



founded 1881

December 17, 2007

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 2007N-0356  
Behind the Counter Availability of Certain Drugs; Public Meeting, 72 Fed. Reg.  
56769 (October 4, 2007)

Dear Sir or Madam:

In the October 4, 2007, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced public meeting, which sought views on issues associated with the public health benefit of certain drugs being available without a prescription but only after intervention by a pharmacist.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements in the United States, including medicines switched from prescription to OTC status. As such, we have an interest in the subject matter discussed in the notice and at the November 14, 2007, meeting. CHPA presented its views at the meeting, and these comments reiterate our oral remarks.

1. Switch: The Power of Access.

Access to OTC medicines empowers consumers by allowing them to take an active role in their own healthcare. OTC medicines provide consumers with an array of choices in treating their everyday healthcare needs. The U.S. system of general distribution of OTC medicines provides consumers with a wide array of convenient retail outlets from which to purchase the OTC medicines of their choosing – convenience in terms of locations and of store hours. This wide array of choices and convenience also stimulates competitive economic pressures to keep costs down, again to the benefit of consumers.

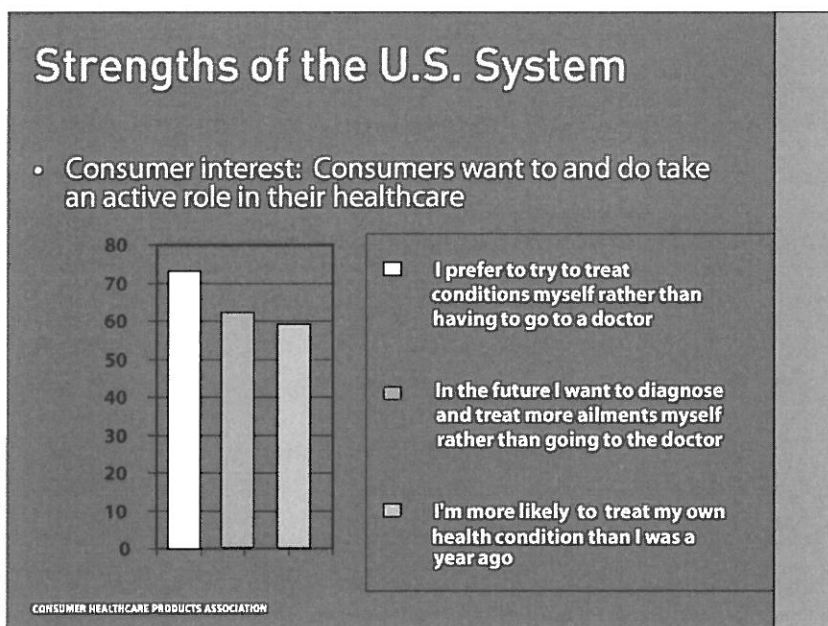
At the same time, the existing legal framework for prescription and nonprescription medicines allows sufficient flexibility for Rx-to-OTC switch sponsors to work with FDA

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to address specific challenges for a specific switch application through an evolving range of methods, including utilization of pharmacists, commitments to distribution restrictions, additional study commitments, or other measures. Through the existing system, U.S. consumers have benefited from a number of innovations in Rx-to-OTC switch, which has also served public health ends.

The threshold question raised by the FDA notice is whether any circumstances could exist that would justify switching a drug but would include sponsor agreement with the agency to place the drug only behind a pharmacy counter. CHPA could foresee situations where a switch applicant would propose and agree to have interaction with a pharmacist or other healthcare professional as an appropriate part of an approval. CHPA does not, however, favor a change in law or regulation to create a new class of medicines, such as a 'behind-the-counter' class of medicines available only after intervention by a pharmacist.

There are many examples of consumer interest in taking an active role in their healthcare. As noted in the chart below, roughly three out of four Americans agree that they prefer to treat their own conditions rather than going to a doctor. Approximately three out of five say that in the future they want to diagnose and treat more of their ailments, and that they are more likely to treat their own conditions now than in the recent past.<sup>1</sup>



<sup>1</sup> "Self-Care in the New Millennium: American Attitudes Toward Maintaining Personal Health and Treatment," Roper-Starch for the Consumer Healthcare Products Association, 2001.

As just one further illustration of consumer interest in their health, four out of five Americans report turning to the Internet for health information.<sup>2</sup>

Access to, and use of, OTC medicines is just one way consumers can take responsible action on this healthcare interest for a range of symptoms and ailments. Access provides tremendous power for consumers. Three brief case studies follow, demonstrating the personal, societal, or public health benefits of the power of access through Rx-to-OTC switches.

Thanks to the Rx-to-OTC switch of a number of nasal decongestants and antihistamines through the late 1970s and early 1980s, MIT economist Peter Temin estimated doctor visits for the common cold fell by over 100,000 visits a year from 1976 to 1989. Temin also calculated an annual gain in consumer welfare of \$700 million thanks to the switch of a wider range of medicines to treat symptoms of the common cold.<sup>3</sup>

In another study, Lipsky found a 15 percent decline in the number of doctor visits for vaginitis from 1990 to 1994 could be attributed to the availability of OTC antifungals for this condition – the era of the early switches for this condition. The decrease in doctor visits resulted in approximately \$45 million in direct cost saving and another \$19 million in indirect cost saving by reducing time lost from work, he calculated.<sup>4</sup> We should also note that vaginal antifungals are indicated for the recurrence of infections after initial diagnosis by a doctor. The sponsors of these medicines conducted studies finding women were just as good as their doctors in recognizing the recurrence of vaginal yeast infections.

Finally, a number of authors have look at the benefits of switching nicotine replacement therapies. Keeler found an a 180 percent increase in demand for nicotine replacement therapy gum thanks to the switch to OTC status, which translated to approximately 195,000 extra quit attempts. He estimated the OTC switch of NRT patches increased volume by 93 percent or 78 percent, depending on the calculation method used, which translates to 380,000 to 450,000 extra quit attempts. Using conservative

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<sup>2</sup> Burst Media survey, August 2007, available through [www.burstmedia.com](http://www.burstmedia.com).

<sup>3</sup> Temin, "Realized Benefits from Switching Drugs," 35 *Journal of Law and Economics* 351 (October 1992). (This study and Temin's earlier work on the switch of hydrocortisone have been praised as the most authoritative analyses on the benefits of prescription-to-nonprescription switch. See, for example, Keeler, et al., "The Benefits of Switching Smoking Cessation Drugs to Over-the-Counter Status," 11 *Health Economics* 389 (2002).)

<sup>4</sup> Lipsky, et al., "Impact of Vaginal Antifungal Products on Utilization of Health Care Services: Evidence from Physician Visits," 13 *Journal of the American Board of Family Practice* 178 (2000).

assumptions on quit rates, the value of benefits conferred to quitters in longer, higher quality lives would have been \$6 billion had nicotine replacement therapy gum gone OTC one year earlier, and \$1.2 to 1.4 billion had patches gone OTC one year earlier. Net social benefits were calculated at \$1.6 to 1.8 billion. The study found no evidence of significant health costs from harm or injury from misuse due to lack of a doctor's supervision.<sup>5</sup>

Shiffman found similar results on the use of OTC nicotine replacement therapy, finding an increase in use of 150% in the first year after the switch, estimated to yield between 114,000 to 300,000 new former smokers annually in the U.S.<sup>6</sup>

## 2. The Switch Construct.

Applications for Rx-to-OTC switch need to be approached with an open mind. While it is easy to think about OTC medicines with a narrow, pre-determined mindset, that runs the risk of forgetting about existing examples that demonstrate the principle of keeping one's mind open to the full range of possibilities of what can be an OTC medicine. For example, the opinion is sometimes expressed that OTC medicines should be for short term use with readily self-recognizable symptoms. But this is not always the case, as seen in fluoride toothpastes and fluoride rinses, which were switched to OTC status and introduced in the 1950s and 1960s.<sup>7</sup> The use of fluoride-containing OTC medicines is chronic, and a number of the conditions being prevented are not typically amenable to self-diagnosis.

Minoxidil for hair re-growth is another example of an Rx-to-OTC switch with an indefinite, long term use, and the product also has different strengths for men and women, which of itself demonstrates the point that one size doesn't necessarily fit all when it comes to Rx-to-OTC switch.

A second narrow opinion that is sometimes expressed is that you cannot switch an ingredient when there is a concern about a masking potential of another disease. Yet the sponsors of switch applications for the H2s (cimetidine, ranitidine, famotidine, and nizatidine) and for omeprazole were able to provide information to the agency through

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<sup>5</sup> Keeler, et al., "The Benefits of Switching Smoking Cessation Drugs to Over-the-Counter Status," 11 Health Economics 389 (2002).

<sup>6</sup> Shiffman, et al., "Public Health Benefit of Over-the-Counter Nicotine Medications," 6 Tobacco Control 306 (1997).

<sup>7</sup> See ingredient listing at 21 CFR 310.201, including sodium fluoride (proposed for a switch January 20, 1956, where the agency noted "these drugs were previously limited by their new-drug applications to use under professional supervision . . . . Evidence now available through investigation and marketing experience shows that the drugs can be safely used by the laity in self-medication if they are used in accordance with the proposed labeling." 21 Fed. Reg. 431 [January 20, 1956]; and finalized March 3, 1956 [23 Fed. Reg. 1417]). Sodium monofluorophosphate followed a similar route: See 21 Fed. Reg. 8512 (November 6, 1956), and 21 Fed. Reg. 10275 (December 21, 1956).

label comprehension studies and/or actual use studies in their switch applications to address masking concerns.

As to specific switch applications and their specific challenges, it can be helpful to think about challenges through the clusters into which many of them fall: self-selection concerns; emergent signs or symptoms; and how to add value through enhanced, targeted information. In turn, a number of Rx-to-OTC switches have been able to meet these challenges through the existing regulatory system with a range of approaches.

Self-selection concerns: Here, the concerns cluster around the core issues of whether consumers for who the product is indicated appropriately choose it, and whether consumers for whom the product is not indicated are discouraged from using it. The concern around use of the emergency contraceptive levonorgestrel by young women under 18 is an example of a self-selection concern. In this case, the switch sponsor was able to work with the agency under existing law and regulation to meet this self-selection concern by agreeing to: (1) distribution limitations only through outlets with pharmacies; (2) pharmacist intervention for age verification, since the package includes the prescription drug as well, and the age verification by a pharmacist is needed to assure the product is not illegally dispensed without a prescription to a woman under 18; and (3) packaging requirements (the prescription and nonprescription product being in the same package).

Nicotine replacement therapy sponsors similarly addressed self-selection concerns focused on age, since these medicines are labeled for use in those 18 and over. Here, at least one of the NRT sponsors committed to a Phase 4 study on age verification monitoring, among other steps.

Emergent signs or symptoms: Concerns about a masking potential, or signs or symptoms of a disease that a consumer might otherwise miss on their own, are a second cluster of concerns. As noted above, the H2s and omeprazole faced concerns of this type, which were successfully addressed through label comprehension and actual use studies.

Targeted information: Finally, there are instances where the challenge to a particular switch can be met through tools and information that go well beyond the traditional “Drug Facts” label. Here, the question is: Does the proposed feature or intervention add demonstrable value to support optimal health outcomes that include the use of the medicine. (To illustrate: Consumer group A could be more likely to continue to use a drug for a condition if information beyond labeling were available in a supportive, nurturing tone emphasizing benefits of treatment; while consumer group B might be more likely to continue to use the same drug if information beyond labeling were available in a more directive tone emphasizing risks of stopping treatment.)

Nicotine replacement therapies are examples of the use of targeted information to address switch challenges. These products are accompanied by a wealth of information beyond the traditional “Drug Facts” label, including an audio tape or CD; web-based support programs; call-in numbers for support; and, early after the initial NRT switch,



training of pharmacists and others to lead smoking cessation support groups. In the case of at least one of the NRT sponsors, the company worked to develop web-based, custom-tailored cessation program to improve smoking cessation rates.<sup>8</sup>

In all of these cases, what needs to drive the ultimate Rx-to-OTC switch decision is an assessment of the approaches to address specific challenges in a specific switch application, rather than trying to define a pre-determined additional class of medicines.


### 3. Conclusion.

We continue to advocate for wider access to nonprescription medicines through prescription-to-nonprescription switch. But a change in law or regulation is not needed to expand access to nonprescription medicines. The existing two-class system works and it works well to the benefit of consumers and in serving public health. Consumer choice, convenience, and a competitive environment to efficiently serve consumers are drivers in the U.S. system, and the U.S. system amply demonstrates the power of access.

Importantly, flexibility is built in to the existing framework, with sponsor having the opportunity to design the appropriate tools to address the challenges to that particular medicine. An agreement between a sponsor and the agency to include consultation with a pharmacist or other healthcare professional, and placement behind a pharmacy counter, is certainly an appropriate tool toward this end and a demonstration of flexibility, as FDA has shown by approving labeling for levonorgestrel that requires that it be placed behind a pharmacy counter.

The U.S. has a successful track record in Rx-to-OTC switches in which we can all be justifiably proud, as consumers are the winners. Innovations in Rx-to-OTC switch are proving the power of access today.

Sincerely,



David C. Spangler  
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& International Affairs

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<sup>8</sup> Strecher, et al., "Randomized controlled trial of a web-based computer-tailored smoking cessation program as a supplement to nicotine patch therapy," 100 Addiction 682 (2005).