XII

Resolution

Evidence Generation to Inform Policy

USP will generate and disseminate evidence upon which informed choices can be made for investment in regulatory and quality systems, and reforms to regulatory paradigms that advance quality, patient safety, and public health.

Year 3 Update

Policymakers and stakeholders continue to grapple with long-standing vulnerabilities in the medicines supply chain. Factors including geopolitical dynamics, increasingly common natural disasters, and disruptions due to factors yet unknown necessitate the continuation of heightened efforts to build a more resilient global medicines supply chain and thereby help protect and improve public health. USP has devoted considerable effort to advancing medicines supply chain resilience by engaging directly with global stakeholders to understand related challenges and opportunities, and to inform policy recommendations, informational materials, and advocacy. USP has also continued to expand medicines quality-related research to build strong evidence and materials that can advance the policy advocacy and capability-building essential to medicines supply chain resilience.

Key areas of progress over the past fiscal year include:

Supply Chain Resilience Dialogue and Insights – USP engaged with stakeholders from across the globe with diverse perspectives to understand their challenges in strengthening supply chain resilience, generate dialogue to inform policymakers' understanding of global supply chain vulnerabilities and their potential impact on the availability of quality medicines, and advance USP solutions to bolster supply chain resilience.

- As part of the U.S.'s 2023 host year activities for the Asia-Pacific Economic Cooperation (APEC) forum, USP and FDA co-hosted the APEC Medical Product Supply Chain Dialogue in April 2023. This two-day meeting featured knowledge sharing and discussion of many topics important to advancing supply chain resilience. These topics included upstream supply chain vulnerabilities, mitigating and managing risks in excipient quality, manufacturing solutions to bolster resilience, strengthening quality assurance, regulatory reforms to

strengthen preparedness efforts, good distribution practices, post-marketing surveillance, and online pharmacy risks and safety solutions.

- USP completed one-on-one interviews with more than 40 global supply chain experts to inform regulatory policy reform opportunities and engaged in roundtable discussions with stakeholders to better understand challenges and opportunities to advance policy.

Quality Research – USP sponsors research to inform and enable evidence-based policy decisions that can help increase the availability of quality medicines.

- USP worked with the Center for Analytics & Business Insights (CABI) at Washington University in St. Louis to sponsor and help shape a research study to assess the perception of risk along the global medicines supply chain. The work was led by Anthony Sardella, Senior Research Advisor at CABI and a recognized leader in analytics and policy issues associated with the pharmaceutical supply chain.
- During the year, USP-sponsored academic fellows published several peer-reviewed articles and presented their work at national and international scientific and public health conferences. Topics included substandard and falsified medications, procurement of materials used for medicines manufacturing, and antimicrobial resistance.

Medicine Supply Map – USP actively utilized its Medicine Supply Map surveillance system to assist stakeholders, including U.S. federal agencies and the U.S. Congress, in their efforts to identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain, deliver insights that can guide risk mitigation strategies and investments, and help inform policy changes that advance supply chain resilience. During the year, Medicine Supply Map focus areas included insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, such as antimicrobials and cancer medicines. USP shared related insights with stakeholders to facilitate decision-making and inform policy and legislation aimed at bolstering supply chain resilience.

- Five analyses that used Medicine Supply Map data were published during the year.
- Medicine Supply Map analyses contributed to myriad media stories highlighting challenges related to drug shortages. The analyses also were leveraged in several comment letters to U.S. federal agencies, informed testimony that USP provided to the Senate Homeland Security and Governmental Affairs Committee (HSGAC), and were utilized in an HSGAC report on drug shortages and national security.
- Through partnership with stakeholders such as the End Drug Shortages Alliance, the Medicine Supply Map contributed to analyses of the impact of recent supply chain disruptions, such as the closure of Akorn Pharmaceuticals.

Public-Private Partnerships – USP engaged with diverse stakeholders through public-private partnerships on supply chain issues to generate dialogue and evidence that can inform policy. This included work in USP's capacity as a Center of Excellence in global medical product quality and pharmaceutical supply chain security, as designated by the APEC forum.

- USP continues to be a member of the Healthcare and Public Health Sector Coordinating Council, which together

with the Government Coordinating Council forms a public-private partnership to protect national healthcare infrastructure. USP will continue to be an active participant in conversations, share learnings generated from the Medicine Supply Map and quality-related research, and provide insights into policy recommendations.

- USP continues to work with the U.S. FDA, the Administration for Strategic Preparedness and Response, the Biomedical Advanced Research and Development Authority, and the Federal Emergency Management Agency on supply chain-related issues. This included providing Medicine Supply Map data and data-derived insights to inform policy decisions to reduce supply chain vulnerabilities.

Planned for Remainder of the Cycle

- USP will continue to refine and leverage information gathered from stakeholder interviews to influence global regulatory reform.
- USP will continue to seek opportunities to fund work that will generate new evidence to support access to quality medicines.
- USP will continue to leverage insights from the Medicine Supply Map to inform policy decisions and provide valuable, actionable insights to help identify, prevent, and mitigate future disruptions to the supply of medicines.

Contact

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