

Speech that FDA Regulates

William A. McConagha
Office of Accountability
Food & Drug Administration

Risk Communication Advisory Committee
February 28, 2008

1

Purpose of Presentation

- ◆ To give a broad overview of the types of speech that FDA regulates, and
- ◆ To discuss the limits of FDA's jurisdiction over speech

◆ For purposes of this presentation, the terms "FDA requires" and "FDA prohibits" have been used as shorthand to describe requirements and prohibitions set forth in the FDCA, its implementing regulations, or both.

2

FDA Regulatory Portfolio

- ◆ FDA has an extremely broad regulatory portfolio.
- ◆ FDA has jurisdiction over drugs, devices, biological products, foods (including dietary supplements) and cosmetics.

3

FDA's Mission

FDA's mission is to protect and promote the public health:

- FDA's jurisdiction extends to the physical aspects of articles – including their physical integrity and purity, and way in which they are manufactured, packaged, and stored.
- But, FDA's jurisdiction also extends to commercial speech associated with these articles – including their labels, labeling, and other promotional statements made for the articles.

4

Types of Speech that FDA Regulates

FDA's regulatory interest in speech is multi-faceted.

- ◆ Consider, for example, the life-cycle of a prescription drug:
 - At one end of the spectrum, the claims made for the drug confer FDA's jurisdiction over the product in the first place.
 - At the other end of the spectrum, there are regulatory issues associated with the advertising and sale of that prescription drug long after it is approved for marketing in the United States.

5

Types of Speech: Intended use

Under the Federal Food, Drug, and Cosmetic Act (FDCA), whether FDA has jurisdiction to regulate an article as a drug, cosmetic, dietary supplement, or device depends on the **intended use** of that article.

- ◆ For example, under section 201(g)(1)(B) of the FDCA, an article meets the definition of a drug if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.
- ◆ To establish jurisdiction, FDA uses commercial speech about an article as evidence of the manufacturer's intent for that article.

6

Types of Speech: Labels

A "label" is defined in the FDCA as a display of written, printed, or graphic matter upon the immediate container of any product.

- FDA reviews and approves virtually all of the content on the labels of those products that it pre-approves.
- Even for FDA-regulated articles that are not subject to pre-approval, FDA requires certain information to appear on the product labels.
- In the case of dietary supplements, FDA requires that certain claims be accompanied by a disclaimer.
- FDA requires some labels to be organized in a specified format.
- FDA prohibits labels from containing certain information.
- In all cases, the FDA prohibits labels or labeling from being false or misleading in any particular.

7

Types of Speech: Labeling

Labeling is defined in the FDCA as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article

As with labels, FDA's authority over product labeling is generally twofold:

- FDA requires that certain words appear in product labeling.
- FDA also prohibits labeling from containing certain information

8

Types of Speech: Advertising

FDA also has jurisdiction over aspects of the advertising for certain FDA-regulated products.

- "Advertising" is not defined in the FDCA, but it is commonly understood to include the promotional materials or statements made for a product that do not meet the definitions of "label" or "labeling" in the FDCA. Advertising can include commercials on radio or TV, or promotional statements that appear in newspapers, or magazines.
- Most of debate in this area focuses on advertising for drugs.
- FDA has primary jurisdiction over advertising for prescription drugs and a certain, limited category of medical devices.
- FTC has primary jurisdiction over advertising for OTC drugs.

9

Advertising (cont'd)

- **Print advertisements:** FDA's regulations require that the advertisement present a true statement of information in brief summary relating to the side effects, contraindications and effectiveness of the prescription drug at issue.
- **Broadcast advertisements:** FDA's regulations require (1) that the advertisement disclose information relating to the major side effects and contraindications and (2) that either adequate provision be made for dissemination of the FDA-approved labeling for the prescription drug or that the advertisement contain a brief summary of all necessary information related to side effects and contraindications.
- For both forms of advertising, FDA's regulations prohibit an advertisement for a prescription drug from including a representation or suggestion, not approved in the drug's labeling, that a drug is better, more effective, or useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience.

10

Types of Speech: Other Oral Representations

Since an article's legal status is tied to its intended use, FDA has a regulatory interest in oral representations made about FDA-regulated articles:

- Product reps (or detailers)
- Manufacturer-sponsored symposia
- Trade shows

11

Cross-cutting Themes

If we look beyond the legal definitions of label vs. labeling vs. advertising, important cross cutting themes emerge:

- In some instances, FDA requires that certain words be used in association with an article.
- In other instances, FDA prohibits certain words from being used in association with an article.
- In still other instances, FDA will allow the use of certain words in association with an article, but only if they have been authorized or pre-approved.
- Depending on the intended audience, FDA prescribes the manner in which certain information is organized or presented.
- FDA enforcement actions are sometimes grounded in the statements made – or not made – about an article.

12

The Limits of FDA's Jurisdiction

- ◆ Article I to the United States Constitution: "Congress shall make no law respecting the establishment of religion, or prohibiting the free exercise thereof; **or abridging the freedom of speech**, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

13

What does free speech mean?

- ◆ Free speech means:
 - The right to speak
 - The right to receive information
 - The right not to speak (i.e., freedom from compelled speech).
- ◆ But keep in mind --
 - None of these rights is absolute.

14

The degree of Constitutional protection depends in part on the nature of the speech

- ◆ Highest level of protection –
 - Political speech
 - literary speech
 - scientific exchange
- ◆ Moderate level of protection –
 - Commercial speech (even if potentially misleading)
- ◆ Not Protected –
 - Defamation
 - obscenity
 - proposing illegal activity

15

What is commercial speech?

- ◆ Typically involves speech that proposes a commercial transaction
- ◆ Commonly used factors include:
 - promotional nature of a communication
 - relation to specific products
 - economic motivation
- ◆ Compare to:
 - scientific exchange

16

How Courts Analyze the Validity of Government Action under the First Amendment

Central Hudson Gas & Electric Corp. v. New York Public Service Commission, 447 U.S. 557 (1980).

Sets forth the current test for analyzing government restrictions on commercial speech; has also been used to analyze government speech requirements (compelled speech).

17

The *Central Hudson* Test

1. Commercial speech is not entitled to First Amendment protection if it:
 - promotes an illegal product or activity; or
 - is false or inherently misleading (not merely potentially misleading).

18

The *Central Hudson* Test (cont.)

2. The government interest asserted to justify the restriction must be substantial.

Examples of substantial government interests:

- Promoting health and safety
- Protecting consumers from fraud

19

The *Central Hudson* Test (cont.)

3. The restriction must directly advance the substantial interest asserted by the government.

- Government must have **evidence** that the restriction advances the substantial interest; the agency's opinion that the restriction will be beneficial is not enough.
- Showing **direct** advancement is key; courts strike down restrictions that provide only tangential, speculative, or remote support for the agency's goal.

20

The *Central Hudson* Test (cont.)

4. The restriction must be no more extensive than necessary.

- Does not mean that the restriction must be "absolutely the least severe that will achieve the desired end," but if court finds that there are "numerous and obvious" alternatives to the restriction that create less of a burden on speech, the restriction will be struck down.
- Courts determine for themselves whether there are less restrictive alternatives; they don't generally defer to agency's judgment.

21

Recent FDA-related First Amendment Cases

- ◆ *Washington Legal Foundation v. Friedman*, 13 F. Supp.2d 51 (D.D.C.1998)
 - Decision on appeal: *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).
- ◆ *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)
- ◆ *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002)
- ◆ *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004)

22

Conclusion:

- ◆ FDA regulates commercial speech in a variety of ways:
 - Speech is required in certain instances
 - Speech is restricted in others
- ◆ FDA's exercise of authority must remain consistent with the First Amendment

23