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Public Health Groups Doubt FDA's ACNU Proposal Will Expand OTC Access, Benefit Public Health

Public Citizen, National Center for Health Research, American Heart Association Have Concerns

by Malcolm Spicer

Agency has comments from Public Citizen, National Center for Health Research and American Heart Association to consider among 182 submitted on proposed published in June. FDA set a non-binding target date of October to publish "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" final rule.

Expanding access to nonprescription drugs and improving public health aren't likely to result from a US Food and Drug Administration proposed rule targeting those and other goals, say Sidney Wolfe and other public health advocates.

The agency has comments from Wolfe and others submitted in November to consider among the 182 submitted to the docket – *FDA-2021-N-0862* – for the proposed published in June; the FDA has set a non-binding target date of October to publish a "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" final rule.

Before the agency publishes a final rule, the Public Citizen's Health Research Group and the National Center for Health Research advocacy groups and the American Heart Association recommend changes they say will ensure access to OTC drugs will be expanded and public health will benefit as a result.

Wolfe, Public Citizen's Health Research Group founder and senior advisor, argues that the proposed rule leaves too much chance and offers too little evidence supporting the FDA's plan to

require OTC switch sponsors to submit, along with new or abbreviated drug applications, separate documents supporting making drugs available through an additional condition for nonprescription use (ACNU) approval.

"I am not aware of any US study that has researched the effectiveness/outcome of the 'additional condition for nonprescription use.' Without such information on at least several specific drugs before finalizing the regulation as well as solving the problems above, the regulation is not approvable," Wolfe, a longtime critic of FDA's regulation of the pharma industry and of drug manufacturers, stated in *comments*.

The FDA says an ACNU approval will be needed when a firm convinces the agency that labeling on a package isn't sufficient to ensure a consumer can appropriately self-select and use a drug as a nonprescription product; consumers could access additional information needed for self-selection online or through other digital connections. The proposed ACNU rule states that a sponsor must first show the agency that traditional OTC labeling wouldn't work to switch an Rx ingredient before submitting its ACNU proposal for the ingredient. (Also see "*Expanding US OTC Switches Turns On Flexibility In FDA Drug Approval Process And For Consumers*" - HBW Insight, 27 Jun, 2022.)

> *"I am not aware of any US study that has researched the effectiveness/outcome of the 'additional condition for nonprescription use'." – Sidney Wolfe, Public Citizen*

The proposed rule also would allow the same ingredient at the same dose to remain available Rx after being approved for nonprescription sales so consumers who cannot or will not use digital connections to determine if they should use an ACNU-approved drug.

Wolfe stated that additional information available online won't be enough to safely guide consumers to self-selection of drugs for which indications, warnings and directions won't fit on a container label.

"Pharmacists are the only health professionals who could theoretically ensure appropriate self-selection or appropriate actual use," he wrote.

'Several Serious Problems With Implementing' …

However, pharmacists have indicated in surveys that they are reluctant to diagnose consumers'

conditions and prescribe treatments, Wolfe added.

A review of 65 published studies looking at other countries' experience with pharmacists providing additional condition for use without a doctor's prescription showed a lack of support for pharmacists prescribing largely was linked to accountability for prescribing; limited pharmacist diagnosis skills; lack of access to patient clinical records; and organizational and financial support, according to Wolfe's comments.

Those concerns, he said, "highlight several serious problems with implementing such a system" in the US. Potential problems include:

- limited pharmacist diagnosis skills;
- lack of access to patient clinical records;
- accountability for prescribing;
- shifting of cost from insurers to patients since OTC drugs are usually not covered by insurance;
- costs of additional training for pharmacists as well as reimbursement for their time needed to advise consumers on ACU-approved OTCs.

The agency has made drugs for chronic conditions a centerpiece of its initiative launched in 2012 to make more ingredients available OTC; because determining whether a drug to treat high cholesterol isn't as straightforward as reaching for aspirin or other oral analgesic for a headache, for instance, the FDA also has placed at the center of its initiative an expectation that consumers would need access to information not available on a Drug Facts label, such as online, to determine whether they should use a drug indicated for a chronic condition and available nonprescription. (Also see "*Innovation In OTC Switches Takes Multimedia Approach In US FDA Draft Guidance*" - HBW Insight, 17 Jul, 2018.)

… Where's The 'Mechanism To Ensure Appropriate Use'? …

The National Center for Health Research notes that although the FDA proposes an ACNU process would "ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner," the agency "has not identified a mechanism to ensure appropriate use."

Based on the NCHR's experience with US consumers, "we believe it would be impossible to do so" and it doesn't support the proposal, according to its *comments*.

The center agrees 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."

However, although the proposal intends to increase options for switch sponsors to develop and market safe and effective OTCs, "there is no way to ensure that it would 'improve public health'," the NCHR added.

"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."

In Comments And In Person, Pharmacist Groups Remind US FDA They'll Provide ACNU Help

By Malcolm Spicer

28 Nov 2022
Pharmacist groups' representatives, in meeting with FDA officials, reiterate argument for greater role in access to OTCs through "additional conditions for nonprescription use." Group not at meeting, American Society of Health-System Pharmacists, suggests "intermediate approach to nonprescription status."

Read the full article here

… Maximize 'Equitable Access To Those With Limited Health And Digital Literacy'?

President Michelle Albert stated in the American Heart Association' *comments* that an ACNU requirement could limit rather than expand access to a drug made available nonprescription. Proposing digital channels for consumers to self-select a nonprescription drug isn't enough, Albert wrote.

> ***"We have concerns that the proposed rule does not adequately ensure that the ACNU be operationalized in a manner that maximizes equitable access to those with limited health and digital literacy or other limitations who otherwise would be eligible to obtain a nonprescription drug with an ACNU." – AHA President Michelle Albert***

The AHA has "concerns that the proposed rule does not adequately ensure that the ACNU be operationalized in a manner that maximizes equitable access to those with limited health and digital literacy or other limitations who otherwise would be eligible to obtain a nonprescription drug with an ACNU. Ensuring equitable access through the offering of modalities or multiple modalities (i.e., telephonic as well as kiosk or mobile application options to accommodate those with different digital literacy or comfort levels) designed to maximize access to eligible individuals is an important factor that should be included in the criteria for approval," she wrote.

Determining the dosage of a drug and access to repeat purchases also should be explained in an ACNU final rule, suggests the AHA, which also includes the American Stroke Association.

"Requiring demonstration that the ACNU maximizes equitable access and how dosage and refill determinations will be made should be included as part of [NDAs and ANDAs]," Albert wrote.

As well, problems with an ACNU process which prevent a consumer from completing it should preclude purchasing the targeted product, according to the AHA. An ACNU sponsor "should be required to demonstrate in the application that safeguards are in place to deny access to the drug."

'Fail First' Requirement In ACNU Proposal Prompts Adverse Reactions Across US Drug Industry

By Malcolm Spicer

28 Nov 2022
PhRMA captures tone of its comments saying "proposed rule might play an important role" in making more drugs available OTC. AAM also references gauntlet, saying proposed pathway "would, in theory, broaden the types of nonprescription drugs available to consumers." CHPA discusses same concerns as well as additional questions for FDA.

Read the full article here

The association also argues the FDA add to ACNU post-marketing provisions "a patient-friendly website" and a telephone number for consumers to report issues. Information from consumers "will be essential and valuable if the FDA plans to expand this program or needs to make additional modifications."

Additionally, the AHA recommends "stronger warning language" on labels for ACNU drugs with potential for more adverse effects. It asks the FDA to add the phrase "as it could lead to serious adverse effects leading to hospitalization and injury" after "this step" in the label warning statement included in the proposal, "You must complete an extra step to see if this drug is safe for you before you use it. Do not take this drug without completing this step."