Public Citizen Comment Re: Docket No. USTR-2024-0002, "Request for Comments on Promoting Supply Chain Resilience"

April 22, 2024

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the U.S. and around the world to make medicines available for all through tools in policy and law.

As the U.S. approaches strengthening supply chain resilience through trade and investment policy, we would like to highlight the following considerations.

1. Medical supply chain resiliency requires participation by diverse actors worldwide.

U.S. trade policy should actively support the increased timely production of standard-of-care medical tools by diverse suppliers globally – both at home and abroad.

Recent medicine shortages in the U.S. and abroad have highlighted the fragility of global supply chains. Overreliance on too few suppliers has left us with an unpredictable system vulnerable to shocks. This vulnerability was put on full display during the COVID-19 pandemic, as countries including the U.S. struggled with shortages and long delays in medical tools needed for pandemic response.

As the U.S. attempted to increase manufacturing, pharmaceutical companies without sufficient capacity to scale up production to meet global need prioritized sales to high-income markets. At the same time, these companies also refused to share technology, leading to vast inequity in access to countermeasures and prolonging the pandemic.

Global threats such as future pandemics require solutions that favor solidarity and global cooperation. This will entail diversifying supply while being mindful to not inadvertently disrupt access to affordable medicines that much of the world relies on.[1] For example, India is a major producer of generic drugs. The U.S. and developing countries alike depend on production of finished drugs and active pharmaceutical ingredients from India and China. Supplementing these developing country contributions with new affordable sources should be beneficial, whereas dismissing their importance or seeking to displace this supply could have serious unintended consequences for health and pharmaceutical access.

Increased domestic production can help address shortages, particularly, as suggested in the literature and proposed legislation on public production, where appropriate government oversight and transparency are exercised in exchange for incentivizing onshoring.[2] However, this alone cannot address

[1] Mariana P. Socal et al. *Competition And Vulnerabilities In The Global Supply Chain For US Generic Active Pharmaceutical Ingredients*, Health Affairs (Feb. 15, 2023), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01120 (The study found that about one-third of the U.S. supply of APIs from 2020 and 2021 were manufactured by a single facility, and another third were manufactured by two or three facilities. India, China, and Italy were found to be the top producers of APIs for the U.S.).

[2] *See* the Affordable Drug Manufacturing Act, https://www.congress.gov/bill/118th-congress/senate-bill/3398/text; *See also* Dana Brown and Christopher Morten, *Public pharma is the best solution to the ongoing problem of drug shortages*, Stat News (Aug. 9, 2023)

supply chain vulnerabilities. Instead, capable facilities worldwide producing quality-assured medicines must contribute to timely and affordable supply.

2. Supply chain policy should not undercut U.S. global health commitments to regional production and local procurement.

There is a growing consensus toward strengthening regional international production capacities to support emergency response, address local health needs, and advance global science and research. Diversified global production contributes to supply chain resilience, making the system more responsive to shocks, and increasing collective pandemic preparedness. U.S. trade policy should be coherent with these goals.

The U.S. is making commitments and investments supporting regional production and local procurement, as outlined in the 2024 U.S. Global Health Security Strategy and in recent White House statements, supporting African producers, so that countries are better equipped to protect themselves.[3][4] The Biden Administration recognizes that sustainable global manufacturing and supply chain capacity is important for building more resilient systems.

The White House described the importance of these investments as follows:

> "The United States is investing in sustainable and resilient global medical manufacturing and supply chain capacity. Robust systems for production and delivery of MCMs not only helps improve health – ensuring more people are able to routinely receive life-saving vaccines and therapeutics like antiretrovirals (ARVs) – they also serve as an essential foundation for effective emergency response. Sustainable systems must provide the infrastructure, resilience, quality assurance, operational efficiency, steady demand, and public confidence necessary to respond promptly and effectively to emergencies while ensuring the continuity of essential healthcare services."[5]

The U.S. is not alone in this. A priority of Brazil's G20 Health Working Group is prevention, preparedness, and response to pandemics, with a focus on local and regional production of medicines, vaccines, and

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https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/ ("Given recurring shortages — and the broader context that Americans pay the world's highest drug prices — it's no wonder that a movement for public pharma is picking up steam. States from Michigan to Maine are exploring getting back into the business of making medicines. The most prominent is California, which has committed tens of millions of dollars to making low-cost, off-patent versions of insulin and naloxone. California Gov. Gavin Newsom said in 2022 that "[n]othing epitomizes market failure more than the cost of insulin" and that "California is now taking matters into its own hands." The first CalRx insulins are expected to be available on the market in 2024.");
Similarly, the government owned, contractor operated model offers structural advantages over other models of public-private cooperation, for example where millions of taxpayer dollars are funneled into scaling up production during emergency response, *See, Deploying the Government Owned, Contractor Operated Model*, PrEP4All, Public Citizen, Partners in Health (March 8, 2022),
https://www.citizen.org/article/deploying-the-government-owned-contractor-operated-model/

[3] *U.S. Government Global Health Security Strategy 2024* (April 2024),
https://www.whitehouse.gov/wp-content/uploads/2024/04/Global-Health-Security-Strategy-2024-1.pdf

[4] *FACT SHEET: Update on the United States Commitment to Expanding Access to Medicines Around the World* (March 29, 2024),
https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/29/fact-sheet-update-on-the-united-states-commitment-to-expanding-access-to-medicines-around-the-world-2/

[5] Ibid.

strategic health supplies.[6] Sustainable and geographically diversified production is also a key aim of the World Health Organization (WHO) Pandemic Agreement[7] as well as capacity building efforts such as the mRNA Technology Transfer Program, a global initiative co-led by the WHO and the Medicines Patent Pool.[8]

These investments and initiatives are valuable assets in the global endeavor to create more resilient and responsive systems. A U.S. approach that inhibits production abroad would undermine actions already underway to strengthen supply chains.

3. A more open intellectual property and technology transfer environment can improve resiliency.

To effectively prioritize resiliency, U.S. trade policy should support all countries responding to disruptions and potentially contributing to diverse and timely supply.

Excessive intellectual property rules in trade agreements entrench monopolies at the expense of diverse, affordable and local supply. Even countries that do not have trade agreements with the U.S. have been pressured against the use of IP flexibilities, limiting available policy tools to address shortages or build resiliency.

USTR has already taken steps in this area by no longer pressuring countries against the use of compulsory licensing for pharmaceuticals, acknowledging public health exceptions to data exclusivity in trade agreements, and no longer pursuing agreements with IP provisions beyond those required by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

We encourage USTR to continue this progress by supporting local production in its Special 301 Report on intellectual property practices, and by not criticizing health protective policies. USTR also should explore non-enforcement or removal of IP restrictions in existing trade agreements that undermine access to medicines. The TRIPS Agreement leaves countries room to adopt national policies that favor public interest, competition, foreign direct investment, technology transfer, and local innovation. Governments should be empowered to use this policy space to address medicines inaccessibility and overconcentration of production. This is important for economic development as well as for bolstering emergency response, where scalable production and robust supply will be all the more possible.

We appreciate the opportunity to comment. Thank you.

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[6] *G20 Health Working Group*, G20 Brasil 2024, https://www.g20.org/en/tracks/sherpa-track/health

[7] *Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response*, World Health Organization, https://apps.who.int/gb/inb/index.html

[8] *mRNA Technology Transfer Programme*, Medicines Patent Pool, https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme