Legal Opinion Letter

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PROPOSAL LIMITING DISTRIBUTION OF HEALTH CARE INFORMATION INFRINGES ON FREE SPEECH RIGHTS

by
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The California Senate is considering an amendment to the state's Confidentiality of Medical Information Act which would unconstitutionally infringe on the First Amendment rights of pharmacies to provide to patients, and the rights of patients to receive, health information. The bill, S.B. 401, requires pharmacies to obtain full consent from customers before pharmacists can prepare and distribute a variety of in-pharmacy communications in situations where the materials are paid for by a manufacturer or distributor of prescription drugs. Without such authorization, pharmacists would be prohibited from using the patient's medical information to make any written communication which mentions the trade name for a medical product, other than the specific drug or therapy being dispensed. The bill suffers from several fatal constitutional flaws, and likely would not withstand the close scrutiny the U.S. Supreme Court applies to commercial speech restrictions.

The First Amendment protects a pharmacy's right to communicate with patients. *See, e.g.*, *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976). The Supreme Court, in cases involving pharmacy speech, has applied the test first enunciated in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Under the *Central Hudson* test, the constitutionality of a government-imposed restriction on commercial speech is evaluated using a four-factor test: (1) whether the speech is misleading or concerns an unlawful activity; (2) whether there is a substantial state interest to be achieved by the restrictions; (3) whether the restrictions directly and materially advance the asserted interest; and (4) whether the governmental interest could be served as well by a more limited restriction. Under the first factor, if the speech in question is neither misleading nor concerns unlawful activity, the state's power to regulate is limited; for the state restriction to be upheld, the next three prongs of *Central Hudson* must be met.

In the case of pharmacy communications described in S.B. 401, the speech concerns lawful activity that is not inherently misleading (at least as long as sponsorship is clearly disclosed). The question then becomes whether there is a substantial governmental interest that S.B. 401 purportedly would achieve. The bill's supporters argue that the State has a substantial interest in preventing pharmacies from using their patients' individually-identifiable health information to "sell" them products. However, that interest is not "substantial": Advising patients about their health

conditions and treatment options — information that can help patients make better health care decisions — has been part of the traditional practice of pharmacy for centuries.[1]

Even assuming, however, that California has a substantial interest that would be served by S.B. 401, a government speech restriction that (as is the case here) is "irrational" and "inconsistently applied" will not be held to advance the government's interest directly and thus will fail to meet the third requirement of *Central Hudson*. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). S.B. 401 would restrict messages sponsored by pharmaceutical companies, yet permit — without the need for consent — the identical messages if sponsored by a governmental agency, the pharmacy, a non-profit organization or a health plan. For example, information about a new dosage form which may provide easier dosing and prevent potential misuse, or information about a clinical trial for a new drug, would be permitted without restriction if provided as a public service, while the identical message sponsored by a pharmaceutical company would not. Such "inconsistent application" is fatal to S.B. 401's assertion that its restriction directly advances a substantial government interest. *See, e.g., Coors Brewing Co.*, 514 U.S. at 487.

Finally, in contravention of *Central Hudson*, California has not used the least restrictive means available to further its asserted consumer-protection interest. Less restrictive measures could include requiring the disclosure of sponsorship to ensure that patients are not misled as to the source or funding for the communication.

The conclusion that S.B. 401 would not withstand First Amendment scrutiny receives strong support not only from the *Western States* and *Virginia State Board of Pharmacy* cases discussed above, but also from other recent case law in which federal courts around the country have made clear that governmental attempts to restrict truthful speech about health and medical products will be required to satisfy First Amendment scrutiny. *See, e.g.*, *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001), *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999).

Intriguingly, a broad and diverse group of advocates, including the California Pharmacists Association, the National Consumers League, the California Hispanic Healthcare Association, Kaiser Permanente, the California Retailers Association, the National Association of Chain Drug Stores, Poz Magazine, and the Black AIDS Institute, oppose S.B. 401. These organizations, from across the ideological spectrum, have all expressed concern that S.B. 401 would have the unfortunate effect of restricting the flow of important health information to patients, and would therefore be contrary to well-recognized public health objectives. They advance the point that while pharmaceutical advertising must be accurate and balanced with respect to benefits and risks, legislation that is premised on the notion that patients are better off receiving less information is ill-considered.

S.B. 401 is an unconstitutional restriction on the right of pharmacies to provide information to patients and of pharmacy patients to receive this information. In the managed care era, in which most patients have limited time with their health care professionals, patients need more health information, not less.

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[1]Indeed, the privacy regulations issued by the U.S. Department of Health and Human Services in August, 2002, pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), recognize that this type of messaging, even if sponsored, is "treatment" that does not require the patient's prior authorization. Under federal law, these communications are not considered "marketing." *See* 67 Fed. Reg. 53181 (Aug. 14, 2005).

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