

BEFORE THE
Food and Drug Administration
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852

In re:) Docket No. 02N-0209
)
Request for Comments)
on First Amendment Issues)

**COMMENTS OF FREEDOM OF
EXPRESSION FOUNDATION, INC.**

FREEDOM OF EXPRESSION FOUNDATION
CRAIG R. SMITH, PRESIDENT
171 CLAREMONT AVE.
LONG BEACH, CA 90803
562-434-2284

02N-0209

C54

Table of Contents

I. Introduction	1
II. The Unconstitutional Regulation of Commercial Speech	2
A. Past Infractions of the FDA	4
B. Restricting Information	8
C. Regulating Abuse	9
D. The Special Case of Tobacco Advertising	10
III. Conclusion	11

**Before the Food and Drug Administration
Rockville, MD**

**Request for Comments)
on First Amendment Issues)**

Docket No. 02N-0209

**COMMENTS OF FREEDOM OF
EXPRESSION FOUNDATION, INC.**

I. Introduction

FREEDOM OF EXPRESSION FOUNDATION, INC., (“FOEF”) hereby respectfully submits the following Comments with respect to the request for comments by the Food and Drug Administration (“FDA”) regarding First Amendment issues.¹ FOEF respectfully submits that if a product is legal, the advertising thereof is presumptively protected by the First Amendment unless it is provably false or misleading. We further argue that in light of the First Amendment rulings discussed below, the presumption lies with the manufacturers and advertisers of legal products. The burden of proof is on the FDA. Furthermore, FOEF will demonstrate that in the past the FDA has abused its authority. Finally, by the First Amendment analysis presented here, FOEF will demonstrate that the FDA needs to terminate forays across its congressionally imposed borders

The Freedom of Expression Foundation, Inc. is a private nonprofit membership corporation that seeks, through research, commentary, and educational programs, to

¹ *Request for Comments on First Amendment Issues*, FDA Docket No. 02N-0209, 67 Fed. Reg. 34942 (May 16, 2002).

preserve and advance the First Amendment rights of the mass media, particularly the electronic mass media, and the freedom of the press, both print and electronic, from governmental intrusion in the editorial process and the dissemination of information by the press to the public. FOEF's members and contributors include private foundations, publishers of daily newspapers, broadcast licensees, program suppliers, and other corporate entities and private citizens who support the research and educational objectives of FOEF. The Foundation's many publications include a scholarly study of the intent of the founders, *To Form a More Perfect Union* (University Press of America) and a scholarly study of the history of the First Amendment, *Silencing the Opposition* (State University of New York Press). As President of the Foundation and as Director of the Center for First Amendment Studies at California State University, Long Beach, I submit the following comments for your consideration.

II. The Unconstitutional Regulation of Commercial Speech

In the past, the FDA has crossed the constitutional line when it comes to regulating the advertising of legal products. The FDA should return its and the courts' traditional and precedential position that commercial speech is entitled to First Amendment protection. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) ruled that commercial speech is protected and holds the presumption against government regulation. *Bates v. State Bar of Ariz.*, 433 U.S. 350, 365 (1977), for example, prevented the state from regulating the advertising of lawyers.

The Court has consistently held this position because:

“ . . . people perceive their own best interests if only they are well enough informed and . . . the best means to that end is to open channels of communication rather than to close them . . .”²

Clearly, governmental authority to restrict advertising is constrained by First Amendment principles “ . . . and specifically by the principle that disclosure of truthful, relevant information is more likely to make a positive contribution to decision-making than is concealment of such information.”³ Manufacturers of legal products should be allowed to proclaim the benefits of these products as well as their composition if they so choose

Furthermore, the FDA should be aware that the government may not censor a particular commercial message because some members of the population believe the message to be of slight worth. “Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price.”⁴ In short, the government may not substitute its opinion regarding the worth of the advertising for that of advertiser short of demonstrating misleading content or a clear and present danger.

We respectfully remind the FDA, that when the government restricts commercial speech, courts must consider governmental ends and means.⁵ Courts may not simply defer to governmental authority⁶ The test for determining the constitutionality of regulation of commercial speech is found in *Central Hudson, supra*. A four-pronged test must be satisfied before the government can restrict commercial speech.

² *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980) at 562 (citations omitted); see also *Edenfield v. Fane*, 113 S. Ct. 1792, 1800 (1993)

³ *Peel v. Attorney Registration & Disciplinary Commission of Illinois*, 496 U.S. 91, 108 (1980) (citing *Virginia Pharmacy*, 425 U.S. at 770).

⁴ *Edenfield, supra*, 113 S. Ct. at 1798; *Virginia Pharmacy, supra*, 425 U.S. at 765.

⁵ *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 519 (1981).

⁶ *Peel*, 496 U.S. at 108; see also, *Turner Broadcasting Systems, Inc. v. FCC*, 114 S. Ct. 2445, 2471 (1994)

- 1 If the communication is neither misleading nor unrelated to unlawful activity,
- 2 the [government] must assert a substantial interest [and] the limitation on expression must be designed carefully to achieve the [government]'s goal. Compliance with this requirement may be measured by two criteria:
- 3 The restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose[:]
- 4 If the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive [constitutional scrutiny].⁷

Clearly, regulations proposed for legal and non-misleading activities must meet a high standard. If the government cannot satisfy the second, third and fourth prongs of the test, the restrictions cannot pass constitutional muster.⁸

The FDA must also be cognizant of the fact that advertising of legal products may not be regulated or suppressed because of its *content* unless that content is misleading or presents a clear and present danger.⁹ In fact the FDA should take particular cognizance of the fact that statutes are “presumptively inconsistent with the First Amendment if” they impose a financial burden on speakers because of the content of their speech.¹⁰ Having established this basic First Amendment environment, we now turn to specific problems raised by the actions of the FDA in the past.

⁷ *Central Hudson*, 447 U.S. at 564

⁸ *Id.* at 566; see *Shapiro v. Kentucky Bar Ass'n*, 486 U.S. 466, 472 (1988).

⁹ *Turner Broadcasting System Inc. v. FCC*, 114 S. Ct. 2445 (1994).

¹⁰ *Simon & Schuster v. Members of the New York State Crime Victims Board*, 502 U.S. _____ (1991). See *R.A.F. v. St. Paul*, 505 U.S. 377 (1992).

A Past Infractions of the FDA

As we have noted in other filings before the FDA,¹¹ the administration has attempted to make speech about pharmaceutical products into a “special case.” It has also used a wider than acceptable net to attempt to capture “promotional activity” of pharmaceutical products under its purview. These attempts to move beyond the boundaries assigned to the FDA, as we shall show, have violated the First Amendment rights of pharmaceutical companies, their advertisers, and consumers.

The FDA’s authority with regard to labeling and advertising is limited by the 1938 Food, Drug, and Cosmetic Act and the 1962 Drug Amendments.¹²

In the 1990s, the FDA gave a distorted reading to its authority. Companies were understandably reluctant to challenge that authority given the FDA’s approval authority over their products. Thus, while the law confined labeling to discourse “accompanying” a drug, the FDA expanded the definition to include all manner of communication including “Brochures, booklets, mailing precis . . . bulletins, calendars, price lists . . . recordings, exhibits, literature . . . visual matter.”¹³ The FDA then expanded its authority over advertising to include “published journals, magazines . . . newspapers” and broadcast advertising.¹⁴ Together these aggressive interpretations gave the FDA virtual control over all pharmaceutical company communication with consumer.¹⁵ With these expansive rules, the FDA also established prior restraint over pharmaceutical communication to consumers, a clear violation of the basic principles of the First Amendment.¹⁶

¹¹ *Comments of the Freedom of Expression Foundation*, Docket No. 95N-0253.

¹² 21 U.S.C. sec. 301, 21 U.S.C. sec. 502 (n)

¹³ 21 C.F.R. 202.1 (1)(2).

¹⁴ 21 C.F.R. (1) (2).

¹⁵ See 1995 *Notice*, supra note 22, at 4.

¹⁶ Many scholars have documented that if the First Amendment was intended for anything, it was intended to prevent censorship of speech and press prior to its broadcast or publication. See, for example, Leonard Levy, *The Emergence of a Free Press* (New York, 1985) and Craig R. Smith,

When the FDA attempted to expand their purview even further to include the speech of scholars and scientists, the courts restricted their power to do so.¹⁷ The importance of this ruling, and others we discuss below, is that they insure that the FDA is subject to First Amendment testing, and that the presumption lies with the speaker NOT the FDA. The most recent iteration of this position came in 2002 when the Supreme Court upheld the Ninth Circuit Court of Appeals ruling in *Thompson v. Western States Medical Center*, which struck down a section of the Food and Drug Administration Reform Act of 1997.¹⁸

We would add that past attempts by the FDA not only to *regulate* speech, but to *suppress* it partially or completely in some contexts, for example, on billboards, on shirts and other items that may be purchased or distributed as souvenirs at events, and by restricting the permissible format for such speech in print media read by minors, are far too restrictive and too suppressive for purposes of advancing the FDA's goal of protecting the public health, where other means are available. Such behavior clearly violates the *Central Hudson* test. In 1996 *44 Liquormart v. Rhode Island* directly addressed a state's attempt to ban the advertising of commercial speech because the state had an interest in reducing the use of the alcohol products being advertised. The unanimous decision struck down a Rhode Island statute and similar regulations in ten other states. The Rhode Island restriction was unconstitutional because "alternative forms of regulation that would not involve any restriction on speech" were available.¹⁹ The Supreme Court unanimously reaffirmed that position in 1999 in *Greater New Orleans Broadcast Assn. v. United States*. Again writing for the Court, Justice Stevens argued that if the product is legal, "the speaker

To Form a More Perfect Union (Lanham, Md., 1993).

¹⁷ *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C., 1998).

¹⁸ 535 U.S. _____, April 29, 2002.

¹⁹ 116 S. Ct. 1510.

and the audience, not the government, should be left to assess the value of accurate and non-misleading information" about it.

All of the above involve restriction of the print media, as well as suppression and coercion of free speech in their most obvious manifestations. Such regulation cannot be deemed, under any reasonable test, to be constitutional.

In a long line of cases, the Supreme Court has ruled that local governments may not discriminate between one kind of speech over another, for example, commercial versus ideological speech. The Supreme Court held in *City of Cincinnati v. Discovery Network* (1993) that the city could not restrict the *space* available for newspaper stands.²⁰ Writing for the majority, Justice Stevens argued:

In our view, the city's argument attaches more importance to the distinction between commercial and non-commercial speech than our cases warrant and seriously underestimates the value of commercial speech . . . In sum, the city's newsrack policy is neither content-neutral nor . . . 'narrowly tailored.' Thus, regardless of whether or not it leaves open ample alternative channels of communication, it cannot be justified as a legitimate time, place, or manner restriction on protected speech.

The protection of commercial speech began with the *Bolger* case of 1975, continued in *Virginia Pharmacy, supra* (1976), and culminated in the four part test provided in *Central Hudson Gas, supra* (1980), which has regularly been re-asserted by the Supreme Court ever since. Furthermore, since 1973 the Court has held that it does not matter whether the burden imposed on the targeted speech is direct or indirect.²¹ A re-affirmation of this position came in *R.A.F. v. St. Paul* (1992) which said a law is "facially unconstitutional if it prohibits otherwise permitted speech solely on the basis of the subject the speech addresses."

²⁰ See also *Lakewood v. Plain Dealer Publishing* (1988).

²¹ See *Committee for Public Education & Religious Liberty v. Nyquist*, 1973).

City of Los Angeles v. Taxpayers for Vincent (1984) also states that attempts to tax speech because of its content are unconstitutional.²² The government may not regulate speech in a way that is prejudicial to some ideas at the "expense of others." Thus, the FDA faces an enormous burden of proof if it seeks to regulate speech based on its content, scientific or otherwise, that is not labeling or advertising under its direct authority.

B Restricting Information

The FDA also needs to take cognizance of the fact that the Supreme Court has ruled that barring a compelling government interest, the government may not prohibit the distribution of information about products including their composition. As recently as 2001, the FDA's attempt to restrict claims made by dietary supplement manufacturers was struck down. In *Pearson v. Shalala*,²³ the District court held that the FDA had violated the First Amendment rights of the producers and advertisers of the supplement. In an important statement supporting our position on the issue of burden of proof, the court ruled that "the mere absence of significant evidence in support of a particular claim does not translate into negative evidence against it."²⁴ While the court acknowledge the FDA's role in preventing "consumer fraud," it overturned the rule at hand because it was deemed more restrictive than necessary.²⁵ Furthermore, in applying a balancing test, the court claimed that "even if the plaintiffs' Folic Acid Claim is in some respects 'potentially misleading,' the resulting injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury plaintiffs have continually borne in the two years

²² In *Minneapolis Star & Tribune v. Minnesota Comm'r of Revenue* (1983), the Court overturned a law that imposed differential tax consequences on speech based on its content (See also *Arkansas Writers Project v. Ragland*, 1987 and *Grosjean v. American Press*, 1936.)

²³ 130 F. Supp. 2d 105

²⁴ *Ibid.* at 115.

²⁵ *Ibid.* at 113-14.

since *Pearson* was decided.”²⁶ The message in this case and the one that follows is that the FDA cannot ignore the First Amendment rights of manufacturers and advertisers, nor can they be punished for “potential” harms. The harms must be REAL and documented.

As we have shown above, the FDA was brought account in the Ninth Circuit court for its attempts to quash pharmacists promoting and advertising particular compounded drugs. In *Western States Medical Center v. FDA* , the court struck down sections of Food and Drug Administration Act of 1997 and was sustained by the Supreme Court in April of 2002. In this case, pharmacists created mixes of drugs that were individualized and then advertised their service. The court concluded: “When exemptions and inconsistencies counteract the alleged purpose of a speech restriction, the restriction fails the direct advancement test.”²⁷ In invalidating 21 U.S.C. Sec. 353a, the Ninth Circuit ruled that the statute violated the First Amendment rights of the pharmacists seeking to advertise their service. Again, the courts applied the *Central Hudson* test outlined above, a test that regulators at the FDA might consider framing and placing on their desks. The FDA should not be allowed to restrict truthful claims about legal products.

C. Regulating Abuse

The long-term effects of the FDA’s past proposals – including attempts to regulate tobacco and alcohol products– should also be considered in terms of their impact on the First Amendment rights of consumers and advertisers. In the name of protecting public health and by manipulating the public interest standard, the FDA could similarly gain control over advertising of any product that could prove harmful if abused. For example, the government could restrict or require additional labeling on high-calorie foods to warn

²⁶ *Ibid.* at 119.

²⁷ *Western States*, 238 F.3d at 1095.

against obesity; could restrict or require ads for hair products to warn that overuse could lead to baldness or a rash; could restrict or require advertising for eggs or egg products because excess consumption could lead to heart disease; could require warnings that wearing the wrong size shoes can lead to blisters. The list is endless, and the prospects unsettling. Such regulations are effectively unworkable, establish a bad precedent, ultimately lead, through chilling effect, to avoidance of advertising, and thereby result in a significant interruption in the flow of information to the public, and ignorance on the part of the public which uses such media to educate itself about the marketplace products. Use of the public health standard must be carefully restricted to misleading and/or 'clear and present danger' situations in order to avoid undermining First Amendment freedoms.

D. The Special Case of Tobacco Advertising

Lest the FDA be tempted to move again against non-pharmaceutical products, FOEF submits that past attempts by the FDA to regulate the advertising of tobacco products were without authority. The entire basis for its claim of jurisdiction and authority rests upon the dubious proposition that cigarettes are actually and intended to be nothing more than a nicotine delivery device. It is clear that the FDA needs to go back to ground zero in making a clear determination of what a drug is.

In the case of tobacco products, it was eventually demonstrated that the FDA had no legal authority to regulate tobacco products, and no corresponding authority to regulate advertising of such products. We would encourage the FDA to avoid such forays across its congressionally imposed boundaries; they violate the First Amendment and they violate the FDA's congressional charge.

The rationale for the attempted regulation of tobacco products misstated the application of First Amendment law. Though the FDA claimed it was permissible to regulate advertising under the First Amendment as a “reasonable” regulation under *Central Hudson* and *Fox*, and claimed it does not have to choose the “least restrictive” mode of regulation, it ignored the underlying principles of the First Amendment, which is to promote freedom of expression to the fullest extent possible - not to permit government to regulate speech to the fullest extent permissible. The underlying policies expounded in *Central Hudson* and *Fox* impose a rule of reasonableness only to the extent necessary to avoid deceiving the public. In *Lorillard Tobacco Co. v. Reilly*, (2001), the Supreme Court made clear that even the advertising of tobacco products in the view of children is protected under the First Amendment. The same policy should reign at the FDA

III. Conclusion

At the core of the First Amendment proscription against governmental interference with speech is the “principle that each person must decide for him or herself the ideas and beliefs deserving of expression, consideration and adherence. Our political system and cultural life rest upon this ideal”²⁸ Governmental restrictions pose the risk that government may manipulate the public debate through coercion, rather than through persuasion.²⁹ Governmental manipulation of the public debate cannot be justified if we are to have a free marketplace of ideas. Such manipulation is inimical to the First Amendment and undermines the entire political system, which is premised upon citizens’ ability to express

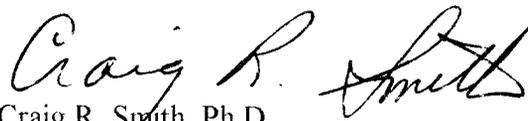
²⁸ *Turner, supra.* at ___; see *Leathers v. Medlock*, 499 U.S. 439, 449 (1991); *Cohen v. California*, 403 U.S. 15, 24 (1971).

²⁹ *Simon & Schuster, Inc. v. Members of the New York State Crime Victims Bd.*, 502 U.S. ___, (1991)

their views, however disagreeable, or however contrary, to the government's. Prior restraint of expression is justified only when a clear and present danger can be established; prior restraint cannot be imposed by administrative fiat.

The answer does not lie in excessive regulation of legal products, nor in paternalistic restriction of speech, nor in coercion of manufacturers to speak against their interests. All these measures ultimately punish consumers who use advertising to make rational decisions about the marketplace and their own needs and health. The answer lies in protecting the free flow of commercial information to the greatest degree possible consummate with safety and security of the general public.

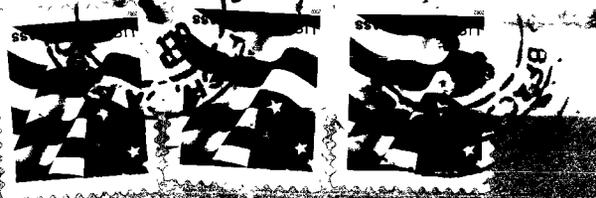
Respectfully submitted,

A handwritten signature in black ink that reads "Craig R. Smith". The signature is written in a cursive style with a large, stylized "C" and "S".

Craig R. Smith, Ph.D.

President

FREEDOM OF EXPRESSION
FOUNDATION, INC.



Communication Services

MAR 27

C.S.U.

LONG BEACH, CA 90840-2407

Food & Drug Administration
5630 Fender Lane
Room 1061
Reshville, Ark.
20852