

Is it constitutional for states to regulate pharmaceutical gifts and meals to doctors?

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We've all seen them in the waiting room of the doctor's office—pens, notepads, magnets, and clipboards adorned with the logos of brand-name drugs. These freebies may seem inconsequential, but a large and compelling body of evidence shows that even these small gifts may influence which drug a doctor prescribes.

"What most people haven't seen is many of the other giveaways that pharmaceutical and medical-device companies routinely provide to [doctors](#), ranging from elaborate meals in local restaurants to expensive resort travel in the form of continuing medical education. Some companies spend more money on advertising their products than on research and development on new products, and prescribing physicians are their most promising target for promotional activities," said Marcia Boumil, MA, MS, JD, LLM, associate professor in the department of public health and community medicine and assistant dean, conflict of interest administration, at Tufts University School of Medicine.

As a result, many states have enacted laws limiting marketing practices by pharmaceutical companies, but are these laws constitutional? In an article, published in the current issue of the *Journal of Health & Biomedical Law*, Boumil examines whether these laws may violate the First Amendment in light of a recent Supreme Court precedent (*Sorrell v. IMS Health, Inc.*).

"These pharmaceutical gift laws are controversial but work to protect patients and lower healthcare costs by creating an environment in which

doctors can make treatment decisions without undue influence," said Boumil. "Despite the intent and value of these laws, courts might now find they violate the First Amendment because the states might not be able to prove that the laws serve a clear and compelling state interest."

Sorrell v. IMS Health, Inc. was a 2011 decision by the U.S. Supreme Court that struck down a Vermont law preventing drug companies from purchasing prescriber-identified prescription data, a process known as data mining, and using it for marketing purposes, such as planning a marketing pitch to a particular physician based on the physician's prescribing habits.

The Supreme Court examined the case with a heightened level of scrutiny because the Vermont law prohibited pharmaceutical companies from using the information to enhance their marketing efforts, yet did not restrict researchers, journalists, and insurance companies from using the same information for their benefit. The Court held that a law which prohibits data mining for some purposes but not others is inherently suspect.

The Supreme Court decision determined that the law also violated First Amendment protections because Vermont had not clearly established evidence of a legitimate state interest for regulating commercial speech, although Vermont asserted that the law protected medical privacy, reduced health care costs, and safeguarded public health.

In light of the Supreme Court's willingness to apply this heightened standard of judicial scrutiny to state laws restricting commercial speech, which is endemic to state regulation, it is no longer clear that the pharmaceutical gift laws enacted in approximately 25 states would withstand a constitutional challenge, Boumil said. She noted that that the Vermont law, designed to diminish conflicts of interest in medicine, might have been more carefully crafted.

"If this same degree of scrutiny were applied to state pharmaceutical gift laws, states may be required to prove that these laws serve a clear and compelling state interest using hard data—no easy task," she continued.

"The regulation of pharmaceutical giveaways and some marketing approaches, while important to minimize undue influence in the selection of drug choices, is now uncertain if a constitutional challenge is brought," Boumil added. "While the legality of state restrictions is being debated, hospitals, academic institutions, and the pharmaceutical industry itself can work to create their own policies that protect patients and minimize healthcare costs."

Boumil is also director of the Master of Public Health/Juris Doctor joint degree program at Tufts University School of Medicine and Northeastern University School of Law.

More information: Boumil, M. *Journal of Health and Biomedical Law*. 2012 (June); 8(2). "Pharmaceutical gift laws and commercial speech under the first amendment in the wake of *Sorrell v. IMS Health, Inc.*"

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