June 23, 2025

The Honorable Kristi Noem
Secretary
Department of Homeland Security
Washington, DC 20528

Dear Secretary Noem:

The undersigned organizations, collectively representing national interests in the pharmaceutical supply chain, including all state pharmacy boards, wholesale distributors, pharmacists nationwide, and the pharmacies that dispense needed medications to patients, write to urge you to reverse a Biden Administration ruling announced by the U.S. Customs and Border Protection (CBP) that would, for the first time, require that country-of-origin (COO) marking be included on prescription drug labels that are dispensed by pharmacies and provided directly to patients. Many of us joined in urging CBP to reconsider its ruling. CBP has not answered our request but has instead recently announced an intention to begin enforcing its requirements. As explained more fully below, if implemented, CBP's ruling would interfere with other federal and state statutory and regulatory requirements governing the dispensing of prescription drugs; unduly burden pharmacies; and, ultimately, place patient safety at risk.

I. Background

CBP is charged with interpreting and enforcing Section 304 of the Tariff Act which generally requires that articles of foreign origin (or its container) imported into the U.S. shall be marked with its country of origin. CBP's regulations have made clear that all commodities imported into the United States, unless excepted by law, must be conspicuously labeled with the country of origin so that the "ultimate purchaser" in the United States can make an informed purchasing decision.[1]

[1] CBP regulations define "ultimate purchaser" generally as "***the last person in the United States who will receive the article in the form in which it was imported***; however, for a good of a NAFTA or USMCA country, the "ultimate purchaser" is the last person in the United States who purchases the good in the form in which it was imported." 19 C.F.R. § 134.1(d)(emphasis added). The regulation acknowledges that it is "not feasible to state who will be the 'ultimate purchaser"' in every circumstance" and provides a number of examples to illustrate how CBP makes this determination. The examples explain, in essence, that if a manufacturer "subjects the imported article to a process which results in a substantial transformation of the article," the manufacturer is considered the ultimate purchaser. In contrast, if the manufacturing process "leaves the identity of the imported article intact" or if "the article is to be sold at retail in its imported form," the retail customer is considered the ultimate purchaser. Id. So, determining the "ultimate purchaser" for purposes of COO marking requirements necessitates a highly fact-specific inquiry.

Prescription drugs are often imported in bulk quantities and are then dispensed by pharmacists to patients after providing dispensing related services in accordance with state and federal law. The pharmaceutical and pharmacy industries have operated **for decades** under the premise that the pharmacies—not the customers at the pharmacy counter—are the ultimate purchasers for purposes of country-of-origin labeling requirements and that such requirements were met so long as a drug's COO appeared on the packaging received by the pharmacy. CBP had been silent on the issue until this ruling, which was made during the Biden Administration in response to a request for internal advice.[2] According to this Ruling Letter and subsequent Fact Sheet, CBP has suddenly changed course and takes the position that the "ultimate purchaser" is the pharmacy's *retail customer* and accordingly, prescription medication dispensed by the pharmacy and sold to retail customers must include the COO marking on the packaging.[3]

The American Pharmacists Association (APhA), the American Society of Health-System Pharmacists (ASHP), the Healthcare Distribution Alliance (HDA), the National Association of Boards of Pharmacy (NABP), the National Association of Chain Drug Stores (NACDS), the National Association of Specialty Pharmacy (NASP), the National Community Pharmacists Association (NCPA) and the Retail Industry Leaders Association (RILA) believe that the Biden Administration CBP's interpretation of Section 304 was based on incorrect assumptions, which led to the interpretation of the term "ultimate purchaser" in a manner that is contrary to the facts and is inconsistent with congressional intent. On behalf of our members, we respectfully request that you direct CBP to reverse its ruling or otherwise exempt pharmacies from this burdensome requirement.

II. CBP's Application of COO Marking to Pharmacies Under the Previous Administration Was Legally Flawed

As we explained to CBP more fully in our reconsideration request, pharmacies—not the patient — should be considered the ultimate purchasers of the medications they dispense for purposes of the COO marking laws. The rationale outlined in the Ruling Letter was premised on a fundamental mischaracterization of pharmacies as "repackagers" of prescription drugs.

However, pharmacies provide a range of professional services that go far beyond the simple act of physically placing drugs into separate containers. These services include medication management, patient counseling, drug utilization reviews, and ensuring the safe and effective use of medications. Pharmacists are trained healthcare professionals who assess patient needs, monitor drug interactions, and provide personalized care. In short, pharmacists **dispense** medication to individual patients pursuant to a prescription, they do **not repackage** it into retail

[2] U.S. Customs and Border Protection, Internal Advice Letter H283420 (June 14, 2024), https://rulings.cbp.gov/ruling/H283420 [hereinafter ("Ruling Letter")]. CBP acknowledged that, until this Ruling Letter, there had been no other rulings or guidance to address the "specific issue of country of origin marking of repackaged pharmaceuticals from a retail pharmacy." Ruling Letter at 3.

[3] U.S. Customs and Border Protection, Fact Sheet, Marking of Prescription Medication for Retail Sale, https://www.cbp.gov/sites/default/files/2024-08/FACT SHEET Marking Prescription Medication for Retail Sale.pdf.

containers. A patient who obtains a prescription drug from a pharmacy does not receive the drug in the same form in which it was imported. The patient instead receives a valuable professional service that is bundled along with the drug. The dispensing pharmacy, therefore, should be considered the ultimate purchaser for purposes of COO marking.

Indeed, pharmacies that dispense medication to individual patients are not considered repackagers by the Food and Drug Administration (FDA), and they are distinct from commercial drug repackagers under the Drug Supply Chain Security Act (DSCSA) and the Federal Food, Drug, and Cosmetic Act (FDCA). Pharmacies are a crucial link in the pharmaceutical supply chain, and they must comply with a complex set of federal and state regulations governing the dispensing of prescription medications. Commercial drug repackagers are subject to different regulatory requirements, including adherence to good manufacturing practices, labeling, and FDA registration regulations. Notably, under these statutory regimes enacted since the 1904 Tariff Act, Congress did not require country-of-origin marking for products dispensed by pharmacies even though there were multiple opportunities to do so. Under the DSCSA, prescription drugs are required to be labeled with a product identifier for tracking and tracing purposes at the package level that is intended by the manufacturer for sale to the dispenser.[4] This is a **clear manifestation that Congress considered pharmacies, not individual customers, to be the ultimate purchasers** of prescription drugs in the supply chain.

CBP ultimately failed to consider the complex regulatory regime governing the prescription drug supply chain and oversimplified the role of pharmacies when it rendered its decision outlined in the Ruling Letter.

III. CBP's Interpretation of Section 304 of the Tariff Act Under the Previous Administration Threatens Patient Safety and Is Not Workable

1. Adding Extraneous Information to Prescription Labels Creates Patient Safety Risks

CBP also failed to consider how its Ruling Letter would affect patient safety or its potential to conflict with other prescription labeling laws. Pharmacy operations are shaped by state board of pharmacy regulations, which include requirements for prescription labels to enhance patient safety. State boards of pharmacy, along with FDA, regulate the information that a pharmacy must provide to the patient when dispensing a medication. Because of the wide variability in prescription container labels, the U.S. Pharmacopeial Convention (USP), in conjunction with the Institute for Safe Medication Practices, developed standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by

[4] 21 U.S.C. § 360eee (11)(A).

pharmacists.[5] NABP passed a resolution supporting state boards in requiring a standardized prescription container label.[6] The NABP resolution explains that "the purpose of the prescription label is for the patient" and that "the **only** information needed on the label is **information the patient needs to take the medication correctly**." The resolution further states that the "elimination of data elements not required for patient safety will increase readability and understanding by allocating more white space, increasing the ability to use larger font size, providing more space so as not to truncate medication names or directions, and affording space for a description of the medication on the patient's medication container label." A systematic review of studies investigating the textual elements on drug labels confirms that only the most essential instructions should be included on a pharmacy label, because of the limited space available on the label, and that these instructions should be presented in a concise way.[7]

According to USP's guidelines, information that is critical for patients' safe and effective use of the medicine should be prominently displayed on the prescription label. This includes the patient's name, drug name and strength, and explicit clear directions for use in simple language. Other less critical but important content (including the pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and certain auxiliary information) can be included on the label, but should not supersede the critical patient information listed above. Auxiliary information should be limited, evidence-based, presented in a standardized manner, and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts).

COO information is simply not needed for the safe and effective use of prescription medication. Adding this information to the prescription label would reduce the amount of white space on the label and potentially detract from the critical information that is required to appear on the label. Because this information is not critical auxiliary information, **adding COO information could run afoul of state pharmacy laws and regulations**, putting pharmacies in an untenable position.

2. *CBP's Interpretation of Section 304 Under the Previous Administration is Not Workable*

CBP's ruling completely ignored the fundamental framework that governs the roles and responsibilities of trading partners in the drug supply chain and failed to take into account the enormous regulatory burden that the Ruling Letter would impose on pharmacies when it decided

[5] *See*, USP Press Release, USP-NF General Chapter 17 Prescription Container Labeling (Nov. 13, 2012), https://www.usp.org/health-quality-safety/usp-nf-general-chapter-prescription-container-labeling.
[6] *See*, NABP Resolution No. 108-1-12, Uniform Outpatient Pharmacy Prescription Container Labels Designed for Patient Safety, https://nabp.pharmacy/news/news-releases/uniform-outpatient-pharmacy-prescription-container-labels-designed-for-patient-safety-resolution-108-1-12/.
[7] E. Maghroudi *et al*., "The impact of textual elements on the comprehensibility of drug label instructions (DLIs): A systematic review." PLOS ONE 16(9): e0258020, https://doi.org/10.1371/journal.pone.0258020.

that COO marking is required for each prescription bottle they dispense. Pharmacies and other trading partners in the prescription drug supply chain are already subject to various requirements under the DSCSA for the purpose of establishing an interoperable and electronic method to identify and trace prescription drugs at the package level as they move through the supply chain.

The DSCSA established an elaborate tracking and tracing system that requires the cooperation of various trading partners, who have built or reconfigured their systems and workflows to comply with these requirements. These security requirements include adherence to standards for the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner and the verification of product at the package level. Notably, **Congress did not include country-of-origin information on the list of information that must be exchanged by trading partners in the prescription drug supply chain,** even though it had a clear opportunity to do so if it intended for Section 304 of the Tariff Act to apply to **dispensers**.

Congress was aware of the U.S. country-of-origin marking requirements when it enacted the DSCSA. If Congress intended that pharmacy bottles dispensed to individual patients be imprinted with COO information, it would have required trading partners in the prescription drug supply chain to exchange electronic package-level COO information along with all the other transaction information that they are required to exchange.

3. ***The Ruling Letter Imposes Excessive Costs with No Commensurate Benefit***

In addition to incorrectly applying the law, the Ruling Letter imposes costs on industry that far exceed any conceivable benefit to consumers. Patients do not purchase prescription medications off-the-shelf whereby they would plausibly look at the container label for COO before purchasing. Patients purchase medications after taking other factors into consideration, including the advice of their prescriber, potential side effects and drug interactions, and whether the drug is covered by their insurance. Patients do not select which medicine to take based on the country of origin, nor do they have the ability to do so.

Furthermore, CBPs' requirement would require pharmacies to reconfigure their workflows and pharmacy technology systems – at an unsustainable cost. The various DSCSA requirements described above were phased in gradually, beginning in 2013, in part due to the complexity of requiring multiple types of trading partners in the supply chain to integrate with one another. Since the enactment of the DSCSA, FDA has recognized the challenges for industry trading partners associated with implementing the law and consequently issued several compliance policies extending the deadlines for the industry to come into compliance with various requirements. Industry participants have reported difficulties with establishing the necessary connections among their trading partners to facilitate secure, interoperable, electronic DSCSA data exchange.

In response to these concerns, FDA has exempted pharmacies and other trading partners from these enhanced drug distribution security requirements and has extended various deadlines for compliance "to accommodate additional time that trading partners in the prescription drug supply chain need to implement, troubleshoot, and mature systems and processes to fully implement" these systems. FDA has also conducted pilot projects and published guidance to facilitate the creation of a uniform methodology for the secure interoperable exchange of product tracing information.

Despite FDA's guidance and the enormous resources industry has spent on these efforts, it has taken **more than a decade** for the entire prescription drug supply chain to build and implement interoperable systems to effectuate this law. Pharmacies have naturally developed their processes and workflows around the DSCSA requirements. Even pharmacies that have fully implemented interoperable systems would not receive country-of-origin information from their trading partners—either electronically or otherwise—since country-of-origin information is not an element that is required to be provided in the transaction documentation. There is not a feasible way to automatically populate a technology system with COO information at the package level, so the addition of this information to the dispensed container would have to be done through a manual process that would impede the safe and efficient dispensing of prescriptions to patients.

Adding these steps would disrupt the pharmacy workflow, cause more delays and backups in filling prescriptions for patients, and could require pharmacies to hire additional personnel. Forcing pharmacies to incur additional personnel costs and make additional outlays for technology adjustments to comply with this rule is untenable for the industry, which is already straining to comply with DSCSA requirements. Moreover, pharmacies are currently facing unsustainable financial pressures because they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs, forcing many pharmacies to close. This new COO marking requirement would add a financial burden to the industry that cannot be recovered through reimbursement, threatening to further exacerbate the financial crisis.

Under the statute, articles can be exempt from country of origin marking if they cannot be marked after importation except at an expense which is economically prohibitive.[8] CBP's Ruling Letter imposes excessive costs with no commensurate benefit, is an unnecessary and unwarranted application of origin marking law, and will have severely disruptive operational impacts on pharmacies, all from a sudden, unanticipated ruling. Moreover, the Ruling Letter is a prime example of regulatory overreach and runs afoul of the President's deregulatory initiative aimed against regulations that impose significant costs upon private parties that are not outweighed by public benefits.[9]

[8] 19 U.S.C. § 1304(a)(3)(K).
[9] 90 Fed. Reg. 10,583 (Feb. 25, 2025).

IV. COO Information Can Be Provided by Less Burdensome Methods

Although we dispute the Ruling Letter and do not agree that U.S. patients are well-served by having COO information on the label of their prescription bottles, we stand ready to work with you to identify other ways to provide such information to patients. As explained above, the Ruling Letter is overly burdensome primarily because compliance will require a manual process since COO information is not currently being exchanged by trading partners and is therefore not imported into the pharmacy technology systems that are used to mark the labels for the prescription bottles. One solution is to allow pharmacies to provide COO information to patients only upon request. This approach would empower and encourage patients to interact with pharmacy personnel regarding their prescription medication. Pharmacies can facilitate patient inquiry by posting a sign at the pharmacy point-of-care or by providing an information leaflet explaining that this information is available upon request. Another potential solution is to make COO information publicly accessible through a website that is maintained by a government agency (e.g., the FDA) and populated by information obtained from manufacturers.

V. Conclusion

We urge you to work with CBP to ensure this erroneous interpretation of the COO marking requirements is reversed or to otherwise exempt pharmacies from these burdensome marking requirements. Thank you for your consideration.

Sincerely,

American Pharmacists Association (APhA)
American Society of Health-System Pharmacists (ASHP)
Healthcare Distribution Alliance (HDA)
National Association of Boards of Pharmacy (NABP)
National Association of Chain Drug Stores (NACDS)
National Association of Specialty Pharmacy (NASP)
National Community Pharmacists Association (NCPA)
Retail Industry Leaders Association (RILA)

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The American Pharmacists Association (APhA) is the largest association in the United States, advancing the entire pharmacy profession and representing our nation's over 340,000 pharmacists, 30,000 student pharmacists, and more than 400,000 pharmacy technicians. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care.

The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients.

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.

NABP is the independent, international, and impartial 501(c)(3) nonprofit Association that assists its state member boards and jurisdictions for the purpose of protecting the public health. NABP was established in 1904 to assist the state boards of pharmacy in creating uniform education and licensure standards. Today, we help support patient and prescription drug safety through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy accreditation and inspection programs.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and

help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries.

The National Association of Specialty Pharmacy (NASP) is a non-profit trade organization representing the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; some pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies. NASP is the unified voice of specialty pharmacy in the United States

Founded in 1898, the National Community Pharmacists Association (NCPA) is the voice for the community pharmacist, representing over 18,900 pharmacies that employ more than 205,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible health care providers.

The Retail Industry Leaders Association (RILA) is the U.S. trade association for the world's largest, most innovative, and recognizable retail companies and brands. The organization convenes decision-makers, advocates for the retail industry, and promotes operational excellence and innovation. RILA members include more than two hundred retailers, product manufacturers, and service suppliers, who together employ over 42 million Americans and account for $2.7 trillion in annual sales and hundreds of thousands of stores, manufacturing facilities, and distribution centers domestically and abroad.