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This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness
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3. The American Pharmaceutical Supply Chain: Will COVID-19 Drive Manufacturing Back Home?

Gregory H. Levine, Jenna McCarthy, and Beth P. Weinman, *Ropes & Gray LLP*
Grant Sims, *NYU Stern School of Business*

As the COVID-19 pandemic has roiled the global economy, international trade and travel have dropped to their lowest levels in years. This has placed global supply chains under enormous stress, disrupting the smooth flow of goods and raw materials between countries. Under normal circumstances, such disruptions might only be inconvenient. But during a global pandemic, they can have serious public health consequences. Indeed, the COVID-19 crisis has exposed the degree to which many countries rely on other nations to produce critical pharmaceuticals, active pharmaceutical ingredients ("APIs"), and other medical supplies. In the United States, this realization has generated rare bipartisan consensus, as policymakers of all stripes have begun to call for measures to secure the country's medical supply chains and reduce its heavy dependence on foreign manufacturers.

This article begins by briefly discussing the root causes of medical product manufacturing offshoring, namely the incentive structures that have driven many drug companies, API manufacturers, and device makers to move their operations abroad over the past few decades. It then assesses the nature and extent of the U.S.'s dependence on foreign-made drugs, focusing first on what we know and don't know about the volume of the American drug market that is comprised of imported finished drug products and active pharmaceutical ingredients, and then on the specific nations from which those drugs and API are being imported. We then outline the national security and public health risks posed by heavy dependence on foreign pharmaceutical and medical device suppliers. These include, among other things, shortages of critical pharmaceuticals and other medical products arising from geopolitical factors as well as poor quality manufacturing.

The remainder of the article will address current measures being taken to cope with shortages caused by the COVID-19 public health emergency, how this emergency has raised awareness of the need for comprehensive solutions to long-standing reliance on foreign manufacturing, and the types of proposals being offered. More specifically, the article will address how manufacturers, hospitals and healthcare providers, non-profits, and new industry entrants are taking advantage of regulatory flexibility offered by FDA under its emergency use authorities. It will also analyze proposals offered by academics, government policymakers, and private industry to reduce reliance on foreign drug and medical product manufacturing in order to mitigate drug supply chain vulnerabilities in light of growing economic and geopolitical uncertainty as well as increased recognition of the threats posed by global pandemics. In particular, the article will describe several legislative proposals ranging from enhancing drug and device shortage reporting requirements to involving government in the manufacture of generic drugs as well as regulatory initiatives, such as the Food and Drug Administration's Emerging Technologies Program. The article will also address the Trump Administration's $350 million contract with Phlow, a new pharmaceutical company tasked with producing certain critical generic drugs, and other proposed solutions for incentivizing domestic medical product manufacturing.