

FDLI'S FOOD
and DRUG
POLICY FORUM

A Reply to Professor Sugarman

Bert W. Rein

Founding Partner of Wiley Rein LLP

VOLUME 5, ISSUE 6 // JUNE 29, 2015

THE FOOD AND DRUG LAW INSTITUTE
1155 15TH STREET NW, SUITE 910 // WASHINGTON, DC 20005
www.fdl.org



FDLI'S FOOD AND DRUG POLICY FORUM

Judy Rein JD, MA
FDLI, Director of Publications

FDLI'S FOOD AND DRUG POLICY FORUM EDITORIAL ADVISORY BOARD

Victoria W. Girard (Chair)

Georgetown University

Barbara A. Binzak Blumenfeld PhD, JD

(Board Liaison) Buchanan Ingersoll & Rooney PC

James Boiani
Epstein Becker & Green, P.C.

Thomas Cluderay
Environmental Working Group

Lisa Davis
Quarles & Brady LLP

Jeffrey Francer
PhRMA

Jennifer Hillman
University Health System

Elizabeth Isbey
McDermott Will & Emery

Ralph Ives
AdvaMed

Beth Krewson
Incyte Corporation Experimental Station

Marian Lee
Gibson Dunn & Crutcher LLP

Erik Lieberman
U.S. Food Imports LLC

Jonathan McKnight
FDA – CBER

Nicholas Nowakowski
Oakland Law Group, PLLC

Megan Olsen
Walgreens

Flora Orekeke
British American Tobacco

Kirsten Paulson
Pfizer, Inc.

Christine Perez
American College of Cardiology

Mark Schwartz
FDA – CBER

Laura Sim
Covington & Burling

Josephine Torrente (Vice Chair)

Hyman, Phelps & McNamara, P.C.

Alan Traettino
Stryker Corporation

Daron Watts
Sidley Austin

Brian Wesoloski
Mylan Pharmaceuticals, Inc.

PROMOTING DIALOGUE

This special edition of the Food and Drug Law Institute's *Food and Drug Policy Forum* features a response to an earlier article—offering a very different perspective. We encourage readers to react to published *Policy Forum* articles by authoring responses that develop diverse views and reasoning. FDLI is committed to supporting dialogue around the complex issues facing our field.

In this case, the growing debate around First Amendment rights in commercial speech has elicited two very different analyses from leaders of the food and drug bar. In April 2015, FDLI published UC – Berkeley Professor Stephen Sugarman's defense of broadly permissible "compelled speech" in the context of food labeling: "Should Food Businesses Be Able to Use the First Amendment to Resist Providing Consumers with Government-Mandated Public Health Messages?" With this June 2015 *Policy Forum* we are publishing a response to Professor Sugarman's argument from Bert Rein, founding partner of Wiley Rein LLP.

—Editor

A Reply to Professor Sugarman

By Bert W. Rein, Founding Partner, Wiley Rein LLP

In the April 29, 2015 FDLI *Food and Drug Policy Forum*, Professor Stephen Sugarman sought to justify Government-compelled disclosure of information that consumers might find “interesting” as consistent with the First Amendment in almost every case. Professor Sugarman believes that the Supreme Court was mistaken in affording First Amendment protection to commercial speech and should have found compelled disclosure of commercially-relevant information constitutional a priori. Recognizing that a long line of Supreme Court precedent differs from his view, he then argues that the First Amendment should be satisfied whenever the “government has a good and not a frivolous reason for a disclosure requirement”—otherwise termed “rational basis” review. As a fallback, he contends that disclosures could be phrased as government messages and be forced on private enterprises as “a condition of operating a business in the jurisdiction” with the only vague limitation being the “takings” clause of the Fifth Amendment. Professor Sugarman makes his policy preference perfectly clear, summarizing that “Courts should not interfere with government actions like these by using the First Amendment of all things to protect business from such regulation.”

I think Professor Sugarman has read the Supreme Court’s relevant decisions far too narrowly. While the *Barnette* and *Wooley* cases¹ addressed government mandated speech that could be considered “political” or “ideological” (i.e., reciting the Pledge of Allegiance or driving with a “Live Free or Die” license plate), their critical underlying principle is that, in a free society, the government should not be entitled to force private persons to be government spokesmen. In that thesis, there is no principled reason why what has been labeled the freedom not to speak should not apply to individuals or organizations engaged in commerce. Professor Sugarman’s contrary suggestion that government may impose spokesperson obligations on those who individually or collectively wish to exercise their economic freedom by operating a business rests on an “everything is forbidden unless it is allowed [by government]” premise that is inconsistent with our free enterprise society.

But, notwithstanding his excessive zeal in defending government speech control, Professor Sugarman has raised important questions about the proper application of the First Amendment to product-related “compelled speech.” Doctrine and case law in that area are far from clear and outcomes are determined by a relatively crude characterization whether the mandated statements are political or “controversial,” in which case they are virtually certain to be barred, or “commercial,” in which case they are likely to be sustained if truthful and, at least on face, noncontroversial.² In a major recent decision, for example, the District of Vermont denied a preliminary injunction sought by food manufacturers on First Amendment grounds to block a Vermont law requiring “clear and conspicuous” disclosure of genetically modified products or genetically modified ingredients in packaged foods (GMOs). The court rejected the argument that GMO disclosure was “political speech,” distinguishing the political motive of the legislature in enacting it from the content of the speech requirement, and holding the GMO disclosure to be product related and non-political. The court also rejected the manufacturers’ contention that the GMO requirement discriminated among speakers by viewpoint because it did not require “a no-GMO” disclosure. The court ruled that the GMO disclosure was not a state “preferred message” and noted that Vermont did not foreclose manufacturers from offsetting any feared negative reaction by supplementing the state’s mandatory disclosure with their own messages about GMO safety. The court then determined that the required disclosure was constitutional under *Zauderer* because it was commercial, purely “factual,” not “controversial,” and supported by a rational state interest—i.e., not solely imposed to satisfy consumer curiosity. The required “rational interest” was supplied by the Vermont legislature’s record recognizing “scientific debate” about GMO safety, concerns about the

1

environmental impact of raising GMO crops, and the need to accommodate the religious concerns of some Vermont citizens thus satisfying *Zauderer's* rational basis standard.³

There is certainly room for disputing the court's conclusion that the Vermont GMO requirement is not controversial. When consumers are made aware that the state considers GMO presence to be relevant to a purchasing decision, it strains credulity to believe that GMO labeling is merely factual and non-controversial. Given the court's acknowledgement of the absence of any accepted scientific evidence that GMOs have adverse health consequences, the state's implied espousal of a contrary view clearly takes sides in what is both a political debate over how much consumer precaution is warranted as food science evolves and an economic contest between organic foods and lower-priced comparable non-organic commercial products.

But a critique of the District Court's GMO holding, whether or not valid, does not answer the more fundamental doctrinal question of how compelled speech should be analyzed constitutionally. A more precise classification of compelled speech practices than either Professor Sugarman or the District Court attempted could lead to an analytic approach to compelled speech that is more consistent with the fundamental values of the First Amendment the Supreme Court first acknowledged in *Barnette*.

At first blush, compelled government speech about commercial products seems so routinely accepted that First Amendment concerns appear a bit contrived. Since biblical times, governments have required accurate disclosure of fair weights and measures. Standardized naming of products, ingredient listings, and safe use instructions are rarely questioned and generally considered necessary enhancements of a competitive market. Professor Sugarman would undoubtedly view this as confirming that the First Amendment is out of its element in the world of commercial speech.

There is, however, an alternative and sounder way to explain this observation without disavowing the core principle that the individual right to determine what to say and what not to say should not be lightly overridden by collective government fiat. A government that has the constitutional power to regulate commerce can reasonably defend a compelling interest in preserving market integrity, combatting fraud, and ensuring proper product use. Requiring disclosure to support those interests at the point of sale through labeling and postings is narrowly tailored to protect the market and consistent with the interest of honest sellers. Thus, a broad range of posting and labeling disclosures, even if contested, should survive even the most rigorous standard of First Amendment review—strict scrutiny.

Giving fair recognition to the threshold principle that commercial speakers can be compelled to communicate a government message only when the government establishes a sufficient interest to warrant intrusion and narrowly tailors its requirements, however, lays the foundation for a better resolution of controversial compelled commercial speech issues. First, as the Supreme Court held in *Zauderer*, the government's interest in ensuring a marketplace free of deception provides a firm foundation for corrective disclosure—that is, disclosure to guard against deception by omission or half-truth. But even there, the government must tailor corrective disclosure to address the identified risk of deception and must ensure that the correction can be shown to be truthful and non-controversial. In other words, where the claim of deception turns on a disagreement about a lawful product's quality, relative to alternatives, the government cannot claim a corrective interest. In those circumstances, the government interest being advanced is the dissemination of the government's judgmental message, an interest that might support a government information campaign but is insufficient to justify an impairment of the First Amendment right to remain silent.

Even Professor Sugarman's broad view of the government's power to compel speech allegedly related to its general public health interest acknowledges that where such disclosure requires private expenditure or forecloses preferred use of package space, Fifth Amendment takings interests may be implicated. In other words, where the government demands that a commercial speaker disseminate its message simply because it is effective or convenient, Professor Sugarman concedes that a presumptive taking for a public purpose has occurred.

To be clear, legitimate government interests justifying some compelled speech at private expense are not confined to remedying deception. The government, for example, may have a substantial interest in protecting consumer health or the environment from chemicals or minerals lawfully used in certain products. By requiring disclosure of those substances whose adverse environmental effects are well established, the government seeks to advance its environmental interests by persuading consumers to consider purchasing less deleterious substitutes and thus influencing manufacturers to consider alternative product designs. The courts understandably have been sympathetic to requiring such advisory disclosures.⁴

Harder questions arise when the substantiality of the government's interest in mandatory disclosure is questionable. For example, in *American Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014), USDA had imposed elaborate country-of-origin labeling requirements on imported meat. The actual purpose of these requirements, as found by the World Trade Organization, was to persuade consumers to "buy American," thus promoting the interests of the domestic meat industry over meat importers. Nevertheless, finding the required disclosure to be objective and factual, the D.C. Circuit upheld it under *Zauderer* without assessing the validity of the government's asserted interest. What the case should have turned on, but did not, was whether a government interest in "buy American" was properly cognizable under the First Amendment and whether the labeling requirement was tailored to advance that interest when market forces would have prompted U.S. producers to promote their own interests by making U.S. origin claims. Under proper scrutiny, the decision was almost certainly wrong.

The Vermont GMO labeling decision suffers from the same analytical deficiency. A legislative record showing that a small minority of scientists question the safety or environmental impact of GMOs cannot withstand scrutiny of whether the state has established a substantial interest in an advisory disclosure. And, even assuming the state could identify a small religious minority that sought to avoid GMO products, their interest is hardly a substantial state interest, particularly when producers are free to truthfully label products as non-GMO and would clearly do so if a substantial number of consumers believed that characteristic to be important. Thus, compulsory disclosure of GMO products or ingredients cannot be justified constitutionally merely because it is objectively determinable. Nor is the Vermont disclosure narrowly tailored to cure a market imperfection, or advance a safety or environmental objective. It thus should have been recognized as espousing the sort of "voyeurism" the Second Circuit properly condemned in *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996).

In sum, a compelled commercial speech analysis focusing only on whether a government message is truthful and non-controversial fails to recognize the captive speaker's First Amendment right to control its own communications and ignores the essential evaluation of the government's claim of a substantial interest in disseminating the compelled message. Both these factors must be considered if the First Amendment's essential command is to be honored.

ENDNOTES

1. 319 U.S. 624 (1943); 430 U.S. 705 (1977).
2. *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985).
3. *Grocery Manufacturers Ass'n et al. v. Sorrell* (No. 5:14-CV-117, D. Vt. April 27, 2015).
4. E.g., *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114 (2nd Cir. 2009).

ABOUT THE AUTHOR

Bert W. Rein is a founding partner of Wiley Rein LLP and a member of the Appellate, Food & Drug Law, and Intellectual Property practices at the firm. He is widely recognized as a leading commercial litigator and international law expert, and has been recognized by the *Legal Times - The National Law Journal* as both a "Visionary" and Washington's "Leading Food and Drug Lawyer."

4

ABOUT THE FOOD AND DRUG POLICY FORUM

FDLI's *Food and Drug Policy Forum* provides a marketplace for the exchange of policy ideas regarding food and drug law issues. The *Forum* welcomes articles on cutting-edge state, national, and international policy issues related to food and drug law.

FDLI's *Food and Drug Policy Forum* is designed to provide a venue for the presentation of information, analysis, and policy recommendations in the areas of food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco.

Each issue of the *Forum* presents an important policy topic in the form of a question, provides background information and detailed discussion of the issues involved in the policy question, relevant research, pertinent sources, and policy recommendations. This publication is digital-only, peer-reviewed, and smartphone enabled.

The *Forum* is published monthly (12 times a year) and is provided as a complimentary benefit to FDLI members. Individual issues of the *Forum* are also available for separate purchase.

The *Food and Drug Policy Forum* Editorial Advisory Board, comprised of representatives of government and leading associations interested in food and drug law issues, as well as food and drug and healthcare professionals, provides peer review and guidance on articles considered for publication.

5

ABOUT FDLI

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications, and member interaction. FDLI's scope includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco. As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.

FDLI's mission is to provide education, training, and publications on food and drug law; act as a liaison to promote networking as a means to develop professional relationships and idea generation; and ensure an open, balanced marketplace of ideas to inform innovative public policy, law, and regulation.

In addition to the *Forum*, FDLI publishes the quarterly, peer-reviewed *Food and Drug Law Journal* presenting in-depth scholarly analysis of food and drug law developments; *Update* magazine, which provides members with concise analytical articles on cutting-edge food and drug issues; practical guides on contemporary food and drug law topics, and numerous comprehensive new books each year.