Statement PhRMA

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PUBLIC HEARING BEFORE THE

NATIONAL TRANSPORTATION SAFETY BOARD AND FOOD AND DRUG ADMINISTRATION

"TRANSPORTATION SAFETY AND POTENTIALLY SEDATING OR IMPAIRING MEDICATIONS"

Witness Panel VII – Warning Labels

November 15, 2001

I am Dr. Bert Spilker, Senior Vice President of Scientific and Regulatory Affairs for 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 live longer, healthier, and more productive lives. Investing more than $30 billion in 2001 in discovering and developing new medicines, PhRMA companies are leading the way in the search for new cures.

In regard to the subject for this panel's focus, I wish to make four points.

1. **All investigational Rx drugs are thoroughly evaluated for ADRs by sponsors. One of the most commonly reported ADRs is drowsiness and this often finds its way into the label of products across many different therapeutic classes.**

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2. Drowsiness is a subjective measure and is not always correlated with performance impairment in clinical studies. It is often very hard to know if drowsiness is drug-related, related to the underlying disease for which a product is prescribed, or related to other factors.

3. The sponsors evaluation of drowsiness may include testing of (1) drug versus placebo, (2) different doses of a drug to evaluate dose-relationships, and (3) drug versus active agent from the same class, with an incidence of drowsiness statistically different from placebo, if applicable. Any adverse event occurring at a rate greater than a predefined threshold, usually 0.5% or 1%, or any adverse event of clinical significance, or any adverse drug reactions that occurs during clinical development will be placed in the drug's labeling. All data are evaluated by the FDA and are supported by adequate and well-designed clinical studies. When clinical trials document that drowsiness due to a drug is statistically significantly greater than placebo, it may require a label precaution.

4. Current FDA approved label language is adequate to present this information to physicians and to patients. Warnings in product labels currently exist to alert prescribing physicians to the potential hazards of vehicle operation while using medications that can cause drowsiness. These safety warnings are communicated to subjects when physicians prescribe to patients. Patient package inserts (PPI), when provided, reflect these warnings in easily understood language for the public.

Pharmacists are already required in many states to attach a peel-off label on the pill bottle mentioning when a drug may cause drowsiness and also to avoid using with alcohol or other depressants. In addition many pharmacies hand out patient information leaflets informing patients of safety related information when purchasing medication.

In summary, there currently exist ample opportunities for physicians and patients to be informed about a product's safety profile. We recommend that there not be any changes to FDA's current practice of label design for prescription drug products.

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