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July 28, 2022

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Information Collection under the Paperwork Reduction Act of 1995; 87 Fed. Reg. 38313. Docket No. FDA–2021–N-0862.

Dear Sir or Madam:

Amwell is pleased to submit comments on the information collection incorporated into the proposed rule on Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU) published by FDA on June 28, 2022 ("Proposed Rule"). The Agency has invited stakeholders to provide input on "premarket applications, postmarketing reports and recordkeeping, and labeling for nonprescription drug products with an additional condition for nonprescription use." Amwell is responding as an interested party to share its perspective on how the Proposed Rule's requirements can be addressed with a proven and connected digital care platform.

Amwell acknowledges that FDA is proposing a new paradigm and has put forth a detailed articulation of a new pathway to treatment through the ACNU. In the absence of worked examples, some stakeholders may see this as a barrier to access since the reporting requirements are new and may be perceived as a burden. Historically, creating nonprescription access to a prescription drug was accomplished through a "switch" of the drug, with FDA approval, to over-the-counter (OTC) status. To date, it has not been an OTC convention to follow consumers and track their success or failure in selecting and using the nonprescription drug product.

FDA is taking a positive step by seeking advice and guidance on the reporting requirements. We believe that FDA's proposal, if appropriately implemented, will enable access to drugs that are otherwise unavailable for consumer self-care in the absence of an ACNU. ACNU-enabled treatments will also expand access to a new generation of nonprescription products that treat many common and chronic conditions. In so doing, FDA will address the issue of undertreatment associated with these conditions.

Current technologies now make it possible to identify and track individuals as they qualify for, receive, and use an ACNU-enabled drug product. The Office of the National Coordinator of Health IT (ONC) has paved the way by establishing common data standards governing the collection and sharing of healthcare information.

In the Information Collection Notice, the Agency is soliciting comments on the alternative reporting mechanism requiring the applicant to submit a single, consolidated report for all consumers affected by the same failure in the implementation of an ACNU rather than a report for each individual impacted by the same failure. To that end, we are expressing our views concerning the feasibility or practicality of producing the proposed reports and parameters that might be applied to determine the appropriate timing of reports.

The ACNU process can be designed to identify consumers as they interact with labeling specific to the ACNU. Once identified and validated, individuals may meet additional conditions by answering questions through interactive, asynchronous conversation and, as needed, authorizing an automated query of their personal health data against objective criteria to guide appropriate self-selection or appropriate actual use, or both, by that consumer without the supervision of a healthcare practitioner.

There are likely many ways an ACNU can be implemented and satisfy the proposed reporting requirements. A connected, digital care platform can collect and record data along the consumer journey, from the point of initial interaction with the ACNU through fulfillment and ongoing use. Doing so creates a sharable record of the consumer, including their receipt and use of a treatment over time. This platform also enables the aggregation of meaningful, reportable, de-identified consumer data to capture Real World Evidence at a population level.

Concerning the central question about "*submitting an individual report to FDA for each individual failure in implementation of an ACNU encountered by a consumer resulting from the same cause of failure, as opposed to a single, consolidated report*", we believe that the nature of the failure should determine the proper reporting response. As with scheduled prescription drugs and medical devices, a scale of failure spans the potential for harm. Those failures determined to be lower risk might be reported on a consolidated basis, while failures determined to introduce high risk might be reported for each individual affected. The FDA might also consider establishing classes of failure with specific criteria and ascribing reporting requirements specific to each class of failure.

Most importantly, any reporting requirement can be met using interoperable data and system-connected processes. The recording of data is intrinsic to the digital process and the reporting can be engineered to automatically generate according to ACNU determinations. The information collection, storage, and transfer should not unduly introduce a burden as many of these processes are part of health IT operations today and can be a reference, and in some cases a resource, for ACNU programs.

Thank you for your time and attention to the important issue of undertreatment. We applaud your leadership with the introduction of the Proposed Rule. Please do not hesitate to contact me if you have any questions.

Respectfully submitted,

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