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Non-Profit Groups Urge Obama Administration, NIH to Lower Price of Government-Funded, \$129,000 Per Year Prostate Cancer Drug

The groups asked the National Institutes of Health to "take this opportunity to act" to lower the price of the prostate cancer drug Xtandi and show leadership on deterring discriminatory pricing practices.

Washington, DC — Today, 11 public interest policy and advocacy organizations sent a letter to the National Institutes of Health (NIH) in support of a January petition submitted by Knowledge Ecology International (KEI) and Union for Affordable Cancer Treatment (UACT), which <u>asked the NIH to use its statutory authority</u> to lower the price of an <u>expensive prostate cancer drug</u> that was developed with the support of federal funds.

## The letter is available here: <a href="http://goo.gl/sf0rbW">http://goo.gl/sf0rbW</a>. The groups included:

- Center for the Study of Responsive Law
- Universities Allied for Essential Medicines (UAEM)
- American Medical Students Association (AMSA)
- National Physicians Alliance (NPA)
- Alliance for Retired Americans
- RxRights

- Essential Information
- Public Citizen
- The Other 98%
- U.S. PIRG
- Community Catalyst

Astellas Pharma, a Japanese pharmaceutical company, sells the taxpayer-funded late-stage prostate cancer treatment, Xtandi (enzalutamide), for over \$129,000 per year in the United States. That price is two to four times higher than the price in other high-income countries such as the United Kingdom, Canada, and Germany.

"It is outrageous that Xtandi, a cancer drug created as a result of American taxpayer-funded research, is being sold in the United States for \$350 per day. This is far more than Astellas Pharma, the Japanese manufacturer, is charging in other developed countries," **said Richard Fiesta, executive director of the Alliance for Retired Americans.** "We urge Director Collins use his authority to make this cancer-fighting drug available to the public by forcing the company to charge a reasonable rate."

Two prominent researchers at the University of California, Los Angeles (UCLA) — including Dr. Charles Sawyers, a Lasker Award winner who now sits on the board of Novartis and runs a lab at Memorial Sloan Kettering Cancer Center — developed Xtandi with the support of NIH and United States Army grants, which funded phase 1 and 2 clinical trials that were later used to secure FDA approval.

The non-profit organizations, which represent the interests of U.S. taxpayers, consumers, and patients, as well as university students and physicians, raised concerns about the discriminatory price of Xtandi, and echoed the KEI and UACT request, noting that the NIH should exercise its powers under the Bayh-Dole Act to lower the price of Xtandi, a late-stage prostate cancer treatment.

"The public shouldn't have to pay with their lives for a product they have already funded with their tax dollars — we call on NIH and UCLA to leverage their rights to ensure this drug is affordable for all," said Merith Basey, the Executive Director of Universities Allied for Essential Medicines.

"People with prostate cancer should not be denied access to an effective treatment because of prices that are higher than anywhere else in the world," **said Jesse Ellis O'Brien, a health policy analyst with U.S. PIRG.** "The National Institutes of Health should use the provisions of the Bayh-Dole Act to remedy the unreasonable price of Xtandi, and to send a message that pharmaceutical companies cannot set excessive prices for drugs developed through taxpayer-funded research."

A 1980 law designed to facilitate technology transfers between non-profit or public institutions and commercial firms, the Bayh-Dole Act also includes safeguards to ensure that patented inventions are available to people who need them in the United States. In their January letter to the NIH, KEI and UACT asked the NIH to use either their royalty-free, non-exclusive license on the patents on Xtandi, or its "march-in rights" to declare the price of the drug unreasonable and allow generic manufacturers to produce the drug for sale at an affordable price.

"When Americans through their government pay for the research and development costs that lead directly to the invention of a pharmaceutical drug, they have every right to expect it will be priced reasonably when they, their insurers, or their government must purchase it," **said Robert Weissman, the President of Public Citizen.** "In the case of Xtandi, as so many others, not only has the beneficiary of U.S. government largesse, Astellas, not priced the drug reasonably, it is charging more in the United States than other countries. There's no reason the United States has to be a sucker in the deal. The government retains the power to "march in" and authorize generic competitors to start making the drug – a move that would slash prices. The only question is whether the Obama administration will permit the American people – and the American government itself – to continue to be ripped off."

The ten public interest groups wrote that while they "represent, among others, taxpayers who gladly support the NIH budget because innovation is important," the NIH should heed public concerns that drug prices are too high, explaining that "some answers may lie in plain view."

Whether the NIH uses its march-in rights or royalty-free license on the Xtandi patents, the groups urged the NIH to hold "a transparent, public hearing to have a serious and thorough discussion of the important issues raised regarding this drug, its price, and access," stating that such a hearing "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."

#### Reshma Ramachandran, the FDA Task Force Co-Chair for the National Physicians

**Alliance,** echoed the call for a public hearing. "Increasingly so, we have become witnesses to our patients' struggles to pay for lifesaving medicines, often at the expense of their other daily needs," **Ramachandran said.** "The National Physicians Alliance strongly supports the call for the NIH to hold a public hearing as a first step to address the growing issue of unaffordable drug pricing. Our patients should not have to pay twice, first through taxes and then again in excessive prices, to receive the drugs they need."

## Ralph Nader, who runs the Center for the Study of Responsive Law, said:

"The pharmaceutical industry spends far more on marketing and advertising to physicians, hospitals, and patients than it spends on research and development. Enormous drug industry funds go to lobbying politicians to prevent the implementation of price restraints on its staggering markups. Billions of U.S. taxpayer dollars and extensive tax credits annually subsidize research that is used to develop drugs, yet the pharmaceutical industry is allowed to endanger patients' health by charging the public exorbitant, unaffordable prices for drugs that are routinely sold for lower prices in other countries. It is urgent to reign in the runaway price-gouging of pharmaceutical products."

#### For additional comments, please contact:

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