, Life-Saving Medicine, High Costs, and the Intractable Patent Puzzle, *Bloomberg Businessweek*, March 5, 2014.

In the middle of February, just as another winter snowstorm was about to hit the East Coast, Nina Mahmud flew from her home in Florida to Washington, D.C., to try a Michael Moore-style stunt to save her father-in-law's life.

A representative of Bayer (BAY:GR) was set to speak at a hearing of the U.S. International Trade Commission. Mahmud was going to ask her how the pharmaceutical giant could let her father-in-law, a shopkeeper in Egypt suffering from liver cancer, bankrupt himself to pay for a life-saving treatment. The drug, Nexavar, costs him about \$115 a day in Egypt, she said, while his monthly salary is less than \$300.

4. The lack of patented cancer drugs on the WHO and country Essential Medicines List (EML) is a shame for big pharma, not a defense.

It is true that the WHO has almost no patented drugs on its model essential medicines list, and none for cancer, and many developing countries do not have many or any patented cancer drugs on similar national lists of essential medicines. This does not mean that such medicines are not essential for keeping someone alive. It means they are so expensive a country with few resources cannot justify spending money on them. For every industry lobbyist, and for every member of the USTR staff, the White House, the Vice-President's Office, the USPTO, the US Department of State, the Department of Commerce, and the Department of Health and Human Services (DHHS), ask yourself, would you choose an insurance program for yourself or your

family that did not pay for patented cancer drugs? If not, why should people living in developing country be treated as if they did not benefit from access to those same drugs?

It is true that some people living in developing countries do not have access to medical services that make some cancer treatments feasible. It is not true that everyone living in a developing country lacks the services to make those treatments feasible. People living in developing countries should have the freedom and the opportunity to expand access to cancer treatments, whenever and for whomever this is possible. The lack of universal access is not an argument for reducing access even further. I'm not sure why anyone has to even say this, but judging from some of the testimonies at the February 24, 2014 hearing, it apparently bears repeating.

5. Boeing submission to the ITC

On February 7, 2014, the Boeing Company submitted a written statement to the United States International Trade Commission (USITC) investigation of India (No. 332-543) concluding that "In Boeing's experience, India has a legal framework that is adequate to protect IP with no known cases of IP violation involving Boeing's activities in the defense and aerospace sector." In preparation for its submission, Boeing conducted a detailed review of its activities in India "including the export of Boeing products, as well as sourcing activities" and determined that India had in place an adequate legal IPR framework for "Boeing's aerospace and defense products in India." In its written submission, Boeing highlighted the fact that "Boeing is the largest single producer, by dollar value, of US exports to India." In the Boeing 2012 Current Market Outlook for India, the company forecast that the Indian aviation market would "require 1,450 new commercial jets, valued at approximately \$175 billion, over the next 20 years." In terms of Indian IPR legislation, Boeing commented that "Indian IPR laws applicable to the range of Boeing's business activities in India are comparable to IPR regulations in other developed countries, as India is signatory to all major conventions and treaties on this subject."

5. Don't be on the wrong side of history

Take a look at these videos, and ask yourself, do you want to be on the wrong side of history?

<http://vimeo.com/fireintheblood/videos>

<http://truevisiontv.com/films/details/81/dying-for-drugs>

Annex A: US Compulsory Licenses

Annex B: European Compulsory License

Annex C: Prices and meta data concerning NME Oncology Drugs approved by the USFDA from January 2011 to December 2013.

ANNEX D: Cost of Selected Drugs Used in Cancer Therapy

ANNEX F: Boeing Submission to the International Trade Commission