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PROCEEDINGS

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FDA MARCH 22-23, 2012 HEARING ON RX TO OTC SWITCH - CLOSING REMARKS

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I would like to summarize what I took away from the wide spectrum of views we have heard during the meeting.

I think the pharmacy organizations are generally supportive of the concept of making more prescription drugs non-prescription, with conditions of safe use that require pharmacist involvement. They feel that pharmacists are adequately trained to assist consumers in identifying whether they have particular conditions, in selecting appropriate medications, and monitoring their use over time. They have identified as advantages the ability to provide access to medical care to people who might not otherwise have access, and to provide access whenever it is needed, and close to home. They believe that this will improve medication compliance and overall healthcare outcomes, and they point to the fact that they are often the first line of contact with patients in need of healthcare and that they can refer patients to healthcare providers when they identify that they need additional care or the care of a physician. Pharmacists cited many specific examples where pharmacists have taken on an expanded role in patient care, including collaborative practice agreements in several states and medication therapy management models where studies have shown improved health outcomes.

We heard from educators about the training that pharmacists receive in pharmacy school and about continuing education requirements that could be used as a means to provide additional training for pharmacists if the new pharmacy paradigm were adopted.

Pharmacy groups did discuss several issues that would need to be addressed, including pharmacy reimbursement for services and integration of the new paradigm into the workflow of the pharmacy.

We also heard support for making drugs non-prescription based on conditions of safe use that rely on new technologies instead of pharmacy intervention, or perhaps in some cases in addition to it, to guide consumers in making the right medication choices. Algorithms and other tools could be made available through kiosks, smartphones or other technological advances that would simplify decision-making for products that require more sophisticated analysis and guidance to enable patients to take them safely and effectively without a prescription.

Some have suggested that making non-prescription drugs available with conditions to assure safe use could actually facilitate efficient and effective engagement with physicians and other members of the healthcare team. Numerous drugs and categories of drugs were cited as examples that might be considered for this new paradigm. These included medications such as epinephrine for allergic reaction, Naloxone for drug overdose, contraceptives, smoking cessation products, antihypertensive and diabetic medications, just to name a few.

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But others, including patient advocacy groups, voiced strong views that some of these products are not suitable for non-prescription use, even with conditions of safe use. There were opposing and strong views expressed about whether drugs to treat various diseases, such as asthma, would fit the new paradigm because of the characteristics of the disease.

We heard from others that this new paradigm is inappropriate, and that it could reduce the quality of patient care. Concerns were raised about the ability of pharmacists to evaluate patients and make difficult diagnostic decisions and medication choices for patients in the place of physicians. Concerns were raised about fragmenting patient care and missing opportunities to identify more serious conditions because of reduced patient interaction.

Some groups argued that there was no evidence that the new paradigm would reduce costs or improve patient care and wanted proof that the new paradigm would work. Some groups argued that the existing system of prescription and non-prescription drugs was adequate and should not be changed. They noted that FDA has already approved non-prescription drugs with additional educational materials and aids for self-selection and that various ways of making drugs available could be employed without creating a new category of non-prescription drugs with conditions of safe use.

There were practical considerations raised, such as the need to consider the effects of conditions of safe use on the drug distribution system and the need to develop a business model for the various ideas that would lead to adoption by pharmacies and others in the healthcare system. And we heard from some people about the challenge of conducting studies that would be needed to show how non-prescription drugs with conditions for safe use could be safely and effectively used by the consumer.

So we have received a lot of input and we are going to be looking very closely at what we have heard and at the comments submitted to the docket. During the course of the hearing, in some cases we asked that certain information referred to during the testimony be submitted to the docket. We will review the information that we receive and decide whether, and if so how, to go forward with this. As Dr. Woodcock indicated in her opening remarks, we will likely need to proceed through rulemaking to develop a new framework for doing this. So there will be many opportunities for further public input if the initiative does go forward.

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