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SYMPOSIUM ON COMMERCIAL SPEECH AND PUBLIC HEALTH -- Introduction

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INTRODUCTION

Americans have access to more health-related information today than ever before. Consumers are bombarded with medical messages and flooded with health-based claims. Television and magazine advertisements inform consumers about everything from insomnia and erectile dysfunction to the importance of dietary fiber and the allegedly wondrous properties of pomegranates. Product labels and promotions provide more food for thought about fat, sodium, and carbohydrates; nutritional supplement makers further supplement consumer nutritional information. Were that not enough, the internet provides access to still more data (and opinion), much of it of questionable provenance and reliability.

Does this cornucopia of information inform consumers and make them better off? Or is it too much? Can consumers adequately process all the messages they receive to make more informed decisions? If health information overload is producing a cacophony of competing voices, do consumers need help from government agencies or other expert intermediaries? And is the problem one of quantity or quality? That is, would consumers be better off hearing less, or just hearing less information of a certain type from certain sources. More information may be better only if it is sufficiently accessible, educational, and reliable.

The policy calculus is complicated by the constitutional protection of commercial speech. For several decades, the Supreme Court has held that the First Amendment protects commercial speech, including advertisements and product promotions. As the Court explained in *United States v. United Foods*, "[t]he fact that the speech is in aid of a commercial purpose does not deprive respondent of all First Amendment protection."[1] Protections provided for commercial speech may

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[1] 533 U.S. 405, 410 (2001).

be less robust than those for core political speech (at least for now), but are still substantial.[2] Among other things, the Court has held the First Amendment embodies a clear preference for more speech, not less. This doctrine applies with no less force in the health context. From the start, the Supreme Court has applied its commercial free speech doctrines in a health-policy context, beginning with *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*[3] in 1976 and continuing through *Thompson v. Western States Medical Center*.[4]

Does the constitutional protection of commercial speech impair the government's ability to protect and promote public health? Or does the commercial speech doctrine itself enhance consumer education and harness market competition to advance public health? Do First Amendment limitations on regulation of commercial messages unduly retard governmental efforts to safeguard consumers? Or do they properly constrain illiberal paternalism? If the Court has been over-protective of health-related commercial speech, is there a principled place to redraw the line? And how should those governmental agencies entrusted with the power to protect public health and welfare respond to these constitutional constraints?

The editors of *Health Matrix* have assembled a group of experts from academia and legal practice to address these and related questions arising at the intersection of commercial speech and public health. Some contributors focus on the legal and constitutional questions provoked by First Amendment protection of health-related commercial speech, while others focus on matters of policy. The resulting collection seeks to inform the ongoing debate about the best legal and prudential balance between commercial free speech and public health, particularly in the context of Food and Drug Adminis-

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[2] The current test for the constitutionality of limitations on commercial speech is provided by *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 566 (1980). Under this test, if speech concerns lawful activity and is not misleading, the government can adopt regulations pursuant to a "substantial" governmental interest, but only if the regulations "directly advance" and are not more extensive than necessary to advance the stated interest.

While the Court continues to apply the *Central Hudson* test, several justices on the Court have signaled their disagreement with it. *See* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996); *see also United Foods*, 533 U.S. at 409-10 (noting "criticism" of *Central Hudson* test by multiple justices); Thompson v. W. States Med. Ctr., 535 U.S. 357, 367-68 (2002) (same).

[3] 425 U.S. 748 (1976) (holding that a state ban on advertising prescription drug prices by licensed pharmacists violates the First Amendment).

[4] 535 U.S. 357 (2002) (holding that a federal prohibition on advertising preparation of compounded drugs violates the First Amendment).

tration (FDA) regulation of pharmaceuticals and other medical technologies.

Economist J. Howard Beales, former Director of the Federal Trade Commission's Bureau of Consumer Protection, surveys the economic literature on the market for information and considers its impact on commercial speech in the public health context.[5] His Article warns of the often-overlooked costs of limiting a robust marketplace of product-related and health-related information and questions the presumption that governmental restrictions on health-related information will advance public health. According to Beales, government intervention in the market for health-related information should focus on enhancing market performance, such as by reducing information costs and protecting against false or misleading claims, rather than directing or supplanting market outcomes. Ensuring the reliability and availability of relevant information is almost always preferable to suppressing information, he argues, noting that regulation of commercial speech may have unintended and potentially counterproductive effects. Thus, his paper questions whether the ubiquity of health-related commercial speech is much of a problem at all.

Professor Lars Noah argues that there exists a conflict between the Supreme Court's "robust" commercial speech doctrine and the FDA's efforts to protect public health through the regulation of pharmaceuticals and other medical technologies.[6] According to Noah, efforts to restrict or suppress information about drugs and devices are in tension with underlying First Amendment values and face greater judicial opposition than more targeted efforts to prevent fraud, cure potentially misleading messages, or otherwise promote health-related messages. Noah suggests that there is an inherent problem with applying a legal framework developed around the regulation of "vice products" to the regulation of drugs and other medical technologies, and that the FDA needs to confront the limitations existing commercial speech doctrine imposes on regulatory efforts.

Professor emeritus Margaret Gilhooley focuses on direct-to-consumer drug advertisements.[7] Summarizing arguments she has made at greater length elsewhere,[8] she argues that the First Amend-

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[5] *See* J. Howard Beales III, *Health Related Claims, the Market for Information, and the First Amendment*, 21 HEALTH MATRIX 7 (2011).

[6] *See* Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31 (2011).

[7] *See* Margaret Gilhooley, *Commercial Speech, Drugs, Promotion and a Tailored Advertisement Moratorium*, 21 HEALTH MATRIX 97 (2011).

[8] *See* Margaret Gilhooley, *Drug Safety and Commercial Speech: Television Advertisements and Reprints on Off-Label Uses*, 47 SAN DIEGO L. REV. 845 (2010).

ment does not preclude Congress from regulating direct-to-consumer commercial messages about drugs, particularly with regard to off-label uses. If adoption of such a policy requires the Supreme Court to revisit *Western States*, she would welcome this development if it were to allow the FDA to adopt further protections for public health.

Former FDA Chief Counsel Gerald Masoudi and Christopher Pruitt encourage a more cautious approach to the regulation of commercial speech in the health context.[9] According to Masoudi and Pruitt, several existing FDA policies and regulations already curtail constitutionally protected commercial speech. Allowing a government agency to serve as a "gatekeeper of speech" is troubling, they argue, particularly since some regulatory policies can be difficult to challenge in court. As a consequence, Masoudi and Pruitt urge the FDA to continue the initiative it began in 2002 to review whether its regulations, policies, and enforcement practices are consistent with First Amendment values.[10]

Gregory Conko takes an equally skeptical view of FDA regulation of speech, focusing on FDA policies regarding "off-label" uses of pharmaceuticals and medical devices.[11] While the FDA is concerned about the promotion of unapproved uses for regulated drugs and devices, Conko argues such risks may be outweighed by the potential benefits of such uses, and that drug companies and device manufacturers should not be barred from promoting off-label uses. Conko argues that the FDA's current policy is unwise and likely unconstitutional, and suggests alternative, less-burdensome ways the agency could address concerns about health risks from unapproved uses.

Professor David Yosifon takes an entirely different tack, sidestepping the First Amendment questions altogether and focusing instead on the corporate form and the obligations of corporate managers.[12] Professor Yosifon believes corporations have a tendency to communicate with consumers in ways that advance corporate interests at the expense of public health. Yet his Article suggests the problem is not First Amendment protection of corporate or commercial speech, but the internal norms that allow corporate executives to disseminate misleading or unhelpful messages to their customers. Yosifon sug-

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[9] *See* Gerald Masoudi & Christopher Pruitt, *The Food & Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX 111 (2011).

[10] *See* 67 Fed. Reg. 34,942 (May 16, 2002).

[11] *See* Gregory Conko, *Hidden Truth: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, 21 HEALTH MATRIX 149 (2011).

[12] *See* David G. Yosifon, *Discourse Norms as Default Rules: Structuring Corporate Speech to Multiple Stakeholders*, 21 HEALTH MATRIX 189 (2011).

gests that reconceiving the obligations of corporate managers to encompass the well-being of consumers and other stakeholders could be a more effective way to constrain corporate behavior without triggering conflicts over the proper scope of commercial free speech.

Information is power—the power to protect and persuade, and perchance to manipulate and mislead. The power to control information entails great power over individual behavior and collective choice. The First Amendment, as currently understood, significantly limits the government's ability to restrain or control what information the public receives. If the government wants to influence or channel consumer choices, it may have to regulate conduct directly or seek to induce desired behavior by releasing yet more information into existing streams. The First Amendment makes it easier for government to increase the flow than control the current.

As the torrent of health-related information accumulates, policymakers will confront still more questions about the desirability and efficaciousness of measures designed to enhance health and welfare. The First Amendment's limitations may be a good thing, or they may unduly constrain public-spirited interventions. Either way, questions about the proper balance between commercial speech and public health will remain with us for some time.