UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

[redacted]

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

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 [redacted]

[redacted]

the following observations that we hope will be of assistance:

[redacted]

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, free samples, 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

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

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

[redacted]

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

[redacted]

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

First Amendment. The Court concluded that the First Amendment protected the pharmaceutical

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

certain claims violated the First Amendment. In *Thompson v. Western States Medical Center*,[37]

opposed to a ban on commercial speech that is not inherently unlawful or misleading.[43]

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

Constitution and ultimately may not have benefitted consumers. Measures that place fewer