

**TESTIMONY OF BERTRAM A. SPILKER, Ph.D., M.D.,
SENIOR VICE PRESIDENT, SCIENCE AND REGULATORY AFFAIRS,
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
BEFORE THE FOOD AND DRUG ADMINISTRATION**

**Joint Meeting of the Nonprescription Drugs Advisory Committee and
the Pulmonary-Allergy Drugs Advisory Committee**

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I am Bert Spilker, Senior Vice President for Science and Regulatory Affairs of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Investing over \$30 billion this year in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

PhRMA's members are the source of nearly all new drugs that are discovered, made, and used worldwide. Virtually all major new OTC drugs are based on the prescription drugs that are discovered and developed by PhRMA members. Accordingly, PhRMA has a vital interest in the issues being considered by the advisory committees today, and the precedent that could be set for future Rx-OTC switches.

The petition under review seeks unprecedented action by FDA -- the switch of particular drugs from prescription to nonprescription status over the clear objections of the NDA holders for the individual drugs. Currently, the switch of a prescription product to OTC status is initiated by the NDA sponsor, or with its approval, through the submission of a new application or a supplement with extensive data to support safe and effective OTC use and appropriate OTC labeling for a specific drug. A departure from this well-established model would raise serious scientific, public policy, and legal issues. FDA has recognized for

decades that having sponsors alone initiate Rx-OTC switches is in the interests of public health. My comments here will focus on the scientific and public health implications of permitting a switch to occur without the consent and participation of the NDA holder. The legal and policy questions presented by the Blue Cross petition are equally critical to consider before a decision is made. These latter two issues concern whether FDA has the statutory and constitutional authority to compel an OTC switch over an NDA sponsor's objections, and whether it is good public policy to shift drug costs from third-party payers like Blue Cross to patients themselves by removing prescription status. PhRMA will address these important matters in separate written comments to the docket.

From a clinical perspective, the consideration of an OTC switch must be based on whether a sufficient body of data establish that a particular drug will be safe and effective for self care under the labeled conditions for use. This evaluation is necessarily conducted product by product, based on the specific data and merits of each product. Extensive prescription use is essential to the full characterization of a drug's clinical profile, and is thus a prerequisite for OTC consideration. New information is often learned through commercial use that simply cannot be identified based on the limited number of patients involved in clinical trials conducted for initial product approval.

It is also critical to develop additional clinical data on a drug's use under OTC conditions. For example, will consumers properly comprehend product labeling and not self-diagnose and self-medicate if they experience symptoms that should trigger a physician consultation? Significant issues can arise under OTC use that do not exist, or are of considerably less concern, when a drug is used in accordance with a physician's prescription and supervision. For example, a drug may present possible drug interactions that a physician

could identify and manage, if more closely monitoring a patient. A switch should typically not be permitted unless considerable data are developed in addition to the data already present in the NDA for prescription use. It is wholly inappropriate to consider a switch on the basis of conclusory assertions, or on the basis of anecdotal or otherwise limited data.

Drug manufacturers have the most comprehensive and detailed knowledge of their drugs, including information bearing on whether a drug is a suitable switch candidate. These firms are also in the best position to decide whether to invest in the development of additional information necessary to support a switch, and at what rate over time this investment should occur. A third party does not have the same expertise or experience with a drug, and is not therefore as able to assess whether a switch is premature and would expose the public to health risks. For these reasons, evaluation of a switch without the sponsor's full cooperation and involvement is highly problematic, and could lead to exposing patients to drug risks before they are adequately assessed.

Forcing a manufacturer to sell a drug OTC risks disrupting the drug development process. This would be a major and unprecedented change from U.S. drug development practices today. Sponsors carefully establish research plans and development strategies for a product's full life cycle, and these plans would be disrupted in a serious way by unanticipated switches mandated by FDA or a third party. Introducing uncertainty into the issue about possible OTC switches would significantly complicate the already difficult considerations that underlie a company's decision to proceed with drug development, and could chill many areas of research and development. Whether the government has the legal right will be left to discuss at a later time.

I hope that you will take these points into account in evaluating the petition before you, and in considering the precedent you will be setting. This petition cannot be viewed in isolation. Granting the switches proposed over the sponsors' clear objections would mark a major change in current practice. If FDA agrees to these switches the changes discussed today will be the tip of the iceberg. What classes of drugs will be next, and what classes of drugs will be exempt? Once the bell has been sounded inviting third parties to prompt such switches, it will be impossible to unring, and who is to say which groups can request such changes and who cannot. It is likely that many products will be proposed for such changes of status on a very frequent basis by those who have a strong self-interest in the change.

Thank you for your time and attention.