

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

Janet Woodcock:

Should there be more flexibility in our concept of non-prescription drugs?

OTC drugs have had great success in providing consumers with excellent self-care options and, at the same time, providing significant health care savings from averted prescriber and emergency department visits. But our concept of self-care is really limited to conditions that can be self-diagnosed and self-treated, based on the information on the standardized 'drug facts' box on the non-prescription drug carton, combined with common knowledge and common sense.

The question we are addressing today and tomorrow is: Can we broaden the assistance that a consumer gets, for example, by augmenting the drug fact box information with information technology approaches, or by utilizing pharmacist assistance to help the consumer understand the condition or the treatment better, thus increase the types of medicines that could potentially be available without prescription?

FDA has determined that such a change would require rulemaking, and we are holding this hearing to gather information from stakeholders about the possible impacts of changing the OTC regulations, and of introducing this additional paradigm.

Some have asked us, as we have been in the process of exploring this, whether certain changes could be accomplished voluntarily by sponsors of drugs. And while it is possible that a single manufacturer could establish an enhanced OTC program, competitors could not be required by FDA to do so. Therefore, FDA could not view such a program as being essential to the non-prescription status of the drug. It would simply be an enhancement. Therefore, we feel that we would need to be able to require such changes, if they were actually needed to make the drug appropriately non-prescription.

What specific types of medication might be considered? In general, we are considering the ways in which the drug fact box information could be supplemented. First, the rules for non-prescription status were established a considerable time ago, as most of you know. That was at a time when widespread access to information technology did not exist, compared to the information technology world that we live in today. We also have to consider the fact that this world is rapidly evolving and that consumers of tomorrow will have access to all sorts of media, and sources of information, that simply weren't available 20 or 30 years ago. So, it is clear that there now may be interactive mechanisms that can take the consumer through the process of self-diagnosis and medication selection in a much more comprehensive manner than could happen by simply reading the drug facts box. It is quite likely that these steps could be displayed in a manner that could extend the concept of self-diagnosis and self-selection of treatment to additional conditions or drugs.

That is one of the things that we would like to discuss: Could information technology be deployed in ways that could augment the consumers' ability to diagnose their condition, really understand their condition, understand a drug and whether it's right for them, and even assist them in understanding how to use the drug properly, for example, with diagrams or demonstration videos?

Once we really get into this, there are multiple media mechanisms that could be employed.

Importantly, we are not considering altering the process of the OTC switch itself; in other words, the scientific process. Comprehension and use studies could still be indicated to inform the evaluation of the proposed switch. Any decisions would be data driven and based on the data for that individual product, and whatever technology enhancements were going to be employed with it. This is more about how the information would be made available to the consumer, not what quantity of evidence would be needed to decide that the product could be non-prescription.

Now, a second scenario for evaluating self-care could involve pharmacist involvement. Pharmacists could help the consumer verify the diagnosis, perhaps by going through an algorithm with them, or interpreting results of various tests for them. They could help in deciding whether the medication was right for the consumer, and they could reinforce the directions for appropriate use of the medication. So, having the pharmacist assist and having pharmacist involvement be another condition of safe use, is another type of expansion of the non-prescription concept that we are exploring.

We are also interested in input regarding pharmacist interactions with patients who already have diagnosed disorders. As we all know, large numbers of Americans who have chronic conditions, are not adherent to their medications, resulting in a significant amount of preventable harm. We are interested in ways that the pharmacy community, who are much more accessible to our population, could improve access and adherence to these types of medicines.

Now of course this particular aspect raises concerns about separating patients from appropriate medical care. I would point out we are talking about the future here. As our electronic health records and other electronic tools, such as e-prescribing, move forward, and, as patient portals evolve where patients are able to link with their health care providers, we will see even greater use of information technology in health care. Pharmacies, patients, and providers will be linked in new ways. Greater pharmacist involvement could provide an avenue to bring non-adherent individuals back to health care and get them involved in their health care. Methods to inform and link providers from the pharmacy could be developed. I think we already recognize that this is extremely important in managing continuity of care for patients, because right now, about 20 percent of patients who receive a prescription do not fill that prescription. Often, providers are unaware that their patient did not even collect the medication that was intended, so much stronger links are needed. I strongly believe that medicine needs to take medical care to where the patients are. This is one way that we will really improve both access and adherence, extremely important aspects of particularly chronic care of patients.

An additional role of pharmacists that we are considering, would be to dispense what I refer to as antidotes to individuals who could self-identify as having conditions where such an antidote might be needed and who had previously had such antidote dispensed to them. An example would be EpiPens, when they are used for anaphylaxis. Frequently people lose their EpiPens or the EpiPen gets broken. They are then at risk of a life-threatening event without access to that product. Another example would be glucagon injections for diabetics who are subject to hypoglycemia. This is another area where people can experience life-threatening events, and we think new approaches should be considered.

Pharmacists' involvement in dispensing non-prescription drugs raises another unresolved issue; that some of these drugs would have conditions of prescription use at the same time as they would have conditions of non-prescription use. Currently this scenario does prevail. As many of you know, we have different strengths and dosage forms of the same drugs, some of which are prescription and some of which are non-prescription. But we do not have the identical drug presentation available in both type of status. We would have to explore how to deal with that, since in some of the scenarios, we are proposing that the difference would be the condition of access, not the actual physical state of the drug.

Another thing we want to discuss in this meeting is that all of these potential changes raise issues of reimbursement, cost, liability, and so forth. We have asked a lot about this in our notice to stakeholders, because these are obviously very important issues, both to consumers, and to the provider community and the business community. We look forward to hearing your comments on these issues. FDA may be less knowledgeable on many of these aspects than many of the people who are attending this meeting. So, we really are sincerely seeking input.

Finally, there may be additional scenarios for non-prescription use that we have not entertained. We are really interested to hear your ideas. In addition, we are interested in crafting something for the future, a future that is not going to look anything like the past of 20 years ago. I would like us to have additional flexibility for non-prescription use, and the ability, as new circumstances and technologies arise, to incorporate those into our regulatory practices in a fluid and forward-thinking way.

Revised by author, based on oral remarks transcribed by National Capitol Contracting (200 N. Glebe Rd. #1016; (703) 243-9696 Arlington, VA 22203 4/23/12) at the March 22-23, 2012 FDA hearing on novel conditions of use for nonprescription medicines.