LEHIGH UNIVERSITY

Department of Biological Sciences
111 Research Drive
Bethlehem, PA 18015-4732
(610) 758-3680 Fax (610) 758-4004
http://www.lehigh.edu/~inbios/

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Ln., Room 1061
Rockville, MD 20852

In RE: Docket Number 2005N-0354 Consumer Directed Promotion of Regulated Medical Products

Direct to consumer advertising of any medical product is necessarily superficial and narrowly focused. Messages are designed to capture an opportunistic moment of the viewer's time, and plant impressions of a specific product, filtered to highlight selected information that might draw the attention of the viewer. The presentations often suggest that consumers should ask their physicians about a specific product, but fail to address the broader circumstances surrounding complex medical indications. And then the advertisement is gone, usually leaving little or no recognition within the target audience to follow a more responsible approach to learning about health issues.

Consumers who are targets of advertising are prompted to draw conclusions about their health, and to favor a particular remedy for their concerns. The product is highlighted, while ignoring pathways toward a refined diagnosis or alternate treatments. Anxieties are exploited to motivate consumers to pursue and purchase drugs. Now, having planted those impressions, the advertiser disappears, usually bearing little if any future responsibility.

Most consumers who are the targets of marketing cannot be presumed to be wise about medical issues, and they have certainly not provided their informed consent to become participants in drug development. They can become the unwitting victims of whatever misimpressions or misinformation is spread, or their own incorrect conclusions based on fleeting exposure to a self-serving corporate message. Consumers may ultimately suffer from unanticipated negative outcomes of the advertised treatment. Their objectivity to the advertised product is biased by exposure to the advertisement, so there is no way that patients can meet the standards of informed consent for the use of products.

Even in an ideal situation, FDA approval can be based on very limited patient exposure to the risk of drugs. A clinical trial may involve hundreds or thousands of treatment cases for a product that is then marketed to millions. Those involved in the clinical trial receive the opportunity to obtain deep information about the

drug, and to give real and willing consent to be treated. But, following approval, patients receive only very superficial guidance, they are not offered deep information, and they do not consent to be subjects in an experiment. In many cases, consumers may join the first large group to experience a new treatment. While this may be standard practice, it does not invite access to information, possibly including negative outcomes, that may develop during or following the course of their treatment.

In the distant and recent past, we have witnessed numerous examples of negative outcomes from unacknowledged consequences of particular drugs and medical devices. It is difficult to avoid the conclusion that many patients have been drawn into personal jeopardy through advertising. The simple conclusion is that direct to consumer advertising should be discontinued.

If advertising is permitted, it certainly must be held to a far higher standard of responsibility than seen in recent years. And, if permitted, the future interests of the consumers must be protected. **I believe and recommend that six percent of the total dollar amount that pharmaceutical companies spend on marketing should be directed toward a new and entirely independent nonprofit organization dedicated to the protection of the public from undesired outcomes of pharmaceuticals and medical devices.** One obvious activity of this organization should be the management of a voluntary registry of patients and their prescription records. Such a database could be used to provide future tracking to detect unanticipated outcomes of treatment, and also to alert registrants of advances in best practice of medicine, discovery of new drug interactions, contraindications, alternate treatments, etc. In this way, some of the rights of patients could be protected, while providing a partial remedy for compromises to their informed consent.

Thank you for your careful consideration of these issues.

Barry Bean, Ph.D.
Professor of Biological Sciences
Lehigh University