

Comments of Robert Sachs on the National Institute of Standards and Technology (NIST)

Proposal to Eliminate Unreasonable Pricing as a Standalone Basis for Government Exercise of March-In Rights Under 37 CFR Sec. 401(6)

I'm a 72-year-old battling advanced prostate cancer but am by no means unique. Another 1.9 million Americans will be newly diagnosed with cancer this year, among them nearly 250,000 men with prostate cancer.

In addition to battling prostate cancer for the past six years, I've served since 1998 as a trustee of the Dana-Farber Cancer Institute, one of the pre-eminent academic cancer hospitals and research institutes in the world and am a former board chair of the National Coalition for Cancer Survivorship. Although my board service has informed my views, I submit these comments on my own behalf.

Serving on the Dana-Farber and NCCS boards has given me a much greater appreciation of the vital need for government, industry and philanthropic support for cancer research. Needless to say, ongoing research and future discoveries are likely to save the lives of millions of more diagnosed with cancer. However, I do not believe scientific research and cancer patient interests need be at odds here.

During NIST's recent webinar of the proposed rule changes, many proponents cast the proposed march-in rights modification as a choice between continued investment in research and innovation or government regulation of drug pricing. In my view, this postulation poses a false choice. Since the enactment of Bayh-Dole in 1980, including its march-in provisions, both academic research and the pharmaceutical industry have thrived.

I therefore file these comments in opposition to NIST's proposed modification of 37 CFR Sec. 401(6) to eliminate unreasonable pricing as a standalone basis for the exercise of Bayh-Dole march-in rights. Not only does the proposed modification undermine the plain language of Bayh-Dole mandating that benefits of government-funded inventions be made "available to the public on reasonable terms." It would deprive cancer and other patients of their principal statutory recourse to obtain potentially life-saving drugs "on reasonable terms."

Along with thousands of other men confronted with the most aggressive forms of prostate cancer, I've been the beneficiary of Xtandi, a life-extending drug co-marketed in the US by Astellas, a Japanese-owned pharmaceutical company in partnership with Pfizer. The average U.S. wholesale price of Xtandi is greater than \$150,000/year, four times what the same drug is sold for in Canada and more than five times the price Xtandi is available for in Japan.

According to the Redbook survey, the U.S. average wholesale price (AWP) was \$109 for a single 40 mg capsule of Xtandi in 2018. In 15 high-income countries surveyed, the AWP for Xtandi was less than half the U.S. price. In 11 of the 15 it was less than one-third and in six it was less than one-fourth.

Upon learning that cancer patients in other developed countries can purchase Xtandi for a fraction of the cost it's sold in the U.S. I was shocked to find out that its pre-clinical development was funded by US taxpayers with grants made by NIH and DoD to researchers at UCLA. UCLA subsequently licensed a company named Medivation which in turn sold global rights to Astellas for \$765 million in 2009, retaining a 50% ownership interest. Then, in 2014 after FDA approvals were obtained, Medivation was acquired by Pfizer for \$14 billion.

In announcing the acquisition, Ian Read, Chairman and Chief Executive Officer, Pfizer, declared, "The proposed acquisition of Medivation is expected to immediately accelerate revenue growth and drive overall earnings growth potential for Pfizer." Not mentioned was that the \$14 Billion acquisition cost would be borne by cancer patients, and disproportionately so in the United States.

When Astellas and Pfizer are pricing Xtandi in the U.S. at almost \$450/day for a standard dose of the drug, the time is long past due for the Government to exercise its march-in rights. Unfortunately, NIST's proposed "clarification" of march-in-rights would undermine this possibility.

I do not hold myself out as an expert on drug pricing, but one does not have to look much beyond the Congressional Budget Office March 2019 in-depth analysis of "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid" to appreciate that my Xtandi experience is not atypical.

Proponents of NIST's elimination of "reasonable pricing" as a standalone basis for exercise of march-in rights argue that this rule change is necessary to ensure continued institutional and industry investment in research. Yet they do not present any evidence that the establishment of government march-in rights has had any such deleterious effect on research.

They further paint a picture that exercise of march in rights would somehow amount to comprehensive price regulation when in fact exercise of march-in rights would only allow market-place competition in those instances where, the Government finds that a drug is not available to the American public "on reasonable terms."

As documented in the comments (see p. 30) filed in this proceeding by James Love of Knowledge Ecology International (KEI), "reasonable terms" has been regularly interpreted by

federal and state courts to include price. So, the concept of the exercise of march-in rights to endure that potentially lifesaving drugs are made available to the public on reasonable terms is not something new. The only thing that's changed over the past four decades is that pharmaceutical companies have set prices higher and higher.

March-in provisions were initially included in the 1980 Bayh-Dole Act, P.L. 96-517, which President Biden supported when he served on the Senate Judiciary Committee, and a bi-partisan Congress enacted to address concerns about the commercialization of technology developed with U.S. funding. As a U.S. Senator, Vice President Harris, and as Attorney General of California, HHS Secretary Becerra both championed the federal exercise of march-in rights to bring down the cost of high-priced drugs.

In 2017, the Republican-led Senate Armed Services Committee directed DoD "to exercise its rights...to authorize third-parties to use inventions that benefited from DoD funding whenever the price of a drug, vaccine or other medical technology is higher in the U.S. than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the U.S." And during the 2020 campaign both Presidential candidates proposed tying U.S. drug prices to those paid by consumers in other countries.

Reference to pricing in other countries is one possible standard an agency could use to trigger exercise of march-in rights. But not to be lost here is the fact that companies could ensure that march-in rights are never exercised by exercising restraint in drug pricing. Instead, however, pharmaceutical companies and other rights holders who have benefited from excessive pricing, seek to remove “reasonable terms” as a standalone basis for any exercise of march-in rights.

The Biden Administration has the opportunity to reverse this. For over two years a request filed by prostate cancer patients has been pending before the Secretary of the Army asking DoD to find terms under which Xtandi (originally known as “enzalutamide”) are made available to the American public are “unreasonable,” and invoke DoD’s march-in rights. Doing so would send a clear message that excessive drug pricing will not be tolerated any longer.

On the other hand, NIST’s proposed modification of the march-in rights provision of 37 CFR Section 401.6, put forward during the final days of the Trump Administration, would not only be harmful to millions of cancer patients but represent a stark departure from the Biden Administration’s commitments to contain drug prices and reduce the escalating costs of health care for the American people. I urge you to reject this “clarification.”

