

The Pharmaceutical Industry and OIG Discount Social Science Literature on Physician Lunches

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As described in a recent article in The New York Times, free lunches given to physicians by pharmaceutical representatives are a very regular occurrence.¹ A former pharmaceutical representative, who now owns a national company providing lunches (Lunch and Earn), estimated that pharmaceutical companies are spending as much as \$1 billion dollars per year on these lunches.² Pharmaceutical companies are estimated to spend around \$7 billion per year on *all* marketing efforts aimed directly at physicians not including dispensing drug samples.³ Therefore, the fact that the pharmaceutical industry spends one in seven of its marketing dollars on lunches alone suggests the importance of these lunches to their marketing efforts. The lunches are also valuable to those receiving the lunches. For example, at one health system campus alone, the lunches were valued at \$2.5 million per year.⁴

The lunches, along with other meals and gifts, are important to pharmaceutical companies because they are “the ‘currency’ that buys access to doctors’ offices for drug representatives.”⁵ If the pharmaceutical representatives are not cloaked with these lunches and other meals and gifts, they would likely not have an opportunity to promote their drugs and try to influence physicians’ prescribing behavior. This conclusion can be drawn because physicians admit that the receipt of lunches and other meals and gifts are the sole, or at least a primary reason, for agreeing to meet with pharmaceutical representatives.⁶ These meetings between pharmaceutical representatives and physicians are important to the pharmaceutical companies because they allow for “direct to physician marketing” – the opportunity for pharmaceutical representatives to educate physicians on their drugs and attempt to influence physicians’ prescribing behavior.

Social scientists argue that elimination of all gifts, including meals, and hence the elimination of “direct to physician” marketing, is necessary. Their rationale is that the

¹ Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, July 28, 2006 at A1, available at <http://www.nytimes.com/2006/07/28/business/28lunch.html?ex=1160107200&en=6ccfb90d627ca465&ei=5070>. The former pharmaceutical representative who made these estimates based them on an observation of the amount spent on lunches by the top 10 pharmaceutical companies.

² *Id.*

³ Consumers Union Prescription for Change, *Requiring Drug Companies to Disclose Marketing Expenditures to Physicians*, Jan. 27, 2005, http://www.consumersunion.org/campaigns/learn_more/001813indiv.html.

⁴ Saul, *supra* note 1.

⁵ *Id.*

⁶ Dana Katz, Arthur L. Caplan & Jon F. Merz, *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 3 AM. J. BIOETHICS 39, 40 (citing J. Lexchin, *Doctors and Detailers: Therapeutic Education or Pharmaceutical Promotion?*, 19 INT’L J. HEALTH SERVICES 663 (1989), A. Jacobs, *But Doctors Do See Them: “Freebies” Seem Disproportionately Important*, 319 BRIT. MED. J. 1002 (1999), and A. Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 375 (2000)).

gifts and meals create a conflict of interest and that the promotion by and relationships with pharmaceutical representatives made possible by these gifts and meals lead to bad prescribing behavior.⁷ The conflict of interest created by the gifts and meals is that doctors, like all people, feel the need to reciprocate after being given a gift or free meal. The need to reciprocate has been described by one social scientist in the following way:

“[b]y accepting the gift, the recipient generally assumes certain social duties, such as grateful conduct, grateful use, and reciprocation, and responds accordingly. The gift relationship is one of paradox; gifts must be given freely, but they entail an obligation. The giver must not insist on any return, yet a response is required.”⁸

If doctors are feeling the need to reciprocate from gifts and meals they receive, then they are not solely considering their patients’ best interests when prescribing drugs. Yet, the doctor-patient fiduciary relationship requires that when physicians treat their patients, they are concerned only with their patients’ best interest, not the need to reciprocate.

The second problem created by the gifts and meals, as stated above, is that they provide pharmaceutical representatives with an opportunity to promote their drug and attempt to influence physicians’ prescribing behavior. This promotion and influence has been found to lead to negative results. The promotion during a meal is effective because

“[t]he positive feelings associated with good food are projected on the people and messages experienced while eating. When salespeople combine food with flattery, recipients tend to like them more, regardless of what it is they have to say.”⁹

This effective promotion during the meals and the relationships created through sharing the meal and informational exchanges correlates, according to social science studies, to physicians prescribing generic drugs less often,¹⁰ prescribing less safe drugs,¹¹

⁷ Wazana, *supra* note 6, at 375.

⁸ Mary-Margaret Chren et al., *Doctors, Drug Companies, and Gifts*, 262 JAMA 3448, 3449 (1989) (citing PF Camenisch, *Gifts and Gratitude in Ethics*, 9 J. RELIGIOUS ETHICS 1 (1981)).

⁹ Katz et al., *supra* note 6 at 41 (citing I. Janis, D. Kay, and P. Kirshner, *Facilitating Effects of Eating-While-Reading on Responsiveness to Persuasive Communications*, 1 J. PERSONALITY AND SOCIAL PSYCHOLOGY 181 (1965)).

¹⁰ Wazana, *supra* note 6, at 375 (citing AD Bower & GL Burkett, *Family Physicians and Generic Drugs*, 24 J FAM PRACT. 612 (1987)).

¹¹ Drug Promotion Database, *What Impact Does Pharmaceutical Promotion Have on Behavior?*, available at <http://www.drugpromo.info/read-reviews.asp?id=4> (last visited Oct. 23, 2006) (citing Roy Mapes, *Aspects of General Practitioners Prescribing*, 760 MED. CARE 371 (1977)).

prescribing less appropriately,¹² increasing prescribing costs,¹³ and prescribing less rationally.¹⁴

But despite all of the social science literature indicating that the meals negatively influential physicians' prescribing behavior, the pharmaceutical industry as it self-regulates and the governmental agencies responsible for creating guidelines on the issue and enforcing the law regulating the issue do not appear to believe that a moderate meal can influence physicians. The law in question is the anti-kickback statute which makes it illegal, among other things, to solicit, receive, offer, or pay any remuneration in cash or in kind in return for recommending purchasing for any good or item such as drugs for which payment may be made under a federal health care program.¹⁵ And courts have said that if only "one purpose" of the remuneration is to induce a referral, or in this case, a prescription, then the anti-kickback statute is violated.¹⁶

The pharmaceutical industry issued its most current form of guidelines on how to comply with the anti-kickback statute in 2002, the Pharmaceutical Research and Manufacturers of America Code of Interactions with Healthcare Professionals (PhRMA Code).¹⁷ The PhRMA Code allows meals as long as they are modest in value, include with them scientific or educational information, and are provided in a venue that is conducive to the informational exchange.¹⁸ The Department of Health and Human Services Office of Inspector General (OIG), which is responsible for identifying and eliminating fraud and abuse of the anti-kickback statute, released a special fraud alert in 1994 which said that some marketing practices "interfere with a physician's judgment in determining the most appropriate treatment for a patient."¹⁹ However, it indicated that the only gifts, in this case lunches or other meals, which would be considered to violate the anti-kickback statute, would be those that are more than nominal in value.²⁰ Similarly, in a 2002 OIG Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guideline), the OIG stated that meals given by pharmaceutical companies can "implicate the anti-kickback statute if any one purpose of the [meal] is to generate business for the

¹² *Id.* (citing Marshall Becker, et al. *Differential Education Concerning Therapeutics and Resultant Physician Patterns*, 780 J. MED. EDUCATION 118 (1972) and Paul D. Stolley et al., *The Relationships between Physicians' Characteristics and Prescribing Appropriateness*, 750 MED. CARE 17 (1972)).

¹³ Wazana, *supra* 6 at 375 (citing TS Caudill et al., *Physicians, Pharmaceutical Sales Representatives and the Cost of Prescribing*, 5 ARCHIVES FAM. MED. 201 (1996)).

¹⁴ *Id.* at 375 (citing F. Haayer, *Rational Prescribing and Sources of Information*, 16 SOC. SCIENCE MED. 2017 (1982)).

¹⁵ 42 U.S.C. §1320a-7b. The anti-kickback statute applies to all health care programs. Since most physicians have patients that are beneficiaries of one of these programs, the anti-kickback statute applies to almost every physician.

¹⁶ *United States v. McClatchey* 217 F. 3d 823, 835 (10th Cir. 2000) p. 835 (citing *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998), *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989), and *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985)).

¹⁷ PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS, available at <http://www.phrma.org/files/PhRMA%20Code.pdf>.

¹⁸ *Id.*

¹⁹ *Special Fraud Alert: Prescription Drug Marketing Schemes*, (issued Aug. 1994, republished Dec. 1994), available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

²⁰ *Id.*

pharmaceutical company.”²¹ While this would seem to implicate the anti-kickback statute for all meals provided by the pharmaceutical industry, the OIG Guideline also stated that “compliance with the PhRMA Code . . . should substantially reduce a manufacturer’s risk” of violating the anti-kickback statute, thus indicating that the meals will be allowed.²²

The implication is that the industry and the OIG do not believe the literature finding that lunches or other meals are enough to influence physicians’ behavior. Perhaps, they believe that the social science literature is untrue or that it is not meaningful because it only shows correlation and not causation. Perhaps they believe, as many physicians do, that even if a conflict of interest is created, physicians, unlike other humans, are capable of managing the conflict. Or maybe they believe that the information provided by pharmaceutical representatives during the lunches and meals is valuable information that the physicians might not otherwise receive. Regardless, it is clear that, unless the OIG can be convinced that it must consider the social science findings in issuing guidelines, the lunches and other meals are here to stay.

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²¹ *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003), <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

²² *Id.*