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July 9, 2020

Stephen M. Hahn, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Hahn:

AARP, on behalf of our 38 million members and all older Americans nationwide, applauds the Food and Drug Administration (FDA)'s ongoing efforts to ensure the availability of safe, effective treatments and vaccines for COVID-19. The availability of such products will represent an important step forward as we begin to recover from what has been an unprecedented public health and economic crisis. However, the pandemic has highlighted longstanding concerns about the U.S. drug supply that also warrant immediate attention.

Drug shortages pre-date the COVID-19 pandemic and can affect the health and safety of patients with COVID-19 as well as other diseases. Recent media reports have focused on shortages of sedatives, anesthetics, painkillers, and muscle relaxants needed for patients who need intubation and mechanical ventilation.<sup>1</sup> These shortages can cause delays in treatment or changes in treatment regimens for patients who are seriously ill with COVID-19 and other patients who need critical care. Unfortunately, this problem extends much further than these reports indicate: there are currently over 200 active drug shortages in the U.S.<sup>2</sup>

Many experts, including FDA, have concluded that economic factors are at the root of most drug shortages.<sup>3</sup> However, another factor that has recently taken on increased importance is large, unexpected increases in demand. For example, recent interest in hydroxychloroquine as a potential COVID-19 treatment resulted in shortages that negatively affected patients who need

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<sup>1</sup> <https://www.statnews.com/pharmalot/2020/03/31/a-new-covid-19-problem-shortages-of-medicines-needed-for-placing-patients-on-ventilators/>

<sup>2</sup> <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>

<sup>3</sup> <https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions>

the drugs to treat rheumatoid arthritis and other autoimmune disorders.<sup>4</sup> Similarly, the global demand created by millions of COVID-19 patients has the potential to strain the supply of many other prescription drugs. These shortages could have devastating consequences for all patients, regardless of whether they have the virus.

Another source of concern is the strength of domestic and international pharmaceutical supply chains. In recent decades, drug manufacturing has gradually moved out of the United States. As of late 2019, only 28 percent of the manufacturing facilities making active pharmaceutical ingredients (APIs) to supply the U.S. market were located in the U.S.<sup>5</sup> While moving facilities overseas can lower drug companies' costs,<sup>6</sup> it can also create vulnerabilities in the supply chain. If overseas factories operate at a low capacity for a sustained period, or if exports are slowed or halted, the possibility of widespread shortages will rise. Such risks have always existed but take on added importance in the context of a pandemic, particularly one that has led countries to effectively shut down for weeks or even months at a time.

Unfortunately, FDA cannot reliably predict such supply chain-related shortages because it is often unclear where drug companies source their APIs. Experts believe that about 80 percent of APIs come from China and India, though the exact dependence remains unknown.<sup>7</sup> This lack of transparency makes it impossible for FDA to assess the resilience of the US supply chain. Notably, even if FDA did have access to this information, it lacks power over drug companies' business decisions, including whether and where to make a drug.<sup>8</sup>

The challenges highlighted by the COVID-19 pandemic are long-standing systemic issues and AARP agrees that solutions will require multi-stakeholder efforts and rethinking of business practices throughout the health care system.<sup>9</sup> However, we also believe that the challenges facing the U.S. prescription drug supply warrant immediate action.

Consequently, AARP strongly urges FDA to work to identify the potential authority at its disposal to help ensure adequate supplies so that health care providers and patients have safe access to the affordable prescription drugs that they need. These actions should include improving supply chain transparency and strengthening and diversifying the pharmaceutical supply chains. Moreover, we support efforts to allow states to safely import needed prescription drugs from other countries. It is also critical to ensure that drug shortages do not provide drug companies with an opportunity to further price-gouge patients, as medications need to be affordable for both providers and patients.

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<sup>4</sup> <https://www.washingtonpost.com/business/2020/03/20/hospitals-doctors-are-wiping-out-supplies-an-unproven-coronavirus-treatment/>

<sup>5</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>6</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>7</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>8</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>9</sup> <https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions>

We also encourage FDA to work with complementary federal agencies, such as the Biomedical Advanced Research and Development Authority (BARDA), to help guarantee that providers and patients will have access to every needed prescription drug throughout the duration of this public health emergency.

We appreciate the opportunity to share our concerns about these important issues, and thank you for your work to protect and improve the health and wellbeing of older Americans during this crisis. We hope to continue working with you to strengthen and improve the transparency of our pharmaceutical supply chain and ensure that critical medications are available and affordable to all who need them.

Sincerely,

A handwritten signature in purple ink that reads "Bill Sweeney". The signature is fluid and cursive, with the first name "Bill" and last name "Sweeney" clearly legible.

Bill Sweeney  
Senior Vice President  
Government Affairs