

**Testimony for the Record  
Submitted to the  
U.S. Senate Special Committee on Aging  
for the Hearing on  
Sudden Price Spikes in Decades-Old Prescription Drugs**

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Good morning and thank you Chairwoman Collins, Ranking Member McCaskill, and distinguished Members of the Committee for holding today's hearing as a follow up to the committee's December 9<sup>th</sup> hearing.

My name is Adaora Adimora and I am a physician, researcher and professor of medicine at the University of North Carolina at Chapel Hill. I am an infectious diseases specialist who has been caring for people with HIV infection for more than 20 years. Today I am testifying as the Immediate Past-Chair of the HIV Medicine Association to share how HIVMA members and their patients continue to be affected by the price increase for pyrimethamine, which is marketed as Daraprim. At the Committee's prior hearing, the issue was described as a market failure, and I am here today to share with you the continued impact of that market failure on patients, providers and the health care system.

Nested within the Infectious Diseases Society of America, HIVMA is a national organization representing more than 5,000 physicians, researchers and other medical providers devoted to HIV medicine. Last September, Dr. Stephen Calderwood, the President of IDSA at the time, and I, as the then Chair of

HIVMA, wrote to Turing Pharmaceuticals urging them to reconsider their pricing strategy for pyrimethamine.<sup>1</sup> The letter followed numerous reports from infectious diseases and HIV providers that the price for pyrimethamine had increased dramatically overnight and that noted concerns about the effect the increase was having and would have on the treatment of toxoplasmosis. One of our initial reports specifically noted that the pharmacy department in an Ohio-based hospital had alerted infectious disease physicians that the price of the medication had increased from \$13.50 to \$750 per pill – an increase of 5000%. Turing's response to the letter indicated that they were committed to ensuring access for all patients who need it. But the access issues continued and HIVMA, the Infectious Diseases Society of America, and the Pediatric Infectious Diseases Society wrote in late December to the new Turing interim CEO Ron Tilles highlighting continued patient access problems and urging him to place patients' lives ahead of short term profits by returning the price of pyrimethamine to \$13.50 per pill.<sup>2</sup> To date, Turing has not responded to that request.

Toxoplasmosis is a parasitic infection that mainly affects patients with compromised immune systems, such as patients infected with HIV, those undergoing cancer therapy or following transplantation, and pregnant women and their newborns, because their immune system is unable to control the infection. If not effectively treated, severe toxoplasmosis can cause brain and organ damage

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<sup>1</sup> See Sept. 8, 2015 letter. Available online at <http://www.hivma.org/uploadedFiles/HIVMA/HomePageContent/PyrimethamineLetterFINAL.pdf>. Accessed 3/14/16.

<sup>2</sup>Dec 22, 2015. Letter to Ron Tilles, Turing Interim CEO from Johan Bakken, MD, PhD, President of IDSA, Carlos del Rio, MD and Janet Gilsdorf, MD, DSc. President of PIDS. Email [aweddle@hivma.org](mailto:aweddle@hivma.org) for a copy of the letter.

and result in blindness or death. Patients with HIV infection and other immunocompromising conditions require a minimum of eight months of treatment with many patients requiring a year or more. First approved by the FDA in 1953, pyrimethamine has long been a staple in the treatment of toxoplasmosis. It has been and continues to be recommended in U.S. Department of Health and Human Services Guidelines for the Prevention and Treatment of Opportunistic Infections as the initial drug for treating toxoplasmosis. In response to barriers to obtaining pyrimethamine, the federal guidelines were updated in October 2015 to recommend alternative treatment options in the event that pyrimethamine was unavailable.<sup>3</sup>

My experience with toxoplasmosis is in treating patients with HIV who develop toxoplasmosis in the advanced stages of AIDS when a severely weakened immune system leaves them vulnerable to infections. These patients typically present with a brain abscess that can cause seizures, a rapid decline in neurologic function and mental status, stroke, or death. Patients treated and stabilized in a hospital setting with pyrimethamine would be discharged with a prescription for pyrimethamine to continue treatment at home.

Turing's purchase of Daraprim in August 2015 upended the treatment of toxoplasmosis for patients in the United States. Patients have experienced treatment interruptions or delays, been prescribed alternative therapies or gone

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<sup>3</sup> See *Updates to the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*. October 19, 2015. Available online at: <https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0>. Accessed 3/14/16.

without treatment entirely. Providers have devoted hours and hours or even days to obtaining the medication. Some institutions were forced to extend their line of credit due to the \$75,000 price tag for one bottle.

Patients with health insurance coverage are now subject to prior authorizations requiring multiple levels of appeal, which providers report take two weeks or more to process. Patients without health insurance also face significant delays - sometimes measured in weeks or even months while they wait for assistance through Turing's Patient Assistance Program, if they are eligible for assistance through the program at all.

HIVMA began monitoring access issues in October 2015 and since that time we have received 50 or more case reports from providers regarding the challenges they have faced treating toxoplasmosis. One infectious diseases physician reported last fall that he had been prescribing Daraprim for infants, children and adolescents with toxoplasmosis for 40 years and that for the first time he had to prescribe an alternative therapy because "the drug was out of reach."

The challenges accessing Daraprim continue. As one example, in early February of this year, a physician reported through the Daraprim Access blog that a patient's hospital stay was extended for seven days because of challenges obtaining pyrimethamine on an outpatient basis through the Daraprim Direct patient assistance program. The patient was finally able to acquire a temporary one month's supply through the state's AIDS Drug Assistance Program even though the medication had been removed from the program's formulary. The

physician also noted that even at the 50% discounted rate Turing now offers certain hospitals, the cost was **\$1,125 per day** for the recommended three-pill per day treatment regimen initially required.<sup>4</sup> Prior to August 2015 -- the cost for the same treatment would have been **around \$41 per day**.

Many providers and institutions, including the University of North Carolina at Chapel Hill where I practice, have turned to alternative treatment options for toxoplasmosis, such as compounding the drug in the hospital pharmacy, prescribing Bactrim or contracting with a compounding pharmacy.

Providers have turned to alternative solutions out of necessity to treat a serious illness that requires immediate medical attention. However, they should not be required to do so when there is a 60 year-old medication to treat toxoplasmosis that remains available in other developed countries for as low as \$2.50 per pill or even as low as \$1.00 per pill.<sup>5 6</sup>

On behalf of the infectious diseases and HIV provider community – thank you for your continued attention to unjustified price increases for older, off-patent prescription drugs. My comments today focused on pyrimethamine but within the infectious diseases community we have recently seen other older medications priced out of reach. Policy interventions are urgently needed to promote rational drug pricing for older, off-patent medications that ensure patient access without

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<sup>4</sup> See Access to Daraprim (Pyrimethamine). Amy K - Feb 4, 2016. Available online at: <http://hivclinician.org/pyrimethamine/>. Accessed 3/14/16.

<sup>5</sup> Canada Drugs. Daraprim 25mg and/or Equivalent. <https://www.canadadrugs.com/products/daraprim/25mg>. Accessed 3/14/16.

<sup>6</sup> BBCNews. What's a Fair Price for a Drug? September 22, 2015. Available online at: <http://www.bbc.com/news/health-34322720>. Accessed 3/14/2016.

relying on complex assistance programs or placing unreasonable demands on health care providers. Our patients' lives, our nation's public health and the sustainability of our health care systems depend on our ability to prevent future market failures such as this.