

17 October 2016

The Honorable Sylvia Mary Mathews Burwell  
Secretary, Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
United States of America  
Via email: Sylvia.Burwell@hhs.gov

Dear Secretary Burwell,

We are writing to ask that the United States Government use its rights to inventions it funded to expand access to patented cancer drugs in developing countries. We are specifically urging you to respond favorably to the September 28, 2016 request by the Canadian company Biolyse Pharma regarding the patents on the cancer drug, enzalutamide, now sold worldwide by the Japanese corporation Astellas at very high prices under the brand name Xtandi.

The United States Government is by far the largest investor worldwide in biomedical research, with more than US\$30 billion spent last year by the U.S. National Institutes of Health alone. As organizations and individuals worldwide who support health and equity, we are grateful to the United States—and American taxpayers—for contributions towards better health for all.

Prostate cancer is the second leading cancer in men worldwide, and rates are rising quickly in emerging economies. In sub-Saharan Africa, even countries with low incidences face severe and disproportionate mortality rates.

Astellas is charging an excessive price for Xtandi, even though the drug was invented and developed with funding from the NIH and the U.S. Army. In this case, the United States Government can either be a part of the solution — or, by choosing inaction, to be a part of the problem. As with all inventions developed with U.S. Government funding, the United States retains the right to have the inventions be “practiced throughout the world by or on behalf of the Government of the United States,” pursuant to 35 U.S.C. § 202(c)(4).

The Canadian generic manufacturer Biolyse Pharma has asked DHHS to enter into an agreement that would enable Biolyse to manufacture a more affordable generic version of enzalutamide for export and sale in low- and middle-income countries.

If the U.S. Government enters into an agreement with Biolyse or other generic drug manufacturers, this important cancer medicine will be far less expensive and far more widely accessible. If the U.S. ignores or rejects the request, and no agreement is forthcoming, access to the prostate cancer will be restricted, and unequal. It is appalling to have restrictions on

access to a publicly funded cancer drug, and it is morally repugnant to deliberately sanction unequal access.

Poor access and outcomes can be portrayed as a consequence of market failures, but in this case, the market failures would be a consequence of policy failures. The barriers to more equal access would correctly be perceived as a lack of concern about patients in developing countries, for a disease that disproportionately kills people of African descent.

Having advanced prostate cancer is a personal tragedy. It is a different type of tragedy when a government rejects requests to make affordable cancer drugs available.

We urge you to seize the moment and take leadership that creates new opportunities for treatment for patients who are now excluded from the benefits on advances in treatment for this cancer.

Sincerely,

ACT UP Philadelphia, USA  
African Services Committee, Int'l  
AIDS Action Baltimore, USA  
AIDS Project Los Angeles (APLA Health)  
Alliance for Retired Americans, USA  
Associação SCARJOV, Angola  
Can-Sir, South Africa  
Canadian HIV/AIDS Legal Network  
Cancer Aid Society India  
Cancer Alliance, South Africa  
Cancer Families for Affordable Medicines, USA  
Catholics in Alliance for the Common Good, USA  
Center for Policy Analysis on Trade and Health (CPATH), USA  
Coalition PLUS, Int'l  
Corporación Innovarte, Chile  
Dandora community AIDS support Association (DACASA), Kenya  
Dying for a Cure, UK  
EKPIZO, Greece  
EMPOWER India  
Essential Information, USA  
Gestos, Brazil  
Global Justice Institute, USA  
Grupo de Incentivo à Vida (GIV), Brazil  
Health Action International (HAI)  
Health GAP (Global Access Project), Int'l  
Hepatitis Education Project, USA

HIV i-Base, UK  
Housing Works, USA  
Ifarma Foundation, Columbia  
Initiative for Medicines, Access & Knowledge (I-MAK)  
International Civil Society Support (ICCS)  
Kenya Network of Cancer Organizations  
Kenya NGO Alliance Against Malaria (KENAM), Kenya  
Knowledge Ecology International  
Mesa ONGs con trabajo en VIH Colombia  
Misión Salud, Colombia  
NAACP, USA  
National Physicians Alliance, USA  
NEPHAK-National Empowerment Network of people living with HIV/AIDS in Kenya  
NETWORK Lobby for Catholic Social Justice, USA  
Other 98%, USA  
Oxfam, Int'l  
People of Faith for Access to Medicines (PFAM), USA  
Positive Malaysian Treatment Access & Adocacy Group (MTAAG+), Malaysia  
Public Citizen, USA  
Salud por Derecho, Spain  
Social Security Works, USA  
StopAIDS UK  
Student Global AIDS Campaign, USA  
Treatment Action Campaign, South Africa  
Treatment Action Group, USA  
Union for Affordable Cancer Treatment (UACT), Int'l  
Universities Allied for Essential Meds (UAEM), Int'l  
Veselības projekti Latvijai (Health Projects for Latvia)  
Young Professionals Chronic Disease Network (YP-CDN), Int'l