February 4, 2022
MEMORANDUM

FROM: The Robert J. Margolis, MD, Center for Health Policy at Duke University (Duke-Margolis Center)
RE: Proposals in the PREVENT Pandemics Act discussion draft

The Duke-Margolis Center applauds your effort to move forward a critical set of pandemic preparedness and response measures in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act). The discussion draft contains a number of important proposals focused not only on near-term needs associated with overcoming the current COVID-19 pandemic, but also longer-term review and analysis of our collective shortcomings during COVID-19 so that we are far better prepared to respond decisively to future potential public health emergencies. Consequently, we encourage you and your colleagues to move swiftly toward deliberation and passage of the PREVENT Pandemics Act.

At the same time, we encourage a broader view of public health and pandemic preparedness by more completely incorporating the critical role of public-private collaboration and by leveraging private health care system capabilities to truly enable a robust public-private response to a future health emergency. The preparedness and disaster response apparatus the United States needs for future health emergencies must include concerted links between public health and private sector actors in order to fully support the health care systems, emergency responders, primary care providers, and community organizations that are critical to our response but that have faced challenges in coordination and support under wave after wave of COVID-19 variants. Our response must sufficiently invest in data modernization programs and information exchange linkages, supported by aligned incentives, so that decision makers in all sectors can respond together to the health emergency in real time. It must make use of drastically improved manufacturing capabilities and supply chains that can move from a "warm base" footing to increased production and distribution as needs on the ground evolve over time. It must reflect the shift in our health care policies toward greater support for prevention, early diagnosis, and community-based management.

Reforms that leverage the growing capabilities of health care providers, manufacturers and distributors, and community-based organizations will enable a more complete and timely response to head off serious complications and hospitalizations. These reforms are aligned with other policy initiatives already underway not just for emergency surges, for example around building robust supply chains that avoid drug shortages and health care systems that are better at protecting and promoting population health and equity.

For these reasons, it is very important that the Task Force proposed in Sec. 101 is adequately resourced and staffed, with a sufficiently broad scope so that its findings and recommendations can build upon the PREVENT Pandemic Act's proposals to achieve the ultimate goal of bringing the Federal government, state and local authorities, and our extensive private health care system together in a new public health and disaster response infrastructure. The Task Force is therefore a cornerstone provision in PREVENT's ultimate aims. The team at Duke-Margolis looks forward to sharing our COVID-19 related work and experiences with the Task Force once it is established and begins lines of inquiry.

Building on these general comments, we also include here a number of proposed revisions, refinements, or additions to other proposals found throughout PREVENT. These suggestions are based on two years of work focused on COVID-19 response policies, vaccine and therapeutic development, testing strategies,

and health sector resilience, including more than 50 white papers, policy briefs, and commentaries; multiple Congressional testimonies; and over 20 public events. These comments are also reflective of collaborative work undertaken with the Healthcare Leadership Council and dozens of partner organizations and experts to issue the February 2021 report "National Dialogue For Healthcare Innovation: Framework for Private-Public Collaboration on Disaster Preparedness and Response." The report outlines critical challenges and potential solutions for improving data and evidence generation, strengthening innovation and supply chain readiness, and innovating care delivery approaches to address sustained health emergencies.

We look forward to continued collaboration with your teams over the coming weeks as you advance the PREVENT Pandemics Act's proposals. Please do not hesitate to reach out should you have questions or wish to discuss any of these comments further.

Sincerely,

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Comments on Provisions in the PREVENT Pandemics Act

TITLE I

Sec. 101
As noted above, Duke-Margolis is strongly supportive of the formation of a Congressionally-chartered Task Force to conduct a comprehensive review of our collective response to the ongoing COVID-19 crisis. The structure of the proposed Task Force should engender bipartisan lines of inquiry and leadership, and the scope should be defined broadly enough to enable the Task Force to make meaningful recommendations for both public and private sector improvements to disaster preparedness.

- **Recommendation:** Designating the Task Force as subject to the full requirements of the Federal Advisory Committee Act (FACA) may in fact hamper some investigative and deliberative components of the Task Force's work, potentially hindering exploratory and frank discussions internal to the Task Force. While public transparency is critical for trust and support of the Task Force, previous Congressionally-mandated task forces and commissions provide models for achieving this goal in ways that would not hamper investigations and earnest analyses. We encourage the Committee to reassess the appropriate application of FACA while ensuring that the Task Force's work is meaningfully open to the public.
- **Recommendation:** While the scope of the Task Force's investigative activities as outlined in the discussion draft is sufficiently broad for enabling it to take its work in many important and critical directions, there are several areas where explicit direction from authorizing legislation may be helpful:
    - In previous disaster preparedness recommendations, we identified multiple regulatory waivers or flexibilities that were important for ensuring fast action. Given that, the charge of the Task Force could explicitly include a review of regulatory reforms implemented during the pandemic and identify those that worked well and areas for further improvement. The review should describe the legal and regulatory guidances and waivers (e.g., antitrust, anti-collusion) that could be implemented quickly by specified government agencies or officials during public health emergencies, especially if there are sets of waivers or guidances that could be implemented as a group to encourage private sector collaboration and action.
    - We also identified challenges across differing legal frameworks for Federal emergency response (e.g., Stafford Act, National Emergencies Act, Public Health Emergencies under the Public Health Service Act), which led to differing roles, responsibilities, and flexibilities. The Task Force could examine where there may be opportunities for streamlining, coordinating, and aligning Federal legislative public health authority.
- **Recommendation:** Duke-Margolis also strongly recommends that the proposed timelines be reconsidered and potentially revised to provide the Task Force sufficient time to complete their interim report (required within 180 days of enactment in the current draft) and final report (required within 12 months of enactment with a potential six-month extension). While these timelines do reflect the urgency with which we would hope a Task Force could operate and deliver actionable recommendations, 18 to 24 months for a final report may be more feasible and allow enough time for the Task Force to pursue and close out all possible lines of inquiry.
- **Recommendation:** While the current draft does allow for the Task Force to accept donations that in theory could supplement its operating budget, an over-reliance on outside funding complicates planning and could diminish the Task Force's effectiveness in other ways. We strongly encourage the Committee to pursue additional Federal funding substantially beyond the proposed $3,000,000 so that the Task Force is adequately resourced from its inception, and can complete its work as quickly and comprehensively as possible.

Sec. 102

While there is a clear need for potentially significant reforms across several Federal agencies, including CDC, ASPR, and FDA, as well as HHS- and government-wide coordination activities, it is very likely that any major reforms in authorities and coordination for a public health emergency like a pandemic will be substantially informed by the further assessments and reports included in PREVENT, particularly the Task Force established in Sec. 101. Consequently, we recommend delaying any such major structural and coordination reforms until the findings from this work are known. While some more limited interim reforms may be beneficial, this approach would provide a much more robust suite of recommendations

and analysis to support them, enabling a more effective whole of government response and private sector support in the next major public health emergency.

Sec. 103
While many government agencies and departments have done tireless and important work within their respective authorities to help the United States respond to the COVID-19 pandemic, real and perceived disconnects between them has often meant that up-to-date guidance and public health messaging across the whole of government has suffered – making the day-to-day job of health providers and state health departments more challenging.

Furthermore, the important goal of central coordination in this section, via improvements to the coordinating roles of both the Secretary of Health and Human Services (HHS) and Assistant Secretary for Preparedness and Response (ASPR), would benefit from including adequate avenues and supports for efficient and effective coordination and partnership with the private sector.

- **Recommendation:** For a future emergency, it will be important to ensure adequate legal protections exist to allow for coordination between the public and private sectors. There are opportunities to build on and improve antitrust safe harbors for private sector collaborations that were used during the current pandemic, such as the Critical Infrastructure Partnership Advisory Council or FEMA voluntary agreements. Existing safe harbors should be clearly articulated and publicized so that health care organizations know of them before an emergency occurs, and new safe harbors should be created and similarly publicized.

Sec. 104
In addition to the Public Health Information and Communication Advisory Committee, there is a need for improved collaboration and coordination by creating stronger and more transparent communication channels across key emergency response participants from the health care system, and between the public and private sectors during public health emergencies.

- **Recommendation:** The Secretary of HHS should examine whether existing stakeholder engagement channels can be improved to better engage senior decision-makers from private sector health care entities, building on HHS Sector Coordinating Councils; whether models from other sectors can be adapted for health care, such as the CEO-led Electricity Subsector Coordinating Council; or whether new channels are needed for senior-level engagement.
- **Recommendation:** Our research also identified that HHS needs the ability to quickly convene subject matter experts from private sector health care organizations, including in areas such as production capacity, supply chain and distribution, acute care delivery, community delivered care, testing and treatment, vaccination strategies, and many others. This could be implemented through multiple mechanisms, such as an advisory council for the HHS Assistant Secretary for Preparedness and Response or through a Federal Advisory Committee seated before an emergency. The best structure should be assessed, with the goal that multiple agencies should be able to access the subject matter expertise during the emergency. If implemented as a Federal Advisory Committee, the Congress should review FACA provisions to identify statutory requirements that could be waived or modified during an emergency, such as the ability to quickly seat new members, quickly hold meetings, and discuss sensitive industry topics.

Sec. 112

We support efforts within this section to review actions taken by SAMHSA during the public health emergency to improve provision of mental health and SUD services and requiring SAMHSA to outline additional steps to improve services during public health emergencies.

- **Recommendation:** Consider adding language that specifically directs SAMHSA to examine the impact of regulatory flexibilities enacted during the public health emergency, including methadone take-home flexibilities for Opioid Treatment Programs and flexibilities on initiation of buprenorphine via telehealth, on patient access to Medications for Opioid Use Disorder (MOUD) and develop a plan for extending or making permanent regulatory flexibilities that can reduce barriers to MOUD access and improve patient care.
- **Recommendation:** Consider adding language that directs SAMHSA to include in their report to congress a section on strengthening interagency coordination with DEA, CDC, HRSA, and other federal agencies that play a key role in provision of mental health and SUD services during future public health emergencies.

TITLE II

Sec. 201

The underlying concept of this section, to establish a grant program to support community collaboration focused on inequities and SDOH, is a valuable part of more effective response. We suggest strengthening it by clarifying eligible entities and evidence-based strategies, and adding capacity-building and monitoring and evaluation portions of the program. Accordingly, we offer four recommendations:

- **Recommendation:** Clarify eligible entities by:
    - adding language to include public health departments and other government departments that influence social determinants of health
    - adding language to more effectively support inclusion of smaller or resource-constrained entities. As worded, this could potentially leave out these types of organizations (e.g., a local CBO with few staff) key to addressing SDOH and inequity.
    - adding language to encourage inclusion of organizations that are representative of the communities they serve
- **Recommendation:** Include expectation of an evaluation plan that focuses on both effective approaches and implications for sustaining and expanding effective programs, in coordination with other Federal initiatives that aim to strengthen community collaboration.

Sec. 202

Encouraging assessment of policy effects on disparities is important given the very large disparities in impact of the pandemic. Accordingly, we offer the following recommendations:

- **Recommendation:** Include language to ensure a wide and diverse stakeholder group, including engagement with community-based organizations
- **Recommendation:** Extend assessment to Federal policy interactions with key state and local policies.
- **Recommendation:** Expand scope of study to interactions of strategies to address disparities and outcomes in service delivery models with social services reforms, including braiding and blending funding sources and improving data infrastructure to support a focus on whole-person well-being.

Sec. 211, 212, and 213

This pandemic has shown the value of fast information collection and analysis in order to better understand a new disease, predict outbreaks, and quickly inform policy makers and the public of the most up-to-date information. However, this value has been mostly realized in nations with highly integrated health information systems, while the US public health infrastructure struggles to receive timely, interoperable data from labs and hospital systems and, in turn, to efficiently share data with HHS. It is good that these proposals recognize the importance of data systems, data standards, and fast exchange of data.

- **Recommendation**: Building a sustainable, interoperable public health data system and analytical capacity will require sustained funding and maintenance of the systems during non-pandemic times. We suggest HHS support studies to understand potential day-to-day uses for these types of data and surveillance/analytics systems, such as antimicrobial resistance and/or seasonal viral diseases, as well as the costs involved.
- **Recommendation**: Sec. 213 should specify that electronic health standards should be interoperable, and the ONC study referenced in Sec. 213 should include an analysis of the interoperability of existing lab standards.
- **Recommendation**: The ONC study referenced in Sec. 213 should include CMS as a partner to explore methods to ensure better compliance with standards, potentially through CMS CLIA authority or reimbursement requirements.

TITLE III

Sec. 301

Given the spread of the virus, understanding the long-term health effects of COVID-19 is critically important. We are pleased to see support for this level of research as well as education about the long-term effects of COVID-19 in the bill text.

We highlight that there are several real-world data-based approaches that might support the collection of information to advance present and future research on the long-term effects of SARS-CoV-2 in diverse populations. Among them is FDA's Sentinel Initiative, which helps FDA evaluate the safety and efficacy of medical products using a combination of administrative health insurance claims data and electronic health records. Likewise, the Reagan-Udall Foundation's COVID-19 Evidence Accelerator has been working throughout the pandemic to generate real world evidence for diagnosing and treating COVID-19.

- **Recommendation:** This provision could explore opportunities to not only build new, targeted data infrastructure, but also leverage existing infrastructure and programs like Sentinel and the COVID-19 Evidence Accelerator for ongoing investigation on the long-term health effects and health care needs following COVID-19 infection.

Sec. 302

While the COVID-19 pandemic resulted from a novel virus, there are other potential threats to human health that could cause public health emergencies.

- **Recommendation:** Consider expanding the scope of "pathogens of pandemic concern" to include bacteria, fungi, and antimicrobial-resistant pathogens.

TITLE IV

The provisions listed under Title IV are thoughtful and valuable steps toward building and maintaining an effective supply chain, stockpile, and rapid response capability for medical countermeasures. In particular, grants, contracts, and cooperative agreements for ongoing maintenance of manufacturing capacity for medical countermeasures in times *outside* of public health emergencies is critical to ensuring manufacturing can rapidly scale up production of medical products when needed.

Extending measures to other essential medical products
The provisions under Title IV and Title V are generally positive steps towards increasing manufacturing capacity and supply chain resilience for medical countermeasures. Limiting these provisions to medical countermeasures, however, limits the beneficial effects to that relatively small group of therapeutics and medical devices. These measures should incorporate not just medical countermeasures, but other essential medicines as well. Throughout the pandemic, many essential medicines that may not qualify as covered countermeasures have gone into shortage. In addition, over the past decade, tens to hundreds of drugs have gone into chronic shortage each year. The same advanced biomedical manufacturing capabilities that would enable timely and effective pandemic response can support more robust, reliable manufacturing outside the pandemic, and can potentially enable more efficient pathways to support related public health priorities like inexpensive manufacturing of new antimicrobials for priority resistant organisms. This would both help sustain needed long-term support for reliable pandemic surge capacity and achieve other important public health goals.

Ensuring quality of products procured through federal contracts
Contracts provided to manufacturers through Sec. 401 and 405 should include measures to assess and ensure product quality. These contracts should require favorable FDA inspection outcomes and require participation in FDA's Quality Management Maturity program.

Sec. 401
Assessments of medical product supply chains are in the purview of the Task Force. Clarifying roles and responsibilities among federal agencies (including FDA, BARDA, ASPR's Hospital Preparedness Program, ASPR's Critical Infrastructure Protection Program, etc.) related to ensuring availability of essential medical products is sorely needed, and we suggest that the Task Force should examine how to better define and coordinate federal efforts in this area.

Specifically, a lack of clarity exists around which federal agencies are responsible for proactively ensuring the resilience of medical product supply chains. BARDA is primarily a research organization focused on novel countermeasures, while FDA Drug Shortage Staff is focused on mitigating shortages after they are imminent. Neither is equipped to proactively ensure the availability of existing medicines. The Task Force should recommend how to define responsibility for this gap and consider establishing new joint ASPR/FDA oversight focused on the availability of existing essential medicines.

In addition, the Task Force can assist in improving visibility and communication among stakeholders in the supply chain. Federal and state regulatory agencies can have defined roles for distribution and allocation of countermeasures and medical products. Data-driven allocation of countermeasures should be done based on need and equity with clear expectations among Federal and state agencies. A public-private process should identify what inventory and utilization data is needed for decision-making on distribution, allocation, and purchasing. Purchasing of countermeasures and medical products, ahead of rising demand, necessitates clear communication with manufacturers detailing the complete supply picture.

- **Recommendation:** BARDA is focused only on novel medical countermeasures. The bill should also identify responsibility for establishing warm base manufacturing capacity for other existing essential products that rely on the same types of manufacturing capacity and supply chains in order to maximize public health impact and further encourage sustainable, system-wide change.
    - The Task Force established in Title I should consider public-private partnership efforts to bolster supply chain capacity, resiliency, and transparency including more redundancies in supply chains, greater geographic diversification of manufacturing, and improved inventory practices
    - A joint ASPR/FDA supply chain resiliency rating system is one promising option for measuring and incentivizing greater surge capacity for emergency response and greater resiliency in routine manufacturing.

Sec. 402

Sustaining of warm base capacity is very important, but also potentially costly, especially if done in a fragmented way. Federal contracts (such as those detailed in Sec. 401) alone may be unable to sustain sufficient warm base capacity. Consequently, Federal partners should consider opportunities to engage with the private sector to encourage resiliency and enhance transparency in manufacturing and supply chains while protecting proprietary information. For example, private purchasers of medical products could provide supplemental incentives to manufacturers for greater warm base capacity. The government can help to establish incentives from private purchasers by increasing transparency into manufacturer supply chains and translating this information to purchasers.

- **Recommendation:** To this end, we recommend adding a new section to Title IV calling for the development of a joint ASPR/FDA supply chain resilience rating system for essential medical products, especially drugs. The Margolis Center's 2021 whitepaper on supporting resilient drug supply chains suggests such a rating system could be based on information collected from manufacturers regarding fungibility of materials, types and quality of production equipment, capacity constraints, and inventory and distribution practices. We also suggest further support for the FDA Quality Management Maturity rating program, which is focused more specifically on product quality and the quality culture of manufacturers.
- **Recommendation:** Distributing stockpiled products to individual states introduces complexities to coordination between the federal and state governments for public health emergency response. Congress should carefully assess whether stockpiled products can be distributed directly to healthcare providers.

Sec. 406

Shifting contracting for Strategic National Stockpile purchases from volume-based contracts to longer-term time-based contracts will promote stability of supply for these medical products. The longer-term contracting model can also reduce risk for manufacturers in making needed investments in quality and resiliency. Congress should seek to promote longer-term contracting practices for drug purchasing, as well as contracting practices that encourage investments in supply chain resiliency, both for public health emergency response and in routine manufacturing processes. As noted above, attention to how these steps can be taken to support reliable manufacturing surges in a pandemic may also contribute to reliable supply issues more generally, and could generate more private sector support and synergies.

- **Recommendation:** Longer-term SNS contracts should involve frequent, scheduled ordering (i.e. monthly orders) rather than bulk purchases to encourage inventory turnover and enable sales of product nearing expiry.

Sec. 410

- **Recommendation:** "Virtual" state stockpiles, in which states have guaranteed access to medical countermeasures and supplies from the SNS or another centralized resource, may be a more efficient method for ensuring access than physically distributed state stockpiles. The provisions in Sec. 404 regarding transparent guidance for accessing the SNS support this approach.

TITLE V

Sec. 502

The pandemic demonstrated the critical need for clinical trial platforms that are feasible for busy clinicians to implement during a pandemic, and initiatives like the RECOVERY Trial in the UK showed how this can be done. Consequently, we strongly support efforts to advance FDA and multistakeholder priorities for modernizing clinical trials. In a time where the conduct of clinical trials has grown increasingly complex, advancing adaptive trial designs, decentralized trials, and digital health technologies can help increase clinical research efficiency and make it easier for patients to participate in trials.

- **Recommendation:** To further advance the goals of this section as well as other aspects of this bill, consider adding support for trial networks that support the conduct of trials at the point of care. Point of care trials utilize digital health tools and decentralized trial approaches to engage with frontline health care providers to broaden participation and answer important research questions. Efforts during the pandemic, such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, have included aspects of point of care trials, but faced challenges achieving broad and diverse patient participation. Additional Congressional support for enhancing existing and emerging trial platforms to enable meaningful large-scale trials that maximize learning from patient participation and minimize burden on participating providers can help us answer questions about COVID-19 now and have the clinical trial capacity necessary to address other vital health questions in the future.

Sec. 503

This approach might be extended to allow FDA to incent or require sponsors to participate in master protocols, rather than being beholden to sponsor-initiated requests for expediting development. Such a change may not be tenable in non-emergency situations, but would be very helpful for organizing limited resources and response time for determining safety and effectiveness of treatments (both repurposed and new) in a public health crisis.

- **Recommendation**: Create a research prioritization body, including a national priority disease list and national roadmap for priority investments in clinical trials infrastructure. Paired with the authority already included in this section, this prioritization effort can ensure the country is prepared to adapt quickly to public health emergencies.

Sec. 504

- **Recommendation:** Congress should consider if, along with the expansion of third party review, pandemic readiness platforms supported by NIH in close collaboration with FDA should be developed and sustained outside of public health emergencies (e.g., focusing on therapies for respiratory illnesses) to allow faster, more standardized clinical trials of diagnostics, with the ability to prioritize testing diagnostic products based on scalability, price, and features.

Sec. 505

Generally, RWD/RWE may be helpful in transitioning from an EUA to approval, but concerns about data quality, completeness, and timeliness may need to be addressed on a case by case basis particularly for at-home tests where only limited data may have been reported. FDA could provide further guidance on this topic.

Sec. 506

We commend support for advanced platform technologies, such as the successful mRNA vaccine platform, in this bill. However, the features and benefits of the advanced platform technology designation should be clarified relative to existing regulatory initiatives that could be synergistic and well-coordinated. Existing FDA authority allows the agency to grant products breakthrough or fast track designations, which include the ability for product sponsors to engage earlier and more often with the FDA. Additionally, sponsors may already reference products with similar mechanisms or targets, as would be the case with these advanced platform technologies. In additional to the guidance mandated in the bill, we suggest that the text also require FDA to engage with platform technology stakeholders to determine how best to implement FDA support for advanced platform technologies.

Sec. 507

Generally, information about unapproved products is never disclosed by the FDA. This would open the door for the agency to share some information, which may help overall coordination efforts in a public health emergency depending on how much the FDA decides to disclose.

Sec. 512

- **Recommendation:** Clarify whether this applies only to new drug applications or to existing products. As outlined in the Margolis Center's 2021 whitepaper, appropriate funding through the joint DoD/FDA Shelf Life Extension Program (SLEP) could be leveraged to 1) proactively review the expiration dating of all medical countermeasures and essential medicines and 2) where appropriate, initiate FDA-administered stability testing to extend the expiration dating.

Sec. 513

- **Recommendation:** Unannounced Pilot Programs in China and India should be made permanent with funding appropriated.
- **Recommendation:** Unannounced remote inspections should be implemented in all domestic and foreign facilities.
- **Recommendation:** In addition, FDA should identify additional countries to expand unannounced inspection programs to as soon as possible.
- **Recommendation:** FDA should be given the authority to restrict products from importation into the US if manufacturers and/or foreign countries do not comply with unannounced inspection programs.

Sec. 516

- **Recommendation:** Communication from industry regarding known upcoming medical drug and device shortages should be mandatory.

Sec. 518

- **Recommendation:** Consider opportunities to harmonize these efforts with existing FDA initiatives encouraging adoption of advanced manufacturing technologies, including the FRAME regulatory framework, the Emerging Technology Program, and the CBER Advanced Technologies Team.
- **Recommendation:** To create concrete measures of success, this section should include yearly targets in terms of number and/or share of new approvals using advanced manufacturing technologies as well as number of existing products that transition from outdated manufacturing technologies to advanced manufacturing technologies.
- **Recommendation:** Consider also waiving FDA filing fees for advanced manufacturing technologies.
- **Recommendation:** Direct FDA to identify outdated technologies that should be designated with a "grandfathered" approval status. For "grandfathered" products:
    - Manufacturers must implement a plan to move away from outdated technologies.
    - FDA approval can be revoked if a competitor comes to market with a newer technology.
- **Recommendation:** Clarify what an "advanced manufacturing designation holder" is. Once a manufacturing method is designated as advanced, would others who use the same method need to apply for a designation separately?