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The stated purpose of the proposed FDA regulation is: "To establish requirements for a nonprescription drug product that has an additional condition for nonprescription use that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner."

Pharmacists are the only health professionals who could theoretically ensure appropriate self-selection or appropriate actual use. In a 2012 Brookings workshop, concern was raised that "pharmacists were largely reluctant to prescribe statins without knowledge of a patient's medical history, often referring patients back to the care of physicians. Workshop participants also described how time constraints limited pharmacists' ability to conduct screenings and consultations. Others remarked that additional safety measures, such as mandatory questionnaires, limited consumers' willingness to participate."[1]

Other countries' experience with pharmacists providing this additional condition for use without a doctor's prescription reviewed 65 published studies:

"The aims of this systematic review were to: (1) critically appraise, synthesize and present the available evidence on the views and experiences of stakeholders on pharmacist prescribing and (2) present the perceived facilitators and barriers for its global implementation.

[1] https://www.brookings.edu/events/nonprescription-medications-with-conditions-of-safe-use-as-a-novel-solution-for-undertreated-diseases-or-conditions/

Any lack of support for pharmacist prescribing was largely in relation to accountability for prescribing, limited pharmacist diagnosis skills, lack of access to patient clinical records, and issues concerning organizational and financial support." [2]

These concerns from stakeholders in countries in which pharmacists enable patients to get medicines without a physician's prescription highlight several serious problems with implementing such a system in the United States.

A/ limited pharmacist diagnosis skills

B/ lack of access to patient clinical records

C/ accountability for prescribing

D/ the not unlikely shifting of cost from insurers to patients since OTC drugs are usually not covered by insurance.

E/ The extra costs of additional training for pharmacists as well as reimbursement for the additional time m

Beyond these impediments, I am not aware of any U.S. 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.

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[2] **Tesnime Jebara, Scott Cunningham, Katie MacLure, Ahmed Awaisu, Abdulrouf Pallivalapila and Derek Stewart. Stakeholders' views and experiences of pharmacist prescribing: a systematic review. Br J Clin Pharmacol (2018) 84 1883–1905.**

(E/ Review Fed Reg Notice)—reimbursement mentioned?

F/ Enforcement: Finally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

G/ Organizational and financial support