Documents for the Record – 06/13/23

Majority:

- June 13, 2023 statement for the record from the American Cancer Society Action Network
- June 12, 2023 letter from Bipartisan Policy Center Action
- June 11, 2023 letter from the American Clinical Laboratory Association

American Cancer Society Cancer Action Network (ACS CAN)
Statement for the Record
House Energy & Commerce Health Subcommittee Hearing
on
Legislative Solutions to Bolster Preparedness and Response for all Hazards and Public Health Security Threats
June 13, 2023

The American Cancer Society Cancer Action Network (ACS CAN) advocates for evidence-based public policies to reduce the cancer burden for everyone. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. By engaging advocates across the country to make their voices heard, ACS CAN influences legislative and regulatory solutions that will end cancer as we know it. We commend the Subcommittee for holding today's hearing and we appreciate the opportunity to provide a statement for the record.

Access to effective medications is a non-partisan issue. Most cancer patients rely on drug therapies to effectively treat their disease and, in many instances, save their lives. Yet as of early June 2023, there were 14 oncology drugs on the official U.S. Food and Drug Administration (FDA) drug shortage list — including Carboplatin Injection used to treat triple negative breast cancer, ovarian, head, and neck cancers; Fludarabine Phosphate Injection used for treating B-cell chronic lymphatic leukemia; Dacarbazine Injection for treatment of skin cancer; as well as Amifostine Injection; Azacitidine for Injection; Capecitabine Tablets; Cisplatin Injection; Cytarabine Injection; Dexamethasone Sodium Phosphate Injection; Hydrocortisone Sodium Succinate Injection; Leucovorin Calcium Injection; Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection; Methotrexate Injection; and Streptozocin (Zanosar) Sterile Powder; in addition to many products used in cancer care like intravenous saline solutions.

According to the American Society of Health System Pharmacists, chemotherapy drugs, often without alternatives, are increasingly in short supply and have returned to the list of top-five drug classes affected by shortage.

Shortages of oncology drugs not only exacerbate inequities in health care and disrupt a patient's treatment schedule but can be directly linked to adverse patient outcomes — including life threatening consequences. Health care providers may intentionally give lower doses to stretch a short supply among many patients or simply may not be able to provide cancer treatment at all if there are no other

reasonable second or third-line drug alternatives to the cancer drug in shortage. Additionally, due to shortages, health care providers may be forced into difficult decisions like deciding which cancer patients receive medications and which do not.

Cancer-drug shortages in the U.S. have also caused delays and modifications to clinical trials, threatening progress on new treatments. Cancer drug treatments for the future are determined by the outcomes of clinical trials conducted today. Therefore, drug shortages are negatively impacting cancer patients today — and cancer patients in the future.

We understand that the actual causes of oncology drug shortages are complex and multi-faceted including:

- Manufacturing difficulties including quality compliance that force the shutdown of production lines;
- Failure to accurately project demand for certain drugs;
- Shortages or unavailability of raw materials;
- The small number of companies that have the capacity to produce a drug if one manufacturer ceases production;
- Growth in product use without associated growth in production capacity;
- Tight production schedules that are not readily altered if a manufacturing problem occurs or if demand increases faster than anticipated;
- Business decisions companies make to discontinue manufacturing certain drugs, particularly generic drugs, based on profitability or other business considerations; and
- Limited incentive to invest in low-margin generic drugs.

Today's mitigation strategies are largely about encouraging early notification by manufacturers to FDA, who may then be able to work with the manufacturer to limit the public health impact. Without addressing the root causes of shortages, however, this issue will continue to spike to levels that impact significant numbers of cancer patients, as it has at least 3 times during the past 12 years. We urge the Committee to look at longer-term solutions that change the fundamental underpinnings of the shortages. In the meantime, we urge the industry to work with medical practitioners to help identify alternatives where possible to ensure that cancer patients' treatments are as minimally impacted as possible in light of the shortages.

Drug shortages that have persisted in the U.S. for years are unacceptable to patients who rely on these medications to save their lives. We must move beyond protracted discussions about the problem. It is time for bipartisan engagement in not only addressing the acute need of today's patients, but also in finding long-term solutions to prevent future shortages. Congress and pharmaceutical manufacturers can do more to both anticipate potential shortages and help to ensure that a patient's cancer treatment is not disrupted. To this end, we encourage you to build upon today's hearing and undertake a process of bringing together all of the relevant stakeholders and key thought leadership to identify and create the pathways required for long-term solutions. ACS CAN looks forward to working with you to address the drug shortage issues.

Bipartisan Policy Center Action

June 12, 2023

The Honorable Cathy McMorris Rodgers
Chair
U.S. House Committee on Energy and Commerce
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
U.S. House Committee on Energy and Commerce
2107 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair
Subcommittee on Health
U.S. House Committee on Energy and Commerce
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
U.S. House Committee on Energy and Commerce
272 Cannon House Office Building
Washington, DC 20515

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Guthrie, Ranking Member Eshoo,

Thank you for your leadership in advancing the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) and for scheduling a legislative hearing on June 13, 2023, titled "Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats." In advance of next week's legislative hearing, the Bipartisan Policy Center Action (BPC Action) wanted to express our support for the committee's bipartisan efforts to reauthorize PAHPA and to highlight a few comments that we would encourage you to consider. In addition to providing some overarching concepts of how to better improve coordination and communication within the Department of Health and Human Services (HHS), these comments will also highlight areas of support or requested improvements related to specific bills under consideration.

Overarching concern. As evidenced by our Covid-19 response, one overarching goal of Congress should be to improve coordination and communication within HHS. BPC Action recognizes that it is not possible to legislate culture but Congress can help ensure that HHS is more successful by clearly delineating roles and responsibilities and we recommend Congress maintain key coordination responsibilities within the Office of the Secretary and not transferred to, or retained within, the (new) Administration for Strategic Preparedness and Response

(ASPR). The rationale for that is simple: As an operating division, ASPR will be on par with other operating divisions within HHS, such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). As such, the Secretary should ultimately be the person responsible for resolving differences among operating divisions (e.g., if there is a dispute or concern about which operating division should take the lead on a particular program or policy), not ASPR. To aid in that review, BPC outlined specific roles and responsibilities already described in law which we believe should be retained within the Office of the Secretary.

Specific legislation. BPC Action appreciates the opportunity to provide some comments pertaining some of the legislative proposals in front of the Committee, including the Public Health Guidance Transparency and Accountability Act, the Biosecurity Infrastructure for Operational (BIO) Early Warning Act, and the Improving Data Accessibility Through Advancements (DATA) in Public Health Act.

BPC Action is supportive of the goals and objectives of the Public Health Guidance Transparency and Accountability Act. Similar to what the FDA has done under 21 CFR 10.115, it is important that the CDC also has a transparent process for developing their guidance documents. This will not only aid with better communication, which was a focus of a recent BPC report, but it will also provide additional accountability. A critical lesson from COVID-19 is that CDC guidance documents need to be timely, transparent, and pragmatic. As the committee considers the legislation, we urge you to consider language that would require the CDC, as a part of its guidance process, to require a reference to the statutory or regulatory provision being interpreted.

Additionally, BPC Action has some concerns with portions of the BIO Early Warning Act, specifically as it related to certain functions that are being delegated to ASPR. As noted above, we believe that the major coordinating functions should be retained within the Office of the Secretary, not within the ASPR. Thus, we commend the authors for retaining that purpose within section 2, but are concerned that this policy was not retained within sections 4 and 5 but rather delegated those activities to ASPR. Given that early warning and disease detection programs currently reside within CDC but ASPR maintains the research and development and health care readiness partnerships, we recommend that the critical coordination functionalities and planning be retained within the Office of the Secretary in order to leverage the cross-cutting activities between the two operating divisions.

Lastly, BPC Action wholeheartedly supports the goals and objectives of the DATA in Public Health Act. This legislation will not only help improve our federal data collection and reporting standards, but it will also improve data sharing, consistent with a recent BPC report.

Bipartisan Policy Center Action

We commend the Subcommittee for its ongoing efforts to tackle these critical issues in a bipartisan manner and thank you for your consideration of these comments and suggestions.

Sincerely,

Andrew Hu
Director, BPC Action

Bipartisan Policy Center Action

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Appendix

BPC PAHPA Organizational Authorities

As Congress opts to revisit the role of the Assistant Secretary for Preparedness and Response within the Administration for Strategic Preparedness and Response, ***the Bipartisan Policy Center urges Congress to retain the coordination roles within the Office of the Secretary, while preserving other key functions within the newly created Administration.*** As a recent GAO report has emphasized, the Department of Health and Human Services has struggled over the past decade with persistent deficiencies in establishing clear roles and responsibilities. Functionally, it is difficult for the head of one operating division to direct the head of another operating division, which is why those duties are generally retained within the Office of the Secretary. In addition, in instances when coordination is required beyond HHS to include other executive branch departments, it is important that the Secretary directly be the lead principal.

In light of those principles, we have identified several key functions that should be retained within the Office of the Secretary, including:

- The coordination functions under 42 U.S.C. 300hh–10(b)(4), including:
  - (A)(related to Federal integration),
  - (B) (related to state, local and tribal integration),
  - (D) (related to policy coordination and strategic direction),
  - (F) (related to coordination of grants and agreements),
  - (G) (related to drill and operational exercises, given that these exercises cross Departments), and
  - (I) (related to threat awareness, given that this activity crosses Departments).
- Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), under USC 300hh-10(d).
  - Under 42 U.S.C. 300hh–10, the statute notes that "[t]he Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the 'PHEMCE'). The Assistant Secretary for Preparedness and Response shall serve as chair of the PHEMCE." Given that members of PHEMCE include officials at the Department of Defense, Department of Homeland Security, and other executive branch departments, rather than have it led by the ASPR, the statute should clarify that the Secretary should lead the PHEMCE.

By retaining this functionality within the Office of the Secretary, the Secretary will be in charge of providing necessary leadership and coordination across agencies such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), and the Administration for Strategic Preparedness and Response.

ACLA STATEMENT OF SUPPORT FOR H.R. 3742

June 11, 2023

ACLA endorses H.R. 3742, introduced by Representative Peters and Chairman Guthrie, that would require the Government Accountability Office (GAO) to evaluate the federal government's collection and sharing of public health data to respond to public health emergencies.

Robust data collection and analysis are essential components of an effective response to a health emergency. However, today's local, tribal, state, federal, and private health information exchange reporting requirements are a patchwork system that generates inefficient and unnecessarily duplicative health data. These inconsistent requirements also burden providers with unnecessary costs.

ACLA, in collaboration with the Johns Hopkins Center for Health Security developed a *Proposal for a National Diagnostics Action Plan*, informed by public and private sector experience during the COVID-19 pandemic. Among the proposal's key recommendations is that the U.S. government "should work to standardize data to improve national visibility and understanding about capacity distribution, trends, and gaps (whether regional or demographically based)." In short, the Plan calls for "a uniform, single, national, accurate, actionable public health data reporting policy that standardizes data sets and delivery mechanisms for data."

ACLA and its members would welcome the GAO's review of our nation's approach to public health data reporting, as proposed by H.R. 3742. ACLA would also be pleased to be a resource for the GAO as it conducts its evaluation.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

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