



March 29, 2023

The Honorable Bernard Sanders  
United States Senate  
332 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Bill Cassidy, M.D.  
United States Senate  
455 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Robert Casey  
United States Senate  
393 Russell Senate Office Building  
Washington, DC 20510

The Honorable Mitt Romney  
United States Senate  
354 Russell Senate Office Building  
Washington, DC 20510

Submitted electronically to: [PAHPA2023Comments@help.senate.gov](mailto:PAHPA2023Comments@help.senate.gov)

**Re: *Pandemic and All-Hazards Preparedness Act (PAHPA) Request for Information***

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey and Senator Romney:

Thank you for providing the opportunity to the Partnership for Safe Medicines (PSM) to comment on the Request for Information (RFI) on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). We applaud the Senate Health, Education, Labor, and Pensions (HELP) Committee’s bipartisan leadership and ongoing commitment to improving the nation’s biosecurity and preparedness infrastructure and look forward to working with the Committee on a timely, bipartisan reauthorization of policies that strongly consider the perspectives of the stakeholder community.

Comprised of nearly 45 member organizations spanning the prescription drug supply chain - from manufacturers to wholesalers and community practitioners to pharmacists and patient advocacy groups - PSM is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines and medical supplies. Our goal is for all consumers to be aware of the prevalence of counterfeit, misbranded or substandard medicines and medical products, and actively work to educate patients, medical professionals, and consumer groups on how to buy medication safely and affordably, without risking their lives.

Developing bipartisan legislation that considers lessons learned during the COVID-19 pandemic response, aims to improve the nation’s public health infrastructure and preparedness to respond to the next public health threat, and adequately resources and funds the safety and security of our prescription drug supply chain is vital to promoting the resiliency and efficacy of our medicines and medical devices and the continuity in access to safe medicines in times of crisis.

PSM appreciates the Committee’s thoughtful approach to seeking stakeholder input in the development of consensus policy proposals. Timely reauthorization and collaboration across the public and private sectors are essential to ensuring the nation’s readiness and ability to proactively address future public health crises. In our comments, PSM reflects on the lessons learned from the COVID-19 pandemic and provides our recommendations to address the most critical national health security threats that demand increased attention.

**Lessons Learned: Counterfeiters Exploited Every Aspect of the COVID-19 Pandemic**

Since the first cases of COVID-19 surfaced in the United States in mid-January 2020, criminals and counterfeiters found ways to profit while endangering everyone with [common scams](#).<sup>1</sup> Americans experienced severe shortages in

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<sup>1</sup> The Partnership for Safe Medicines. “Avoid #COVIDScams - A Partnership for Safe Medicines Public Education Campaign.” <https://www.safemedicines.org/covid-19-resources>.

essential supplies<sup>2</sup>, such as hand sanitizer, paper products, and medical supplies, while illicit trading of counterfeit products and fake medicines surged<sup>3</sup>. Criminals with no legitimate connection to the medical supply market sold fake N95 masks, surgical gloves, disinfecting wipes, and at-home tests at vastly inflated prices. Drug counterfeiters sold ineffective and counterfeit treatments, fake vaccines and fraudulent prescription medicines to treat the virus. Additionally, hucksters peddled misinformation that created demand for pharmaceutical products that had valid uses in other therapeutic areas.

### **COVID-19 Scams Cost Everyday Americans Millions Every Month**

Americans lost approximately \$13.4 million to COVID-19 related scams in the first three months of 2020 alone.<sup>4</sup> The shortage of much needed over the counter (OTC) supplies early on in the pandemic drove Americans to rely on unsafe sources of information and to purchase critical items from new, unverified online sources for medications. The U.S. Homeland Security Investigations' (HSI) COVID-19 crime initiative, [Operation Stolen Promise](#)<sup>5</sup>, seized over \$48 million in illicit proceeds, opened more than 1,000 criminal investigations, and made more than 2,000 seizures of mislabeled, fraudulent, or prohibited COVID-19 vaccines, test kits, and equipment, including the confiscation of [more than 21.2 million counterfeit respirator masks](#).<sup>6</sup>

Concurrently, the Food and Drug Administration (FDA) warned consumers and companies alike of the risks to purchasing medicines, treatments and supplies online, emphasizing the harm fraudulent COVID-19 products could have on patients directly. The FBI also produced [tips for public education](#)<sup>7</sup> on the emerging fraud schemes related to COVID-19 vaccines, and PSM published its own [PSA graphics](#)<sup>8</sup> on how to avoid COVID-19 vaccine scams.

PSM, in our efforts to raise public awareness, actively tracked the prevalence of counterfeit COVID-19 products and medicines flooding the market, including seeing fake COVID-19 vaccines make their way into the global supply chain. In fact, PSM [successfully purchased genuine empty Pfizer and Moderna COVID-19 vaccine vials](#)<sup>9</sup> on eBay, and quickly reported this emerging public health threat to the FDA and manufacturers so relevant agencies and organizations could aptly react.

### **Rogue Actors Took Advantage of the Pandemic to Introduce Dangerous Products Into the US Supply Chain**

For nearly twenty years, Americans have been growing increasingly comfortable ordering consumer products online and, during the pandemic, increased their purchases from [rogue, unlicensed online drug sellers](#)<sup>10</sup> masquerading as pharmacies for a variety of reasons: ease of ordering online during lockdown, disinformation-driven desire for unapproved therapies, and attempts to obtain medicines in shortage.

While most Americans would not easily encounter an unlicensed brick and mortar pharmacy in their hometown, it's easy to find them online. In fact, it's much harder to find actual licensed pharmacies online because of the proliferation of unlicensed ones.<sup>11</sup>

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<sup>2</sup> The Washington Post. "Face mask shortage prompts CDC to loosen coronavirus guidance."

<https://www.washingtonpost.com/health/2020/03/10/face-mask-shortage-prompts-cdc-loosen-coronavirus-guidance/>.

<sup>3</sup> Organisation for Economic Co-operation and Development (OECD). "Webinar Series: Illicit trade at the time of the pandemic."

<https://www.oecd.org/gov/illicit-trade/webinar-series-illicit-trade-and-covid19.htm>.

<sup>4</sup> CNBC. "Americans have lost \$13.4 million to fraud linked to COVID-19." Apr. 15, 2020. <https://www.cnbc.com/2020/04/15/americans-have-lost-13point4-million-to-fraud-linked-to-covid-19.html>.

<sup>5</sup> U.S. Department of Homeland Security, Immigration and Customs Enforcement. "Operation Stolen Promise."

<https://www.ice.gov/topics/operation-stolen-promise>.

<sup>6</sup> Homeland Security Today. "ICE HSI Marks Anniversary of Operation Stolen Promise with \$48M in COVID-19 Fraud Proceeds." Apr 20, 2021. <https://www.hstoday.us/subject-matter-areas/customs-immigration/ice-hsi-marks-anniversary-of-operation-stolen-promise-with-48m-in-covid-19-fraud-proceeds/>.

<sup>7</sup> Federal Bureau of Investigations. "Federal Agencies Warn of Emerging Fraud Schemes Related to COVID-19 Vaccines." Dec. 21, 2020.

<https://www.fbi.gov/news/press-releases/federal-agencies-warn-of-emerging-fraud-schemes-related-to-covid-19-vaccines>.

<sup>8</sup> The Partnership for Safe Medicines. "Tracking COVID-19 Scams." <https://www.safemedicines.org/track-covid-19-scams>.

<sup>9</sup> The Partnership for Safe Medicines. "Vaccine Trash Makes Cash." Mar. 29, 2021. <https://www.youtube.com/watch?v=KG5QmOiW2eU>.

<sup>10</sup> The National Association of Boards of Pharmacy. "Rogue RX Activity Report." <https://nabp.pharmacy/wp-content/uploads/2020/05/Rogue-Rx-Activity-Report-May-2020.pdf>.

<sup>11</sup> Alliance for Safe Online Pharmacies Global Foundation. "2021 Survey: American Perceptions and Use of Online Pharmacies."

[https://asopfoundation.pharmacy/wp-content/uploads/2021/07/ASOP-Global-Foundation-2021-Consumer-Behavior-Survey-Key-Findings\\_Final-7.9.2021.pdf](https://asopfoundation.pharmacy/wp-content/uploads/2021/07/ASOP-Global-Foundation-2021-Consumer-Behavior-Survey-Key-Findings_Final-7.9.2021.pdf).

During lockdown, many Americans moved a great deal of their purchasing power online, including an unsafe spike in the use of unlicensed foreign websites pretending to be safe and legitimate pharmacies. The danger of such pharmacies is well-documented. [NIH-funded researchers recently published the results of an experiment](#)<sup>12</sup> where they ordered antimicrobials from a variety of online pharmacies. The findings: oftentimes, they had their funds stolen with no products delivered and, for the products that were delivered, they saw safety problems in packaging. They also tested the medications received and found they contained contaminants, known impurities, and additional drug analogs of unknown identities.

Unapproved therapies also saw a surge in popularity during the pandemic. Bleach, colloidal silver, honey, and magic lanyards are some of the unapproved therapies with no efficacy evidence that became popular during the pandemic and proliferated online. Additionally, many manufacturers of unapproved COVID-19 tests entered the marketplace, many of which were unreliable in preventing or treating the virus. You can see a variety of these products on the [FDA's photo archive](#).<sup>13</sup>

### **Mitigating Damage From Disinformation that Caused Patients to Hoard Unapproved Treatments**

Online mis- and disinformation campaigns touted the unapproved use of medicines to treat COVID-19 that had no therapeutic evidence, or in some cases, had evidence proving no therapeutic effect. As fraudsters with a variety of motivations continued to push these ineffective treatments anyway, it began to create shortages for the on-label patient communities that depend on these treatments. One such example is [hydroxychloroquine, a drug used by lupus patients](#).<sup>14</sup> The resulting artificially-induced shortage not only allowed the proliferation of COVID-19 disinformation, but it also created a space for rogue actors to take advantage of and introduce unsafe drugs to the secure prescription drug supply chain.<sup>15</sup>

As the Committee evaluates the lessons learned from the COVID-19 pandemic and ways in which to bolster our nation's emergency preparedness for the next public health crisis, we must consider the resiliency of our healthcare system. Stay-at-home orders, isolation, and fear of the spread of COVID-19 gave too many Americans a false sense of security with purchasing necessary medicines and medical products from unsafe, unverified online sources, exacerbating the prevalence of counterfeit medicines within our supply chain. Thanks to this Committee and policies it has passed and implemented, the U.S. prescription drug supply chain is the safest, most secure supply chain in the world, and it is imperative we do not lose sight of those successes.

## **HHS Program Effectiveness & Public Health Emergency Coordination**

### **The Drug Supply Chain Security Act**

Over the past two decades, counterfeiters have become increasingly savvy and expanded into medicines for cancer, heart disease, cholesterol, HIV/AIDS, and many other therapeutics. Congress recognized this as an emerging public health threat and, in 2013, passed the [Drug Supply Chain Security Act \(DSCSA\)](#)<sup>16</sup> to enhance the Department of Health and Human Services' (HHS) ability, through the FDA, to "[protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful](#)."<sup>17</sup>

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<sup>12</sup> National Institute of Health. Mackey TK, Jarmusch AK, Xu Q, Sun K, Lu A, Aguirre S, Lim J, Bhakta S, Dorrestein PC. Multifactor Quality and Safety Analysis of Antimicrobial Drugs Sold by Online Pharmacies That Do Not Require a Prescription: Multiphase Observational, Content Analysis, and Product Evaluation Study. *JMIR Public Health Surveill.* 2022 Dec 23;8(12):e41834. doi: 10.2196/41834. PMID: 36563038; PMCID: PMC9823576. <https://pubmed.ncbi.nlm.nih.gov/36563038/>.

<sup>13</sup> Food and Drug Administration. Photo Archives. "Fraudulent Coronavirus Disease 2019 Products."

<https://www.flickr.com/photos/fdapictures/albums/72157713334402986>.

<sup>14</sup> Lupus Foundation of America. "State Action on Hydroxychloroquine and Chloroquine Access." <https://www.lupus.org/advocate/state-action-on-hydroxychloroquine-and-chloroquine-access>.

<sup>15</sup> Ibid.

<sup>16</sup> Congress.gov. H.R.3204 - Drug Quality and Security Act. <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>.

<sup>17</sup> Food and Drug Administration. The Drug Supply Chain Security Act. <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>.



The DSCSA provided steps for HHS and FDA to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the U.S., to improve the detection and removal of potentially dangerous drugs from the drug supply chain, and to protect U.S. consumers from substandard medicines, while establishing national licensure standards for wholesale distributors and third-party logistics providers and requiring these entities to report licensure and other information to FDA annually.

Essentially, the DSCSA requires that pharmaceutical supply chain trading partners - from manufacturer to dispenser - use a serialization system to enhance pharmaceutical supply chain security. In general, manufacturers are required to serialize products, and downstream trading partners may only accept serialized products. These trading partners must also exchange and store transaction information as product moves through the supply chain, including product transaction histories. These transaction logs serve as a form of birth certificate for medicines within the U.S. prescription drug supply chains, allowing each stakeholder insight and visibility into where a product originated, when it moved through the supply chain and which trading partners had access to the supply as it moved its way from the factory floor to the hands of patients.

The U.S. has invested hundreds of millions of dollars to implement the DSCSA, and even though it has not yet been fully implemented (it's currently in its final year of implementation), [it has already proved successful in catching and preventing counterfeit medicines from harming patients](#).<sup>18</sup>

In [January 2022](#), a network of little-known drug suppliers and distributors sold illicit and potentially dangerous fake versions of Gilead's HIV medicines that ended up in pharmacies and in the hands of patients.<sup>19</sup> One pharmacist, upon review of the accompanying sales history, became suspicious of the product and used the falsified transaction log information to verify with Gilead and AmerisourceBergen, the listed wholesaler, that the medication passed through their hands, only to realize they were entirely fake, as were the transaction logs accompanying the medication.

Luckily, this pharmacist quickly isolated the fake medicines and prevented it from being dispensed to patients in his community. His verification efforts show how the DSCSA can be used to protect patients and justify the costs borne by supply chain participants during the DSCSA's 10-year implementation.

Final implementation is expected this year, and Congress must ensure it continues to support these efforts to protect patients, not only as part of the safety of our supply chain, but especially during times of crisis. As the Committee works to reauthorize the PAHPA to better prepare and respond to emergency situations, appropriate funding on efforts to protect the supply chain, including FDA's efforts to continue implementing the DSCSA (e.g., through guidance), are critical.

For example, in a hypothetical future fungal pandemic, an Operation Stolen Promise IV could be rapidly set up to actively pursue pandemic-related fraud. Pandemic-specific medicines start experiencing intermittent shortages, bad actors start soliciting pharmacists with too-good-to-be-true offers on medicines in short supply, and pharmacists report these suspicious sale offers to Operation Stolen Promise IV. Law enforcement engaged in Operation Stolen Promise IV then work with pharmacies reporting these suspicious offers to test buy and trace suspicious medicines, in attempts to identify where they actually came from and to build a case if product is found to be illegally diverted or counterfeit.

Moreover, to combat in the influx of untrusted and unverified online websites from taking advantage of patients and consumers during future pandemics and drug shortages, Congress should increase transparency into owners and operators of online websites selling illicit and controlled substances by reinstating broad law enforcement access to bulk WHOIS information and requiring domain name registrars and registries to lock and suspend domain names

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<sup>18</sup> The Partnership for Safe Medicines. "The DSCSA's Impact, PSM's February 28th, 2023 Congressional Briefing." Feb. 28, 2023. [https://www.youtube.com/watch?v=83HIBefMX\\_0&t=263s](https://www.youtube.com/watch?v=83HIBefMX_0&t=263s).

<sup>19</sup> Wall Street Journal. "Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs." Jan. 18, 2022. <https://www.wsj.com/articles/drugmaker-gilead-alleges-counterfeiting-ring-sold-its-hiv-drugs-11642526471>.



known for illegally selling counterfeit prescription medicines, controlled substances, and unapproved medical products.

### **Drug Shortages**

Several factors, including global pandemics and unexpected public health emergencies, can cause or contribute to drug shortages. Ensuring there are as few disruptions to patient care as possible, Congress has already required manufacturers of certain drugs to report to FDA of certain suspected shortages. Further, manufacturers work closely with FDA to address potential drugs shortages.

Emergency importation of products during a shortage is enormously resource-intensive on FDA personnel and increases risks to American patients, no matter how carefully it is monitored, as they operate outside of the controlled confines of the DSCSA and provide limited or no tracing ability for medicines imported. Congress should be very careful not to allow new, non-traditional pathways for medicines in shortage into the nation's closed, secure prescription drug supply chain to address other issues, such as market failures or financial barriers to accessing healthcare, lest it reduce the safety of America's "safest in the world" pharmaceutical supply chain.<sup>20</sup> Congress needs to ensure that emergency response efforts, or efforts to address short-term drug shortages, do not undermine or undo crucial DSCSA provisions and implementations.

Unclear or vague definitions around drug shortages only hurt innovation, patient access, and trust in the U.S. prescription drug supply chain. Legislative proposals that attempt to redefine problems such as financial barriers to care as shortages are ill-conceived and put patient safety at undue risk during times of crisis. Rather than focusing on dubious and unnecessary legislation, Congress should focus legislative efforts on discouraging dangerous buying habits that push Americans to rely on unsafe, unverified sources, often foreign networks trafficking in illegal, illicit or inferior products. The growth of counterfeit medicines and fake pills is already a significant public health crisis and Congress must do more to discourage consumer behavior that can jeopardize patient safety.

### **Public-Private Partnerships**

The COVID-19 pandemic emphasized the critical importance of public sector and private industry collaboration to tackle emerging public health threats swiftly and efficiently. Coordinated public awareness campaigns that leveraged the influence and reach of industry and government enabled federal, state and local entities to rapidly disseminate real-time information and public safety alerts as we learned more and more about the virus and its impacts on our communities.

The value of public-private partnerships within the healthcare sector cannot be understated and offer opportunities for states and localities, community-based organizations, private sector and non-government stakeholders, such as hospitals and health care providers, and government to all raise awareness in a coordinated fashion. Campaigns, such as the [DEA's One Pill Can Kill Campaign](#)<sup>21</sup> and the FDA's [BeSafeRX Campaign](#)<sup>22</sup> offer models that can be scaled up during a pandemic and by which the Committee can base future public-private partnerships off of.

The Committee should also evaluate the pandemic's successful public-private partnerships and take steps to bolster and expand those most impactful. Enhancing and augmenting collaboration between industry and government supports pharmaceutical supply chain resilience and should not be limited to just times of public health emergencies. Both the public and private sectors have strengths and weaknesses, and neither sector can work independently to address the comprehensive needs during global pandemics or public health emergencies. Educational campaigns & PSA coordination are key activities to alerting the public of potential risks to patient safety and patient health.

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<sup>20</sup> U.S. Congress, 117th Session, Senate Health, Education, Labor, and Pensions Committee, "Executive Markup of S. 4348, S. 958, S. 4353, H.R. 1193, and S. 4052." June 14, 2022. Statement by Former Ranking Member Richard Burr. <https://www.help.senate.gov/hearings/s-4348-s-958-s-4353-hr-1193-and-s-4053>.

<sup>21</sup> Drug Enforcement Administration. "One Pill Can Kill Campaign." <https://www.dea.gov/onepill-toolbox>.

<sup>22</sup> Food and Drug Administration. "BeSafeRx: Your Source for Online Pharmacy Information." <https://www.fda.gov/drugs/quick-tips-buying-medicines-over-internet/besafexr-your-source-online-pharmacy-information>.

As it reflects on lessons learned from the pandemic, the Committee has an opportunity to assess the strengths and weaknesses of both the public and private sectors, identify areas of partnership that would be most valuable, evaluate the impacts and effectiveness of existing partnerships during the COVID-19 pandemic, and determine which should be enriched. PSM frequently engages in partnerships with law enforcement coalitions, patient advocacy groups, community stakeholders, and other public health organizations in the face of public health threats, [such as the current crisis of fake Adderall made with methamphetamine](#)<sup>23</sup> or the [danger of Mexican pharmacies selling counterfeit medicine](#)<sup>24</sup>, and can offer further insights into valuable programs and approaches that have proven most successful in educating and raising public awareness.

### **PSM Policy Recommendations**

The emergence of the COVID-19 pandemic underscored the importance of having a comprehensive emergency response infrastructure in place for pandemics and public health crises. Supporting quality assurance programs and establishing a drug distribution system that is without compromise are simple ways in which we can reduce the number of counterfeit prescription drugs and medical products defrauding patients and compromising care.

As the Committee works on updating and refining the U.S. response to global pandemics and public health emergencies, PSM urges you to keep in mind the following policy recommendations:

- **Maintain U.S. prescription drug supply chain integrity** by reinforcing policies and regulations that heighten the safety and efficacy of U.S. prescription drugs, secure and protect the pharmaceutical supply chain, and educate the public on the prevalence of fraudulent medical products and counterfeit medicines. This includes increasing spot checking of packages for medicines in shortage or likely to be in shortage.
- **Increase communication and information sharing** between state regulators and federal health authorities to discourage “disinformation-driven prescribing” practices that cause drug shortages and drive black markets in medicine.
- **Leverage public-private partnerships between industry, law enforcement, patient groups, and other relevant stakeholders.** As we witnessed during the COVID-19 pandemic, warnings or fears of shortages alter consumer behaviors and that patients will consider purchasing medicines and medical supplies from unregulated, unapproved, and unverified sources during times of uncertainty and crisis. Congress should formalize public-private partnerships with relevant stakeholders in order to rapidly disseminate public safety alerts, associated risks to health, and potential dangers of going outside the safe and secure prescription drug supply chain.
- **Ensure online sellers operate in compliance with existing laws, regulations and platforms’ terms of service, and domain registrars.** Fake online pharmacies have been selling questionable - if not outright dangers, substandard or illegal and illicit substances - to Americans for years. To reduce this threat, Congress should increase transparency into owners and operators of online websites selling illicit and controlled substances by reinstating broad law enforcement access to bulk WHOIS information and requiring domain name registrars and registries to stop doing business with illegal actors endangering public health online. Congress can use the FDA and the Department of Commerce’s National Telecommunications and Information Administration’s (NTIA) [trusted notifier pilot program](#)<sup>25</sup> as a model for legislative improvements.

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<sup>23</sup> The Partnership for Safe Medicines. “Counterfeit Adderall Pills.” <https://www.safemedicines.org/2021/10/fake-adderall.html>.

<sup>24</sup> The Partnership for Safe Medicines. “Fake Blood Thinners Found in Mexican Pharmacies.” <https://www.safemedicines.org/2022/04/buying-medicine-in-mexico.html>.

<sup>25</sup> National Telecommunications and Information Administration. “NTIA, FDA Pilot Program to Curb Access to Illegal Opioids Online Delivers Promising Results.” U.S. Department of Commerce. <https://ntia.gov/blog/ntia-fda-pilot-program-curb-access-illegal-opioids-online-delivers-promising-results>.



- **Assume fraud will begin quickly** and stand up anti-fraud programs, using the “Operation Stolen Promise” model as quickly as possible in a pandemic or emerging public health emergency. Congress should also urge law enforcement agencies to use the DSCSA to increase spot checks of medicines that are likely to be in shortage to help prevent the entry of fraudulent products into our supply chain.

In closing, PSM applauds your bipartisan commitment to improving the nation’s public health response capabilities during times of crisis and emergency. PSM looks forward to working with the Committee, under your leadership, to develop a cohesive and holistic domestic national strategy for addressing future global pandemics, drug shortages, and emergency situations.

We thank you for the opportunity to submit comments on the Reauthorization of PAHPA and stand at the ready to assist the Committee however necessary. If you have any questions regarding our comments or need more information, please contact me or feel free to have a member of your team reach out to Stacey Barrack, PSM’s Director of Government Affairs.

Sincerely,

A handwritten signature in black ink that reads "Shabbir Imber Safdar".

Shabbir Imber Safdar  
Executive Director

