

## Jeopardizing U.S. Drug Development March 24, 2013

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Senator Ron Wyden (D- OR) is a man with an idea for lowering health care costs. Unfortunately, it’s an idea which proved disastrous the last time it was forced on the National Institutes of Health. But that hasn’t dissuaded the Senator from trotting it out again. He believes if a company commercializes a new drug whose development is in some way relatedto a cooperative R&D agreement (CRADA) it had at one time with NIH, that the government can then insure “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”

Sen. Wyden seems sincere in his concern with the ever escalating costs of medicine. Unfortunately, his proposed solution empowering the government bureaucracy to second guess industry drug pricing decisions simply because they worked with NIH would make things worse. We could see fewer new drugs at any price. We may see more research shifted to India and China as our public research institutions are viewed as unreliable partners. And we may throw away a key strategic advantage of the hard pressed U.S. life science industry—its ability to draw on the unparalleled resources and expertise in our federal laboratory and university research systems.

If this path is chosen, we have fair warning of the hazards. We’ve been down it before.

Influential members of the House of Representatives coerced NIH into adopting this approach twenty years ago. The upshot was not a decrease in drug pricing, but a breakdown of industry/NIH cooperation as companies rightly feared how such a vague formula would be applied. The result was that some of the best minds at NIH and industry stopped working together with the ultimate loss felt by patients praying for relief of their suffering. Why would we expect a different outcome now?

The current round started when Senator Wyden wrote to NIH Director Dr. Francis Collins on March 19, 2013 expressing his concerns with the pricing of Tofacitinib (Xeljanz) a Pfizer drug that’s the first oral medication for the treatment of rheumatoid arthritis.

“While it is correct that the expenses of drug discovery and preclinical and clinical development were fully undertaken by Pfizer, taxpayer-funded research was foundational to the development of Xeljanz” according to the letter. Senator Wyden concludes by asking NIH to convene an outside panel to “reexamine the pricing of medicines and treatments developed with public funds.”

(<http://www.wyden.senate.gov/news/press-releases/wyden-urges-nih-to-reexamine-policies->)

As the letter arrived at NIH, the New York Times published an article “Seeking Profit for Taxpayers in Potential of New Drug” on the Wyden proposal. (<http://www.nytimes.com/2013/03/19/business/questions-for-public-private-pact-that-led-to-xeljanz.html?emc=tnt&tntemail0=y&_r=1&>)

Interestingly, in Pfizer’s reply it appears that there was no licensed product from NIH directly involved in making the drug in question. Nor was Xeljanz developed with federal funds. (<http://www.pfizer.com/news/newyorktimes_nih_policy.jsp>). An instructive article, “**Pfizer’s Xeljanz story reveals why new drugs are so costly**” details their 16 year struggle as Pfizer scientists labored to commercialize the new treatment. (http://www.theday.com/article/20121111/BIZ02/311119920/1070/BIZ)

However, let’s not debate the particulars of this case, but examine the underlying theory the Senator promotes. Fortunately, we have real life evidence for what happened when the formula was actually tried in the 1990’s.

Influential members of the House of Representatives, including then Congressman Wyden, pressured NIH into incorporating a “reasonable pricing” (as defined by the government) provision for drugs assisted in some way by NIH cooperative R&D with industry. While perhaps seeming reasonable to the Representatives, the industry response was not positive. They simply walked away.

Proponents of “reasonable pricing” make a fundamental miscalculation. Federally funded inventions are more like ideas than products. In the case of a CRADA, there may be no government invention involved, just interesting very early stage research. While federal and university scientists are valuable sources of new ideas for treating disease, the risk and expense of commercialization falls squarely on the industry partner. *Thus, drugs are not “developed” with federal funds.*

Commercializing a new drug costs companies billions of dollars, more than 10 years of effort, submitting to rigorous FDA approvals, culminating more often than not in failure. For the few drugs which are successful, many face foreign price controls with countries like India increasingly attacking the underlying patent or forcing compulsory licensing. Greece is contemplating a new twist: they want to use compulsory licensing so they can buy Indian versions of our patented drugs.

In short, the life science industry—which we still dominate-- is under siege both here and abroad. Virtually every day sees stories of companies downsizing their research staff and consolidating facilities in an attempt to remain afloat.

This downsizing means that our biomedical industry increasingly sees academic and federal research facilities as valuable research partners. Senator Wyden posed an important question to Dr. Collins: *“What is the public benefit from drug development partnerships with industry?”*

Luckily, there’s an excellent response. It comes from the NIH report repealing the original “reasonable pricing” clause. Here’s its conclusion:

On the basis the information gathered for this report, NIH believes that its stewardship of the federal resources that support biomedical research has protected the taxpayers' interests. NIH and its recipient institutions apply the provisions of Bayh-Dole to best advantage in seeking the optimal return on investment in terms of public health benefit.

NIH also concludes that contravening the provisions of Bayh-Dole may have a deleterious effect on biotechnology development. Current practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available. The transfer of federally funded technology has also resulted in financial returns from licensing activity, and such funds are used to buttress the biomedical research enterprise that has made the U.S. the world leader in this field.

**Requiring direct financial recoupment of the federal investment in biomedical research can potentially impede the development of promising technologies by causing industry to be unwilling to license federally funded technologies. The "reasonable pricing" provisions that NIH once required in all CRADA and exclusive license negotiations did just that. Of even greater concern should be the potential that the economic disincentives of recoupment will make it expedient for industry to move research outside the federal milieu. Such action would diminish the strides made under the Bayh-Dole Act and have the unintended consequence of removing the research from federal oversight, a particular concern when the research involves lines of investigation that are especially critical or sensitive.**

**It is impossible to overstate the achievements or the global macroeconomic impact of U.S. taxpayer-supported biomedical research. Federally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have been improved and extended, have been the beneficiaries of the remarkable medical advances that have come from this enterprise.** (emphasis added)

<http://www.ott.nih.gov/policy/policy_protect_text.aspx#a>.

Well said. Perhaps we should listen.