I. The World of Pharmaceutical Marketing

An abundance — arguably, an overabundance — of literature addresses the evils or virtues of pharmaceutical marketing to physicians and, in particular, the traditional activities of pharmaceutical sales representatives. From grassroots bloggers to academicians to judges, much ink has been spilled on whether pharmaceutical sales reps exceed the bounds of ethical marketing — or whether they fill a necessary role in modern medicine by informing overworked physicians about new drugs and devices that can help save the lives of patients. This article will not add to that discussion, but instead, reviews current case law to discuss developments in the realm of pharmaceutical marketing, with a focus on “detailing” (face-to-face sales and promotional activities directed to physicians and pharmacy directors) and off-label activities.

II. Pharmaceutical Marketing: What’s IN, What’s OUT, What’s NEXT

A. What’s IN: Prescriber-Identifying Info

In recent years three Northeastern states — Vermont, New Hampshire, and Maine — enacted legislation that restricted the sale, disclosure, and use of prescriber-identifying information for purposes of pharmaceutical marketing. The states’ primary justifications expressed for adopting these laws, in general, were to safeguard medical privacy, contain costs through the promotion of less costly (generic) drugs, ensure receipt of unbiased information, and reduce the likelihood that pharmaceutical marketing would lead to prescription decisions that were not in the best interest of patients or the state.

Under federal law, and as a matter of routine business, pharmacies receive prescriber-identifying information when they process prescriptions. Many pharmacies sell this information to “data miners,” firms that analyze prescriber-identifying information and produce reports on physicians’ prescribing behavior. In turn, data miners lease these reports to pharmaceutical manufacturers, and detailers use the reports to fine tune their marketing approaches. The state statutes in Vermont, Maine, and New Hampshire effectively sought to prohibit this arrangement. In Vermont, for instance, pharmacies were precluded from selling prescriber-identifying information or allowing it to be used for marketing unless the prescriber consented, and pharmaceutical manufacturers and marketers were prohibited from using prescriber-identifying information for marketing.

All three state statutes were challenged in their respective federal district courts by data miners as well as an association of brand-name pharmaceutical manufacturers, Pharmaceutical Research and Manufacturers of America (PhRMA).
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America (PhRMA). The cases alleged that these statutes violated the First Amendment as incorporated by the Fourteenth Amendment. Ultimately, appeals to the circuit courts resulted in conflicting conclusions. The Second Circuit Court of Appeals struck down the Vermont statute as unconstitutional, whereas the First Circuit upheld the New Hampshire and Maine statutes. That circuit split prompted the United States Supreme Court to grant certiorari in Sorrell v. IMS Health Inc., 131 S.Ct. 2653 (2011).

On June 23, 2011, the Supreme Court struck down the Vermont statute as unconstitutional. The 6-3 decision, authored by Justice Kennedy, first explained the process of marketing drugs to physicians through “detailing” and recognized that sales reps “can be more effective when they know the background and purchasing preferences of their clientele.” Knowledge of a specific physician’s prescription practices greatly improves a detailer’s ability to determine which doctors are likely to be interested in a particular drug — and how to best present a sales message to those physicians. The Court further recognized that detailing is expensive, and as a result, it is most often used to promote high-profit, brand-name drugs that are still protected by patent.

The Supreme Court found that Vermont’s statutory prohibition of these activities violated the First Amendment. First, the Court ruled that the statute was subject to heightened judicial scrutiny (as opposed to intermediate scrutiny) because it was designed to impose a specific, content-based burden on protected expression. The statute disfavored marketing, which constitutes speech with a particular content. Moreover, it disfavored specific speakers (detailers):

As a result of these content- and speaker-based rules, detailers cannot obtain prescriber-identifying information, even though the information may be purchased or acquired by other speakers with diverse purposes and viewpoints. Detailers are likewise barred from using the information for marketing, even though the information may be used by a wide range of other speakers. For example, it appears that Vermont could supply academic organizations with prescriber-identifying information to use in countering the messages of brand-name pharmaceutical manufacturers and in promoting the prescription of generic drugs. But [the statute] leaves detailers no means of purchasing, acquiring, or using prescriber-identifying information. The law on its face burdens disfavored speech by disfavored speakers.

Vermont’s express purpose was thus to diminish the effectiveness of marketing by manufacturers of brand-name drugs, which warranted heightened scrutiny. Under this standard, Vermont did not demonstrate that its statute directly advanced a substantial governmental interest and that the statute was drawn to achieve that interest. The Court rejected Vermont’s argument that the statute was justified by a need to protect medical privacy and prevent physician harassment by detailers or the alternate goals of improving public health and lowering healthcare costs.

In so ruling, the Court explained (one might say signaled) that a more “coherent” policy to protect physician confidentiality, such as a law like HIPPA that would allow sale or disclosure of information in certain instances, might pass muster. Vermont, however, had allowed prescriber-identifying information to be made available to “an almost limitless audience,” with only a narrow class of disfavored speakers: pharmaceutical manufacturers and detailers.

The Court also dismissed Vermont’s argument that its statute was constitutional because physicians could opt out of the prohibition simply by providing their consent. “Vermont has given its doctors a contrived choice: Either consent, which will allow your prescriber-identifying information to be disseminated and used without constraint; or, withhold consent, which will allow your information to be used by those speakers whose message the State supports.” The Court refused to sanction a rule that required physicians to acquiesce in the state’s goal of burdening disfavored speech by disfavored speakers (i.e., marketing by detailers).

The decision went even a bit further, rejecting outright Vermont’s attempts to protect physicians from alleged harassment by detailers. Noting that “[n]o one says that those who must endure speech they do not like, but that is a necessary cost of freedom,” the Court recognized that physicians can, and often do, simply decline to meet with detailers. To the extent pharmaceutical marketing does, in fact, affect physicians’ treatment decisions, “it does so because doctors find it persuasive.”

Sorrell suggests a judicial recognition that “detailers are people too” — and their use of prescriber-identifying information is indeed permissible — at least until a state enacts more narrowly tailored restrictions that can withstand heightened scrutiny. Whereas Sorrell is a step forward in terms of “what’s in” for current pharmaceutical marketing, there is a co-existing body of law that points directly to pharmaceutical marketing activities as a substantial source of liability. Put simply, off-label promotion is “what’s out.”

B. What’s Out: Off-Label Promotion

Under the Food, Drug, and Cosmetic Act (FDCA), a company is prohibited from introducing a new drug, biologic, or medical device into interstate commerce unless that product and its label have been approved, licensed, or cleared by the Food and Drug Administration (FDA). FDA restricts the promotion of the product to its approved indications only and prohibits marketing or promoting unapproved or so-called “off-label” use. Although pharmaceutical and device manufacturers may not promote their products for unapproved uses, physicians may still prescribe drugs, biologics, and devices for other, unapproved uses. In fact, “[o]ff-label use of many devices and drugs is an accepted medical practice.” According to the Office of the Inspector General, “[i]t is not known exactly how much revenue is attributable to off-label uses, but at least one
researcher has estimated that off-label uses account for about 21 percent of prescription drug sales. To put that number in context, if a fair estimate of annual prescription sales is about $234 billion, then off-label prescription sales amount to more than $45 billion in sales per year.

Therefore, it appears that off-label drug or device use is an acceptable practice by prescribing physicians, and corresponding off-label prescription sales are acceptable. Standing in the middle are pharmaceutical sales reps, whose activities in promoting prescription drugs or devices for off-label use are forbidden — and a resulting source of substantial potential liability.

1. Criminal & Civil Enforcement
As indicated above, the FDCA prohibits off-label promotion of a drug or device, and the FDA may enforce violations on criminal and civil bases. A detailed discussion of criminal and civil investigations arising from off-label promotion is beyond the scope of this article. Suffice it to say that recent reports of criminal prosecutions, civil exclusions, and multi-million dollar settlements have splashed across the headlines of the pharmaceutical industry, with more investigations likely on the horizon.

2. Quasi-Private & Private Civil Actions
While FDA regulations prohibit off-label promotion of a drug or device, the FDCA does not create a private right of action. Thus, a private plaintiff must find a viable
cause of action, and plaintiffs have done so through quasi-private and private actions.

a. Quasi-Private: Qui Tam ("Whistleblower") Actions Under the False Claims Act

Off-label marketing allegations may form the basis for qui tam actions under the federal False Claims Act. The False Claims Act prohibits the presentation of false claims to the government, and the Act may be enforced through civil actions initiated by the government. Alternatively, a qui tam action may be filed by private individuals (relators) on behalf of the government. The government may choose or decline to intervene.

Private individuals have a monetary incentive to pursue an action under the False Claims Act — because such relators are entitled to a percentage of any recovery made on behalf of the government. In fact, internet sites unabashedly promote qui tam actions to pharmaceutical company employees. One blog states:

If you are a current or former employee of a pharmaceutical company and believe that your employer is engaged in unlawful practices, including promoting its medications for off-label uses thereby engaging in Medicaid and/or Medicare fraud, you may be entitled to a multi-million dollar award. You can help your fellow hardworking taxpayers — and earn millions of dollars in the process — by blowing the whistle on unlawful pharmaceutical practices.

In the pharmaceutical setting, relators (including former pharmaceutical drug and device sales reps) have alleged that pharmaceutical manufacturers engaged in off-label marketing to increase sales of their products for purposes not approved by the FDA. An example is found in Hopper v. Solvay Pharmaceuticals, Inc., 588 F.3d 1318 (11th Cir. 2009). The relators did not allege that Solvay itself submitted false claims to the government; rather, they alleged that every time federal funds (e.g., Medicare, Medicaid) were used to pay for an off-label prescription, the third party who requested payment had made a false claim. The district court dismissed the relators’ complaint as failing to plead specific false claims with particularity, and the Eleventh Circuit affirmed. Notwithstanding the detailed allegations in the complaint of an alleged scheme to market off-label uses of the drug, the relators failed to allege the existence of a single physician who wrote a prescription with such knowledge, a single pharmacist who filled such a prescription, or a single state healthcare program that submitted a claim for reimbursement to the federal government. The court thus rejected “inference upon inference” that suggested Solvay’s marketing campaign influenced some unknown third parties to file false claims.

The dismissal of the relators’ complaint in Hopper stands in contrast to a First Circuit decision, United States ex rel. Ducbury v. Ortho Biotech Products, 579 F.3d 13 (1st Cir. 2009), where the relators alleged that the pharmaceutical marketer gave a provider more than $5,000 in prescription drugs so that the provider could submit the product for reimbursement to Medicare. These types of allegations were sufficient to plead that the defendant intended its false statements to be material to the government’s decision to pay a claim. Given the lure of financial incentives for relators, as well as new provisions in federal healthcare reform, qui tam actions are expected to increase. Moreover, the Department of Justice has publicly stated that it considers the False Claims Act to be “one of the most powerful tools” in its effort to combat healthcare fraud.

b. Private Actions: RICO

Another line of attack against off-label pharmaceutical marketing arises under RICO, the Racketeer Influenced and Corrupt Organizations Act, and related state unfair competition laws. Plaintiffs including consumers, insurers, health maintenance organizations, third-party payors, and pharmacy benefit organizations have alleged RICO claims against pharmaceutical and device manufacturers; they allege that the defendant manufacturers engaged in a fraudulent scheme to promote and sell drugs or devices for off-label uses in violation of FDA regulations. Recent cases, including a decision from the Eleventh Circuit Court of Appeals, show that RICO cases can be difficult to prove where, for example, the plaintiffs cannot allege economic injury that arose from the alleged misrepresentations. Even so, the availability of treble damages, as were awarded to the Kaiser Foundation Health Plan in the Neurontin litigation, makes RICO an attractive cause of action for plaintiffs.

c. Other Private Actions Under State Law

As indicated above, plaintiffs alleging that a defendant pharmaceutical manufacturer engaged in off-label marketing may assert federal claims (False Claims Act, RICO) but will likely add state law claims as well. An example of this attempt was discussed in Zafarana v. Pfizer Inc., 724 F.Supp.2d 545 (E.D. Pa. 2010), in which consumers brought a class action against Pfizer arising from alleged off-label promotion of twelve prescription drugs. Plaintiffs asserted a claim under the New Jersey Consumer Fraud Act; the court summarily dismissed any personal injury component of this claim as being subsumed by the New Jersey Product Liability Act. This left a claim under the consumer fraud statute to recover increased amounts that the plaintiffs had paid for treatment; however, the court found that the plaintiffs had not alleged that defendants caused them to overpay for treatment because they did not show that, in the absence of such conduct, they would have been prescribed a different medication.

The court next addressed a claim under Pennsylvania’s unfair trade practices act and ruled that the plaintiffs could not prove justifiable reliance due to the learned intermediary doctrine. Stated differently, any alleged misrepresentations were made to prescribing physicians, not to the patients themselves. It is too soon to tell whether the learned intermediary defense will be a dispositive tool to fight off-label marketing allegations. At the least, Zafarana currently establishes a valid defense to state law claims of off-label promotion.

The above cases reveal a tenuous legal landscape for pharmaceutical marketing. Even after
the “win” on First Amendment grounds in Sorrell, there is much to be feared in off-label promotion. Looking forward, pharmaceutical manufacturers should take note of an impending obligation that directly relates to the activities of detailers: disclosure of payments.


Effective January 1, 2012, manufacturers will be required under the “Physician Payments Sunshine Act” to publicly report gifts and payments made to physicians and teaching hospitals. The Act does not restrict financial relationships between pharmaceutical companies and physicians but instead requires public disclosure. Payments requiring disclosure will include compensation, food, entertainment or gifts, travel, consulting fees or honoraria, funding for research or education, stocks or stock options, and ownership or investment interest. Certain items are exempt from disclosure, such as educational material for patients, rebates and discounts, and drug or device samples (which, as noted earlier in this article, make up the vast majority of pharmaceutical marketing expenditures).

Disclosures must include the name, address, and Medicare billing number of the physician; value, date, and nature of payment; and if a payment is related to marketing, education, or research specific to a drug or device, the product must be identified. Penalties for noncompliance include a fine of up to $10,000 for each transfer of value that is not reported; penalties may be imposed up to $100,000 for knowingly failing to report (not to exceed $1 million annually).

Similar to overall provisions in the FDCA, there is no private right of action contained in the Physician Payments Sunshine Act. The possibility exists, however, that private plaintiffs will attempt to use a failure to disclose as evidence related to other claims.

III. Steps to Take Now to Avoid the Increasing Scrutiny of Pharmaceutical Marketing

Given the heightened focus on pharmaceutical marketing activities, and corresponding liability that can arise based on violations of applicable law, pharmaceutical companies may consider the steps outlined
below to minimize potential liability. The suggestions listed below provide an overview of steps that may be taken.

A. Review Of Internal Policies & Procedures
Pharmaceutical companies already have in place policies against off-label promotion of their products by sales representatives. Review of policies and procedures would be prudent to confirm compliance with current and forthcoming laws and regulations. Related to this review, pharmaceutical companies may want to conduct a “refresher” training course as well as regularly scheduled educational courses to ensure that representatives are aware of what activities constitute acceptable promotion. Documentation of these courses, including names of attendees, course curricula, and training materials, should be maintained in one place and be easily accessible.

B. Accessible Reporting System
Pharmaceutical companies may also enact policies and procedures that would avoid whistleblower actions by having a system in place to adequately address complaints by employees about off-label promotion or other questionable marketing practices. Such a system might include a “hotline” and the name of a specific person who can be contacted with such information. Materials stating whom to contact with such information should be circulated to all employees on a periodic basis, together with the assurance that all complaints will be reviewed and considered. Moreover, employees should be assured that an employee who raises a complaint will not suffer reprisal for reporting of a potential violation.

C. Department/System to Handle Sunshine Act Requirements
Pharmaceutical companies will already have an accounting system in place whereby they can track payments made to healthcare providers. However, listing amounts of payments alone will not be enough to satisfy terms of the new Physician Payments Sunshine Act. One department of the company should be accountable for collecting all information required under that Act, setting up the disclosure system and maintaining responsibility for such public disclosures. Failure to publicly disclose such information can lead to substantial penalties and related litigation. As such, setting up a system to record all payments and handle required information on the “front end” may indeed minimize headaches and liability down the road.

IV. Conclusion
This term, the United States Supreme Court gave a nod to detailers’ marketing techniques, but in so doing, signaled to states that narrowly tailored restrictions on detailers’ direct-to-physician marketing may be permissible. In the meantime, off-label marketing has been — and will continue to be — a significant source of liability for pharmaceutical manufacturers. From criminal prosecutions to private class actions to new legislation, pharmaceutical marketing is under extreme scrutiny. Close attention to current and proposed regulations related to pharmaceutical marketing will be vital to understand, address, and minimize a pharmaceutical company’s exposure to liability.


3 See Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2660 (2011) (discussing Vermont’s statute); Vt. Stat. Ann., Tit. 18 § 4631(a)
AMA reports that since the launch of this program in 2006, more than 27,000 physicians have registered.

10 Compare IMS Health Inc. v. Sorrell, 630 F.3d 263 (2d Cir. 2010), with IMS Health v. Ayotte, 550 F.3d 42 (1st Cir. 2008) (New Hampshire) and IMS Health Inc. v. Mills, 616 F.3d 7 (1st Cir. 2010) (Maine).

11 Sorrell, 131 S.Ct. at 2672.

12 On the same day — June 23, 2011 — the U.S. Supreme Court issued its decision in another case involving pharmaceutical drugs, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). In Mensing, the Supreme Court held that certain federal drug regulations applicable to generic manufacturers directly conflict with, and thus preempt, state law failure to warn claims. It is interesting that two decisions were released, both of which were favorable to pharmaceutical companies — one pertaining to brand name drugs (Sorrell) and the other to generic drugs (Mensing), albeit on different bases (free speech, preemption).

13 Sorrell, 131 S.Ct. at 2659-60.

14 Id.

15 Id. at 2660.

16 Id. at 2663-64.

17 Id. at 2663.

18 Id.

19 Id.

20 Id. at 2667-68.

21 Id. at 2668.

22 Id.

23 Id.

24 Id. at 2669.

25 Id.

26 Id. at 2669-70.

27 Id. at 2669. Indeed, there are “do not call” forms available to physicians. For example, the American Medical Association Physician Data Restriction Program restricts prescribing data from pharmaceutical sales reps, while allowing the information to be used for research purposes. AMA Physician Data Restriction Program, <https://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/ama-database-licensing/amas-physician-data-restriction-program.page>, (last accessed Nov. 9, 2011). AMA reports that since the launch of this program in 2006, more than 27,000 physicians have registered.

28 Sorrell, 131 S.Ct. at 2670.


31 Id.; see also 21 C.F.R. § 201.128 (intended use may be shown by the “labeling claims, advertising matter, or oral or written statements by such persons or their representa-