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SECOND THOUGHTS

Mixing Dinner and Drugs—Is It Ethically Contraindicated?

David F. Essi

Introduction

Over the past 50 years, the medical literature has documented concern about the influence of the pharmaceutical industry on the behavior of health care professionals [1-4]. One area of industry-clinician interaction that requires attention is pharmaceutical speaker programming at restaurants. The current speaker program model is flawed because, while third-party companies are often contracted to oversee compliance with Food and Drug Administration (FDA) guidelines for these events, the responsibility for creating some documentation used to assess whether the pharmaceutical company has complied is delegated to restaurants. Restaurant employees, as directed by pharmaceutical representatives, can manipulate the itemized dinner receipt to mask violations of guidelines before the receipt is sent off to compliance companies. The loopholes in the requirements for industry-clinician interactions, as well as other incentives and disincentives, do not support ethical conduct.

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals provides guidelines for the pharmaceutical industry's interactions with clinicians [5]. Adopted in 2002 amidst the Vioxx controversy (the high-profile drug company-FDA conflict that resulted in market withdrawal of a highly potent analgesic after it was determined to be associated with cardiovascular sequelae, including death), the code articulated minimum standards of conduct that would prevent violations of the federal Anti-Kickback Statute—a criminal prohibition against payments, in any form, made to induce or reward the referral of patients covered by federal health insurance. The code arrived just before the Office of the Inspector General released Compliance Program Guidance for Pharmaceutical Manufacturers in 2003 [6] and was superseded in 2009 to reflect even more stringent requirements, some of which were specific to entertainment and meals provided to clinicians [7].

The PhRMA code defines speaker programs as promotional programs that involve hiring a speaker to educate health care professionals about the benefits, risks, and appropriate uses of a company's medicines [5]. In light of the revised code's assertion that pharmaceutical companies are responsible for the active monitoring of their speaker programs for FDA compliance [7], third-party compliance companies are commonly hired to assist in the planning and documentation of these programs. The aim is to provide an added layer of watchfulness over compliance with regulations. However, this layer of

oversight is circumvented when a restaurant alters dinner service documentation, as directed by pharmaceutical sales representatives.

Planning

In planning the programs, third-party coordinators communicate to prospective restaurants that certain standards must be met to ensure compliance with the PhRMA code [7] and the federal Anti-Kickback Statute. Contracts that detail the regulations are sent to restaurants, which may choose not to sign them but are nonetheless expected to follow the guidelines strictly. Examples of dinner service-related guidelines are:

- no cocktail service
- wine and beer served only during dinner service; no after-dinner drinks
- no specialty coffees
- no "to go" orders, including desserts (though attendees may take leftover or uneaten portions of their meals with them)
- Wine may not exceed an average of $9.00 per glass or $36.00 per bottle.
- Spending per health care provider (HCP), including tax and gratuity, cannot exceed $125.

The creation of highly specific dinner-related guidelines is driven by the desire to avoid the perception that HCPs are being treated extravagantly, as was the case in the recent past.

Documentation

Third-party compliance companies rely on the final itemized restaurant bill to document compliance with regulatory standards. The bill indicates whether prohibited items like hard liquor were sold and whether dinner costs were congruent with attendance. This method of identifying noncompliance is ineffective, however, because the restaurant can alter the receipt to mask noncompliant activities, allowing behaviors that violate federal law to occur without any repercussions.

Changing the number of meals. The purpose of manipulating the number of meals is conceal the attendance of individuals not allowed by the code. The code states that the "inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate" [8]. Their presence at speaker programs is ethically inappropriate because the events are intended as educational sessions for health care professionals and the inclusion of nonrelevant guests reintroduces the opportunity for gift giving into the interaction. This gift giving may generate conflicts of interest (e.g., with obligation to patients or objectivity in research) due to psychosocial norms of reciprocation [9]. Some of the most profound changes that occurred with adoption of the PhRMA code in 2002 involved these very gift-giving practices, the effects of which are bountifully described in the literature [3].

Having worked in the restaurant industry, I can say that it is not unusual to see siblings or spouses of HCPs attending speaker programs. One physician told me that he accompanied a fellow physician to a speaker event only because he wanted to try the restaurant; the drug being presented was irrelevant to his practice specialty. As such, his attendance was not as a physician qua physician, but rather as a physician qua guest.

In situations in which a pharmaceutical representative allows a nonrelevant person to attend a speaker program, he or she risks being caught if the number of meals on the itemized bill is in excess of the number of appropriate attendees documented elsewhere. Concealing this discrepancy can be achieved by asking the restaurant workers to delete a meal from the receipt and allocate the cost associated with that meal to "non-person-specific" charges (i.e., beverages, room fee, etc.). In this way, compliance companies will not be able to detect that extra people attended the speaker program.

Changing the types of drinks served. Another common violation related to hosting pharmaceutical speaker programs at restaurants occurs when attendees order liquor-based drinks. Although servers are often aware that liquor-based drinks may not be served to attendees (because of standards communicated by compliance companies to restaurants), they may get verbal permission from pharmaceutical sales representatives to do so because they feel uncomfortable refusing this otherwise normal request for a liquor-based drink. At the end of the event, the cost associated with liquor-based drinks is converted to wine and beer sales (which *are* permitted beverages) for inclusion in the final bill. Both restaurant and pharmaceutical representatives get what they want: the restaurant increases its sales by attending to guest requests, and the pharmaceutical representatives get to deliver on what their attendees desire at the speaker program (in this case, liquor). During my work in the restaurant industry, one compliance company representative told me that she recognized that guidelines were not always followed and, if evidence of a violation did appear, I should remove the inappropriate charges as directed by the pharmaceutical representative.

Discussion

Ultimately, violations of guidelines can occur because some institutions within American health care are strongly profit-driven and willing to assume risks associated with noncompliance in order to attain both short- and long-term sales goals. In the context of compliance-related interactions among restaurants, compliance companies, and pharmaceutical representatives, the ability to manipulate restaurant compliance documentation inevitably diminishes the riskiness of participating in noncompliant behavior. The ways that companies can fail to comply are innumerable, given the organic development of businesses and business practices.

Sometimes, noncompliance is exposed through the actions of whistleblowers. This was the case in April 2013, when the United States government filed a complaint against

Novartis, a Swiss pharmaceutical company, for violations of both the False Claims Act and the Anti-Kickback Statute specifically related to speaker programs:

> From January 2002 through at least November 2011…Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valturna and its diabetes drug Starlix, at events that were often little more than social occasions for the doctors…. In practice, Novartis held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drug at issue. Instead, Novartis simply wined and dined the doctors at high-end restaurants with astronomical costs, as well as in sports bars, on fishing trips, and at other venues not conducive to an educational program. Novartis's own internal analyses showed that speaker programs had a high return on investment in terms of the additional prescriptions for its drugs written by the doctors who participated in the programs, both as speakers and attendees [10].

This case demonstrates that the safeguards put in place to prevent kickbacks and other undue influences on the prescribing habits of HCPs are insufficient. In fact, they are so insufficient in preventing violations that the aforementioned lawsuit considers almost a decade of noncompliance.

Physician attendance of pharmaceutical speakers programs has repeatedly been shown to effect change in their behavior. Not only has attendance been linked with an increased likelihood of formulary requests for new drugs [11, 12], but the provision of meals to physicians has also been positively correlated with frequency of prescribing a given medication [13-18]. Given the substantial evidence that sales techniques can influence physicians to favor a particular medicine [1-3], it is intuitive from a business perspective that a pharmaceutical company would want to make use of such tactics, especially if there is a mechanism by which illegal and ethically problematic activities could be concealed.

Without following speaker event guidelines, pharmaceutical companies can employ sales techniques that are common in other business sectors. Certain of these, such as kickbacks, are not ethically permissible in the realm of medicine due to the conflicts of interest that they can create. The social action of gift giving is a basic interaction between humans that functions as one method of generating reciprocal obligations, conscious and unconscious. There is no way to know with certainty whether a given medical decision is made on the basis of a conscious or subconscious sense of needing to return the drug company's gift. Without a way to directly assess or verify that a conscious or subconscious bias may conflict with the best interest of a specific patient in

a specific instance, it may be justifiable to say that even the mere perception of the existence of a conflict of interest is enough to oblige disclosure and removing of oneself from a decision in the case at hand. Perceptions alone can create distrust of individual physicians and the health care system as a whole.

There is no strong incentive for compliance companies to ensure that guidelines are being followed. In fact, their interest appears to lie in maximizing a pharmaceutical company's return on investment/marketing costs (i.e., the speaker program): many compliance companies offer other business products that aim to generate returns on investment by using various methods, such as developing "key opinion leaders" [19]. If allowing prohibited sales techniques—kickbacks—can bolster a pharmaceutical company's ability to maximize prescriptions and, hence, profits, and restaurants can whitewash the documentation of noncompliant behavior, compliance companies can allow noncompliance to continue without having any evidence that shows they knew otherwise. Conceivably, any compliance company that deviated from the current standards of monitoring compliance by, for example, implementing more scrupulous oversight measures with on-site personnel or video recording, would disadvantage itself in competing for future clients in the marketplace and maintaining its current business relationships.

Like pharmaceutical and compliance companies, restaurants also lack a substantial interest in following or ensuring compliance with guidelines in accordance with the duties prescribed for them in speaker program contracts. This should not come as a surprise. Restaurants' primary interest is increasing their sales, and thus they may be willing to manipulate itemized receipts as long as they are paid what is due. Restaurants lack both the authority and expertise to ensure any form of meaningful adherence to guidelines, and the culture of the service industry is based on the notion of pleasing customers. In this context, the restaurant's role as an enabler of noncompliance is a particularly interesting component of the ethics of pharmaceutical speaker programs. Speaker programs often occur at mid- to high-end restaurants, which may be more likely to have private rooms where they can take place. At such restaurants, the standard of service requires that virtually every reasonable guest request be fulfilled. Servers have been conditioned to focus on meeting guest expectations by training and gratuity-based compensation. Even if a certain gratuity is guaranteed, as is often the case with speaker programs, the culture of the restaurant industry makes it especially difficult for workers to go against established norms of the service industry in general. In other words, adhering to two-drink maximums—and no cocktail service—is culturally discordant for restaurant workers and impossible once a pharmaceutical representative has given staff an "okay" to meet the request. Restaurant workers are interested in serving not only the attendees of the pharmaceutical speaker program, but also the pharmaceutical representative, who is likewise a guest. The culture of the service industry renders the compliance company's reliance on it to provide oversight of dinner-related stipulations

useless.

Conclusion

Noncompliant activities undoubtedly occur at speaker programs held at restaurants. Some of the methods used to identify potential regulatory violations can be disguised by a simple and effective means of manipulating content on itemized receipts. At best, pharmaceutical speaker programs operate within a poorly designed framework that fails to meet the goal of eliminating excessive spending and gift giving. At worst, the existing structure provides an invitation to circumvent both legal and industry standards. Finally, asking restaurants to participate in enforcement and documentation of guest behavior is contradictory to the goals and norms of the service industry.

Restaurants should play neither a moral nor a legal role in the regulation of the pharmaceutical industry; no legitimate basis for such a role exists. For the most part, restaurants and their staff are unaware of the larger industrial-regulatory framework for HCP-pharmaceutical company interactions, yet they have been charged with documenting and carrying out certain activities related to compliance. This makes their exploitation by pharmaceutical representatives even more egregious. The burden of documentation and oversight should not fall in any way upon restaurant workers, regardless of whether they could effectively monitor for noncompliant activities.

Since the pharmaceutical companies, compliance companies, and restaurants do not have incentives that strongly encourage adherence to pharmaceutical speaker program compliance guidelines, any solution to this problem must involve rethinking the current system's incentives and disincentives. One obvious remedy would entail banning industry-provided meals at speaker programs altogether. Such a ban was enacted statewide in Massachusetts in 2008 [20]. Four years later, however, the ban was repealed after lobbying from pharmaceutical and medical-device companies and restaurateurs, leaving Vermont the only state that currently prohibits industry-provided meals at speaker programs [20].

Other solutions might reimagine pharmacotherapy education altogether, delegating the responsibility to pharmacists or brown-bag sessions. Some clinicians may consider pharmaceutical speaker programs necessary for disseminating information on new drug therapies [21]. This opinion is erroneous, however; major medical centers have already evolved to address educational "gaps" that opened up after the prohibition of sales representatives in hospitals or satellites. Given health care systems' ability to address these educational gaps, the pharmaceutical speaker program marketing tool cannot play an exclusive role in educating physicians and other HCPs about new pharmaceuticals or indications. Rather, a much stronger justification would have to be made in order to allow the current system of speaker programming to continue.

This article has described a system that facilitates the masking of noncompliant activities at pharmaceutical speaker programs held at restaurants, contributing to the body of literature showing that industry-HCP relationships are an ongoing area of concern for the American medical system. Making use of innovative solutions for addressing the conflicts of interest that flow from industry-HCP relationships is an ethical requirement to avoid harm to patients and to help improve the quality of pharmaceutical education. Strategies have been described for eliminating industry influence in practice at both large academic medical centers and family practice settings [22], sometimes termed being "pharma-free" [21]. With the advent of the patient-centered medical home, other options may begin to make more cultural sense, such as increasing utilization of the only medication experts in health care—pharmacists—in novel ways.

The ongoing debate over industry-practitioner interactions is important and may at times seem too large to fix. The apparent insurmountability of these challenges, however, does nothing to lessen the importance of the ethical claims about conflicts of interest and the primacy of our obligations to patients. Digging deeper into the intricacies and hidden aspects of the pharmaceutical industry's marketing practices may help to further clarify what kind of ethical reformation is needed.

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David F. Essi is a doctor of pharmacy student in the School of Pharmacy and Pharmaceutical Sciences at the State University of New York at Buffalo. He received his MA in bioethics from Case Western Reserve University in 2011.

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