Joint Letter: Civil Society Urges US Secretary Burwell to Expand Access to Patented Cancer Drugs in Developing Countries

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Letter to Secretary of Health and Human Services Sylvia Mathews Burwell

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, Colombia

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

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

Misión Salud, Columbia

Other 98%, USA

Oxfam, Int'l

People of Faith for Access to Medicines (PFAM), USA

Positive Malaysian Treatment Access & Advocacy 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),

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