UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Consumer Protection
Bureau of Economics

January 20, 2006

The Honorable Barbara S. Matthews
Assembly Member
Seventeenth District
California Legislature
State Capitol
P.O. Box 942849
Sacramento, CA 94249-0017

Re: California SB 401

Dear Assemblymember Matthews:

The staff of the Federal Trade Commission's ("FTC" or "the Commission") Office of Policy Planning, Bureau of Consumer Protection, and Bureau of Economics[1] are pleased to respond to your letter asking for our views on California SB 401 ("SB 401").[2] Specifically, you indicate your concern that SB 401's prospective amendment of the California Confidentiality of Medical Information Act ("CMIA") may have detrimentally restrained the flow of health information to California consumers. SB 401 would have modified CMIA to require a pharmacy, subject to certain exceptions, to obtain a patient's "opt-in" consent before it may provide a patient with "a written communication" in conjunction with a prescription if it "includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs."[3]

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[1] This letter expresses the views of the FTC's Office of Policy Planning, Bureau of Consumer Protection, and Bureau of Economics. The letter does not necessarily represent the views of the Commission or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] Although the legislative session in which SB 401 was proposed has ended, we understand you would still like our views on the bill because you are concerned that a similar bill may be introduced in the future.

[3] For purposes of this letter, we refer to a communication that "includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed" and is "paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or

This letter briefly summarizes the Commission's interest and experience in health care and medical privacy and provides the staff's opinion regarding the possible impact of SB 401 on consumers. Based on this experience, our review of your letter, and SB 401, the FTC staff make the following observations that we hope will be of assistance:

- The Health and Human Services ("HHS") Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule generally requires an individual's opt-in consent before that individual's health information can be used for marketing. But, in contrast to SB 401, it is our understanding that the privacy rule does not define a health care provider message as a marketing communication that requires a patient's prior, affirmative opt-in approval for receipt merely because it is sponsored. Thus, SB 401 would have been more restrictive than HIPAA's privacy rule.

- SB 401's prophylactic restraint on a type of commercial speech that is not inherently unlawful or misleading[4] may have raised questions under the First Amendment to the U.S. Constitution.

- Proponents of SB 401 expressed concern that a sponsored communication may confuse a consumer about the nature of the communication and imply that the pharmacist sanctions a suggested alternative treatment or that it is a substitute for a doctor's advice. Alternative, less restrictive measures, such as requiring the clear and prominent disclosure of sponsorship, could help to ensure that patients are not misled as to the source or funding for the communication, without limiting consumers' access to potentially useful health information.

A brief summary of the Commission's history in the health care industry and a detailed analysis in support of the FTC staff's conclusions and suggestions is provided below.

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distributor of prescription drugs" as a sponsored communication. For example, such a sponsored communication would include a written communication provided by a pharmacy to a patient in conjunction with the dispensing of a prescription where the communication includes the trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription being dispensed and the pharmacy receives remuneration from a manufacturer, labeler, or distributor for distributing the communication. *See infra* Section II.

[4] Of course, any sponsored communications that contain prescription drug advertising would be subject to general advertising and labeling regulation, such as the Food and Drug Administration's ("FDA") requirements for labeling. *See, e.g.*, 21 U.S.C. § 321(m) (2004) (defining labeling for prescription drugs to include all labels and written, printed, or graphic material upon or accompanying a drug, which would include sponsored communications) and 21 C.F.R. § 201.100(d) (2002) (setting forth the disclosure requirements for promotional labeling).

I. Interest and Experience of the Federal Trade Commission

The FTC enforces Section 5 of the Federal Trade Commission Act ("FTC Act"), which broadly prohibits "unfair or deceptive acts or practices in or affecting commerce."[5] In addition, Section 12 of the FTC Act more specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[6] In undertaking these enforcement responsibilities, the Commission has acquired considerable experience in combating deceptive health care practices and in addressing privacy and consumer protection issues relating to health care.[7] The FTC has been active in recent years in pursuing formal actions in the broader health care industry, including actions relating to pharmaceuticals.[8] The FTC staff also have experience in analyzing disclosures relating to pharmaceutical advertisements.[9] In addition, the FTC

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[5] 15 U.S.C. § 45.

[6] 15 U.S.C. § 52. The FDA and the FTC generally share jurisdiction over prescription drug advertising, although the FDA exercises primary responsibility for such advertising pursuant to a memorandum of understanding between the two agencies. Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).

[7] *See, e.g.*, Press Release, FTC, Online Pharmacies Settle FTC Charges (July 12, 2000) (*FTC v. Sandra L. Rennert et al.*), *available at* http://www.ftc.gov/opa/2000/07/iog.htm; Press Release, FTC, Eli Lilly Settles FTC Charges Concerning Security Breach, Company Disclosed E-mail Addresses of 669 Subscribers to its Prozac Reminder Service (Jan. 18, 2002), *available at* http://www.ftc.gov/opa/2002/01/elililly.htm; FTC, COMMISSION ACTIONS: JANUARY 2002 (Jan. 18, 2002) (File No. 012 3214, *In the Matter of* Eli Lilly and Company), *at* http://www.ftc.gov/os/2002/01/index.htm.

[8] *See generally* FTC, HEALTH CARE ANTITRUST ISSUES (2005), *at* http://www.ftc.gov/bc/healthindex.htm; FTC, FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (June 2005), *available at* http://www.ftc.gov/bc/0506rxupdate.pdf.

[9] *E.g.*, Letter from Mary K. Engle, Associate Director, FTC Bureau of Consumer Protection, Division of Advertising Practices to David A. Balto Re: *Longs Drug Stores Corp.*, FTC File No. 022-3280 (Jan. 13, 2003), *available at* http://www.ftc.gov/os/closings/staff/030113longsdrugstores.htm; Letter from Mary K. Engle, Associate Director, FTC Bureau of Consumer Protection, Division of Advertising Practices to Jeffrey Davis Re: *Wal-Mart Store, Inc.*, FTC File No. 022-3281 (Jan. 13, 2003), *available at* http://www.ftc.gov/os/closings/staff/030113walmart.htm; Letter from Mary K. Engle, Associate Director, FTC Bureau of Consumer Protection, Division of Advertising Practices to Phillip A. Proger Re: *Rite Aid Corp.*, FTC File No. 022-3283 (Jan. 13, 2003), *available at* http://www.ftc.gov/os/closings/staff/0300113riteaid.htm. These letters summarize FTC staff decisions to close inquiries into whether pharmaceutical "switch program" letters sent to patients failed to disclose adequately that the manufacturer of the drug referenced in the letter paid for the mailing or whether the letters contained any false or unsubstantiated claims.

provided comments to HHS on its HIPAA privacy rule when the rule was proposed.[10]

II. Summary of SB 401

California SB 401 would have amended CMIA[11] to change its definition of marketing.[12] As the Legislative Counsel's Digest for SB 401 explains, "[e]xisting law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law."[13]

Under CMIA, this prohibition extends to the marketing of medical information. Specifically, under current CAL. CIV. CODE § 56.10(d): "[e]xcept to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient."[14]

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[10] *FTC Comment to the Department of Health and Human Services Concerning Proposed HIPAA Privacy Rule* (Feb. 17, 2000), *available at* http://www.ftc.gov/be/v000001.htm (supporting the proposed rule's "individual authorization," or "opt-in" approach to the ancillary use of individually identifiable health information for purposes other than those for which the information was collected).

[11] CAL. CIV. CODE § 56 *et seq.*

[12] SB 401, 2005 Leg., 2005-06 Sess. (Cal. June 15, 2005), *available at* http://info.sen.ca.gov/pub/bill/sen/sb_0401-0450/sb_401_bill_20050615_amended_asm.pdf.

[13] Legislative Counsel's Digest for SB 401. *Id.* at * 1.

[14] CAL. CIV. CODE § 56.10(d) (Jan. 1, 2004). *See also* Legislative Counsel's Digest for SB 401, *supra* note 13, at *1 ("Existing law provides that this prohibition also applies to the marketing of any medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.").

CAL. CIV. CODE § 56.10(b) specifies nine instances where a provider of health care, a health care service plan, or a contractor "shall" disclose medical information if "compelled" to do so. For example, medical information shall be disclosed if compelled by a court order or other lawful adjudicative authority.

Current CAL. CIV. CODE § 56.05(f) provides that " '[m]arketing' means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service."[15] The statute also states that marketing does not include certain defined communications, including "[c]ommunications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication."[16] Thus, non-sponsored communications that encourage recipients to purchase or use certain products or services are not deemed marketing. In addition, the Legislative Counsel's Digest for SB 401 states that current law also excludes from the definition of marketing communications "tailored to the circumstances of a particular individual, as specified."[17]

Proposed SB 401 would have amended the definition of marketing under CAL. CIV. CODE § 56.05(f), such that:

> Notwithstanding any other provision of law, "marketing" includes a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs. This paragraph shall not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.[18]

CAL. CIV. CODE § 56.10(c) specifies seventeen instances where a provider of health care or a health care service plan "may" disclose medical information. For example, medical information may be disclosed to health professionals for diagnosis or treatment, including in an emergency situation.

[15] CAL. CIV. CODE § 56.05(f).

[16] CAL. CIV. CODE § 56.05(f)(1).

[17] *See* Legislative Counsel's Digest for SB 401, *supra* note 13, at *1.

[18] SB 401, *supra* note 12, at *3-4 (proposing an amended version of CAL. CIV. CODE § 56.05(f)).

This expanded definition of marketing would have included a written communication provided by a pharmacy to a patient in conjunction with the dispensing of a prescription where the communication includes the trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription being dispensed and the pharmacy receives remuneration from a manufacturer, labeler, or distributor in exchange for doing so (a sponsored communication). It is our understanding that SB 401 would have included as marketing a sponsored communication tailored to the specific circumstances of a particular individual, unless it is for the sole purpose of providing information about drug interactions, adverse events, another health and safety issue, or is an FDA-approved insert. Thus, combined with the existing opt-in provision of CAL. CIV. CODE § 56.10(d), SB 401 would have modified CMIA to require a pharmacy to obtain a patient's opt-in consent before it can provide that patient with such a sponsored, tailored written communication in conjunction with a prescription drug or therapy.[19]

Accordingly, it appears that under SB 401 a pharmacy would have needed to obtain a patient's opt-in consent before it could, for example, attach a sponsored flyer to a bag containing a patient's prescribed arthritis medication if the flyer included an advertisement or coupon for a specific over-the-counter pain reliever. Likewise, SB 401 could potentially have been interpreted to require a pharmacy to obtain a patient's opt-in consent before it could provide a sponsored communication to the patient about another form of the medicine being prescribed, such as a once-a-day dosage instead of a twice-a-day dosage, since this could be deemed a therapy "other than the prescription drug or prescribed treatment therapy being dispensed."

III. Comparison of SB 401 to Federal HIPAA Privacy Rule

The HHS HIPAA privacy rule[20] generally requires an individual's opt-in consent before that individual's health information can be used for marketing.[21] But, according to HHS, under its HIPAA privacy rule "[t]he simple receipt of remuneration does not transform a treatment

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[19] For purposes of this letter, we interpret "a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy" as describing a written, sponsored communication that is provided by the pharmacy at the same time and place that the patient receives the prescribed drug or therapy. Different issues and concerns would be raised if such sponsored, tailored communications are sent to consumers via regular mail or emails delivered at a different time or place from the prescribed drug or therapy.

[20] "Standards for Privacy of Individually Identifiable Health Information." 45 C.F.R. Parts 160 and 164. *See* 67 Fed. Reg. 53181 (Aug. 14, 2002). The rule was issued pursuant to the Health Insurance Portability and Accountability Act, Public Law 104-191, Aug. 21, 1996. You may also want to contact HHS directly for its official interpretation of how HIPAA defines a health care provider message.

[21] 45 C.F.R. § 164.508 (a)(3)(i).

communication into a commercial promotion of a product or service."[22] The HIPAA privacy rule specifically excepts from the definition of marketing communications that are made: (1) "[f]or treatment of the individual" or (2) "[f]or case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual."[23] Thus, a pharmacy communication recommending an alternative or complementary prescription drug, alternative prescribed treatment therapy, or over-the-counter medication may be excluded from the HIPAA privacy rule's definition of marketing, whether or not it is sponsored. In contrast, SB 401's requirement would have considered such a written communication recommending an alternative or complementary treatment to be marketing – thus requiring opt-in consent – simply because the communication is sponsored.

Therefore, returning to the example provided above, the HIPAA privacy rule would not require a pharmacy to obtain a patient's opt-in consent before it could attach a sponsored flyer to a bag containing a patient's prescribed arthritis medication if the flyer included an advertisement or coupon for an over-the-counter pain reliever, which could serve as a supplemental treatment option. Under SB 401, a pharmacy would have been required to obtain a patient's opt-in consent before doing so.

IV. Restrictions on Commercial Speech

SB 401's prophylactic restraint on a type of commercial speech that is not inherently unlawful or misleading may have raised questions under the First Amendment to the U.S.

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[22] DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH INFORMATION PRIVACY AND CIVIL RIGHTS QUESTIONS & ANSWERS, ANSWER ID 285 (Dec. 20, 2002 / July 18, 2003), *available at* http://healthprivacy.answers.hhs.gov/cgi-bin/hipaa.cfg/php/enduser/std_adp.php?p_faqid=285&p_created=1040405601&p_sid=mnk9bFMh&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PWRmbHQmcF9ncmlkc29ydD0mcF9yb3dfY250PTEmcF9wcm9kcz0mcF9jYXRzPTcsMCZwX3B2PSZwX2N2PTEuNzsyLnUwJnBfc2VhcmNoX3R5cGU9YW5zd2Vycy5zZWFyY2hfbmwmcF9wYWdlPTEmcF9zZWFyY2hfdGV4dD1zaW1wbGUgcmVjZWlwdCBvZiBByZW11bmVyYXRpb24*&p_li=&p_topview=1. In response to the question, "Can a provider be paid to make a prescription refill reminder without prior authorization?" HHS's web site answers that it is not marketing in that case, and it also noted that "it is not marketing when a doctor or pharmacy is paid by a pharmaceutical company to recommend an alternative medication to patients." *Id.*

[23] 45 C.F.R. § 164.501. "Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." *Id.*

Constitution.[24] First Amendment commercial speech jurisprudence recognizes the value of truthful information to consumers and to a competitive free enterprise system. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*,[25] the Supreme Court held that commercial speech, including most advertising and labeling,[26] is entitled to protection under the First Amendment. The Court concluded that the First Amendment protected the pharmaceutical advertising at issue there because the free flow of truthful and non-misleading commercial speech empowers consumers to make better-informed purchasing decisions and maximizes

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[24] Such questions are likely to be distinct from those raised by the FTC's "Do Not Call" Registry, created in 2002. *See generally* 68 Fed. Reg. § 4580 (2003) (Statement of Basis and Purpose and final amended Telemarketing Sales Rule); FTC, NATIONAL DO NOT CALL REGISTRY (2005), *available* http://www.ftc.gov/donotcall/. First, SB 401 would have required a pharmacy, subject to certain exceptions, to obtain a patient's opt-in consent before it can begin to provide them with a sponsored communication. By contrast, the Do Not Call List is an opt-out system, in which consumers must register to stop unwanted telemarketing phone calls by entering their telephone numbers into the Do Not Call Registry. The registry does not prevent sponsored communications, except when consumers specifically opt-out of receiving them. Thus, the registry is narrowly tailored to achieve its particular purpose. In contrast, SB 401 would have swept more broadly to prevent all sponsored communications, unless a consumer affirmatively opts-in to receive them.

Second, the Do Not Call Registry contains an exception for "established business relationships" between a consumer and a telemarketer. SB 401 would have prevented communications between parties to a pre-existing relationship. In addition, concerns about sponsored communications, *see infra* Section V., could be addressed by requiring a clear and prominent disclosure of sponsorship, but a similar, less restrictive alternative was not available in the Do Not Call context. *See generally Mainstream Mktg. Servs., Inc. v. FTC*, 358 F.3d 1228 (10th Cir. 2004), *cert. denied*, 125 S. Ct. 47 (2004) (upholding the constitutionality of the FTC and Federal Communications Commission rules that together created the Do Not Call list, 16 C.F.R. § 310.4(b)(1)(iii)(B) (FTC rule); 47 C.F.R. § 64.1200(c)(2) (FCC rule), against arguments that they violated the First Amendment).

It is worth noting, however, that the FTC strongly supported HIPAA's "opt-in" approach to the ancillary use of individually identifiable health information for purposes other than those for which the information was sought. *See FTC Comment to the Department of Health and Human Services Concerning Proposed HIPAA Privacy Rule*, *supra* note 10. Thus, not all "opt-in" approaches are necessarily constitutionally suspect.

[25] 425 U.S. 748 (1976).

[26] Commercial speech includes most advertising and labeling. *Id.* at 771 (advertising); *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980) (advertising); *In re R.M.J.*, 455 U.S. 191 (1982) (advertising); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (labels); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (advertising and labels).

consumer welfare in a competitive free-market economy.[27]

Subsequently, in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*,[28] the Supreme Court articulated a four-part test for evaluating whether government restrictions on commercial speech are constitutional. First, if the commercial speech concerns unlawful activity or is misleading, it is not protected by the First Amendment and may be banned entirely. Second, if the commercial speech concerns lawful activity and is not misleading, the court will ask "whether the asserted governmental interest is substantial."[29] Third, if it is substantial, the court "must determine whether the regulation directly advances the governmental interest asserted. . . ."[30] Fourth, the court must determine "whether [the regulation] is not more extensive than is necessary to serve that interest."[31] To survive a First Amendment challenge, a government actor has the burden of proving that its restriction on commercial speech satisfies this four-pronged test.[32]

Several decisions have applied *Central Hudson*'s four-part test to restrictions on health care-related commercial speech imposed by the FDA. For example, in *Pearson v. Shalala*,[33] the D.C. Circuit recognized the government's substantial interest in ensuring the accuracy of consumer information in the marketplace, and stated that banning potentially misleading health claims would appear to directly advance that interest.[34] The court, however, explained that, in the case of commercial speech, the First Amendment embodies a "preference for disclosure over outright suppression."[35] Given this preference, the court concluded that the FDA "disregards a 'far less restrictive' means" of advancing its interest "when the government chooses a policy of suppression over disclosure – at least where there is no showing disclosure would not suffice to cure misleadingness. . . ."[36] Thus, the court held that, because the FDA had not considered whether disclaimers could have eliminated the potential for misleading consumers, its ban on

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27 *Virginia Bd. of Pharmacy*, 425 U.S. at 765.

28 447 U.S. 557 (1980).

29 *Id.* at 566.

30 *Id.*

31 *Id.*

32 *Id.*

33 164 F.3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 172 F.3d 72 (D.C. Cir. 1999).

34 *Id.* at 655-56.

35 *Id.* at 658.

36 *Id.*

certain claims violated the First Amendment. In *Thompson v. Western States Medical Center*,[37] the Supreme Court applied the *Central Hudson* test to strike down another FDA drug advertising ban where there were other, less speech-restrictive means available to advance the government's goals. There, the Court observed that "[i]f the First Amendment means anything, it means that regulating speech must be the last – not first – resort."[38]

V. Less Restrictive Alternatives

Proponents of SB 401 indicated concerns that a consumer who receives from a pharmacy a communication sponsored by some other entity, such as a manufacturer, labeler, or distributor, may become confused about the nature of the communication and conclude that it implies a pharmacist's sanction of a suggested alternative treatment or that it is a substitute for a doctor's advice.[39] Requiring a clear and prominent disclosure of sponsorship could address the issue of consumer confusion about the source of such a written communication, without eliminating the benefits consumers may receive from truthful advertising.[40] Of course, any sponsored communications that contain direct-to-consumer pharmaceutical advertising would be subject to general advertising and labeling regulation, such as FDA's requirements for labeling.[41]

It is well-established that government may "require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent deception."[42] Not only is such an approach consistent with the First Amendment, the

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[37] 535 U.S. 357 (2002).

[38] *Id.* at 373.

[39] *E.g.*, CALIFORNIA ASSEMBLY COMMITTEE ON HEALTH SB 401 BILL ANALYSIS at 3 (June 28, 2005), *available at* http://www.leginfo.ca.gov/pub/bill/sen/sb_0401-0450/sb_401_cfa_20050628_110823_asm_comm.html.

[40] *Cf.* FTC GUIDES CONCERNING USE OF ENDORSEMENTS AND TESTIMONIALS IN ADVERTISING, 16 C.F.R § 255.5 (Jan. 2005) (Disclosure of Material Connections), *available at* http://www.ftc.gov/bcp/guides/endorse.htm ("When there exists a connection between the endorser and the seller of the advertised product which might materially affect the weight or credibility of the endorsement (i.e., the connection is not reasonably expected by the audience) such connection must be fully disclosed. . . .").

[41] *See supra* note 4.

[42] *Virginia Bd. of Pharmacy*, 425 U.S. at 771 n.24. *See also Zauderer v. Office of Disciplinary Council of Supreme Court of Ohio*, 471 U.S. 626 (1985). There, the Supreme Court upheld the constitutionality of an Ohio attorney advertising requirement that an attorney include in his advertising "purely factual and uncontroversial information about the terms under which

courts have repeatedly found it to be the preferred approach for curing deceptive speech, as opposed to a ban on commercial speech that is not inherently unlawful or misleading.[43]

The FTC, operating within the First Amendment analytical framework discussed above, has a long history of favoring disclosures over outright bans when such disclosures are a viable means to protect consumers from deceptive speech.[44] When it does conclude that certain commercial speech is misleading and considers possible remedial measures, the Commission is careful to ensure that those measures are not overly burdensome and do not exceed what is necessary and appropriate to remedy the deception. This approach minimizes restrictions on truthful speech and recognizes that courts have indicated disclosure requirements may still violate the First Amendment if they are "unjustified or unduly burdensome."[45] The benefits of this approach are especially significant when the information relates to consumer health.

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his services will be available." *Id.* at 651. The Court stated that "warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception." *Id.* (quoting *In re R.M.J.*, 455 U.S. at 201).

[43] *See, e.g., Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 110 (1990); *see also In re R.M.J.*, 455 U.S. at 206 n.20; *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988). This was also the cornerstone of the court's ruling in the *Pearson* case, discussed above, where FDA's prohibition of certain health claims for dietary supplements was struck down and the agency instructed to consider allowing qualified claims. 164 F.3d at 657.

[44] The Commission seeks bans when the speech itself is inherently deceptive. For example, the Commission has sometimes sought bans on the use of trade names that are deceptive and cannot be qualified without resulting in a confusing contradiction in terms. *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C. 138, 252-53 (1998), *aff'd sub nom. Jones v. FTC*, 194 F.3d 1317 (9th Cir. 1999) (affirming FTC order banning the use of the term ABS, or antilock brake system, to describe non-anti-lock brake systems); *Resort Car Rental System, Inc. v. FTC*, 518 F.2d 962, 964 (9th Cir. 1975) (affirming FTC order prohibiting use of trade name "Dollar-A-Day" in connection with rental car agency); *Continental Wax Corp. v. FTC*, 330 F.2d 475, 479-80 (2d Cir. 1964) (upholding the excision of the "Six Month" portion of the trade name "Six Month Floor Wax"). *See also FTC Staff Comment Before the FDA Concerning First Amendment Issues* 16 (Sept. 2002) ("the Commission has generally favored disclosures over banning claims as a means of curing deception . . . ."), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf.

[45] *Zauderer*, 471 U.S. at 651; s*ee also Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994). For example, a requirement that a company disclose more information than is necessary to prevent deception may be held to be unconstitutional. *See FTC v. Nat'l Comm'n on Egg Nutrition*, 570 F.2d 157, 164 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978).

Conclusion

Combined with CMIA's existing opt-in provision, SB 401 would have modified CMIA to require, subject to certain exceptions, that a pharmacy obtain a patient's opt-in consent before it can provide a patient with a sponsored "written communication" in conjunction with a prescription if the communication includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed. This requirement would have been more restrictive than HIPAA's privacy rule.

SB 401's prophylactic restraint on a type of commercial speech that is not inherently unlawful or misleading may have raised questions under the First Amendment to the U.S. Constitution and ultimately may not have benefitted consumers. Measures that place fewer burdens on speech could include requiring the clear and prominent disclosure of sponsorship to ensure that patients are not misled as to the source or funding for the communication.

Sincerely,

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