Testimony Before the Committee on Energy & Commerce, Subcommittee on Health United States House of Representatives April 25, 2013

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Good morning Chairman Pitts, Ranking Member Pallone, and members of the Committee. The National Association of Boards of Pharmacy (NABP) appreciates the opportunity to appear before you today and provide information in regard to safeguarding the integrity of the nation's drug supply chain. I am Carmen Catizone, executive director of the Association.

NABP is the impartial professional organization that supports the state boards of pharmacy in protecting the public health. NABP aims to ensure the public's health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs.

Twenty Five Years of "Proposed" and" Delayed"

The issues before the Committee are not new. In fact the timeline for trying to secure our nation's prescription drug supply chain extends farther back than many would care to admit and farther back than should be permitted. Quoting from the FDA's web site: "The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law by the President April 12, 1988. The PDMA was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs."

The activities that ensued since that time can best be described using two words, "proposed" and "delayed." The language found throughout multiple Federal Register notices since the implementation of the PDMA 25 years ago read similarly over and over. One example reads "On February 23, 2004 (69 FR 8105), FDA published a delay of the effective date of certain requirements in a final rule published in the Federal Register of December 3, 1999 (64 FR 67720)." The proposals presented by the FDA and supported by the states were continuously delayed and defeated by pressure from the industry.

NABP supports the implementation of a national system for the oversight and regulation of the prescription drug supply chain provided such system is comprehensive and does not discard the effective protections already in place and readied for implementation by the states, particularly California. In addition, NABP supports a national system provided it allows the states to have input into the development and recognizes the authority of the states to implement necessary modifications to address significant instances that may arise and were not contemplated or included in any national proposal. The national system supported by NABP is absolutely essential to the protection of the public we serve and to ensuring that the medications patients across the United States are dispensed or administered are safe and not counterfeit, diverted, or injurious in any way.

As some of you may be aware, NABP is intimately involved in the oversight of wholesale distributors as a result of our Verified-Accredited Wholesale Distributors (VAWD) program. To date, NABP has surveyed and accredited approximately 552 wholesale distributors across the states. As a result of those surveys and the valuable information and expertise that NABP gained, we can report to you that some of the issues originally driving the enactment of the

PDMA in 1987 have been addressed and resolved. There are, however, still a number of critical concerns that threaten the distribution supply chain that must be addressed. It was our hope that many if not all of these issues would be the focus of legislation proposed and adopted by the House and Senate. Our analysis of the legislative proposal released just a few days ago indicates that it may not address these serious issues.

Besides some of the high profile abuses that have been reported in the media, NABP observed first hand and reported to the applicable state and federal authorities breaches in, and compromises to, the prescription drug supply chain. These breaches and compromises include, but are not limited to, the lack of complete or the absence entirely of pedigrees or other required transaction documents, pedigrees or other transaction documents that indicate a product passed through multiple entities some licensed and others not, multiple wholesaler companies located in a one-room strip mall business office claiming some form of common ownership, wholesalers receiving and storing products under conditions that render the medications adulterated or contaminated, and wholesalers and pharmacies, establishing as their sole operating model the purchase and sale of shortage drugs and inflating the prices of these products by a thousand-fold – an unconscionable action when it comes to drugs that are needed by patients suffering from life-threatening conditions such as cancer.

The States Serve as the Last Defense for Patients and Consumers

The states are both the front line and last line of defense in the prescription drug supply chain. Since the inception of the PDMA, the states have had to forge a system of oversight and regulation to protect the integrity of products in the supply chain absent a national system because for 25 years the industry has fought such state and federal efforts and delayed implementation of a proposed solution.

The Institute of Medicine's report, "Countering the Problem of Falsified and Substandard Drugs," notes that "crime and corruption drive the business of falsified medicines." The report further documents that "medicines can change hands many times in myriad countries before they reach patients." One of the primary recommendations of the IOM report is critical to the considerations before this Committee and bears noting this morning:

"The IOM committee calls for strengthening the drug distribution system in order to improve the quality of medicine and protect consumers. Top among its priorities is restricting the U.S. wholesale market to firms vetted by the National Association of Boards of Pharmacy. This action would tighten the American drug distribution chain and build momentum for better controls on drug wholesalers in developing countries."

Recommendations

1. Support the existing and successful public-private partnership system, VAWD that NABP established with the states and is endorsed by the Institute of Medicine. NABP asks the Committee to consider the priority recommendation of the IOM and support the effective public private partnership that currently exists between NABP and state and federal regulators, protecting the integrity of the drug supply chain at no cost to the American taxpayers.
2. No further delays. NABP believes that the time has long passed for any continued delay in addressing and resolving the challenges confronting our nation's prescription drug supply chain. The timeline for federal action in the proposed legislation extends the wait of consumers and patients for a protected supply chain to 35 years! California's requirements can be operational over the next three years and help to build the uniform and national standards that all stakeholders support. In comparison over the past 30 years the following notable advances occurred:
    a. Internet, broadband, www (browser and html)
    b. PC/laptop computers
    c. Mobile phones
    d. E-mail
    e. DNA testing and sequencing/human genome mapping
    f. Magnetic Resonance Imaging (MRI)
    g. Microprocessors
    h. Fiber optics
    i. Office software (spreadsheets, word processors)
    j. Non-invasive laser/robotic surgery (laparoscopy)
    k. Open-source software and services (e.g., Linux, Wikipedia)
    l. Light-emitting diodes
    m. Liquid crystal display (LCD)
    n. GPS systems
    o. Online shopping/e-commerce/auctions (e.g., eBay)
    p. Media file compression (jpeg, mpeg, mp3)
    q. Microfinance
    r. Photovoltaic solar energy
    s. Large- scale wind turbines
    t. Social networking via the Internet
    u. Graphic user interface (GUI)
    v. Digital photography/videography
    w. RFID and applications (e.g., EZ Pass)
    x. Genetically modified plants
    y. Bio fuels
    z. Bar codes and scanners
    aa. ATMs
    bb. Stents
    cc. SRAM flash memory
    dd. Anti-retroviral treatment for AIDS

3. All participants in the supply chain must be accountable. Exemptions should not be granted to pharmacies.
4. The tracking and traceability of products should be to the package level and operational in 2015 and 2016 in order not to retreat on the advances made by California and the timelines already committed to by a growing number of the industry.
5. Pharmacies and wholesale distributors must append and pass pedigrees or other equivalent transaction documents within the next two to four years.
6. Establish a process for the routine and regular verification of product serial numbers.
7. Provide the Food and Drug Administration (FDA) with the full scope of authority and resources needed to implement and enforce a national system.

Conclusion

NABP thanks the Committee for the opportunity to appear today and present information and concerns from the state boards of pharmacy. The Association and its member state agencies support a comprehensive national solution to the challenges facing the integrity of our prescription drug supply chain. However, that supply chain must place public safety first and not undo the significant advances made by the states and FDA to ensure that American citizens across the country receive safe and effective medications.

Thank you.