Hearing Entitled "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"
House Energy and Commerce Subcommittee on Health
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Testimony of

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Introduction

Health Subcommittee Chairman Carter, Ranking Member DeGette, Committee Chairman Guthrie, Ranking Member Pallone and Members of the Subcommittee, thank you for the opportunity to testify today about the state of the U.S. drug supply chain.

My name is Josh Bolin and I am Associate Executive Director of Government Affairs and Innovation for the National Association of Boards of Pharmacy, or NABP.

NABP is a 501(c)(3) nonprofit association that, for over 120 years, has protected public health by assisting its member boards of pharmacy in all 50 states that are responsible for regulating the practice of pharmacy and the supply chains within their states. With my testimony today, I would like to highlight the threats to regulated supply chain(s), as well as other patient safety threats posed by the internet and other emerging, un, or underregulated markets.

Background: Drug Supply Chain Security Act (DSCSA)

As the Subcommittee is aware, the Drug Supply Chain Security Act (DSCSA) passed into law in 2013 and provided a phased window for the pharmaceutical supply chain to achieve interoperable data sharing and electronic tracing of products to prevent suspect and illegitimate products from harming patients.

The DSCSA provides essential tools that trading partners in the supply chain, and state and federal regulators can utilize to detect unsafe medications. First, products should now be serialized down to the individual saleable unit—meaning there is a unique number for each product and product packaging contains a 2D barcode that can be scanned. Once scanned, trading partners and regulators can ask about the legitimacy of the product's identifiers, or who owned the product previously. (See Figure 1)

Figure 1 – What Tools Does DSCSA Provide to Detect Counterfeit Medications?

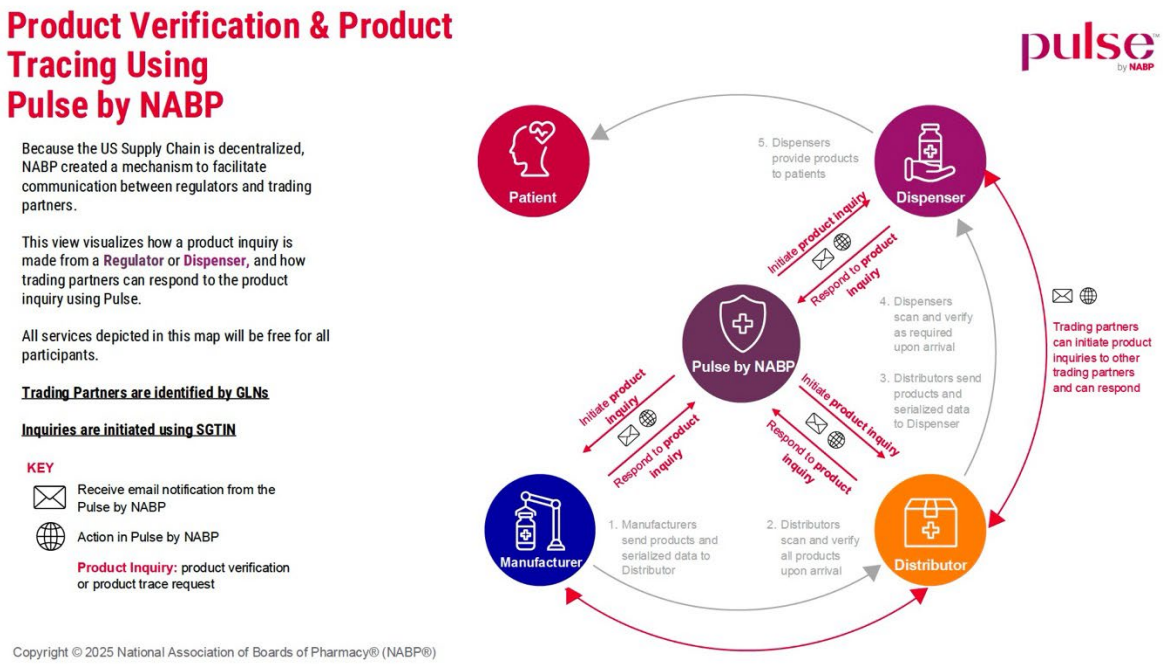
Massive amount of data is needed to communicate across the supply chain. For just a single year of supply chain data, you are talking about 16-20 *billion* transactions that need to be sifted through in order to fully utilize the DSCSA tools.

DSCSA Implementation: Progress to Improve Supply Chain Security

Given the massive amount of data, NABP started working with our member boards of pharmacy and all sectors of the supply chain to conduct pilots that led to the development of Pulse by NABP™, which is NABP's digital platform for DSCSA that we launched in January. The best way to think about Pulse is that it is a directory for all the manufacturers, distributors and

pharmacies in the supply chain, as well as all the products that move through it. Utilizing Pulse, regulators and trading partners can scan the 2D bar code of a product and ask questions of trading partners about the product. NABP is providing the tools to our members and every pharmacy in the U.S. supply chain at no cost – because the tools of DSCSA only work if they are accessible and easy to use. (See Figure 2)

Figure 2 – How Does Pulse Support Supply Communication?



We rolled out Pulse to our member boards of pharmacy in mid-January. The very first scans that were conducted utilizing Pulse helped the Arkansas and Mississippi Boards of Pharmacy in identifying illegitimate/counterfeit GLP-1 medications that had made their way into our "legitimate" supply chain. From a congressional perspective, DSCSA WORKED, but it illustrated that our supply chain is susceptible to illegal actors. Since January, we have nearly 30 states utilizing the tool and not just boards of pharmacy, but non-Board of Pharmacy regulatory authorities, including Attorneys General and Drug Enforcement Administration field offices.

Figure 3 – Illegitimate Product Identified in Arkansas Using Pulse by NABP

Addressing Emerging Threats to Supply Chain Security

While we've made progress and DSCSA helps, we still face challenges and threats to supply chain security. First, regarding medications offered over the internet - NABP has a host of resources we can share about the dangers of purchased medications over the internet, but the primary highlight is that in our work, we estimate that 96% of online pharmacies in operation at any given time are illegal, violating state and federal laws. And research shows the majority of Americans falsely believe that websites offering prescription medicines have been approved by FDA or boards of pharmacy. People increasingly trust that medications on the internet are safe and regulated, but that is not always the case.

Second, NABP's members have flagged a disturbing trend in the "loosely" regulated space of medspas. For example, one state board uncovered an operation where a medspa had set up shop in their home and was "compounding" or "mixing" purported "GLP-1 medications" with vitamin B-12, in their bedroom. This medspa was "compounding" using active pharmaceutical

ingredient that was obtained not from an FDA-registered API manufacturer as required by law, but from an international online source advertising cheap weigh loss APIs. The medspa simply mixed these ingredients, drew it up in syringes and then mailed them to individuals in plastic bags. This is just one example from a state that has authority to regulate these entities. Unfortunately, we know that activities like this are going on in every state—but most state boards lack the authority to do anything about it.

While there are absolutely legitimate sources for obtaining medications on the internet, unfortunately, bad actors are using the opacity and capacity of internet platforms to peddle medications, putting profits over patient safety. And to be clear, legitimate compounding has an essential role in our supply chain to ensure patients have access to medicines they need that are not commercially available, but those simply mixing medications in nonsterile environments and calling it compounding are a threat to that legitimate practice. Given the popularity of certain medications – those who believe they can make a dollar over demand for a popular medication—will do just that irrespective of the impact it has on patients.

With that, I would like to thank the committee for the invitation and for your attention, and I would be happy to answer any questions.