

NIH won't cut price of taxpayer-funded prostate cancer drug

June 20 2016, by Linda A. Johnson

The federal government has declined a petition to lower the price of a drug for advanced prostate cancer developed with taxpayer money.

The public interest group Knowledge Ecology International petitioned the National Institutes of Health in January to reduce the \$129,000-a-year list price of Xtandi, made by the Japanese drugmaker Astellas Pharma.

The petition was supported by the Union for Affordable Cancer Treatment, Democratic presidential candidate Bernie Sanders and two congressmen, Rep. Peter Welch, D-Vermont, and Rep. Lloyd Doggett, D-Texas.

NIH Director Dr. Francis Collins, in a letter released Monday by Knowledge Ecology, said that there was no justification for allowing a generic drugmaker to produce Xtandi because there is no shortage of it.

The group said it will appeal the decision to Sylvia Burwell, the Secretary of Health and Human Services.

Astellas Pharma and its partner, San Francisco-based Medivation Inc., jointly market the drug, with Astellas selling Xtandi outside the U.S.

Knowledge Ecology had asked the NIH to use its "march-in rights" to break the companies' monopoly before the patent on Xtandi expires. According to the group, a rarely used law called the Bayh-Dole Act

would allow the NIH to both give any generic manufacturer a non-exclusive license to make Xtandi and to use its own royalty-free license to have Xtandi manufactured for use by the federal government. The law was enacted in 1980.

The U.S. government covers much of the cost for Xtandi prescriptions filled under federal health programs such as Medicare, Medicaid and the Veterans Administration.

Knowledge Ecology said in a statement released Monday that Collins' letter indicated NIH didn't evaluate evidence presented by the group and the Union for Affordable Cancer Treatment that Astellas charges much more for Xtandi in the U.S. than in other countries. The two groups say the U.S. list price for Xtandi, which amounts to \$88.48 per pill, is two to four times the price in other wealthy countries.

"Price discrimination against U.S. residents is not consistent with making the product 'available to the public on reasonable terms,' as required by the Bayh-Dole Act," Knowledge Ecology wrote. "Nor did Dr. Collins address the evidence that the unreasonably high price for Xtandi limits patient access, places the drug on restrictive formularies, causes strain to health care budgets, and requires patients to pay unreasonably high coinsurance and copayments, all justifications for the use of the NIH's march-in rights."

A review of NIH reports on the issue indicates that the agency has considered requests that it exercise march-in rights for three drugs and one medical device between 1997 and 2013, and in each case determined that the requirements to do so had not been met.

Astellas said in a statement that many patients with low incomes and either no or inadequate insurance get Xtandi for free, and about 80 percent of patients covered by Medicare or private insurance get it with

a monthly copayment of \$25 or less. Their health plans pay the remainder.

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