

VIEWPOINT

Ensuring Access to Medications in the US During the COVID-19 Pandemic

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The coronavirus disease 2019 (COVID-19) pandemic continues to rapidly evolve. Given the origins of COVID-19 in China, there were initial concerns regarding medication shortages due to the reliance of the US on overseas manufacturing of active pharmaceutical ingredients.^{1,2} Although no major disruptions in pharmaceutical access have occurred thus far, the future of the pandemic and its effect on the US drug supply remains far from certain.

The pharmaceutical supply chain represents a series of interdependent steps that ultimately produce the products that are used by consumers in the US. From manufacturers, pharmaceuticals are shipped through wholesalers or distributors and on to retail, specialty, and mail-order pharmacies as well as to hospitals, nursing homes, prisons, clinics, and other sites of care. Retail pharmacies have an especially important role in this process, dispensing more than 85% of all prescription medications in the US.³ From manufacturers to end users, the pharmaceutical supply chain is vast, employing tens of thousands of workers who manage the annual distribution of an estimated nearly 6 billion prescriptions in the US.³

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Although early reports regarding drug shortages have focused on overseas manufacturing, the effect of the COVID pandemic on the distribution of medications within the US is also a concern. There have been reports that some pharmacies have closed due to the pandemic, and widespread illness, quarantines, and social distancing measures may increasingly disrupt pharmacy access. In addition, given a surge in demand for certain types of health care, there will be heightened need for many medicines such as those used to treat respiratory disease and critical illness.⁴ There may also be demand surges for specific medicines based on media coverage, emerging evidence of benefit, or other factors. These events, such as those that have already occurred for acetaminophen and hydroxychloroquine, may contribute to “stock outs” at distributors and pharmacies and, if left unregulated, worsened access for many in need.^{5,6} Federal and state regulators, as well as distributors and pharmacies, should take several emergency response and preparedness measures to address these possibilities.

Develop an Essential Medicines Strategy

Federal and state preparedness efforts should focus on what the World Health Organization (WHO) considers “essential medicines,” which are medicines that satisfy the priority health needs of the population and should be available in the health system at all times, in adequate amounts, with quality ensured, and at a price the individual and community can afford.⁷ Such treatments include antibiotics, antivirals, antidiabetic agents, cardiovascular drugs, respiratory agents, contraceptives, mental health products, and analgesics. To implement an essential medicines strategy, the US Food and Drug Administration (FDA) should first develop a list of essential medicines. Such a list is critical in shaping regulations that ensure access to essential medicines is not interrupted during this and future crises.

Prevent Stockpiling and Drug Shortages

Efforts are needed to guard against surges in medication use as well as stockpiling that may cause shortages and inequitable access. One major wholesaler recently announced steps to protect its inventory, including to identify and mitigate the risk of drug shortages by allocating specific products, including antibiotics, antiviral agents, and respiratory medicines.⁸ This allocation strategy should include other essential medicines and be required for all wholesalers. Restricting the retail dispensing of essential medicines to a 30-day emergency supply, including for cash-paying customers, would also reduce the likelihood of demand surges and drug shortages.

Expand Capacity for Mail-order and Home Delivery

Rapid increases in the capacity for mail-order and home delivery are vital. Many retail pharmacies do not offer home-delivery services, and mail-order pharmacies account for less than 10% of all retail prescriptions dispensed in the US.³ The scope of these delivery systems should be increased given potential for quarantines or widespread pharmacy closures. Following the lead of several large pharmacy chains,⁹ public and private payers should also provide incentives for pharmacies, particularly independent stores located in underserved areas, to offer home delivery services at no cost.

Finance an Emergency Supply of Essential Medicines

Given the uncertainty around where and when disruptions to the supply chain may take place, health care

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insurers are also relaxing refill criteria, so as to allow for individuals to stockpile additional medicines. For example, some insurers have announced policies that waive typical refill "windows," thereby allowing for early refills for individuals to ensure a sufficient stockpile at home in the event of abrupt disruptions in medication access.⁹ These measures are necessary but may not be sufficient for the millions of US residents already burdened by their out-of-pocket prescription costs; payors should also consider waiving co-payments, particularly for low-income individuals, so as to allow them to stockpile emergency supplies of essential medicines.

Implement a Long-term Strategy to Safeguard Access

While the nation and world are rightly focused on the COVID-19 pandemic, this is not the first time that national emergencies have threatened medication access in the US, nor will it be the last. To foster emergency preparedness, federal and state public health agencies should establish and maintain central inventories of essential medicines that can be distributed at state or local levels based on need. The security of such national stockpiles would be further enhanced by increasing domestic production of these medicines so as to protect the supply chain and product availability from unpredictable

global events, such as other countries' decisions to cease importing specific products into the US.⁴

Even if these steps were undertaken, there is no guarantee that new challenges would not arise. For example, what if a product such as tocilizumab, which is in clinical trials as a treatment to manage the cytokine storm associated with fulminant viral pneumonia, proves efficacious as a treatment for patients with COVID-19 and severe respiratory compromise? Is the supply chain prepared for this? Are price controls in place to protect the public and ensure that patients have access to this "essential medicine"? Who will pay for the soaring demand for such a treatment?

For many individuals in the US, barriers to accessing medicines are nothing new. Economic, clinical, social, and structural factors cause many individuals to go without essential medicines every day. However, the COVID-19 pandemic poses urgent and in some cases, novel challenges, and does so on an order of magnitude greater than ever before. Fortunately, rapid mobilization and transformation of the pharmaceutical manufacturing and distribution system is possible, and many who are involved with and affect the supply chain, ranging from regulators to distributors to pharmacies, have already demonstrated a commitment to meet challenges that arise. Despite this, there is more work to do, and not a moment to lose.

ARTICLE INFORMATION

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REFERENCES

1. US Food and Drug Administration. Coronavirus (COVID-19) supply chain update. February 27, 2020. Accessed March 24, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>

2. Oehler RL, Gompf SG. Shortcomings in the US pharmaceutical supply chain: potential risks associated with international manufacturing and trade-related tariffs. *JAMA*. Published online March 16, 2020. doi:10.1001/jama.2020.1634

3. *Medicine Use and Spending in the United States: A Review of 2018 and Outlook to 2023*. Published May 2019. Accessed March 23, 2020. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>

4. Ferguson NM, Laydon D, Nedjati-Gilani G, et al; Imperial College COVID-19 Response Team. Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand. Published March 16, 2020. Accessed March 23, 2020. <https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf>

5. Erman M. J&J's Tylenol production at maximum capacity as coronavirus boosts demand. *Reuters*. March 19, 2020. Accessed March 23, 2020. <https://www.reuters.com/article/us-health-coronavirus-johnson-johnson/jjs-tylenol-production-at-maximum-capacity-as-coronavirus-boosts-demand-idUSKBN2162FU>

6. Marchione M. Malaria drugs' promise for coronavirus spurs hope, shortages. *New York Times*. Published March 23, 2020. Accessed March 23, 2020. <https://apnews.com/2f3dd1099c6054bb5015391b9a6f3b0c>

7. *World Health Organization Model List of Essential Medicines: 21st List 2019*. World Health Organization; 2019. Accessed March 23, 2020. <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1>

8. McKesson's response to coronavirus (COVID-19). Posted March 20, 2020. Accessed March 24, 2020. <https://www.mckesson.com/About-McKesson/Coronavirus-Response/>

9. CVS Health announces additional COVID-19 resources focused on patient access: latest enhancements will help prevent interruption of medication availability. March 9, 2020. Accessed March 24, 2020. <https://cvshhealth.com/newsroom/press-releases/cvs-health-announces-additional-covid-19-resources-focused-patient-access>