

March 28, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Burwell and Director Collins:

When Americans pay for research that results in a safe and effective drug, an unreasonably high cost should not limit their access to it. New treatments are meaningless if patients cannot afford them. Therefore, we welcome the recent commitment from Health and Human Services Secretary Sylvia Burwell that the National Institutes of Health (NIH) was “prepared to use its [march-in] authority if presented with a case where the statutory criteria are met”¹ We strongly encourage the NIH to use its authority to hold a public hearing on the request put forth by certain public interest groups to help establish whether or not these criteria are met in the case of Xtandi (enzalutamide).

The 1980 Bayh-Dole Act gives federal agencies, including the NIH, the authority to license a patent when “action is necessary to alleviate health or safety needs which are not reasonably satisfied”² or if the invention is not “available to the public on reasonable terms.”³ Price can be a clear barrier to access for consumers, and despite this law being in place for over 35 years, the NIH has never used this broad and powerful authority to protect consumers from excessive prescription drug prices.

NIH was recently petitioned⁴ to exercise these march-in rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles UCLA through taxpayer supported research grants from the U.S. Army and NIH grants.⁵ The petition states that a Japanese licensee,

¹ March 2, 2016 letter attached, p. 2

² 35 U.S.C. § 203(a)(2)

³ 35 U.S.C. § 201(f)

⁴ Letter from Knowledge Ecology International and the Union for Affordable Cancer Treatment to Secretary Sylvia Mathews Burwell, Department of Health and Human Services, Director Francis Collins, National Institutes of Health, and Secretary Ashton Carter, Department of Defense, regarding Xtandi march-in request (Jan. 14, 2016) (online at <http://keionline.org/node/2412>)

⁵ ClinicalTrials.gov Identifiers NCT00510718 and NCT01091103

Astellas, is charging Americans \$129,000 for this drug, which sells in Japan and Sweden for \$39,000, and in Canada for \$30,000. We do not think that charging U.S. residents more than anyone else in the world meets the obligation to make the invention available to U.S. residents on reasonable terms.

An open and transparent public hearing on Xtandi by the NIH⁶ would help to provide insight into NIH's decision-making process on this case. In addition, we think that a public hearing is important to allow the public to engage in a dialogue with the Department of Health and Human Services and NIH in order to better understand its position on the use of march-in to address excessive prices. The NIH granted a hearing in 2004 to probe similar issues in a march-in request pertaining to the prices of Norvir (ritonavir), an antiretroviral marketed by Abbott Laboratories. As a result of the march-in request, the company lowered the price of ritonavir for public payors, including AIDS Drug Assistance Programs (ADAPs) and Medicaid, and expanded its patient assistance programs.⁷

The NIH has a powerful tool to hold drug companies accountable for barriers to access to drugs developed through support of U.S. taxpayers, including price. We look forward to your prompt reply and continuing to work with you to ensure all patients have timely access to innovative, quality, affordable medications.

Sincerely,

LLOYD DOGGETT
United States Representative

BERNARD SANDERS
United States Senator

PETER WELCH
United States Representative

AL FRANKEN
United States Senator

ELIJAH E. CUMMINGS
United States Representative

PATRICK LEAHY
United States Senator

⁶ 37 U.S.C. § 401.6(e)

⁷ *Abbott Announces Several Initiatives to Further Enhance Patient Access, Address Community Concerns Regarding Re-Pricing of HIV Drug, Norvir (Ritonavir)* (Feb. 2, 2004), (online at <http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=48708>)

JAN SCHAKOWSKY
United States Representative

SHELDON WHITEHOUSE
United States Senator

ROSA DELAURO
United States Representative

ELIZABETH WARREN
United States Senator

MARK POCAN
United States Representative

AMY KLOBUCHAR
United States Senator