

## UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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:

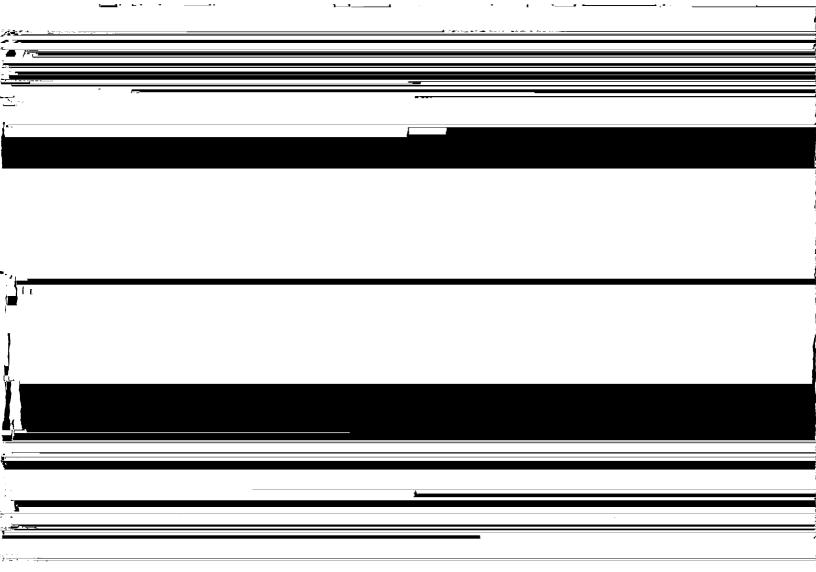
The staff of the Todana Tunda Commission's ("TTC" on "the Commission") Office of

	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
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•	the following observations that we hope will be of assistance:
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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 rifts from mareta mikaidian an athan account of homofita from adding a mart making the communication."16 Thus, non-sponsored communications that encourage recipients

	This expanded definition of marketing would have included a written communication
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	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
	to a continue chisting opt-in provision of CAL. Civ. Code § 50.10(a), 50 401 would have
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communication into a commercial promotion of a product or service."<sup>22</sup> 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



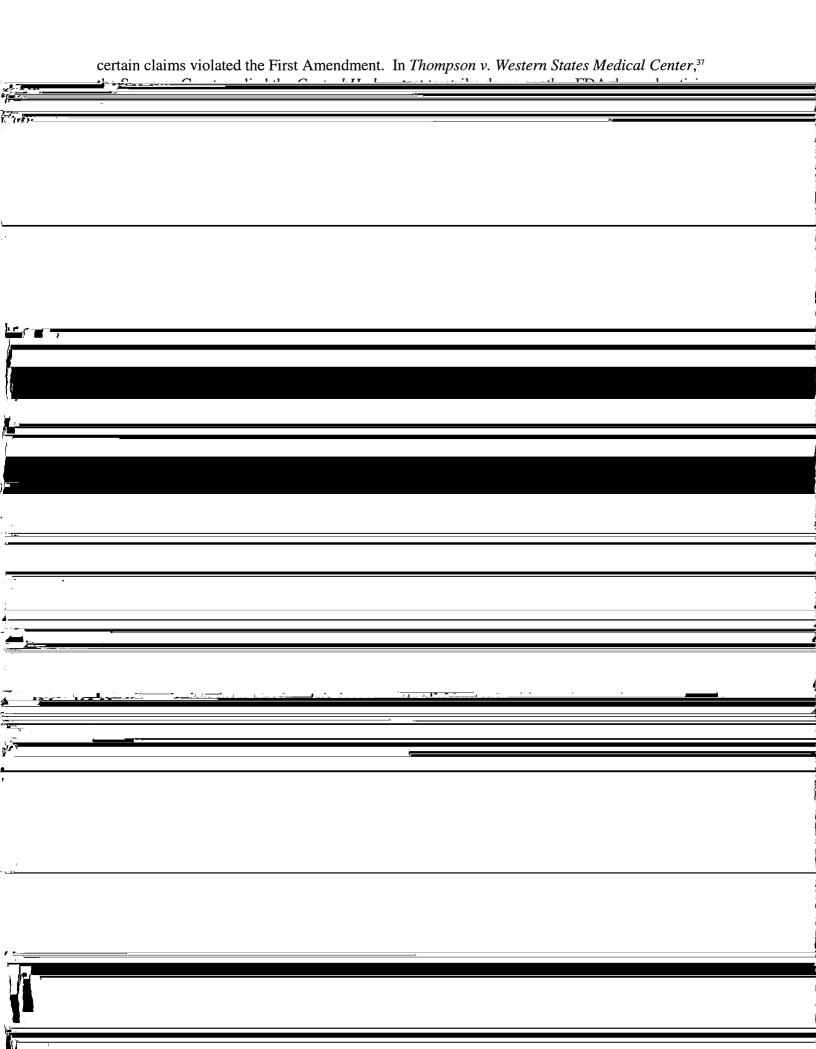
settings of care to the individual."<sup>23</sup> Thus, a pharmacy communication recommending an alternative or complementary prescription drug, alternative prescribed treatment therapy, or overthe-counter medication may be excluded from the HIPAA privacy rule's definition of marketing, whether or not 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.

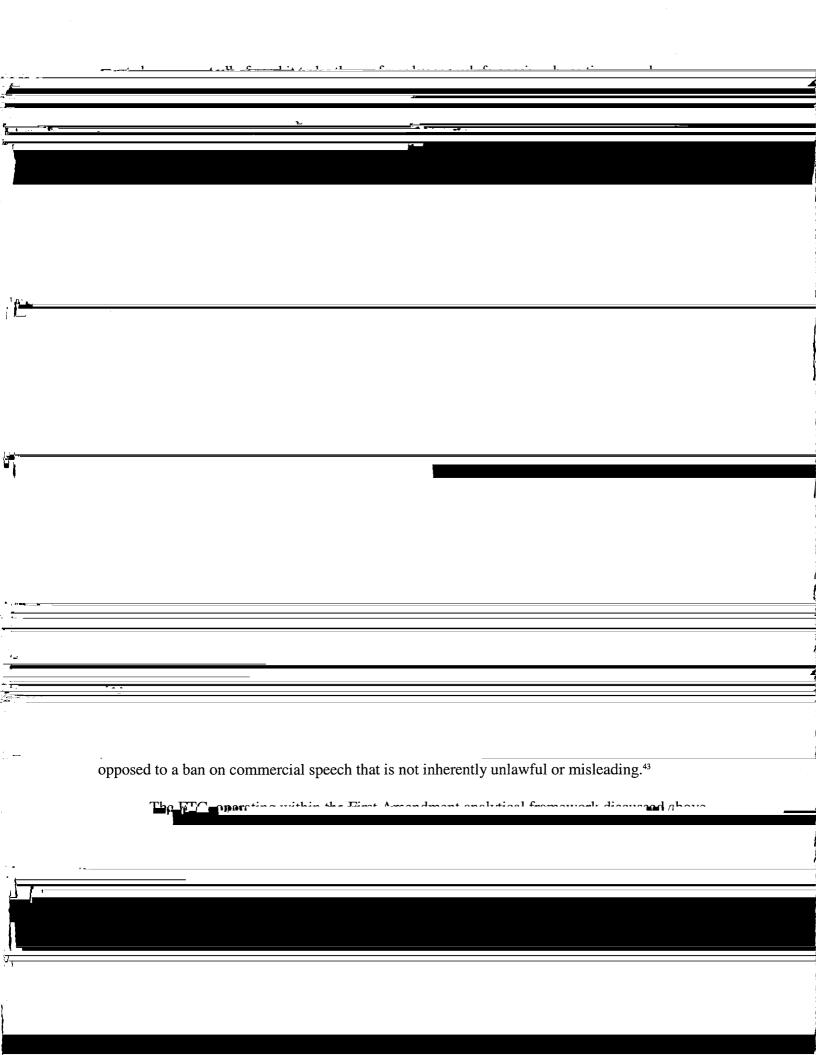
Therefore, returning to the example provided above, the HIPAA privacy rule would not require a pharmacy to obtain a patient's opt-in consent before it could attach a sponsored flyer to a bag containing a patient's prescribed arthritis medication if the flyer included an advertisement

	Constitution. <sup>24</sup> First Amendment commercial speech jurisprudence recognizes the value of truthful information to consumers and to a competitive free enterprise system. In <i>Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council</i> , <sup>25</sup> the Supreme Court held that	
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	First Amendment. The Court concluded that the First Amendment protected the pharmaceutical	,
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consumer welfare in a competitive free-market economy.<sup>27</sup>

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 creech concerns lawful activity and is not misleading the court will ask "whether the asserted governmental interest is substantial." Third, if it is مراه من المناسخة المن





## Conclusion

	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
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	been more restrictive than HIPAA's privacy rule.
	SB 401's prophylactic restraint on a type of commercial speech that is not inherently
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•	Constitution and ultimately may not have benefitted consumers. Measures that place fewer
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Combined with CMIA's existing opt-in provision, SB 401 would have modified CMIA to