



2004 MAY 11 11:07

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

Re: 2004D-0042 - Draft Guidances for Industry on Making Direct-to-Consumer Advertising More User Friendly

May 4, 2004

To Whom It May Concern:

While it may appear laudatory that the main objective of the FDA is to encourage prescription drug firms to present risk information in their consumer-directed advertisements using language that is understandable by a lay user, there is no evidence that the currently required risk information is not being adequately conveyed. Instead of facilitating the expansion of consumer-directed advertisements in the name of patient awareness and education, the FDA should actively regulate current advertising practices to assure an equal balance of risk and benefit information and abate practices that communicate unrealistic expectations associated with prescription drug use to consumers.

In 2002, we reported the deleterious impact of direct-to-consumer (DTC) advertising for AIDS drugs (Klausner, et al. AIDS 2002, vol 16: 15-16) resulting in misperceptions about the seriousness of HIV disease and an associated increase in risky sexual behavior. The data leading to that report resulted in an advisory letter from Dr. Abrams, Director of Division of Drug Marketing, Advertising and Communications to nine pharmaceutical manufacturers, dated April 27, 2001, stating that those DTC promotional materials and activities failed to convey critical limitations about the drugs, were misleading and violated the Federal Food, Drug and Cosmetic Act and its applicable regulations. Those false advertisements were removed from the market.

In 2001, researchers from Dartmouth Hitchcock Medical Center and the VA Medical Center in Vermont published data in The Lancet (Schwartz, et al. Lancet 2001, vol 358, pp.1141-46) demonstrating the striking imbalance between the risks and benefits portrayed in DTC advertising and the strong tendency for the advertisers to medicalize—have consumers consider medical conditions—ordinary experiences like sneezing, hair loss or runny nose. While risk characteristics of prescription drugs were described in detail with frequencies and percentages, the benefits were vague and cited without data. The authors' conclusion was that the provision of complete information about the benefit of prescription drugs would serve the interests of physicians and the public. The authors did not conclude that risk information had to be watered-down.

I am opposed to any new FDA language that would minimize the delivery of risk information to consumers. Offering 1-800 or Internet sites for more information about risk of advertised drugs is neither practical nor an effective way to educate consumers. Instead of facilitating the

2004D-0042

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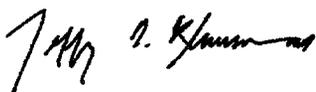
minimization of risk information, the FDA should assure that the risk information balances well-characterized benefit information and that as new risk information becomes available that those data are shared with consumers.

The second guidance document “ ‘Help-seeking’ and other disease awareness communications by or on the behalf of drug firms’ is a transparent attempt to facilitate drug sales by increasing consumer markets at the cost of the American people. The FDA is a public health agency whose mission is to protect the public health. Although prior FDA leadership had determined that “direct to the public prescription advertising was not in the public interest,” more recent leadership has changed that citing free speech concerns. Unfortunately, no agency is left with the responsibility to protect the public’s health concerning pharmaceutical manufacturing. This document on disease awareness communications while supposedly in the interest of consumers to learn about under-diagnosed and under-treated conditions will result in considerable costs for the public with no clear benefit. Since much of pharmaceutical advertising is cited as a cost of doing business, advertising costs are deducted from gross profits, making these costs actual tax deductions borne by the tax payers. Creating a greater demand for prescription drugs specific to chronic conditions will increase health costs further increasing costs borne by tax payers.

If the FDA were serious in trying to increase awareness and education about chronic or untreated conditions it would partner with the Federal health agency charged with this responsibility, the Centers for Disease Control and Prevention—and not with private industry—and develop mechanisms to support a Federal effort, perhaps with funding with increased pharmaceutical industry user fees or specific pharmaceutical industry taxes. Having the Federal government facilitate and pay for private industry marketing does not serve the public health and further erodes any confidence consumers might have in the FDA to protect their interests versus serving the pharmaceutical industry.

Industry efforts to market awareness will further medicalize common conditions not requiring medical attention and could be associated with significant harmful effects associated with side effects from medications and unnecessary medical testing. Perhaps if the focus of the awareness campaigns included an equal or greater amount of disease prevention and health promotion messages the negative impact of the campaigns could be mitigated. So while the insidious nature of hypertension and its untoward effects might be raised, greater time could be spent on intervention awareness that reduce hypertension like tobacco cessation, diet and exercise.

Sincerely,



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