UNITED STATES OF AMERICA

FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition
Bureau of Consumer Protection

might spur price or quality competition with more traditional clinics or physician practices.[5] To that end, the DPH's proposal to permit such clinics is commendable, and its proposal of regulatory flexibility – such that the Secretary of DPH may waive certain requirements as appropriate – might be especially helpful in an emerging market, as health care providers explore different ways to deliver basic care on a competitive basis.

At the same time, the FTC staff believes that the proposed pre-screening requirement for all limited service clinic ("LSC") advertising may be overly restrictive, and we recommend that it be struck. Requiring regulatory pre-approval of all advertising materials might represent an undue burden on LSCs and deprive consumers of useful information about basic health care services. In addition, requiring pre-approval for LSC advertising alone, and not that of other health care clinics, might put LSCs at a competitive disadvantage without offering countervailing consumer benefits.

Interest and Experience of the Federal Trade Commission

The FTC is charged generally under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[6] In addition, Section 12 of the FTC Act specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[7]

For several decades, the Commission and its staff have investigated the competitive effects of restrictions ertaion ae wiasic hpfetics.

seven days of hearings on health care and competition law and policy.[9] In 2004, the FTC and the Antitrust Division jointly released a report – based on those hearings, an FTC-sponsored workshop, and independent research – that covered diverse issues in health care competition and delivery.[10] Both the hearings and the report addressed, among other things, the impact of regulation on the dissemination of useful health care information to consumers and its impact on consumers' access to care.

The Commission and its staff have also undertaken research and advocacy directed specifically at health care advertising issues.[11] For example, the FTC staff has examined nutrition and health care issues in food product advertising[12] and the direct-to-consumer advertising (DTCA) of prescription drugs, dietary supplements, and medical devices, and has filed comments with the Food and Drug Administration ("FDA") regarding DTCA and DTCA regulation.[13]

The FTC's enforcement actions also have shown a special concern with the integrity of health care goods and services advertising. From April 2006 through February 2007 alone, the FTC initiated or resolved 13 law enforcement actions (involving 25 products) involving allegedly deceptive health claims.[14]

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[9] Federal Trade Commission and Department of Justice, Joint Hearings on Health Care and Competition Law and Policy (2003). Links to transcripts and other hearings materials are available at http://www.ftc.gov/bc/healthcare/research/healthcarehearing.htm.

[10] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[11] LSCs are, by definition, novel market entities and their putative advertising practices have not, to the best of our knowledge, been the subject of systematic study. The FTC has, however, conducted and analyzed research in other areas of health care goods and services advertising, including research regarding restrictions on advertising by health care professionals. *See, e.g.*, Federal Trade Commission, Bureau of Economics Report, The Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry [hereinafter Optometry Report] (1980).

[12] *See, e.g.*, P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002) (FTC Bureau of Economics Staff Report), *available at* *http://www.ftc.gov/opa/2002/10/advertisingfinal.pdf*; P. Ippolito & A. Mathios, *Information & Advertising Policy: a Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996) (FTC Bureau of Economics Staff Report), copies available upon written request, with executive summary available at http://www.ftc.gov/be/hilites/fatexsum.shtm; J. Calfee & J. Pappalardo, *How Should Health Claims for Food be Regulated? An Economic Perspective* (1989).

[13] Comments of the FTC Staff Before the FDA In the Matter of Request for Comments on Consumer-Directed Promotion [hereinafter 2003 DTCA Comments] (Dec. 1, 2003), *available at* http://www.ftc.gov/be/v040002text.pdf; Comments of the FTC Staff Before the FDA In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion [hereinafter 2004 DTCA Comments] (May 10, 2004), *available at* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf.

[14] *See, e.g., FTC v. Window Rock Enters., Inc.*, No. CV04-8190 (JTLx) (C.D. Calif. filed Jan. 4, 2007) (stipulated final orders) (Cortislim), *available at* http://www.ftc.gov/os/caselist/windowrock/windowrock.htm*; In the Matter of Goen Techs. Corp.*, FTC File No. 042 3127 (Jan. 4, 2007) (consent order) (TrimSpa), *available at* http://www.ftc.gov/os/caselist/goen/0423127agreement.pdf; *United States v. Bayer Corp.*, No. 07-01

advertising of other professional services.[26] The free flow of truthful advertising can be equally critical to both providers and consumers, and might be especially important where emerging health care entities offer novel and more convenient access to care[27] or price advantages that might be critical to marginal health care consumers.[28] Such interests have, too, been at the core of the Supreme Court's commercial speech jurisprudence since *Virginia State Board of Pharmacy*.[29]

Hence, it is important that regulations aimed at protecting consumers from false or misleading information avoid unnecessarily impeding consumer access to truthful, non-misleading information about the range of available health care services.[30] The FTC has stated that targeted remedies addressing deceptive advertising generally are preferable to broad pre-market approval of health care claims.[31] As noted above, the FTC Act provides the FTC with enforcement authority in the event that false or misleading advertisements do arise, and the FTC has substantial interest and experience in the exercise of that authority in health care markets.[32] The Commonwealth, too, can enforce state law prohibitions against deceptive advertising.[33]

Because the DPH has not yet specified either the process whereby pre-screening is to take place, or the institutional resources to be devoted to such pre-screening, it is difficult to predict the extent to which the proposed regulation would burden truthful and non-misleading commercial speech. Nonetheless, we are not aware of any evidence supporting a special need for pre-screening for LSCs. In the absence of such evidence, general prohibitions against false or misleading advertising are preferable to overly broad restrictions that might prove costly for Massachusetts health care consumers, independent of the DPH's implementation costs.

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[26] *See id.* (comparing evidence regarding health professions advertising to evidence regarding attorney advertising); Timothy Muris & Fred McChesney, *The Effect of Advertising on the Quality of Legal Services*, 65 A.B.A. J. 1503, 1506 (1979).

[27] *See* MDPH Hearings, *supra* note 2; *see also* Council on Medical Service Report (A-06), *supra* note 3 at 1.

[28] Report 7 of the Council on Medical Service (A-06), Store-Based Health Clinics, *supra* note 4 at 1.

[29] Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976) (state's interest in integrity of profession does not justify unnecessary suppression of truthful advertising under First Amendment).

[30] *Cf.* 2003 DTCA Comments, *supra* note 13, at 37 (encouraging FDA to consider ways to facilitate the flow of truthful and non-misleading information in direct to consumer advertisements for prescription drugs).

[31] *See, e.g.*, Comments of the Federal Trade Commission Staff Before the Dept. of Health and Human Services Food and Drug Administration, In the Matter of Request for Comment on First Amendment Issues, 13 (Sept. 13, 2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf.

[32] *See, e.g.*, *supra* notes 6-7 and 14 (regarding FTC authority and enforcement actions, respectively). The threat of enforcement acts, in conjunction with market forces, as a deterrent to the dissemination of false or misleading advertising.

[33] *See, e.g.*, *supra* note 6 (regarding MASS. ANN. LAWS ch. 93A).

If there is evidence that certain claims are likely to mislead or confuse consumers, DPH may want to consider measures – such as agency guidance or mandatory disclosures – that are narrowly tailored to avoid serious harms, but preserve the flow of truthful and non-misleading information.[34]

Conclusions

The Commission staff agrees with the Department of Public Health that a new category of limited service medical clinics has the potential to expand access to health care. The DPH has undertaken an important initiative to facilitate the emergence of this new model of health care delivery within the bounds of responsible practice and professional licensing standards. At the same time, the staff has some concern that certain provisions of the proposed LSC regulations might be unclear or unduly restrictive of emerging clinic practices. In particular, the proposed requirement that all LSC advertising be pre-screened by the DPH is likely to prove an impediment to the dissemination of truthful and non-misleading information about health care alternatives for Massachusetts consumers. For that reason, the staff recommends that the pre-screening requirement be struck, especially as there appears to be no evidentiary basis for requirements above and beyond a prohibition of false or misleading advertising.

[34] *See id.* at 16-17 (regarding the Food Copy Test and FTC guidance on the qualification of certain health claims); *see also id.* at 21 (regarding certain mandatory disclosures).

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