

Before the
Food and Drug Administration, HHS
Rockville, MD 20857

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In the Matter of)

Request for Comment)

On First Amendment Issues)

) Docket No. 02N-0209
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COMMENTS OF THE
AMERICAN CIVIL LIBERTIES UNION

We offer these comments on behalf of the American Civil Liberties Union (ACLU) pursuant to the Agency's "Request for Comment on First Amendment Issues," 67 Fed. Reg. 34942, May 16, 2002. We urge the agency to adopt an approach in its advertising and labeling regulations that is less restrictive of commercial speech. The ACLU is a non-partisan, non-profit organization, consisting of nearly 300,000 members, dedicated to protecting the liberties and freedoms guaranteed in the Constitution and laws of the United States.

The ACLU believes the government has an interest in preventing dangers to consumers' health and safety. Requiring warnings can generally accommodate that interest. Prohibiting information, however, in the interest of protecting consumers, carries with it dangers to freedom of speech.

In light of the evolving law regarding commercial speech, the ACLU urges the agency to modify its current regulations, policies, and practices by adopting a less restrictive approach that respects the protection that the law affords commercial speech.

Advertising and labeling qualify as commercial speech. In deciding what constitutes commercial speech, the Supreme Court announced a three-part test.¹ If the information is an advertisement, refers to a specific product, and is sent by someone with an economic motivation, then the speech qualifies as commercial speech.² In *Bolger v. Young Drug Products Corp.*, the Court addressed a postal regulation that prohibited sending unsolicited mailings regarding contraception.³ The Court held that the speech was commercial because it was concededly an advertisement, refers in part to the sender's contraceptive products along with its helpful information about general contraception and sexual health, and was economically motivated.⁴ Drug and dietary supplement advertisements would certainly qualify under this rubric as commercial speech if they refer to the sender's product and are economically motivated.

Labels are more difficult to classify because the aim might be to solely educate consumers, making them more similar to other forms of free speech and entitled to higher protection under the First Amendment. However they also qualify as commercial speech. In the past, the Supreme Court considered alcohol labels as advertisement, presumably because the alcohol content reflected the

02N-0209

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¹ *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 67 (1983)(held that pamphlets that were informative about both condoms in general and the sender's specific products qualified as commercial speech).

² *Id.* at 67.

³ *Id.* at 62.

⁴ *Id.* at 67.

strength of the liquor and might motivate consumers to buy the particular product.⁵ Similarly, labels of drug and dietary supplements may indicate ingredients whose presence or absence may sway the decisions of consumers towards or away from a product. Thus it is likely that both advertising and labels would qualify as commercial speech under existing Supreme Court precedents.⁶

The agency must use the least restrictive means available when it regulates commercial speech.

The FDA should change its regulations, policies, and practices to achieve its goals without burdening free speech more than necessary. If the agency does not use the least restrictive means available in a regulation concerning commercial speech, it is highly likely that courts will strike down the regulation. Several cases indicate that the Supreme Court will more closely scrutinize any agency actions restricting commercial speech.

One landmark case is *Central Hudson Gas v. Public Service Commission*.⁷ In *Central Hudson*, the Supreme Court invalidated a state law prohibiting a utility from promotional advertising. The state based the rule on its need to conserve fuels.⁸ The Court struck down the law, announcing a four-part test:⁹

- (1) If the commercial speech is false or deceptive advertising, or if it promotes illegal activities, then the speech is *per se* unprotected by the First Amendment.¹⁰
- (2) If the speech does not fall into any of those categories, then the government must justify its restriction with a substantial government interest.¹¹
- (3) The law must directly advance the government interest.¹²
- (4) Finally, according to the *Central Hudson* test, the regulation of speech must be no more extensive than necessary to serve the substantial interest that it advances.¹³

In *Central Hudson*, the state's restriction on protected speech directly advanced a substantial government interest;¹⁴ however, the Court struck down the regulation because the state could have concocted a less restrictive way to achieve its goals.¹⁵

This determinative fourth prong has since been a somewhat controversial subject. The Court has at times used the language "narrowly tailored" to describe this test,¹⁶ but more frequently has used the

⁵ See *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995)(upheld the right of a beer company to display its beverage's alcohol content on the label).

⁶ Some sources have speculated that perhaps food and drug advertisements should fall within the domain of the Federal Trade Commission due to that agency's expertise in advertisement and free speech. Dr. John E. Calfee, Remarks at the Washington Legal Foundation Media Nosh "Free Speech, & Public Health: FDA, Congress, and the Future of Food and Drug Promotion" (May 30, 2002)(FDA regulations are repeatedly struck down in court because unlike the FTC, the FDA regulations infringe far more on free speech than the First Amendment traditionally allows). For the purposes of these comments, however, it is assumed that both labeling and advertisement fall within the FDA's jurisdiction and expertise.

⁷ *Cent. Hudson Gas v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980).

⁸ See *id.* at 558-559.

⁹ See *id.* at 566.

¹⁰ See *id.* at 563-565.

¹¹ *Id.* at 566.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 568-569.

¹⁵ *Id.* at 570-571.

language of “least restrictive means.”¹⁷ This approach requires that the government adopt the least restrictive means available when it restricts commercial speech in any way.

The agency should regulate products comprehensively, when necessary, in ways that do not impose unjustified restrictions on commercial speech.

The agency has solicited comments regarding whether it should regulate some types of products more extensively than others, i.e. drugs versus dietary supplements. The FDA should not regulate certain products’ advertising and labeling more comprehensively than others simply due to product type, because such an approach does not constitute the least restrictive means. Nor is it the most narrowly tailored way to achieve the agency’s objective of furthering public health. Regardless of what legal test is applied, at a minimum, regulation governing commercial speech must be no more extensive than necessary.¹⁸ Thus, the government cannot just apply a blanket solution that is not targeted to further its substantial interest.

The FDA could protect consumers from potentially harmful effects of dangerous drugs by requiring measures other than restrictions on speech in labels and advertisements. For example, it could require a doctor’s prescription for both dietary supplements and drugs that are powerful or have dangerous side-effects. This would promote public health by providing additional guidance and monitoring to consumers without restricting speech.

Meanwhile, those products that do not require comprehensive oversight could be widely available to the public without burdening the speech of the drug industry any more just because the product is a drug rather than a dietary supplement. Both drugs and dietary supplements affect the body and should be treated according to the level of danger they pose rather than what type of product they are. Differentiating according to the dispensing method of the product is by no means the only solution, but is rather an illustration of a way that the FDA could protect consumers with tools already available to it, rather than by burdening free speech. Considering the Supreme Court’s thinking as reflected by *Thompson*, the FDA would benefit from adopting alternatives that are less restrictive of commercial speech.

Current agency DTC print advertisement practices unduly infringe commercial speech.

The agency could adopt regulations that are less restrictive of commercial speech. If it did so, its regulation would be more likely to withstand constitutional scrutiny.

The agency’s position regarding direct-to-consumer print advertisement (DTC advertisement) is not consistent with relevant legal authority because it excessively restricts commercial speech. A prescription drug’s label must contain certain information, including information about the drug’s clinical pharmacology, data from clinical studies, indications and usage, contraindications, warnings,

¹⁶ See *Bd. of Trs. of the State Univ. of NY v. Fox*, 492 U.S. 469, 480 (1989)(adopted a modified version of the *Central Hudson* test by requiring that the government narrowly tailor its regulation to serve its interest rather than the heavier burden of requiring that the government use the least restrictive means possible).

¹⁷ See *Rubin*, 514 U.S. at 476 (used least restrictive approach); *44 Liquor Mart, Inc. v. RI*, 517 U.S. 484 (1996)(applied least restrictive approach); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001)(used narrowly tailored approach to uphold some regulations while using the least restrictive approach to strike down others); *Thompson v. W. States Med. Ctr.*, No. 01-344, 2002 U.S. LEXIS 3035 (U.S. 2002)(used least restrictive approach).

¹⁸ ERWIN CHERMERINSKY, *CONSTITUTIONAL LAW PRINCIPLES AND POLICIES* 890 (Aspen Law and Books 1997)(further commented that the distinction between the two approaches seems “illusory”).

precautions, and adverse effects.¹⁹ These requirements are comprehensive and detailed and are intended for use by the prescribing practitioner. Though the regulation of DTC print advertisements requires a “brief summary,”²⁰ print advertisements for prescription drugs contain almost as much information: the advertisement must list side effects, warnings, precautions, and contraindications that the drug’s labeling contains.²¹ Therefore, the resulting advertisement for consumers’ eyes is almost as technical and difficult to read as that intended for medical professionals. The requirement for printed promotional labeling, which includes items such as booklets, brochures, mailers, and letters, is that it must contain “adequate directions for use.”²²

In essence, the printed promotional labeling must be equivalent to the full label of the medicine.²³ Not only has the agency itself expressed displeasure at these requirements,²⁴ but also it has taken some steps in the direction of revision by issuing its Consumer-Directed Broadcast Advertisements Guidance in 1999²⁵ and a draft Guidance for Industry permitting Use of FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements in 2001.²⁶ However, since then, it has not taken further steps in the right direction.

The current position of the agency regarding DTC advertisements does not directly advance the FDA’s interest, nor are the requirements the least restrictive necessary. Considering that the FDA has time and again recognized that the labeling requirements make what is intended to be promotional material nearly impossible for the ordinary consumer to understand, it hardly seems that the FDA’s current DTC advertisement position would pass the third or fourth prong of the *Central Hudson* test applied in *Thompson*.

The agency could adopt a number of solutions that would accomplish its goals and be no more restrictive of commercial speech than necessary. For example, it could apply its policy regarding broadcast DTC advertisements to print materials.²⁷ Alternatively, it could require that the “brief summary” be more “brief,” and be made more comprehensible to the ordinary consumer.²⁸ Finally, it could take the initiative in proposing that the industry propose and adopt its own standards regarding a clearer and shorter format for print advertisements.²⁹ Such solutions not only foster a more cooperative

¹⁹ FDA & Dept. of Health and Human Servs. Drugs: General, 21 C.F.R. § 201.57 (2002).

²⁰ 21 U.S.C. § 352(n) (2002).

²¹ FDA & Dept. of Health and Human Servs. Drugs: General, 21 C.F.R. § 202.1(e)(3)(iii)(2002).

²² 21 U.S.C. § 352(f)(1) (2002).

²³ FDA & Dept. of Health and Human Servs. Drugs: General, 21 C.F.R. § 201.5 (2002).

²⁴ The FDA has previously noted the technicality of the requirements, calling them “relatively inaccessible to consumers” and “of questionable” value. 60 Fed. Reg. 42,583 (Aug. 16, 1995). This Notice announced a public hearing about DTC promotion, and at the hearing, the FDA Associate Director for Medical Policy at the time, Dr. Robert Temple, stated that the brief summary was an oxymoron. See Richard L. Frank, Remarks at the Washington Legal Foundation Media Nosh “Free Speech, & Public Health: FDA, Congress, and the Future of Food and Drug Promotion” 4 (May 30, 2002) quoting DTC Public Hearing, Statement of Robert Temple, Oct. 18, 1995 (Panel 5)(stated that the “brief summary, which is neither brief nor summary – like the Holy Roman Empire was neither holy nor an empire – isn’t very helpful.”)]

²⁵ CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., CONSUMER-DIRECTED BROADCAST GUIDANCE, (1999), available at <http://www.fda.gov/cder/guidance/>

²⁶ CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY USING FDA-APPROVED PATIENT LABELING IN CONSUMER DIRECTED PRINT ADVERTISEMENTS, (Apr. 1, 2001), available at <http://www.fda.gov/cder/guidance/>

²⁷ See Frank, *supra* note 55, at 4.

²⁸ *Id.*

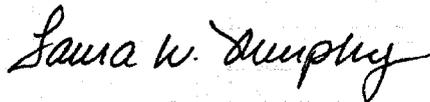
²⁹ Sandra J.P. Dennis & Lawrence S. Ganslaw, *Excessive FDA Scrutiny of DTC Ads Undermines Speech Rights*, 16 WASH. LEGAL FOUND. LEGAL BACKGROUNDER 1, 4 (May 18, 2001).

environment between regulators and the industry, but also promote what is best for consumers, providing them with more concise understandable information about their safety at their fingertips.

In short, the agency's speech-related regulations may advance its public health concerns without unduly restricting commercial speech. The agency has a substantial interest in public health that it should advance through regulation, but it must be careful to tailor its regulations, policies, and practices to minimize the burden it places on commercial speech. In some instances discussed above, it is clear that the agency could advance its interests in a way that is less restrictive of commercial speech, or at least more narrowly tailored towards promoting its interest.

Examples mentioned in these comments, such as regulating comprehensively on the basis of prescription rather than simple classification as a drug or dietary supplement reflect the recent thinking of the Court.³⁰ Because the courts have, and may in the future, strike down FDA rules limiting speech when there are less restrictive means of accomplishing the FDA's consumer health and safety goals, we encourage the Agency to adopt less restrictive means where possible.

Dated: July 26, 2002



Laura W. Murphy
Director



Marvin J. Johnson
Legislative Counsel

³⁰ See cases cited *supra* note 18.

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1 From This portion can be removed for Recipient's records.

Date *7/26/07* FedEx Tracking Number

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Sender's Name *Maria Stiles* Phone *301 607 3360*

Company *AMERICAN CIVIL LIBERTIES*

Address *122 MARYLAND AVE NE*

City *WASHINGTON*

State *DC* ZIP *20002*

Dept./Floor/State/Room

2 Your Internal Billing Reference

3 To Recipient's Name *Packets Managerial* Phone *301 607 3360*

Company *Buckets Managerial Dept, F.O.A.*

Address *5630 Fisker Lane*

City *Rockville* State *MD* ZIP *20852*

Dept./Floor/State/Room



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4a Express Package Service

FedEx Priority Overnight
Next business morning

FedEx Standard Overnight
Next business afternoon

FedEx 2Day
Second business day

FedEx Express Saver
Third business day

Packages up to 150 lbs.
Delivery commitment may be later in some areas.

FedEx First Overnight
Earliest next business morning delivery to select locations

4b Express Freight Service

FedEx 1Day Freight*
Next business day

FedEx 2Day Freight
Second business day

FedEx 3Day Freight
Third business day

Packages over 150 lbs.
Delivery commitment may be later in some areas.

FedEx Pak*
Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak

*Declared value limit \$500

5 Packaging

FedEx Envelope*

6 Special Handling

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Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

HOLD Weekday at FedEx Location
No available for FedEx First Overnight and FedEx 2Day to select locations

HOLD Saturday at FedEx Location
Available only for FedEx Priority Overnight and FedEx 2Day to select locations

7 Payment Bill to:
 Sender
 Recipient
 Third Party
 Credit Card
 Cash/Check

8 Release Signature

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Total Weight
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