



# HEALTH CARE FRAUD REPORT



Reproduced with permission from Health Care Fraud Report, BNA's Health Care Fraud Report, 07/13/2011. Copyright © 2011 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## Is Health Care Marketing Protected Commercial Speech Under the Supreme Court's Decision in Sorrell?



BY PATRIC HOOPER

### Introduction

**O**n April 4, Rita Guiamelon, M.D., a California pediatrician who has spent most of her career rendering services to poor children and their families, was convicted of a single felony count of violating California Business and Professions Code Section 650(a) ("Section 650"), which prohibits doctors from paying

*Hooper is a founding partner of Hooper, Lundy & Bookman in Los Angeles. He specializes in litigation against the federal and state governments involving health care matters. He can be reached at [phooper@health-law.com](mailto:phooper@health-law.com).*

for "inducing" the "referring" of patients. People v. Guiamelon, Los Angeles Superior Court No. BA361105.

Dr. Guiamelon's conviction and pending appeal furnish a useful backdrop for examining the potential impact of the Supreme Court's June 23 opinion in *Sorrell v. IMS Health Inc., et al.* U.S. Supreme Court docket no. 10-779, 2011 WL 2472796 (June 23, 2011), which involves the subject of commercial free speech in the context of marketing by pharmaceutical manufacturers.

### Dr. Guiamelon's Case

Believing it was perfectly legal to do so as long as she gave them IRS Form 1099s to reflect her payments to them, Dr. Guiamelon had paid "marketers" in her community to make her preventative pediatric and family planning services known to the uninsured.

Due to the demographics of her office location, her patients consisted largely of poor Hispanics, who are reluctant to approach government agencies for help. The marketers passed out flyers and otherwise publicized Dr. Guiamelon's services. They were instructed by Dr. Guiamelon to market her services only to the uninsured.

Dr. Guiamelon paid the marketers for their services at the rate of \$20 for each patient she was able to qualify as a beneficiary in one of two federally and state funded health care programs for uninsured patients who do not qualify for Medicaid – (1) the Family Planning, Access, Care and Treatment ("Family PACT") and (2) the Children Health and Disability Prevention ("CHDP") programs. See California Welfare and Institutions Code Section 14132(aa) and Health and Safety Code Section 124025.

These public health care programs are expressly intended to provide access to preventative health care

services for the uninsured. Private doctors, such as Dr. Guiamelon, enroll patients who qualify in these programs at their offices after which the patients may apply and qualify for extended benefits in other state programs, including Medicaid (“Medi-Cal” in California).

The \$20 marketing fees were absorbed by Dr. Guiamelon as a cost of doing business. No charge for the marketing services was made to the Programs or the patients. Dr. Guiamelon was fully transparent about these payments, as evidenced by the fact that she paid the marketers with office checks describing the services as “marketing” and gave the marketers IRS Form 1099s reflecting the payment for their marketing services.

Because the services were preventative in nature, including such items as vaccinations, no issue of medical necessity is implicated by her services.

In April 2010, Dr. Guiamelon was arrested and jailed for a day before her family was able to post bail in the sum of \$500,000 for her release.

A jury trial was held in November 2010. Because Section 650 does *not* require the prosecution to prove that a doctor knew her acts were unlawful, the State was able to argue to the jury at trial that it did not matter that Dr. Guiamelon thought she was doing nothing wrong, and it also did not matter that she was helping the uninsured get services they otherwise might not have received.

Thus, the resulting guilty verdict was not a huge surprise and was considered a necessary first step in trying to change the present state of the case law in California concerning Section 650.

Dr. Guiamelon is now appealing her conviction on various grounds, including arguing that Section 650 is preempted by the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, due to the absence of any “knowing and willful” element in Section 650.

Ironically, the primary case being relied on to further this preemption argument is *State v. Harden*, 938 So. 2d 480 (S.Ct. Fla. 2006), where the trial court had declared a Florida statute unconstitutional in a case involving health care marketing based on First Amendment objections, among others. The Florida Supreme Court did not decide the First Amendment issue in light of its ruling on the federal preemption issue.

Unfortunately, while Dr. Guiamelon’s appeal works its way through the court of appeal, she is serving a 36-month period of probation and incurring the horrible collateral consequences of the conviction, including being thrown out of the Medicaid program (and likely excluded from all federal programs), suspended from hospital medical staffs, kicked off private payer panels, such as PPOs and HMOs, and losing her private office practice.

## The Sorrell Decision

On June 23, the U.S. Supreme Court issued its long anticipated decision in *Sorrell*. The Court struck down a Vermont statute that prohibited, among other things, pharmaceutical manufacturers from using the results of “data mining” to market their pharmacy products to doctors (see *related item in the Court Proceedings section*). The “mined” data was obtained from information furnished by pharmacies revealing the prescribing practices of doctors, known as “prescriber-identifying information.” 2011 WL 2472796 at page \*4.

Vermont attempted to justify the legislation by asserting that it fulfilled the twin goals of improving public health and reducing health care costs. 2011 WL 2472796 at page \*16. It was thought that doctors were being unduly influenced by the marketing techniques of the manufacturers, which could adversely affect patients and cause increased costs. The safeguarding of “medical privacy” was also a goal. 2011 WL 2472796 at page \*4.

The Court, however, found the Vermont legislation to impose both content- and speaker-based burdens on protected “expression” (commercial free speech), thus requiring a heightened judicial scrutiny; and the Court concluded that neither justification “withstands scrutiny” under such a heightened review standard. *Id.*

The particular provision relevant here is that which barred disclosure of information when “recipient speakers will use the information for marketing.” 2011 WL 2472796 at page \*5. However, the state could supply the prescriber identifying information to academic organizations to counter the messages of brand-name pharmaceutical manufacturers and in promoting generic drugs. *Id.*

## Sorrell’s Potential Impact

Importantly, much of the Court’s reasoning arguably applies to health care anti-kickback laws, such as Section 650 and the federal anti-kickback provisions prohibiting remuneration for “recommending” the purchasing or ordering of health care services and goods. 42 U.S.C. § 1320a(b)(1)(B) and (2)(B). Recommending particular health care services or goods is obviously a primary purpose of marketing in the health care industry.

Correspondingly, just as discussed in *Sorrell*, such health care marketing efforts can result in creating potential conflicts of interest which can in turn be detrimental to the best interests of patients and can increase health care costs in some situations. See Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies, or Cost-Effectiveness? Application of the Medicare Anti-kickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L. J. 279, 282 (1999).

Yet, marketing health care services necessarily contains an important commercial free speech component, as recognized by the Supreme Court in *Sorrell*. As in *Sorrell*, the government’s enforcement efforts may unduly burden such expression by excessively regulating (and at times punishing) certain speakers and content for no compelling purpose.

An example of such speaker and content regulation in health care marketing is that the simple “advertising” of a provider’s health care services or products to the public is ordinarily considered to be “legal,” especially if it performed by an employee of a provider, as opposed to an independent contractor. This is especially true if it is done for the purpose of making a provider’s services known to the public, as opposed to the purpose of inducing the referral of patients to a particular provider.

In fact, in Dr. Guiamelon’s case, the State conceded that a provider could pay an independent contractor, such as the owner of a billboard, to advertise the provider’s services without running afoul of Section 650.

Such advertising could urge would-be patients to use the providers services.

However, the State argued that if the independent contractor were compensated for the very same advertising services on a per patient basis, such advertising would be a crime under Section 650.

Health care industry members and their attorneys know well (and indeed perpetuate) the many subtle “nuances,” which can complicate the analysis of marketing arrangements under the federal and state anti-kickback laws. For a detailed discussion of such issues, see W. Bradley Tully, *BNA’s Health Law & Business Series, Federal Anti-Kickback Law, “Marketing,”* Section 1500.07.E.

The Court’s reasoning in *Sorrell* arguably now adds another factor to consider in the analysis and should give government enforcement officials cause to rethink their approaches to pursuing health care marketing activities.

This is especially so since violations of the anti-kickback laws can serve as predicates for civil false claims actions thus expanding even further the broad reach of these laws. See, e.g., *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.* 423 F. 3d 1256 (11<sup>th</sup> Cir. 2005) [defendant’s failure to comply with the anti-kickback statute could give rise to liability under the False Claims Act, 31 U. S.C. Section 3729 et al], and more recently, *United States ex rel. Wilkins v. United Health Group Incorporated*, \_\_ F. 3d \_\_ (3<sup>rd</sup> Cir. 2011) 2011 WL 2573380.

## Conclusion

Marketing health care services and products can fulfill important public purposes, especially where such marketing improves access to health care. Health care

enforcement officials should confer with health care policy makers to strike a new balance regarding the dissemination of health care information in light of *Sorrell*.

Unfortunately, for Dr. Guamelon, the time may have passed. Her efforts to reach out to the uninsured were thwarted by her arrest and conviction under Section 650.

If the conviction is upheld, uninsured persons, needing preventative health care, will be deprived of information that could give them access to doctors who could provide such services through programs that will cost the patients nothing.

Such regulation on commercial speech smacks of the same potential “viewpoint” discrimination and paternalism criticized by the Court in *Sorrell*. 2011 WL 2472796 at pages \*8 and \*16.

Yet, unless the Court’s decision is heeded by health care enforcement officials and policy makers, the message will remain that the government knows best how to protect health care consumers’ choices of providers and how to make access to care available to the uninsured.

In *Sorrell*, the Court cautioned that the First Amendment “directs us to be especially skeptical of regulations that seeks to keep people in the dark for what the government perceives to be their own good.” Criminalizing or otherwise burdening marketing efforts in health care will continue to keep people in the dark—even those who could benefit most from knowing of a particular provider’s services.

The Supreme Court’s decision in *Sorrell* has now been brought to the attention of the court of appeal in Dr. Guamelon’s case as an additional reason for setting aside her conviction, a conviction which is in no one’s best interests, especially the patients who will no longer receive Dr. Guamelon’s services.