

# NATIONAL WOMEN'S HEALTH RESOURCE CENTER, INC.

*The national clearinghouse for women's health information*

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July 10, 2000

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

Dear Sir/Madame:

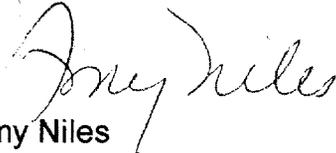
On behalf of the National Women's Health Resource Center, Inc. (NWHRC), I am pleased to submit written testimony regarding the regulation of over-the-counter products.

While my schedule did not allow me to provide comments in public, I hope the attached will be taken into consideration by the FDA in upcoming weeks.

Should you have questions, I may be reached at (202) 537-4702.

Thank you.

Sincerely,



Amy Niles  
Executive Director

00N-1256

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**Regulating Over-the-Counter Products**  
**Testimony provided to the Food and Drug Administration by the**  
**National Women's Health Resource Center, Inc.**

**DOCKET NO. OON-1256**  
**Over-the-Counter Drug Products Public Hearing**

**Introduction**

On behalf of the National Women's Health Resource Center, Inc. (NWHRC), I am pleased to submit written testimony regarding the regulation of over-the-counter products.

Established in 1988, the NWHRC is a non-profit independent organization that serves as the national clearinghouse for women's health information. Its primary goal is to provide women with the information and resources they need to make informed health decisions. The Center accomplishes its mission by distributing publications to consumers, such as the *National Women's Health Report*, linking women to local and national health resources, providing women with information at its "one-stop shop for women's health information" on the Internet - [www.healthywomen.org](http://www.healthywomen.org) -- and partnering with corporations, organizations, and federal agencies to launch national public education campaigns. Examples of partnerships with Federal agencies have included our involvement with the Take Time to Care Program, sponsored by the FDA Office of Women's Health, and Pick Your Path to Health, sponsored by the HHS Office of Women's Health.

As the national clearinghouse for women's health information, our work is vitally important for the following reasons:

- \* Women make the majority of health care decisions for their families.
- \* Women not only care for themselves, but they are, more often than not, the caregivers for their partners, children and parents.
- \* Women account for two out of every three health care dollars purchased, or \$500 billion annually.
- \* Women purchase sixty percent of all prescription medicines.
- \* Women make the majority of visits to physicians.

I have been Executive Director of the National Women's Health Resource Center, Inc. (NWHRC) since 1992, and have been associated with the Center since 1989. As Executive Director, I have watched the NWHRC grow over the years, paralleling the growth in the consumer movement toward self-care. My background is in business (masters in business administration) with a focus on health care administration.

### **Why the Interest in OTCs?**

Today, women are taking charge of their health. Although the physician/health care professional remains a woman's primary source of information, women are increasingly seeking health information from other sources, including the media, Internet, consumer advocacy organizations, friends and family. Over the last decade, women have assumed very active roles in their own health care. They are seeking out information, engaging in conversation with their physicians/health care providers about their health, and importantly, becoming more and more interested in identifying treatment options and complementary approaches to traditional therapies.

This important trend over the past decade toward consumer participation in their own health care has led to tremendous growth in the self-care movement. In 1996, the American Pharmaceutical Association reported that of approximately 3.5 billion health problems treated annually, some two billion are treated with nonprescription drugs.

According to Kline & Company, over-the-counter (OTCs) medications have saved consumers more than \$20 billion in health care costs - taking into account prescription costs, doctor visits, lost time from work, insurance costs and travel. Over-the-counter switches have provided consumers with increased access to effective drugs. Switches have also expanded the range of conditions that can be treated with OTC medications, and have expanded the least expensive form of health care today: self-medication with OTC medicines.

### **Regulating OTCs**

As part of the public hearing on over-the-counter medications, the FDA has raised several very important issues, which are addressed briefly below.

#### Criteria to be considered regarding Rx-to-OTC Switch

The NWHRC supports the continued use of statutory and regulatory criteria already established by the Food, Drug and Cosmetic Act for evaluating switches:

1. Safety and effectiveness
2. Ability for consumers to use the product on the basis of its labeling.

#### Types of Drugs or Diseases which are or are not suitable for self-medication

Not all drugs in every product category are equal. Therefore, the NWHRC's position is that EACH DRUG'S INDIVIDUAL RISKS AND BENEFITS need to be evaluated, and it is this analysis that must drive the Rx-to-OTC switch decision. Each drug must be evaluated based on existing data and on a case-by-case basis.

### Classes of Products that should or should not be available as OTC medicines.

Again, the FDA should not categorically review and approve, or not approve, certain classes of drugs for OTC use. As stated above, every drug must be evaluated based on benefits and risks associated with safety, effectiveness, and labeling.

The issue of efficacy between OTC products is best handled through labeling. In a category of products, it is clear that one OTC product may be more effective than another. One OTC may also be more difficult to administer than another. However, both, based on benefit/risk analyses, have proved to be effective, and this efficacy is best translated through labeling. It is ultimately up to the consumer, in conjunction with his/her physician/health care professional, to discuss OTC options, and identify the best product for the given disease or condition.

### The FDA's Role in Initiating Switches

It is the opinion of the NWHRC that the manufacturer of the drug being reviewed is in the best position to determine appropriateness for OTC switch. It is the manufacturer, after all, that has access to data and studies. While the Rx-to-OTC switch process is a collaboration between the FDA and manufacturer or sponsor, the decision to switch must be based on scientifically documented benefit/risk analyses. Finally, currently the FDA may not switch an approved drug from Rx to OTC over the objection of the sponsor, without providing a trial-type hearing. This process is fair and equitable, and should remain in tact.

### How the FDA can be Assured that Consumers Understand the Issues Relating to OTC Availability of Drug Products

The primary way that the FDA can be assured that consumers understand issues related to OTC availability and usage is to ensure that labeling of OTC products remains clear and truthful. The labeling must state: (1) The intended uses and results of product use; (2) the adequate directions for proper use; and (3) the warnings against unsafe use, side effects, and adverse reactions in terms that render them likely to be read and understood by the ordinary individual, including individuals of low comprehension.

Another way that the FDA can be assured that consumers understand OTC issues is to depend on organizations such as the Consumer Health Care Products Association, and our organization, the NWHRC, to develop initiatives to educate members and our respective constituencies about over-the-counter medications.

The FDA should also depend on Federal agencies and the various Offices of Women's Health, to develop and disseminate information about OTCs to consumers. This information should be available in both English and Spanish.

Selection of Treatment

FDA has raised questions regarding how treatment regimens can be selected when there are coexisting prescription and OTC therapies available for a given disease.

From a consumer perspective, one must realize that the use of a prescriptive medication may or may not rule out the use of an effective OTC product to treat a certain disease or condition, and vice versa. The benefits to the consumer of having coexisting therapies, is that he/she has CHOICES AND OPTIONS. The key, is that the consumer should be speaking with his/her physician/health care professional about all effective treatment options - both prescriptive and over-the-counter - and that the decision to use or not use an OTC product is based on existing knowledge and scientific facts.

Thank you for the opportunity to submit written testimony, and I am available for questions as need be.

Respectively submitted:



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