

September 26, 2022

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2021-N-0862: Nonprescription Drug Product With an Additional Condition for Nonprescription Use, Proposed Rule

Submitted via email for [Docket No. FDA-2021-N-0862](#)

Dear Food and Drug Administration staff:

The American Pharmacists Association (APhA), the National Community Pharmacists Association (NCPA), the American Society of Consultant Pharmacists (ASCP), the National Alliance of State Pharmacy Associations (NASPA), and the National Association of Chain Drug Stores (NACDS) are writing to request that a public listening session for the record be held to identify and discuss patient safety considerations related to the Food and Drug Administration (FDA)'s recently proposed rule entitled "Nonprescription Drug Product With an Additional Condition for Nonprescription Use." **We also request that FDA extend the comment deadline for this proposed rule by at least 90 days to allow stakeholders to appropriately respond.**

APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for older adults. ASCP's thousands of pharmacist members manage drug therapies and improve the quality of life of geriatric patients and others living in various settings, including sub-acute and long-term care (LTC) facilities, skilled nursing facilities (SNFs), assisted living facilities, group and adult homes, psychiatric hospitals, hospice programs, correctional facilities, home and community-based care.

NASPA is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' 80 chain 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 pharmacy community appreciates FDA's intent behind this proposal to improve public health by broadening the types of nonprescription drug products that are available to consumers. However, we have significant concerns that the essential role a pharmacist plays in helping patients safely use medications has not been appropriately considered or addressed within this proposed rule, in addition to logistical and operational issues.

We believe that a listening session or public hearing on the record will enable FDA to more fully understand the logistical and operational impact that this rule could impose at pharmacies, in ways that written comments to the docket cannot provide. At such a meeting FDA would be able to ask questions to further inform the practical implementation of the rule, if finalized. Without a clear and practical regulatory approach to implementation and compliance, patient access to these products may be compromised.

According to the proposed rule, under an additional condition for nonprescription use (ACNU), a drug manufacturer must ensure that patients can appropriately self-select a medication. That a patient seeking this new category of medication would need to meet qualifying criteria of the ACNU underscores the patient safety imperative for involving pharmacists in the provision of care for these therapies. While FDA has provided various examples of how patients may determine if the medication chosen is appropriate (e.g., online questionnaires, videos with assessment, information provided via in-store kiosks or apps,) on their own, these methods do not adequately support safe use of medications that might otherwise require a prescription.

Pharmacists are an important part of the comprehensive health care team. They educate and counsel patients to help them find the best medication and use their medications correctly and safely. We believe pharmacists must play an integral role in guiding patients to determine whether a particular nonprescription drug product with ACNU is appropriate for an individual patient's healthcare needs.

APhA, NCPA, ASCP, NASPA, and NACDS appreciate FDA's efforts to broaden access to safe medications, however, we strongly believe the pharmacist's role is essential to this process, in addition to the logistical and operational issues. We look forward to continuing this discussion in a public listening session for FDA staff to hear from stakeholders about the role pharmacists must play in this process and an appropriate extension of the comment deadline for this proposed rule by at least 90 days to allow stakeholders to appropriately respond.

If you have any questions or require additional information, please contact APhA's Heather Boyd, MPP, Director, Health Policy at hboyd@aphanet.org; NCPA's Steve Postal, JD, Director, Policy & Regulatory Affairs at Steve.Postal@ncpa.org; ASCP's Jim Lewis, Director of Policy and Advocacy at jlewis@ascp.com; NASPA's Joni Cover, JD, Vice President of Strategic Initiatives at jcover@naspa.us, and NACDS's Sara Roszak, DrPH, MPH, Senior Vice President of Health and Wellness Strategy and Policy at sroszak@nacds.org.

Sincerely,

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