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TESTIMONY

Before

**THE COMMISSIONER OF FOOD AND DRUG ADMINISTRATION
OTC PART 15 HEARING**

on

PROCESS FOR DESIGNATION OF DRUGS AS OTC

Presented by:

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**SESSION 9: PROCESS ISSUES
JUNE 29, 2000**

00N-1256

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I am Dr. Allan Korn, Senior Vice President, Clinical Affairs and Chief Medical Officer, of the Blue Cross and Blue Shield Association. The Blue Cross and Blue Shield Association represents the 47 independent Blue Cross and Blue Shield Plans that provide health coverage to over 74 million Americans. Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage through a variety of products. Thank you for the opportunity to appear before the Food and Drug Administration at today's public hearing on over-the-counter (OTC) drug products.

Although the Federal Register notice announcing today's hearing lists several areas that the FDA will examine as it reviews its approach to regulating OTC drug products, I will focus my remarks on the process for designation of drugs as OTC. Specifically, I will address the following two questions posed in the Federal Register notice for today's hearing:

- Under what circumstances should FDA actively propose OTC marketing for a drug in the absence of support from the drug sponsor?
- Should FDA be more active in initiating switches of prescription products to OTC use?

As I explain in greater detail below, BCBSA recommends that the FDA adopt a fundamental policy that a drug should be designated as prescription only where it is **not** safe and effective for the drug to be designated as OTC.

We recommend a policy of proactive and continuous review of prescription drugs to identify drugs that are appropriate for OTC designation based on clinical and safety evaluations. One way to prioritize the FDA's work would be to begin reviewing drugs that are OTC or in a third-class of drugs in other industrialized countries with requirements of safety and effectiveness for such drugs. BCBSA also recommends that any interested party be permitted to initiate -- by a petition accompanied by credible evidence -- a process for the FDA to consider whether a drug is appropriate for OTC use.

Background on Designation of a Drug as OTC

Since 1951, the Durham-Humphrey Amendment to the Federal Food, Drug and Cosmetic Act has required that all drugs safe enough to be sold OTC be designated as such. The law states that drugs should require a prescription only if "toxicity or other potentiality for harmful effect" makes it necessary for a licensed practitioner to supervise the patient.

In practice, however, the vast majority of new drugs come to market through a new drug application that specifies that a drug is for prescription use only. The prescription designation ensures that a licensed practitioner supervises use of the drug by the patient. Licensed practitioners report important safety information to the FDA or the manufacturer regarding adverse reactions, or other safety concerns. The prescription status of the drug allows the FDA to learn about the drug's safety profile in a more controlled environment than if the drug were OTC.

Under the current regulatory scheme, there are mechanisms to allow for a drug that is initially designated as prescription to become designated as OTC where such use is safe and effective.

A manufacturer may initiate a switch through the filing of a new drug application, or a supplement to a new drug application. In recent years, the vast majority of drug switches have been initiated by such filings. Switches at the end of a drug's patent life are encouraged by a provision of the Hatch Waxman Act that allows an extension of market exclusivity (protection from generic competition) for three years if the manufacturer provides new clinical studies that the FDA deems essential for switch approval.

In addition, the FDA or any interested party may initiate a switch under the regulations at 21 C.F.R. 310.200 and 201. To our knowledge, these regulations have not been invoked in recent years to authorize a switch. The citizen's petition submitted by Blue Cross of California in 1999 to request a conversion of nonsedating antihistamines to OTC status falls under this regulatory authority.

Additional regulatory authority promulgated in the 1970's allowed for a review of the safety and effectiveness of all OTC products on the market as of that time under a process known as the OTC Drug Review process. Under this process about 33% of OTC ingredients were found to be ineffective. Also, during this process more than 40 primary product ingredients were reclassified from prescription to OTC status.

The clinical criteria for evaluating whether a drug is appropriate for a switch appear to be the same, regardless of the mechanism for the switch. These criteria focus on safety and effectiveness criteria, i.e., the drug must be safe and effective when used without the supervision of a licensed practitioner. Safety means a low incidence of adverse reactions or significant side effects under adequate directions and warnings. Also, there must be a low potential for harm that may result from abuse under conditions of widespread availability. Effectiveness means that the pharmacological effect of the drug, when used under adequate directions will have a reasonable expectation of clinically significant relief of the type claimed. The benefit to risk ratio is considered in determining safety and effectiveness. Labeling must be clear and truthful in all respects and may not be misleading in any particular.

BCBSA Recommendation

Despite the fairly broad statutory criteria for designating a drug as an OTC drug, the conditions under which a drug has been switched have been fairly limited.

BCBSA recommends that the FDA adopt a fundamental policy that a drug should be designated as prescription only where it is **not** safe and effective for the drug to be designated as OTC. In order to achieve this objective, BCBSA recommends that the FDA engage in a deliberate process for switching drugs from prescription to OTC status where such designation is safe and effective for the consumer.

One way to prioritize the FDA's work would be to begin by reviewing drugs that are OTC or in a third-class of drugs in other industrialized countries with requirements of safety and effectiveness for such drugs. The FDA should begin its review with drugs for which a drug manufacturer has made representations to other governments (e.g., European Community governments, Canada, etc.) that a drug is safe and effective for OTC drug use. This sort of comprehensive review has a precedent in the OTC Drug Review. However, this review should not be a one-time effort, but should be an ongoing, continuous activity.

Another basis for review should be individually initiated petitions that are supported by credible information meeting the switch criteria. Many parties – other than manufacturers – have an interest in the switch process. These parties should be allowed to participate in the FDA's scientific and clinical evaluation of drugs potentially eligible for switch. We do not believe that designation of a drug should be purely an economic decision for the manufacturer of the drug.

The proactive review process described above will go a long way to assuring that clinical criteria are paramount in determining whether a drug is appropriately classified. Such a process undoubtedly would require additional resources. We believe that such resources would serve the public well.

Consumers benefit when drugs are appropriately switched to OTC status. Consumers are knowledgeable about their health care and value access to OTC drugs. Self-treatment offers consumers convenience – a physician's visit is not necessary for a prescription.

There also is evidence that when a drug moves from prescription to OTC status prices quickly move into line with what consumers can afford. A competitive market drives down costs. For example, OTC Zantac 75 (75 mg) had a cost of \$.28 per tablet when purchased at a Target store in Minneapolis in February 2000, while the Average Wholesale Price for prescription-strength Zantac (150 mg.) was \$1.77 per tablet.

Whether or not designation results in coverage by a third party payer should not be a consideration for the FDA. The designation of whether a drug is prescription vs. OTC has important consequences for the portion of the health insurance dollar available for breakthrough therapies and life saving prescription drugs. A more proactive approach for designation of drugs as OTC will result in a wiser use of scarce health insurance premium dollars.

A recent study sponsored by the RxHealth Value Coalition, a broad-based coalition of consumer groups, unions, health plans, employers, clinicians, and advocates (BCBSA is a member), and conducted by Brandeis University and PCS Health shows that prescription drug costs for a continuously insured population of individuals grew at an annual rate of 24.8% (age adjusted) per year from 1996 –1999.

Another study sponsored by BCBSA and conducted by the University of Maryland shows that the pipeline is full and that new high cost drugs will make up 40% of drug costs in the future.

These studies raise the question of whether – because of rapidly increasing prescription drug costs – employers can afford to keep offering coverage. There also is the question of whether employees will be able to afford their share of premiums, copayments, and deductibles. When health plans' costs increase, employers tend to shift costs to employees and the rapid increase in prescription drug costs are likely to make drugs a focus of increased cost sharing. Revision of the OTC designation process so that only drugs that truly need physician supervision are designated as prescription drugs – and thus covered by health plans – is critical to assuring that coverage is available to and affordable for employees.

Conclusion

To conclude, BCBSA recommends that FDA adopt a fundamental policy that a drug should be designated as prescription only where it is **not** safe and effective for the drug to be designated as OTC. In order to achieve this objective, BCBSA recommends that the FDA engage in a deliberate process for switching drugs from prescription to OTC status where such designation is safe and effective for the consumer.

This policy would best be carried out through a two-part approach:

- (1) Adoption of a policy of proactive and continuing review of prescription drugs to identify drugs that are appropriate – based on clinical and safety evaluations -- for OTC designation; and
- (2) Consideration of switch petitions from parties other than manufacturers.

BCBSA believes that the approach recommended above will empower consumers to safely self treat with OTC drugs at affordable prices.

BCBSA applauds the FDA for addressing this critical health care issue and supports the agency in its endeavor.