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U.S. Senate Committee on Commerce, Science and Transportation  
Subcommittee on Consumer Affairs, Foreign Commerce and Tourism

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Good Afternoon--

On behalf of EthicAd and the health care community we represent, thank you to the Subcommittee for this opportunity to comment on direct-to-consumer (DTC) advertising. This is the area to which our organization is dedicated.

EthicAd is an independent and neutral non-profit organization composed of leaders of the academic health care community. Dr. Michael E. DeBakey is our Chairman Emeritus. EthicAd's goal is to promote the development of DTC advertising in a manner that maximizes public health benefits. We do not oppose DTC advertising, nor are we critics of the pharmaceutical industry. Rather, we support the idea that industry should work with other stakeholders to define voluntary, self-regulatory standards for DTC. Those standards should be designed to assure the American public that the DTC advertising they see represents reliable, accurate, and trustworthy medical information.

Many of the members of EthicAd, including myself, have worked closely with industry in the development of professional education programs. But, DTC represents a new and radical departure from the traditional relationship between industry, health care providers and consumers. Even for friends of industry, DTC advertising raises important issues.

The pharmaceutical industry has a long and honorable tradition of collaboration with the health care community in the development of high-quality professional and patient education programs. This traditional relationship is usually a collaborative effort. Health care professionals help develop the content in order to assure its accuracy and its balance. Health care providers serve in the role of “learned intermediaries.” They present and interpret industry-sponsored educational materials to patients. This traditional system provides important checks and balances on the marketer—a process very familiar to this distinguished committee.

DTC represents a dramatic change in this traditional relationship. DTC removes these important checks and balances. DTC provides an opportunity for industry to act autonomously to develop and disseminate consumer health education without any outside input or review by the medical community.

The issue is not the relatively innocuous television and magazine advertisements. These highly visible programs are monitored closely by the FDA. They represent only the tip of the iceberg. Industry is investing hundreds of millions of dollars in a wide variety of consumer Web sites, patient informational programs and “relationship marketing” projects. The overwhelming majority of these arrangements are not reviewed by FDA. Who then assures the reliability of this information?

Currently, this DTC content is developed by marketing departments and their advertising agencies, subject only to internal medical-legal review within a given company. Most DTC programs are not pre-approved by the FDA. Does this current system assure consumers of reliable and unbiased health care information?

Industry has no uniform standards, or content development processes, other than the requirement that they are “expected to” comply with FDA requirements. But, there are an estimated 60-70,000 pieces of DTC material developed per year. FDA has only 13 full-time

reviewers. As a practical matter, the FDA can review only a sampling of these materials. Clearly, DTC presents great potential for abuse.

There is wide disparity in how different companies approach DTC. Many pharmaceutical companies are socially responsible and ethical in preserving consumer trust. These companies have proactively defined their own internal DTC standards and consistently develop programs in collaboration with outside health care professionals and consumer groups. They give consideration to their responsibility to promote public health as well as sell products.

Other companies take a narrower view. They focus on DTC merely as a mechanism to drive sales. The consumer is often unable to differentiate between the quality and design of DTC programs. The lack of consistent standards has raised "red flag" warnings. It fuels the Subcommittee's interest.

There are no standards, best practices or even clear goals for DTC. There should be.

We applaud the exceptional work of FDA. The Agency has balanced conflicting demands of its stakeholders to review mountains of promotional materials using extremely limited resources. FDA is the American consumer's best protector in this area. It requires increased resources to manage increased demands placed on it by DTC.

But, FDA regulations alone will not solve DTC problems. These regulations represent minimum legal requirements. They do not--and cannot--define optimal behavior. Clearly, something more is needed.

We do not believe that legislative action is required at this time. Instead, we suggest that there is immediate need for industry collaboration with other stakeholders in the development, or support, of voluntary self-regulatory goals, standards, and best practices. These standards will assure the American public that the DTC health care information they receive is reliable, understandable and trustworthy.

Rather than wait for government or industry action, the academic health care community that EthicAd represents has developed suggested standards and best practices. These specific standards are summarized in my full written testimony.

EthicAd has begun to recognize publicly those companies that develop high quality DTC programs. We will also review and certify DTC materials for accuracy, educational quality and medical reliability. This information will be available on our Web site and through the DTC advertisements that carry the EthicAd® Seal.

We believe that reasonable people develop responsible solutions. We welcome--and need--the active involvement of the pharmaceutical industry, and all other stakeholders, to implement voluntary DTC standards.

Thank you for the opportunity to share these views and to answer your questions.