

Andy Slavitt  
Acting Administrator for the Centers for Medicare & Medicaid Services (CMS)  
Via Email: Andy.Slavitt@cms.hhs.gov

Francis Collins, M.D., Ph.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892  
Via: Francis.Collins@nih.hhs.gov

Dear Administrator Slavitt and Director Collins,

I am a private biotechnology consultant representing Biolyse Pharma Corporation in St.Catharines Ontario. I have attached a letter from Bridgitte Kiecken, the President of Biolyse Pharma, offering to supply Medicare and programs with generic versions of enzalutamide, a drug to treat prostate cancer, at \$3 per 40 mg tablet. In 2014, Medicare was paying \$69.41 per tablet for Xtandi, the Astellas version of the drug, so the Biolyse offer involves dramatic savings to the U.S. government.

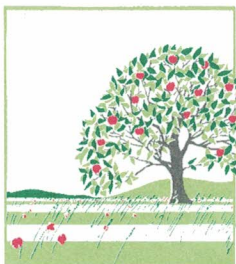
The federal government has a royalty free right to use the following three patents on this product: 7709517, 8183274 and 9123941. The Biolyse offer is contingent upon the federal government using the royalty free right to obtain less expensive supplies of the drug.

Separately, Biolyse Pharma would be interested in approaching the NIH to use its rights in the patents to supply affordable versions of enzalutamide in developing countries, including South Africa.

I would be interested in talking with your staff about this offer,

Sincerely,

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Andy Slavitt  
Acting Administrator for the Centers for Medicare & Medical Services (CMS)

April, 22<sup>nd</sup>, 2016

Dear Mr. Slavitt,

Biolyse Pharma is a Canadian company that specializes in the manufacturing as well as the development of sterile oncology drugs.

We are presently writing to express our willingness to supply a generic version of enzalutamide to prostate cancer patients in the United States and in the developing world.

Presently enzalutamide is sold under the name Xtandi by Astella Pharmaceuticals. It is our understanding, that in 2014, prostate cancer patients receiving reimbursement for their medication were paying an excess of \$250 dollars for their daily regime of four tablets of 40mg of enzalutamide. Astella is presently selling in Canada and in other jurisdictions Xtandi for approximately 30% of what it is presently charging in the United States. Biolyse Pharma would be able to supply enzalutamide for approximately \$3.00 USD per tablet.

Medicare has a royalty free right in all three patents in the FDA orange book for enzalutamide. We believe we can have generic versions approved by the FDA in less than three years if CMS is willing to allow Biolyse Pharma to supply the drug using the U.S federal government's worldwide royalty free license.

Sincerely,

Brigitte Kiecken  
President