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ASSOCIATION FOR CLINICAL ONCOLOGY
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March 28, 2023

The Honorable Bernie Sanders
Chairman
Senate Committee on Health, Education, Labor and Pensions
U.S. Senate
428 Senate Dirksen Office Building
Washington D.C. 20510

The Honorable Bill Cassidy
Ranking Member
Senate Committee on Health, Education, Labor and Pensions
U.S. Senate
428 Senate Dirksen Office Building
Washington D.C. 20510

Dear Chairman Sanders and Ranking Member Cassidy:

Thank you for the opportunity to weigh in on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). The Association for Clinical Oncology (ASCO) appreciates the committee's efforts to improve upon the programs in PAHPA to better prepare the U.S. and its health care system for future public health crises.

ASCO is a national organization representing physicians who care for people with cancer. With nearly 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, equitable cancer care.

The COVID-19 pandemic has exacerbated many long-standing access and quality issues that threaten the resilience of our nation's healthcare supply chain. In particular, the public health crisis has magnified the dangers inherent in failing to address gaps and deficiencies in the pharmaceutical and medical supply chains, including overall manufacturing quality. Supply chain issues can adversely impact patient care by delaying treatment, worsening patients' health outcomes, or requiring patients to switch to non-optimal treatment regimens.

In the oncology space, providers and their patients cannot afford to be exposed to medical protocols that aren't top-tier and well-researched. Moreover, many patients with cancer are immunocompromised due to treatment or the disease itself and need the highest quality medical supplies to maintain their personal health. Within the oncology pharmaceutical supply chain, patients and providers continue to face shortages of potentially life-saving treatments. For example, the cytotoxic chemotherapy drug, Fludarabine, remains on the Food and Drug Administration's (FDA) drug shortage list and has stayed on the list for most of 2022 and throughout the pandemic. The shortage has resulted in an increase in cost when providers can obtain the drug. Alternatively, if providers

cannot access the drug, they are forced to consider less optimal contingency plans to ensure their care continues.

ASCO and other stakeholders have long collaborated on efforts to improve our nation's supply chain and mitigate drug shortages. In fact, ASCO and our partners were amongst the first groups to identify drug shortages as a matter of national security. While progress has been made in many areas, COVID-19 highlighted major challenges that still require policymaker action. ASCO and other stakeholders developed the following recommendations to guide policymakers in their efforts to address these challenges. These recommendations are meant to provide a range of potential policy and marketplace changes to improve supply chain quality and resilience.

Recommendation One: Incentivize advanced manufacturing technology and develop new continuous manufacturing technology for critical drugs and active pharmaceutical ingredients (APIs).
We recommend legislative and regulatory solutions that strengthen our nation's supply chain by incentivizing the development and use of advanced and continuous manufacturing technology for critical drugs and APIs, including support for advanced manufacturing grant appropriations. Further, we recommend these technologies be adopted and implemented in both domestic and foreign manufacturing facilities.

Recommendation Two: Improve the function and composition of the Strategic National Stockpile (SNS).
The COVID-19 pandemic highlighted weaknesses in our supply chain, including difficulty accessing the SNS, as well as deficiencies in the medications and devices included in the SNS. We recommend regulatory and legislative actions that improve the function, composition, and accessibility of the SNS during public health emergencies.

- Finalize and regularly update a list of medicines and devices necessary to respond to potential national-scale public health emergencies, which should be included in the SNS. These drugs may differ from those on the essential medicines list.
- Increase transparency regarding the specific products and quantities of such products included in the SNS.
- Add monoclonal antibodies for known pathogens to SNS and expand SNS scope for biological attacks to include pandemic preparedness and response.
- Incentivize the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the SNS:
    - Implement systems to help facilitate the communication of inventory and availability in geographic regions so that facilities can share inventory when necessary and able.
        i. Consider expansion of the Hospital Preparedness Program;
        ii. Ensure physician offices, nursing homes, ambulatory surgical centers, dialysis providers, and other non-hospital settings are included in communication and distribution programs;
        iii. Use data from wholesalers and distributors to forecast supply, rather than requiring regular hospital inventorying of drugs, devices, and personal protective equipment (PPE).
- Implement enhancements to the Office of the Assistant Secretary for Preparedness and Response (ASPR) SNS Control Tower – a program ASPR defines as providing data from commercial partners across PPE categories and pharmaceuticals to help federal response officials with understanding supply and demand in emergencies and with decision-making on when and where to deploy SNS supplies:

    - Improve control tower visibility in the supply chain, including the upstream supply chain:
        i. Upstream refers to processes that occur prior to the finished product, such as securing APIs, excipients, raw materials, components, parts or accessories, and other starting materials.
        ii. Expand control tower scope beyond the current 38 pharmaceutical products to additional critical medicines, including all medicines, medical devices, and PPE. The control tower would be responsible for monitoring the supply chain, proactively identifying medical products at risk of shortage, identifying solutions, and tracking the return on U.S. government investments in improving the resiliency of the supply chain.
- Create a workable process for SNS requests:
    - Establish a process for planned non-emergency distributions from SNS to medical facilities of medications and devices prior to their expiration dates at discounted prices to promote practiced workflows and decrease wastage of expired and obsolete products.
    - Publish a clear, nationally consistent process for making requests from the SNS including publication of contact information for key personnel in each agency that has responsibility for managing requests and distributions from the SNS.
    - Engage pharmacists, physicians, other clinicians, and supply chain experts to develop processes for maintaining and refreshing products in the SNS.
    - Create a standard distribution logistics process for medications, devices, and related supplies from the SNS, which incorporates feedback from clinicians and supply chain experts, including clear expectations for how updates to these processes will be publicized, if needed, in the event of a national emergency.
    - Publish criteria, including an overarching organizational strategy, which will be used to prioritize distribution of products from the SNS, including clear expectations for how updates to these criteria will be publicized, if needed, under both normal operations and in the event of a national emergency.

Recommendation Three: Improve multinational cooperation on supply chain resilience.
We recommend regulatory and legislative actions that increase the overall resilience of the U.S. supply chain by enhancing international cooperation and collaboration with foreign supply chain partners, including but not limited to foreign governments and manufacturers.

- Enhance support for innovation and public-private partnerships for research, development, and deployment of effective and affordable disease-tracking tools, diagnostics, therapeutics, and vaccines;
- Advance and support intergovernmental, regulatory, and private sector partnerships:
    - Such partnerships would advance research, development, and deployment of effective infectious disease tracking tools, diagnostics, therapeutics, and vaccines, including by establishing and leveraging public-private partnerships and supporting advance purchase agreements, as necessary and appropriate; improve infection control within healthcare settings; combat the threat of antimicrobial resistance; expand lab capacity through the provision of material and technical assistance.

Recommendation Four: Incentivize quality and resilience.
We recommend regulatory and legislative action that creates incentives for manufacturers to improve drug and device manufacturing quality. Further, we recommend that policy solutions are focused on outcomes that improve the overall resilience of our nation's medication and device supply chains.

- Require the FDA to provide ratings of the quality management processes of medication and device manufacturers that are predictive of supply chain and manufacturing vulnerabilities and to make the ratings publicly available.
- Identify key starting materials, APIs, and finished dosage forms of essential medicines, including vaccines, that should have domestic manufacturing capacity to improve the resilience of the U.S. drug supply and incentivize their production without limiting access to foreign sources of the product. A fact-based approach should be used to decide what drug products and ingredients need to be shored.
- Reduce instances of contamination in finished drug products.

Recommendation Five: Replicate asks for critical drug manufacturing transparency and oversight for medical devices and ancillary supplies (e.g., PPE).

The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 included drug manufacturing provisions designed to mitigate and reduce drug shortages. We recommend legislative and regulatory action to extend similar provisions to the manufacturing of medical devices and enhance reporting requirements for device manufacturers.

- Amend the CARES Act provisions on device reporting:
    - To require that a device manufacturer that fails to report a discontinuance or interruption in supply is deemed to have committed a "prohibited act" under section 301 of the Federal Food, Drug, and Cosmetic (FD&C) Act.
        i. Rationale: Currently, the only repercussion for failing to notify is a letter from FDA to the manufacturer and, if they still fail to respond, FDA posts the letter online. Deeming failure to notify as a "prohibited act" provides the agency with broader authority to apply other more substantive penalties.
    - To more closely align the language for device discontinuance/interruption reporting with the language included in the drug discontinuance/interruption reporting requirements in section 506C of the FD&C Act. This includes adding language to: (1) indicate that device reporting is not only required during or in advance of a public health emergency but also required more broadly and (2) require manufacturers to notify FDA of a discontinuance/interruption in the raw materials, components, parts or accessories of the device.
    - Require risk management plans:
        i. Each manufacturer of a device required to report discontinuances or disruptions in supply, or of any raw material, component, part, or accessory of the device, shall develop, maintain, and implement, as appropriate, a risk management plan that identifies and evaluates risks to the supply of the device, as applicable, for each establishment in which such device, or raw material, component, part or accessory of such device, is manufactured. Amend section 704(a)(4) of the FD&C Act to provide the authority to subject a risk management plan under this section to inspection and copying by the Secretary pursuant to an inspection or a request under section 704(a)(4) of this title.
    - Require that device manufacturers report manufacturing volumes:
        i. Similar to the CARES Act provision for drug manufacturers, require device manufacturers to send FDA an annual report on the quantity of devices manufactured, prepared, propagated, or processed at registered facilities.
    - Require FDA to develop ratings for the quality management processes of device manufacturers that are predictive of supply chain and manufacturing vulnerabilities.

- Identify raw materials, components, parts, or accessories of critical devices that should have domestic manufacturing capacity to improve the resilience of the U.S. device supply chain and incentivize their production without limiting access to foreign sources of devices.
- Require device manufacturers to disclose raw material, component, part or accessory sources, and manufacturing locations, including locations of contract manufacturers.

Inclusion of the Verifying Accurate Leading-edge IVCT Development (VALID) Act

In addition to suggested improvements to the SNS, ASCO requests inclusion of the VALID Act into the reauthorization of PAHPA. The VALID Act has not been reintroduced yet this session but has received bipartisan support in the 117th Congress and enjoys broad support from the stakeholder community. The legislation aims to modernize the regulation of all Laboratory Developed Tests (LDTs) and in vitro diagnostic tests (IVDs) under a single framework under the FDA. It would create a flexible, risk-based regulatory system that would incentivize and improve the development of advanced, reliable tests. The VALID Act would be an important step forward for patients and their clinicians who expect the highest quality, innovative tests available to diagnose and treat illnesses. Absent these reforms, the current, outdated oversight of the development and quality of these tests will lead to inaccurate and unreliable tests and undermine clinical decision making and patient health outcomes. As you know, this diagnostics reform language reflects years of engagement and collaboration between Congress and the stakeholder community.

Thank you for the opportunity to provide our comments, concerns, and solutions to strengthen PAHPA and the SNS. We would welcome the opportunity to engage with Congress in a meaningful dialogue about these issues. Please contact Megan Tweed at Megan.Tweed@asco.org with any questions.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology