Hillary for America

October 19, 2015

Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Ostroff:

In recent months, we have seen dramatic price increases in certain drugs on the market simply because they have no generic competition. The FDA has guarded the safety and security of our drugs for decades. Consistent with this critical mission for our nation, I am writing to urge the FDA to do everything in your power consistent with the safety and efficacy of our drugs to bring lower-cost generics to American consumers more quickly and affordably.

As I am sure you are aware, there is an egregious case that has brought this problem to the forefront. Recently, after acquiring the exclusive rights to sell Daraprim® (pyrimethamine), Turing Pharmaceuticals increased the price by over 5,000 percent, putting many people at risk of being unable to acquire the life-saving drug. With no other generic competitor to drive the price down, there is no clear path to ensure that this drug will be affordable in the future.

This drug is used to fight a parasitic infection called toxoplasmosis, which is potentially life-threatening for people with weakened immune systems, including people suffering from HIV-infection or cancer. According to the HIV Medicine Association and the Infectious Diseases Society of America, under this new pricing structure the annual cost of treatment will now be between $336,000 and $634,500 per patient, a cost they describe as "unjustifiable for the medically vulnerable patient population in need of this medication and unsustainable for the health care system."

Despite widespread public outcry and the company's promise to make the drug "more affordable," Turing has not meaningfully lowered the price. The reality is that Turing has created an effective drug shortage in which patients with life-threatening infections have no affordable way to access the supply of standard-of-care drugs. Turing's decision to artificially increase the price of Daraprim by over 5,000 percent overnight exploits vulnerable patients whose lives depend on access to this critical medication.

The FDA should expedite any pending reviews, and encourage applications for review, of other generic alternatives to Daraprim, and make these drugs available to U.S. patients as quickly as possible consistent with safety and efficacy. Additionally, the FDA should explore whether it has the authority and discretion, given the special circumstances involving the potential shortage of a critical drug, to accelerate approvals or allow for temporary importation from other OECD countries. Under Executive Order 13588, the FDA can "expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes, whenever it determines that expedited review would help to avoid or mitigate existing or potential drug shortages."

In the past, the FDA has allowed for temporary importation of drugs that are a substitute of a treatment in shortage in the United States, after careful inspection of facilities and confirmation that the imported drugs meet safety standards. According to public sources, other pharmaceutical companies currently market versions of Daraprim in Britain and Canada. Given the effective shortage of Daraprim, the FDA should explore alleviating the shortage through this kind of temporary importation – as it has in the past.

Beyond the immediate case of Daraprim, the FDA should also work to reduce the generic backlog, and deserves further support from Congress to do so. Patients who rely on this treatment should not have their health and lives put at risk because of an unnecessarily anticompetitive market, and the FDA should act through all of its available authorities to remedy this situation as soon as feasible.

With appreciation and best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

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