

October 19, 2015

The Honorable Edith Ramirez Chairwoman Federal Trade Commission 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580

Dear Chairwoman Ramirez:

Thank you for your leadership and commitment to fighting anticompetitive practices in the pharmaceutical industry to ensure that American consumers can access lower-cost prescription drugs.

I am writing today to express my concern about pharmaceutical companies that exploit their monopoly power to keep the prices of prescription drugs artificially high in a market with no competition, and my concern that some companies may be restricting distribution of their prescription drugs in order to stifle competition. These issues have come to the forefront because of the egregious actions of Turing Pharmaceuticals.

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 and suggesting potentially anti-competitive behavior. 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."

After the dramatic price increase, the price remains artificially high in a market with no competition. I recognize that the FTC has limited authority to address price gouging when it is the result of unilateral action in a market with no competition, but I write today to urge the FTC to consider studying what has become an increasing problem in the pharmaceutical industry – dramatic price increases that result in drugs remaining artificially high and causing real barriers for consumers, while there is a very long lag in approval of potential competitors onto the market. On the one hand, the FTC may have limited ability to regulate this behavior as anticompetitive, and on the other, the FDA is severely delayed in approving generics to

Post Office Box 5256, New York, NY 10185 · www.hillaryclinton.com Contributions or gifts to Hillary for America are not tax deductible.





come on to the market, which may offer some competition. I believe it would be a great service to the Congress and the Administration if the FTC would study and make recommendations on whether and how our laws might be amended to address this problem.

Furthermore, with regard to Turing Pharmaceuticals, I request that you investigate whether the restricted distribution of Daraprim amounts to anticompetitive behavior. Normally, we might expect such a dramatic price increase to encourage other companies to enter the market, seek approval for a generic version, and lower the price, but Turing has restricted distribution of Daraprim—making this sort of market response extremely difficult. In order to receive FDA approval, a generic manufacturer must acquire a limited amount of the branded product in order to show that its drug is equivalent to the marketed drug. However, Turing's restricted distribution program serves as a roadblock for other generic competitors to enter the market. Without the ability to obtain sufficient quantities of Daraprim, competitors will not be able to develop generic alternatives and seek FDA approval—resulting in direct harm to consumers, who as a consequence are subjected to unconscionably high prescription drug prices with little or no means of relief.

This drug is providing a necessary treatment for toxoplasmosis, listed by the Centers for Disease Control and Prevention as one of the neglected parasitic infections in the United States. But there is no justifiable increase for an off-patent drug that has existed since 1953, has not been modified, and has decreased rather than increased access for the patients who need it most. This kind of anti-competitive price gouging with no meaningful innovation combined with a restricted distribution program deserves careful scrutiny.

I urge the FTC to investigate whether Turing's restricted distribution program amounts to anti-competitive behavior in violation of the Federal Trade Commission Act. The importance of this investigation to consumers cannot be overstated—while Turing may be the most extreme case in recent years, the concerns it raises about anticompetitive behavior are serious in a market place where the cost of prescription drugs are rising much higher than other health costs. Thank you for your consideration.

With appreciation and best wishes, I am

Sincerely yours,

Hillary Rodham Clinton