May 29, 2002

Dockets Management Branch
FDA
5630 Fishters Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0209

To Whom It May Concern:

In response to the FDA's request for comments, we are submitting the following comments regarding FDA's regulations, guidelines, policies and practices, and compliance with First Amendment case law.

The National Organization for Rare Disorders (NORD) is a unique federation of voluntary health organizations and individuals dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and services.

People with rare disorders (known as "orphan diseases") are health care consumers who often need a variety of medications. Under the Orphan Drug Act of 1983, a rare disorder is defined as a disease or condition that affects fewer than 200,000 people in the United States. The NIH estimates that there are more than 6,000 disorders cumulatively affecting approximately 25 million Americans.

I. Background: The first sentence of the "Background" section of the Federal Register notice says: "FDA is committed to protecting public health as well as to free and open communication." Nowhere in the Food Drug and Cosmetics Act is FDA assigned the duty of protecting or promoting free and open communication. In fact, the history of the FD&C Act specifically indicates intense political debates have occurred about the need to write pharmaceutical labeling in complicated medical jargon so the public will not understand them. Doctors were particularly concerned that if patients understood lists of side effects, they might experience the symptoms and not take the drugs. Thus, FDA was directed to purposely write labeling information in language that is not understandable to people who have no medical training.

Dedicated to Helping People with Orphan Diseases
Similar debates about "Patient Package Inserts" in the 1970s and 1980s led to defeat of federal legislation that would have provided written information for patients with every prescription drug dispensed. Again the medical community, pharmacists, and the pharmaceutical industry thought such information would frighten patients, and FDA was prohibited from requiring pharmacists and drug companies to communicate understandable drug information to patients. Even today there is substantial opposition from health-related industries to any mandate that would require understandable drug information on pharmaceutical labeling.

Therefore, the “Background” section of the Federal Register notice is misleading. FDA does not ensure that consumers receive accurate and complete information, and most of what we receive is not understandable to people without medical training. When we read in the newspaper that a food, cosmetic, or nutritional supplement company has been prohibited from making false advertising claims, it is usually the FTC that prosecutes the company, not the FDA.

Whether or not consumers benefit from direct-to-consumer (D-T-C) advertising is very debatable. Despite studies that indicate such advertising greatly inflates healthcare spending and inappropriate prescribing, the drug industry says it leads to better-informed consumers. Unfortunately, most prescription drug D-T-C ads are aimed at a small number of very prevalent health conditions that are not life threatening such as arthritis, allergies, erectile dysfunction, etc. It is difficult to imagine these conditions are under-diagnosed. The "education" provided by D-T-C ads is generally of little merit and it is often biased and incomplete.

II. In answer to your specific questions:

**Question 1:** There are very good arguments for regulating speech about prescription drugs. As the Supreme Court has said, the right of freedom of speech does not give one the right to shout “fire” in a crowded theater. Misleading or incomplete information about prescription drugs has great potential to harm. FDA’s duty is to protect the public’s health, and it is their duty to control commercial speech to ensure, for example, that balanced information is made available (e.g., if benefits are explained, an advertisement must also explain the risks). Promotional speech is inherently misleading if it explains only the benefits and not the risks to health.

Your question compares prescription drugs to nutritional supplements. We believe that FDA has been remiss in not requiring nutritional supplement manufacturers to list their side effects and possible interactions with drugs. People are being hospitalized, and even dying, for lack of accurate information about nutritional supplements. At the very least, these products should be labeled like over-the-counter drugs to warn consumers about dangers. False and misleading advertising of nutritional supplements seems to be regulated by the FTC, and the FDA appears powerless to stop false advertising due to the Dietary Supplement Health and Education Act.

We suggest that when a drug requires a legal physician’s prescription, the FDA has determined that the drug has certain qualities that may cause serious health problems if not monitored by a physician. Over-the-counter drugs and nutritional supplements do not require a prescription, so consumers make their own decisions to take them or not based on FDA’s determination that they are generally safe. Thus, it is logical that the government should regulate commercial speech about prescription drugs because their safety profile requires physician monitoring and a legal prescription from a qualified registered health professional. FDA has this responsibility to protect the public’s health.
Question 2: This question is about the FDA's policies on Direct-to-Consumer (DTC) advertising. In a May, 2002 editorial in *The Lancet* (Vol.359, Number 9319), “Europe on the Brink of Direct-to-Consumer Advertising”, which summarizes the negative effects of DTC advertising we have seen in the United States. Marketing expenses by pharmaceutical firms have risen from $860 million in 1997 to $2.5 billion in 2000. The impact of these expenses on drug costs to consumers is staggering. Additionally, only blockbuster drugs are advertised “often in misleading ways”, according to *The Lancet*. During 2000, over 95 percent of DTC budgets were for the 50 top selling drugs, which accounted for almost half of the increase in prescription drug spending in the United States. To understand how harmful DTC advertising can be, one need only look at Viagra advertisements; the drug was developed for erectile dysfunction which affects men who have had prostate surgery or another serious health condition, yet it is advertised by race car drivers and sportsmen who don't even mention erectile dysfunction and they portray the drug as an aide to having fun. The advertising has made Viagra into a major recreational drug, and FDA has done nothing to stop this, despite the fact that numerous deaths have been associated with use of Viagra.

The top selling drugs are generally not those to treat unmet or undiagnosed health needs. They are for allergies, hypertension, arthritis, etc., most of which can be adequately treated at lower cost with old generic drugs. There are dozens of medicines to treat each of these prevalent health conditions. DTC advertising does not help consumers, and it leads to higher health care costs that we all pay for. FDA can only demand retraction of an untruthful and misleading ad AFTER it is broadcast because pharmaceutical companies are not required to get FDA's approval before the advertisements are aired. Thus untruthful and misleading ads are shown to the public, and the damage is done before the government can act. In our opinion, FDA should have more regulatory authority to prevent commercial speech that can cause harm.

Question 3: FDA's regulatory authority over foods and nutritional supplements is inadequate. The supplement industry is like the wild west of the last century, allowing snake oil salesmen to make any false and misleading claims they can invent. Only after the supplement is shown to cause serious adverse events and deaths, is FDA permitted to stop sales. Only the FTC is doing anything to stop the blatant lies of supplement companies. Similarly, false claims on foods are rampant. In any period of several months, one can see TV advertising that claims certain foods prevent cancer, heart disease, etc. Such claims are not accompanied by any statement about how much of a food you have to ingest to get any therapeutic value. These misleading claims also encourage people not to see their doctor, and not to seek medical treatment. FDA needs more regulatory authority to control the untruthful and misleading speech of food and supplement companies. These egregious problems cause physical harm, and thus the FDA should regulate these products to the same extent as they regulate drugs.

Question 4: Disclaimers are not enough to stop false or misleading information on drugs, supplements or foods. People who believe nutritional supplement advertisers usually believe the FDA is an enemy. Thus a statement saying the FDA has not approved the product for its stated claims has no value to people who have lost trust in the FDA. Our government regulates the automobile industry and requires people to use seat belts in cars. It has similar responsibility for human safety in terms of foods, drugs, and supplements. Untruthful, misleading and inaccurate marketing information about health-related products should be prosecuted because it is akin to yelling “fire” in a crowded theater, resulting in serious public health consequences.
Question 5 & 6: Labels for prescription drugs (e.g., package inserts, Physicians' Desk Reference, etc.) are not understandable to people who have no medical education. Such information is written with Latin terminology for physicians, not ordinary consumers. Claims made in advertisements should be understandable, balanced and truthful, which means there should be equal space (or time in the case of TV or radio advertising) for side effects, contraindications and warnings. In TV ads for drugs, for example, the narrator usually says every word clearly until he gets to side effects, and then he says them so quickly they are impossible to understand. This should not be permitted.

Question 7: Speech about off-label uses is allowed under current law if a physician asks for the information. But drug salespeople are not permitted to provide the information if a physician doesn’t ask. We believe this is the proper regulation of off-label speech.

One need only look at the sales of Neurontin, which was FDA approved for a form of epilepsy, and the aggressive marketing that led to two-thirds of the sales of Neurontin for off-label uses. When some of the off-label uses were finally studied, it was found that Neurontin did NOT work on many of those conditions. If pharmaceutical companies are allowed to market drugs for off-label uses, many people will be treated with unsafe and ineffective drugs even though there is no proof they work on an unlabeled disease. Doctors are not prohibited from learning about unlabeled uses through Medline and other unbiased medical information systems. But pharmaceutical salespeople should NOT market them for off-label uses, and drug companies should support the research that will put the off-label use on the label with the proper dosage and side effects.

Question 8: FDA should continue to monitor and regulate the speech of drug companies because in the absence of regulation pharmaceuticals can present a serious public health threat. There should also be more punishments available to the agency, such as escalating civil monetary penalties for violations of the regulations.

Question 9: FDA's regulatory authority over false and misleading claims for foods and nutritional supplements should be strengthen, not weakened. The agency should be given authority to review and approve TV and radio DTC ads BEFORE they are broadcast, not after. FDA needs more regulatory authority, not less, because the health care marketplace represents the difference between life and death to the American public, unregulated pharmaceuticals can be dangerous to the public, and regulation of the industry resulted from serious public health tragedies in the past that killed and maimed Americans before the government was permitted to regulate health products, including the commercial speech of manufacturers.

Sincerely,

[Signature]
Abbey S. Meyers
President

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