

Francis Collins, M.D., Ph.D.
Director National Institutes of Health
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Bethesda, MD 20892
via: francis.collins@nih.hhs.gov

March 21, 2016

Dear Director Collins,

We are writing in support of the request by the Union for Affordable Cancer Treatment (UACT) and Knowledge Ecology International (KEI) that the NIH use the government's rights in patents on the prostate cancer drug enzalutamide (marketed as Xtandi). The request highlighted the problems of access created through Japan-based Astellas Pharma's price of more than \$350 per day in the United States, or \$129,000 per year, for a federally-funded cancer drug invented on U.S. government grants. This price is exorbitant in its own right, but is particularly concerning in light of the fact that it is two to four times more than the company charges cancer patients in other high-income countries.

The first step is to hold a hearing on this request, and to allow the public to weigh in on this important dispute.

As the petition notes, the NIH has two options under the Bayh-Dole Act to address the concerns raised. It can use the royalty-free rights in the patents (under 35 U.S.C. § 202¹), an option that requires the payment of no royalties to Astellas, no finding of abuse, and which is not subject to appeals. Or, it can use its "march-in rights" as described in 35 U.S.C. § 203, an option that requires a finding of abuse, payment of royalties, and allows Astellas special appeal rights.² We believe that the royalty-free option makes more sense, as it eliminates any question about the authority to act.

In either case, a transparent, public hearing to have a serious and thorough discussion of the important issues raised regarding this drug, its price, and access is important to patients and consumers, and may have a deterrent effect of its own right with regard to pricing, distinct from the outcome of the NIH's internal deliberations.

The undersigned groups represent, among others, taxpayers who gladly support the NIH budget because innovation is important. But the NIH must also appreciate that the public is concerned by the high prices of all drugs in the United States, in particular life-saving cancer drugs, and

¹ 35 U.S.C. § 202(c)(4) "With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable [*sic*], irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."

² 35 U.S.C. § 201 defines "Practical Application" as requiring that the invention "is being utilized and that its benefits are ... available to the public **on reasonable terms.**" (Emphasis added.)

that some answers may lie in plain view. We note the recent letter from Rep. Doggett and fifty other members of Congress specifically calling on the NIH to issue guidelines on march-in rights and excessive prices.

The price of cancer drugs is critically important, and we urge the NIH to take this opportunity to act.

Sincerely Yours,

Alliance for Retired Americans
American Medical Students Association (AMSA)
Center for the Study of Responsive Law
Community Catalyst
Essential Information
National Physicians Alliance (NPA)
Public Citizen
RxRights
The Other 98%
Universities Allied for Essential Medicines (UAEM)
U.S. PIRG

cc: Sylvia Mathews Burwell, Secretary of Health and Human Services; Douglas R. Lowy, M.D., Acting Director, National Cancer Institute; Ann M. Hammersla, Director, NIH Division of Extramural Inventions and Technology Resources and Office of Policy for Extramural Research Administration (OPERA)