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Public Hearing: Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription
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Good morning! I'm Scott Melville of the Consumer Healthcare Products Association. Founded in 1881, CHPA represents the companies that develop, manufacture, and market over-the-counter, or OTC, medicines and dietary supplements. Thus we have a deep interest and long perspective on the issues to be discussed over these 2 days. We applaud FDA for holding this public meeting and recognizing the contribution that OTC medicines can and do make to our nation's healthcare system.

Access to appropriate medicines without a prescription empowers consumers to take greater control over their health and provides tremendous public health benefits. Fueled in part by innovations in prescription to OTC switch, the U.S. market for OTC medicines is strong, providing consumers with accessible, affordable, and trusted healthcare options available 24/7 in a wide range of retail outlets, including pharmacies, supermarkets, convenience stores, and other access points.

We welcome the opportunity to discuss our perspectives on the use of innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription.

This morning, I'll review some recent findings quantifying the value of OTC medicines to our healthcare system, and provide examples of how prescription-to-OTC switch demonstrates the power of consumer access.

I will highlight examples of how the OTC industry has worked with the FDA to develop and utilize methods to assess consumer behavior prior to a prescription-to-OTC switch, and where FDA has approved OTC medicines with tools beyond the Drug Facts label to achieve proper selection and use.

Of particular importance to today's hearing, I will discuss how consumers today are accessing information and utilizing tools and technology as never before, especially in the healthcare setting.

These developments have significant implications for our industry and may assist in enhancing the safe use of OTC medicines. But we believe the concept of conditions of safe use can be applied without changing the existing clear distinction between prescription and nonprescription drugs – the Durham-Humphrey drug definition. Our 2-class system – Rx and OTC – has served

the nation well. If a medicine can be safely and effectively used as an OTC, then it should be sold as an OTC.

Many of the questions in FDA's meeting notice speak to pharmacist dispensing of prescription medicines, including refills. This speaks to the practice of medicine and pharmacy and falls outside of our expertise and our comments.

Finally, we envision a future where innovative switches are made possible by a regulatory framework that accommodates greater use of tools and technologies. Application of these technologies on a case-by-case basis can provide a means to achieve novel, future switches – those exceptional cases where reliance on the Drug Facts label alone might be insufficient to assure proper consumer selection and use.

This past year, CHPA commissioned Booz & Company to estimate the value of OTC medicines to the U.S. healthcare system. The study determined value for 7 of the largest OTC treatment categories based on the cost of alternatives, including non-treatment, if OTC medicines were not available. It looked at behavior based on both actual experience with prescription-to-nonprescription switches and a nationally representative survey of 3,200 Americans.

Among the study's key findings:

- OTC medicines save the entire U.S. health care system – employer sponsored health plans; government programs; self-insured and the uninsured -- $102 billion annually.

- For every dollar spent on OTC medicines, the health care system saves six to seven dollars.

- The availability of OTC medicines provides relief for 240 million people in the U.S., 60 million of whom would not seek treatment if OTCs weren't available.

- Without access to OTCs, consumers would resort to more expensive medical care options for minor ailments; driving up costs throughout the health care system and, in some cases, receiving no treatment at all.

- And, the study found that OTC medicines offer an *additional* $23 billion in potential productivity benefits by keeping the American workforce at work and not at home or in doctor's offices.

And it is important to note that this study captures the systemic benefits in 7 major OTC treatment categories *today*. By using tools and technologies in addition to the OTC label to allow more innovative switches, the *future* holds even greater promise for positive public health benefits.

There is a nearly 40 year history of prescription-to-nonprescription switches providing value to consumers directly and to the healthcare system. And there is a long history of switches breaking what were thought to be the standard paradigm for OTC medicines.

Let's look at a few examples:

The 1960s brought the OTC introduction of an ingredient for long-term use, and for conditions that may not be immediately self-recognizable: fluoride for cavity prevention.

Another example from the 1990s involved vaginal antifungals. Here, medical school dean Dr. Martin Lipsky found a 15% decline in doctor visits for vaginal yeast infections in the first 4 years after the switch of prescription medicines for this condition.

The switches of vaginal antifungals were also paradigm busters: The sponsors of these switches conducted studies finding women were just as good as their doctors in recognizing the recurrence of vaginal yeast infections – recurrence being the OTC indication. So here is a clear example of a successful OTC switch that doesn't follow the usual pattern of immediate self-diagnosis.

The late 1990s brought us nonprescription Nicotine Replacement Therapies. One study found a 150% to 200% increase in their use the 1st year after switching to OTC status.

That enhanced access has resulted in tens of thousands of people quitting smoking every year. That's longer, healthier lives. That's a $2 billion dollar social benefit every year.

More recently, consumers have benefitted from OTC access to frequent heartburn and allergy medicines that are labeled for longer than the typical OTC use of 7-10 days. In the case of heartburn medicines, an analysis by Nielsen found an average saving to consumers in prescription and office visits of $174 per OTC user per year, and a three-quarter billion dollar savings to the healthcare system.

Access provides tremendous power for consumers. That's why we continue to advocate for policies that facilitate the switch of appropriate medicines for direct consumer use. That's why we agree with the agency's comments in the notice for this meeting pointing out that "the requirement to obtain a prescription for appropriate medicine may contribute to under-treatment of certain common medical conditions."

In sum, there is a deep history of successful switches that don't meet the typical paradigm for OTC medicines: Switches for use for longer periods of time, even chronic use. Switches for use after initial diagnosis. OTC introductions for prevention.

Many of these breakthrough switches utilize new methods to assess consumer behavior, including label comprehension studies, self-selection studies, and actual use trials.

More recent switches, such as those for frequently recurring heartburn, are examples where specific key questions prior to the switch were answered through the sponsors' self-selection studies and actual use trials.

In the cases of nicotine replacement therapy and orlistat for weight loss or control, the approval of these switches went well beyond the Drug Facts label to include a wealth of tools – such as helplines; or on-line, personalized information -- to support optimal outcomes, including behavior modification. These were evolutionary changes, achieved over decades, that benefitted consumers and our healthcare system.

As we look to the future, we know that today's consumers know more, have access to greater information, and can do more than ever before, thanks in large part to the ubiquitous nature of technology. Our collective challenge is to acknowledge these developments and to keep up with consumer capabilities and demands.

There are now more cell or mobile phones and tablets then there are people in the United States. The day is upon us when consumers can and do access a wealth of information at home, or almost anywhere, to increase their awareness about a disease or condition, or seek information and gain education around conditions and potential treatments.

For instance, one of our manufacturers reports that roughly 2 in 5 of the visits to their website for a particular OTC medicine are from mobile devices. This is double what it was in the first half of 2011.

Consumers can access information in the store.

They can and do access information after a purchase decision.

They can access information when they are using a product in the home.

Google estimates the number of platforms or sources consumers use to make product decisions doubled over the past year. And this information access explosion includes healthcare. It includes OTC medicines. For instance, Google estimates search queries for cold and flu medicines more than doubled from 2009 to 2012. Pain management queries increased 110% over that same time period.

And it's not simply about the internet. There are many ways for consumers to obtain information, from enhanced roles for pharmacists; to diagnostic kits, smartcards, or 2D bar codes; to in-store touch screens, kiosks, and tear sheets. All are tools or technologies to help guide consumers or support a self-selection determination.

Video in print technology – in other words, sound and motion on a chip embedded in print – is being used in magazines and in soft drink promotions today. There is no reason not to think about applying these types of technologies case-by-case where supported by data in the prescription-to-OTC switches of tomorrow.

The point, of course, isn't technology for technology's sake. Rather, the commonality is that industry has a wide and growing array of tools and technologies that can be included and tested in programs to support consumer access to more challenging prescription-to-OTC switches.

As we think about the promise of using more tools and technologies to support innovative switches, it may well be that we need to update the rules that apply to switch approvals and their interpretation. As we do that, it's important to remember 3 core principles under existing law and under the existing regulatory approach that have served our healthcare system so well:

1st, self-selection – the ability for a consumer to pick up a product and read and understand its label -- is the cornerstone of OTC medicines. Even with the addition of tools beyond the package label, a consumer-centered approach remains of highest importance.

2nd, tools or special conditions of use are means to address benefits and risks unique to each switch and should be applied on a case-by-case basis. As history has shown, not all switched products would require special conditions for use, and there will be switches that can continue to rely on the Drug Facts label. Further, application of special conditions authority on a case-by-case basis will assure that the design and application of tools are data-driven. A place of sale restriction such as a behind-the-counter requirement in the absence of data designed to answer a key question for a particular switch does not meet the data-driven test.

3rd, the existing approach of a clear distinction between prescription and nonprescription drugs – the Durham-Humphrey drug definition -- has and should continue to serve our society well. Consumers understand the clear distinction between prescription and OTC products. If a medicine can be safely and effectively used as an OTC, then it should be sold as an OTC.

Finally, pharmacist dispensing of prescription medicines, including refills, speaks to the practice of medicine and pharmacy and falls outside of our expertise. We view drugs under such a scenario as prescription.

In sum, there is tremendous evidence demonstrating the power of access and the public health benefits of OTC medicines today.

We know that there are undertreated conditions because of barriers to treatment.

We know that consumers have a growing ability to access a greater depth and breadth of information than ever before, and that they are doing so through a widening-array of means.

Prescription-to-nonprescription switches have evolved over decades, as have the types of evidence and studies to support them.

Switches have moved beyond the common conception that OTC medicines are for self-diagnosed symptoms, or for a limited duration of use.

If some future prescription-to-OTC switches require looking at the interpretation of existing policies on authority or enforceability, we support that effort and are committed to working with the agency to identify an appropriate path.

Ultimately, we envision a future where innovative switches are made possible by greater use of tools and technologies. Application of these technologies on a case-by-case basis, supported by data, can provide a means to achieve novel, future switches in exceptional cases where reliance on the Drug Facts label alone might be insufficient to assure proper selection and use.

We thank the agency for calling this important meeting, and look forward to continuing to identify ways to enhance the value that OTC medicines provide to American consumers and our healthcare system.