October 24, 2024

Felicia Pullam
Executive Director
Office of Trade Relations
Customs and Border Protection
1300 Pennsylvania Ave, N.W.
Washington, D.C. 20229

Submitted via email: felicia.m.pullam@cbp.dhs.gov

Re: Pharmacy Concerns Regarding U.S. Customs and Border Protection Ruling on Prescription Marking for Country of Origin (COO)

Dear Executive Director Pullam:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) jointly request a meeting to discuss the U.S. Customs and Border Protection (CBP) June 14, 2024 interpretive ruling regarding country of origin (COO) marking for prescription medication bottles that pharmacies dispense to patients, as well as the recently issued CBP Fact Sheet, both indicating that medication bottles that pharmacies dispense to patients must be marked with the COO on the packaging that the patient receives.

We believe that CBP's interpretive ruling was not in line with the spirit of the law, and that CBP should revert to its previous interpretation that pharmacies and medical service providers are the ultimate purchasers of prescription medications. Such an interpretation would then negate the need for COO marking to be included on prescription bottles filled at a retail pharmacy and dispensed to patients.

CBP notes in the recently issued Fact Sheet:

> Marking is required by law (19 U.S.C. § 1304 and 19 C.F.R. § 134.11); however, there are exceptions to the rule. Certain commodities listed in 19 C.F.R. § 134.33 are excepted from individual country of origin marking. This list is known as the J-List. "Chemicals, drugs, medicinal, and similar substances, when imported in capsules, pills, tablets, lozenges, or troches," are excepted articles set forth on the J-List. Articles on the J-List are exempt from having to be individually marked; however, the outermost container that ordinarily reaches the ultimate purchaser of a J-List article must be marked with the country of origin of the article.

However, in the Fact Sheet, CBP goes on to state:

> In situations where imported medication is repackaged in bottles by retail pharmacies and sold for individual use, **the customer at the retail pharmacy is the last person to receive the medication in the form in which the medication is imported, and thus, is**

> **considered the ultimate purchaser for purposes of 19 U.S.C. § 1304.** (emphasis added).

We respectfully disagree. In these circumstances, the last person to receive the medication in the form in which it was imported is the retail pharmacy. Pharmacies do not merely repackage medications from larger bottles into smaller bottles. The dispensing of medications by a pharmacy is part of a suite of services that can only be provided by licensed pharmacists. Pharmacists provide related critical services, including ensuring that the patient receives correct quantities, strengths, indications, instructions, and warnings, as well as patient counseling.

Pharmacies are not mere "repackagers." Each container of prescription medication may only be dispensed pursuant to a legal and valid prescription order. It is notable that FDA exempts pharmacies from the requirements of repackagers when the medication is repackaged under the direct supervision of a licensed pharmacist and dispensed pursuant to a valid prescription for a specific patient. Moreover, the bottle and labeling the pharmacy provides does not include other carton or packaging information that would otherwise be required by FDA such as the National Drug Code (NDC).

In CBP's June 14 interpretive ruling, the agency states that "a retail customer's purchasing decision is not based on a particular service provided by the pharmacists, as such services are uniform from pharmacy to pharmacy. Instead, a retail customer as the ultimate purchaser is deciding whether or not to purchase medication from a pharmacy based on factors such as the medication's country of origin and/or manufacturer." We find this statement to be woefully misinformed. In fact, patients rarely base their decision on what prescription medication to purchase based on the medication's COO and/or manufacturer. First and foremost, patients are prescribed medication by their health care provider; patients do not independently choose which prescription medications to purchase. The prescriber makes prescription medication decisions based on their training and expertise. Second, patients choose their pharmacy based on their relationship with the pharmacist and pharmacy personnel, convenience, insurance coverage, and other factors that are completely unrelated to the country from which the prescription medication was imported. Patients do not purchase prescription medications off the shelf whereby they would plausibly look at the container label for COO before purchasing. Finally, FDA-approved labeling and other information about prescription medication is available to patients who seek additional information before filling or picking up the prescription.

CBP's interpretative ruling is a stark departure from more than a century of standard pharmacy practice. Requiring pharmacies to now include the COO on prescription bottles would impose undue burdens on pharmacy practice. Since pharmacists presently do not provide this information on prescription bottles, pharmacy workflow would need to be reconfigured to allow pharmacists to view the COO and somehow mark that information on the prescription bottle. This would cause widespread disruption of pharmacy practice nationwide as pharmacy computer systems are not designed to capture this information. Every pharmacy computer system nationwide and its software would need to be redesigned and reconfigured to capture this information and mark it on the prescription bottle. This would cost millions of dollars in technology upgrades and could take years to accomplish.

In addition, we fear that this requirement would greatly exacerbate existing prescription drug shortages because pharmacies would be forced to dispense medications in manufacturer-provided

stock bottles that are already marked with the COO. They would not be able to utilize larger stock bottles that are broken down into smaller quantities for dispensing. Hence, we fear that patients may have increasingly difficult experiences obtaining their life-saving prescription medications.

We thank you for your consideration of our concerns. We ask that you respond to this meeting request by contacting Christie Boutte, Senior Vice President, Reimbursement Innovation and Advocacy, National Association of Chain Drug Stores, at cboutte@nacds.org or Ronna Hauser, Senior Vice President, Policy & Pharmacy Affairs, National Community Pharmacists Association at ronna.hauser@ncpa.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

B. Douglas Hoey, Pharmacist, MBA
Chief Executive Officer
National Community Pharmacists Association

cc:
AnneMarie R. Highsmith, Executive Assistant Commissioner, Office of Trade, Customs and Border Protection
Neera Tanden, Director, Domestic Policy Advisor to the President
Xavier Becerra, Secretary, Department of Health and Human Services
Gina Raimondo, Secretary, Department of Commerce
Lee Verbois, Director, Office of Drug Security, Integrity, and Response, Food and Drug Administration