NCHR's Comment on proposed ruling for Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU).

November 25th, 2022

We are pleased to have the opportunity to express our views for the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) on the proposed ruling for Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU).

The National Center for Health Research (NCHR) is a nonprofit think tank that conducts, analyzes, and scrutinizes research on a range of health issues, with a particular focus on which prevention strategies and treatments are most effective for which patients and consumers. We do not accept funding from companies that make products that are the subject of our work, so we have no conflicts of interest.

We appreciate the FDA's interest in establishing requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). FDA states that this would be for drug products that could be "marketed without a prescription if an applicant implements an additional condition to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner." However, the FDA has not identified a mechanism to ensure appropriate use. Based on our experience with patients across the country, we believe it would be impossible to do so. For that reason, we do not support the proposed ruling.

The FDA points out that nonprescription drug products are currently limited to drugs that can be labeled with sufficient information for consumers to appropriately self-select and use the drug product. We agree with the FDA that labeling limitations can "present challenges for adequate communication of information needed for consumers to appropriately self-select or use the drug product without the supervision of a healthcare practitioner." Although the proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, there is no way to ensure that it would "improve public health." Although it would broaden the types of nonprescription drug products available to consumers, it would not ensure appropriate use by those consumers. It could therefore be very harmful to individuals and to public health.

Our nonprofit research center has extensive experience sharing information with patients harmed due to the misuse of medical products because they did not understand the risks. In some cases, the information was not provided to patients or not read by ~~the~~ patients. In other cases, the patients did not fully understand or focus on instructions for appropriate use or contraindications, and therefore were not cautious in their use of the product. The FDA states that their proposed ACNU guidelines are "intentionally broad to give applicants flexibility regarding the types of additional conditions applicants may propose and how those additional conditions can be implemented." Unfortunately, even if the FDA required that manufacturers make printed or

digital instructions easy for the average adult to read and understand, that would still leave approximately half the adult population at risk of being unable to comprehend those instructions. The risks of this proposal would outweigh the benefits even if the FDA could ensure that no more than one-tenth of the patients did not fully comprehend the instructions.

Although the FDA's guidelines are too broad and do not hold manufacturers sufficiently accountable, the problem is more fundamental. Regardless of how the FDA defines terms like "meaningful difference" and "key elements," for example, there is no way to ensure patients will use ACNU products as appropriately as they would if physicians were prescribing them.

If you have any questions, we can be reached at info@center4research.org or (202) 223-4000.