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March 15, 2013

Francis S. Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Director Collins,

I am writing to express my ongoing concerns about achieving a reasonable balance between getting breakthrough pharmaceuticals to market quickly, making sure patients can afford these medicines and protecting the interests of taxpayers.

Twenty years ago this issue was debated in my House subcommittee with respect to taxpayer investments in the chemotherapy drug Taxol. NIH and its mission deserve strong support yet citizens remain concerned about public dollars being used to research and develop drugs and treatments which are then commercialized with the public getting short shrift.

Tofacitinib (Xeljanz), approved last November by the U.S. Food and Drug Administration, is nearing the market as the first oral medication for the treatment of rheumatoid arthritis. Given that the research base provided by the National Institutes of Health (NIH) culminated in the approval of Xeljanz, citizens have the right to be concerned about the determination of its price and what return on investment they can expect. 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.

It is clear that a public-private collaboration took place as described in a NIH press release dated December 4, 2012:

> "In 1993, shortly after O'Shea [John J. O'Shea, M.D.] and his team discovered the JAK3 protein and established its role in inflammation, O'Shea learned that scientists at Pfizer were searching for drug targets to tackle autoimmunity and transplant rejection. Subsequent discussions led to an innovative public-private collaboration between NIH and Pfizer, through a cooperative research and development agreement [CRADA]. This agreement allowed teams from both organizations to work together toward the common goal of finding a new immune-suppressing drug for this debilitating disease."

Partnerships, such as the one described, are important and can be instrumental to medical breakthroughs and innovation. Scientific advances rarely happen overnight or as the result of any single agreement – a partnership, CRADA or license. But there should be a mechanism in place that ensures that the return on taxpayer investment is considered. The CRADA reached between NIH and Pfizer on Xeljanz – like all such agreements made after 1995 – occurred after NIH abandoned the policy requiring "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."

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Developing drugs in America remains a challenging business, and NIH plays a critically important role by doing research that might not otherwise get done by the private sector. My bottom line: When taxpayer-funded research is commercialized, the public deserves a real return on its investment. With the price of Xeljanz estimated at about $25,000 a year and annual sales projected by some industry experts as high as $2.5 billion, it is important to consider whether the public investment has assured accessibility and affordability.

I am therefore requesting information about the CRADA and any other relevant agreements and licenses that helped to develop Xeljanz to gain an understanding of what the public can expect as a return on its research investment. Further, please provide a list of the major medicines and therapies that have come to market as result of research at NIH since 1995.

Finally, in the face of this difficult economic climate and the increasing scarcity of research dollars it is time to revisit the idea of striking a better balance between encouraging profit, innovation, accessibility and affordability. NIH should convene an outside panel to reexamine the pricing of medicines and treatments developed with public funds.

It is my hope that working together we can find a way to better encourage private innovation while ensuring that Americans see a return on their research investment. Please contact Elizabeth Jurinka (elizabeth_jurinka@wyden.senate.gov) on my staff at (202) 224-5244 with any questions.

Thank you for your consideration on this matter.

Sincerely,

Ron Wyden
United States Senator