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Recommended Citation

Katz, D., Caplan, A. L., & Merz, J. F. (2003). All Gifts Large and Small. Retrieved from http://repository.upenn.edu/bioethics_papers/51

Postprint version. Published in *American Journal of Bioethics*, Volume 3, Issue 3, Summer 2003, pages 39-46.
Publisher URL: <http://dx.doi.org/10.1162/15265160360706552>

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Abstract

Much attention has been focused in recent years on the ethical acceptability of physicians receiving gifts from drug companies. Professional guidelines recognize industry gifts as a conflict of interest and establish thresholds prohibiting the exchange of large gifts while expressly allowing for the exchange of small gifts such as pens, note pads, and coffee. Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behavior of the recipient in ways the recipient does not always realize. Policies and guidelines that rely on arbitrary value limits for gift-giving or receipt should be reevaluated.

Keywords

Conflicts, of, interest, gifts, detailing, marketing, pharmaceutical, drug, physicians

Disciplines

Bioethics and Medical Ethics

Comments

Postprint version. Published in *American Journal of Bioethics*, Volume 3, Issue 3, Summer 2003, pages 39-46.
Publisher URL: <http://dx.doi.org/10.1162/15265160360706552>

Title: All Gifts Large and Small: Toward an Understanding of the Ethics of
Pharmaceutical Industry Gift Giving

Running head: All Gifts Large and Small

Word count: 3,942

Abstract: 98

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Partially sponsored by an unrestricted gift from Pfizer, Inc. to the University of Pennsylvania
Center for Bioethics.

Abstract

Much attention has been focused in recent years on the ethical acceptability of physicians receiving gifts from drug companies. Professional guidelines recognize industry gifts as a conflict of interest and establish thresholds prohibiting the exchange of large gifts while expressly allowing for the exchange of small gifts, such as pens, note pads, and coffee.

Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behavior of the recipient in ways the recipient does not always realize. Policies and guidelines that rely on arbitrary value limits for gift giving or receipt should be reevaluated.

Health care professionals commonly receive small gifts, such as pens and note pads, from drug companies seeking to influence their prescribing practices. Gifts, both large and small, have been used by the pharmaceutical industry for almost a century to promote specific products and establish brand recognition (Shaughnessy et al. 1994; Clark 1989). The presumption is that large gifts, such as extravagant vacations, have the capacity to influence behavior, but gifts of *de minimis* monetary value, such as donuts and penlights, do not. Yet, while it may seem both logical and practicable to distinguish small gifts from larger, seemingly more problematic gifts, a large body of evidence from the social sciences shows that behavior can be influenced by gifts of negligible value.

Policy Background

In the 1980s, the large cash payments and lavish gifts some physicians received from drug companies captured public attention (Senate Committee on Labor and Human Resources 1990). There was concern that physician integrity was falling victim to commercial influence in ways that were costly to the health care system in terms of both dollars and public trust. Congressional hearings on pharmaceutical promotion led the American Medical Association (AMA) and the Pharmaceutical Research Manufacturers Association (PhRMA) to adopt voluntary guidelines prohibiting the exchange of cash payments and gifts valued over \$100 (OIG 1991). Under these guidelines, inexpensive gifts, such as pens and notepads, were expressly allowed providing they “relate” to medical practice. The Office of the Inspector General of the Department of Health and Human Services, in a set of studies examining marketing practices, questioned the extent to which those guidelines were being enforced and suggested that allowing small gifts may be contrary to the public interest (OIG 1991, OIG 1992).

Numerous studies of pharmaceutical marketing practices were performed during the 1990s. These studies suggest that the pharmaceutical industry exercised considerable influence over physician prescribing practices and formulary composition (Wazana 2000). The \$12 billion spent annually by the industry on gifts and payments to physicians drew attention from the DHHS Office of the Inspector General and a large-scale study of marketing practices was budgeted for 2002. The study was to examine whether all drug company gifts present an inherent conflict of interest or even a violation of federal anti-kickback legislation (DHHS 2001). However, it was subsequently deleted from the OIG's research agenda (Robert Brown, personal communication, 2003).

In 2001, the AMA and PhRMA responded to the government's renewed interest in gift giving by launching a joint educational campaign. Nine large pharmaceutical companies contributed a total of \$675,000 and the AMA contributed \$50,000 plus staff time in an effort to remind physicians, medical students, and pharmaceutical sales representatives of the importance of following the 1990 guidelines (Okie 2001). During this time, the American College of Physicians and the American Society of Internal Medicine issued a position paper that recognized the potential for small gifts to compromise clinical judgment, but stopped short of calling for the practice to cease (Coyle 2002).

In May 2002, PhRMA issued a new, voluntary code for self-regulation of industry interactions with physicians. The code continues to allow for the exchange of gifts valued less than \$100, but puts "items of minimal value" in their own category. Whereas gifts under \$100 can only be given "on occasion" and must primarily benefit patients, gifts of minimal value, including calendars and stress dolls, should benefit medical practice and can be given

with any frequency. Snacks and modest meals are permissible so long as they are consumed while listening to the sales pitch of a company representative (PhRMA 2002).

No studies have been conducted specifically on the affect of *de minimis* gifts on physician prescribing practices. This may be due in part to the presumption that the size or value of a gift correlates with its potential to influence the recipient. Thus the larger and more valuable the gift, the weightier are the ethical concerns raised about the industry's influence over physicians. Until recently, *de minimis* gifts generated little moral or regulatory concern.

Today, groups such as Public Citizen (Tanner 2001), Physicians for a National Health Program (www.pnhp.org), American Medical Student Association (Romano 2002) and No Free Lunch (nofreelunch.org) oppose all industry gift giving on the belief that the practice conflicts with the professional duties of physicians. The OIG has also issued draft compliance guidelines that suggest industry gift giving may violate federal anti-kickback laws in that the gifts are given to influence prescriptions. From the government's perspective, this is particularly problematic for patients receiving federal health coverage (DHHS 2002). The compliance guidelines are to be finalized in 2003.

The Issue of Small Gifts

The OIG and others have found that nearly all doctors accept small gifts from drug sales people (OIG 1992, Wazana 2000). Drug companies use office trinkets and foodstuffs to entice physicians to speak with company representatives (Jacobs 1999; Lichstein 1992; Ziegler 1995; Braithwate 1984; Hodges 1995). The large majority of physicians meet with industry detailers several times a month (Lexchin 1989, Wazana 2000). Many physicians

cite these gifts as the sole or among the top reasons for seeing drug detailers (Lexchin 1989; Wazana 2000; Jacobs 1999).

Gifts such as pens and notepads, typically emblazoned with product names, are called “reminder items,” but their potential to influence prescribing extends beyond the advertisement they bear. Industry gifts are seen by some physicians as a professional entitlement. This is particularly the case for those in the professionalization process where respect from a sales representative and a free meal are relished. Gifts and foods can be seen as a simple perk or a sign of career accomplishment and status.

Industry proponents assert that because physician-detailer interaction raises awareness of new products, the practice benefits patients. However, no evidence exists to support this claim. In contrast, research suggests that physicians rely heavily on detailers for information and that the more doctors rely on commercial sources of information, the less likely they are to prescribe drugs in a manner consistent with patient needs. Information provided by detailers is often biased, and sometimes dangerously misleading (Lexchin 1989, Ziegler 1995, Avorn 1982). The reviews by Lexchin (1989, 1993) and Wazana (2000) correlate physician-detailer interactions with marked physician preferences for new products that hold no demonstrated advantage over existing ones, a decrease in the prescribing of generics, and a rise in both prescription expenditures and irrational and incautious prescribing.

Many physicians deny the potential for the receipt of small promotional items to undermine their professional objectivity (Wazana 2000; Hodges 1995; Orłowski 1992; Steinman 2001; Rosner 1992; Banks 1992; Chren 1994; Aldir 1996; Gibbons 1998; Thompson 1994; Howard 2000; Davis 2000; Woollard 2003; Gorski 1990; Hume 1990;

Shaughnessy 1994; Roughead 1998). In fact, researchers have found that the more gifts a physician receives, the more likely he or she is to believe that they do not influence behavior (Hodges 1995). While medical professionals may believe themselves to be “more rational and critical” than the average person (Babcock 1997; Shaughnessy 1994), the success of pharmaceutical marketing illustrates that physicians are as susceptible to target marketing as others (Coste 1999). Those who do not acknowledge the power of small gifts are the ones most likely to be influenced because their defenses are down.

Small gifts play an important role in opening doors and promoting friendlier, more cooperative relationships between pharmaceutical sales representatives and physicians. Thus, as the following section explains, the effects of gifts on physician practices can be far greater than their minimal monetary value would imply.

The Effects of Gifts, Large and Small, on Behavior

Gift exchange underlies the human tendency to engage in networks of obligation (Gouldner 1960; Mauss 1954; Levi-Strauss 1969). When a gift or gesture of any size is bestowed, it imposes on the recipient a sense of indebtedness. The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behavior. Many social scientists believe that the predilection to reciprocate is an adaptive mechanism that has helped bind and advance human societies by enabling exchange of food, skills, and goods (Leahey 1978).

The social rule of reciprocity imposes on the recipient an obligation to repay, in kind if possible, for favors, gifts, invitations, and the like (Levi-Strauss; Cialdini 1993, 16). For example, when someone does us a favor, we are expected to return the favor at some point down the road. Hence, the phrase “much obliged” is used as a synonym for “thank you.”

Feelings of obligation are not related to the size of the initial gift or favor. For example, the success secret of the world's record holder for car sales was to send mass-produced greeting cards to his customers every month printed with the simple phrase "I like you" (Cialdini 1993, 174). In another case, the owner of a pharmacy gave patrons a fifty cent key chain when they entered the store and the amount they spent on purchases increased 17% (Friedman 1990). Similarly, when the Disabled American Veterans organization appeals for donations through direct mail solicitation, the response rate is about 18% when no gift is included, and 35% when the envelopes contain an unsolicited gift (e.g., inexpensive, customized address labels) (Cialdini 1993).

Food, flattery, and friendship are all powerful tools of persuasion, particularly when combined. Individuals tend to be more receptive to information when it is received while eating enjoyable food (Janis 1965). This is why food is "the most commonly used technique to derail the judgment aspect of decision making" (Razran 1940). The positive feelings associated with good food become projected on to the people and messages experienced while eating. When sales people combine food with flattery, recipients tend to like them more, regardless of what it is they have to say. Moreover, people are receptive to compliments even when they recognize that their source has a transparent agenda (Friedman 1996). The act of dining helps to foster cozier working relationships that may help break down professional barriers between physicians and sales representatives. Positive social relationships are an effective way of engendering good will and making people want to reciprocate for gifts received (Perez 1989).

An amicable relationship, though, is not a prerequisite for compelled reciprocation. The reciprocity rule is so potent that people who are often disliked or distrusted, such as

politicians and sales people, can get people to comply with their wishes by imposing on them a small, unsolicited favor or gift (Cialdini 1993, 22). This is exemplified by the “benefactor-before-beggar” strategy of the Hare Krishnas. Hare Krishnas commonly gathered in crowded airports and thrust trinkets, such as flowers and pamphlets, into the hands of passersby while saying, “this is our gift to you.” Although recipients often tried unsuccessfully to refuse the small gift and ultimately threw it away, they were frequently so compelled to make a donation that the Hare Krishnas became quite wealthy. However, airport patrons’ complaints about having to donate to the Krishnas resulted in airports prohibiting this mode of solicitation.

Airport patrons could have made the token gift giving of the Krishnas unprofitable by simply refusing to donate. The act of accepting a gift directly from another person without reciprocating is so socially uncomfortable, however, that to many it is preferable to avoid or ban the interaction all together (Cialdini 1993, 22-24). Reciprocation is so highly valued a social norm that those who do not reciprocate are often regarded with disgust and assigned negative labels, such as “moocher,” “ingrate,” “free-loader” and “welsher” (Cialdini 1993, 20). Regardless of the size of a gift, it is widely considered distasteful or bad form to take but make no effort to give in return (Cialdini 1993, 20). Refusal to accept a gift or to give a gift in return signifies a refusal to cooperate, and is often considered a declaration of conflict (Mauss 1954).

The natural tendency for people to accept gifts and kind gestures reduces their ability to choose to whom they wish to be indebted (Cialdini 1993, 30). This is how the reciprocity rule can be exploited. Oftentimes, the initial actor in reciprocal relationships not only chooses the form of the initial favor, but the form of the return favor as well. If physicians

are to reciprocate for small gifts, they cannot do so in any form they please. They are essentially compelled to reciprocate by supporting their benefactor's products.

Small Gifts: The Cost of Doing Business?

In the business world, gifts are a valuable, time-honored marketing tool because they keep doors of communication open between cooperating parties. Medicine, in one view, is also a business. Some believe that modest gift giving is appropriate and acceptable if it helps physicians be aware of and knowledgeable about the broad range of products available to them (Dodd 1999; Benbow 1999). This is based on the premise that industry and physicians' interests do not conflict because both are interested in learning how best to treat patients. It is also premised upon the shallow and contradictory assertion that, but for the gifts, physicians would not spend the time and energy to meet with information-providing sales people even though what they have to gain can be helpful to their practice and their patients.

Lay persons' opinions regarding the acceptability of industry gifts are related to their perceptions of possible effects on prescribing behaviors and costs (Blake 1995). Lay persons -- like physicians -- are likely to approve of physicians' receipt of small promotional items or gifts relevant to patient care, and to disapprove of larger gifts and gifts that do not benefit patient care. In one study, increased education (presumably excluding education in medicine) was correlated with the likelihood that lay persons would find certain gifts inappropriate (Mainous 1995). Patients tend to be aware that physicians accept gifts, to be unaware whether their own physicians accept gifts, and to feel that gifts are more influential and less appropriate than do their physicians (Gibbons 1998).

The ethical acceptability of small gifts should turn on the character of the gift as well as its potential consequences. One fundamental question is whether drug company gift

giving should be classified as a balanced exchange, where parties expect immediate and equal return, or as a negative exchange, where giving is motivated by profit so that parties seek to come out ahead in the transaction (Sahlins 1965). According to PhRMA, the exchange is balanced because gifts are given as compensation for the time physicians spend becoming educated about products (Dembner 2001). However, if the interests of physicians dovetail with those of industry, it follows that gifts are unnecessary because the valuable information provided to physicians is compensation enough for their time.

Industry gift giving should, rather, be viewed as negative exchange because the practice is inherently profit-motivated, and the profit potential significantly exceeds the value of the gift. Drug companies are purely interested and invested in the products physicians prescribe, and they know and expect that their marketing practices will pay off with increased sales. Indeed, former President of Pfizer Pharmaceuticals Gerald Leubach was quoted as saying that marketing “is almost as scientific as anything we do” (Clark 1989).

Drug companies do not deduct the cost of such gifts as charity, but as marketing expenses. For tax purposes, business gifts are hardly considered gifts at all, because their giving does not arise out of a “detached and disinterested generosity” (Commissioner v. Duberstein 1949). In this view, calling the giving of small tokens as part of the sales activity of pharmaceutical firms “gifts” is disingenuous and a transparent attempt to be nonjudgmental. These “gifts” should be recognized for what they are: marketing wares.

While the benefits of promoting good will between physicians and the pharmaceutical industry cannot be discounted, the main objective of drug company gift giving is to create relationships and interests on the part of recipient physicians that conflict with their primary obligation to act in the best interest of their patients. The practice is particularly problematic

because favors and promotional items of negligible value can influence behavior in ways the recipient does not often realize. Research into the so-called “self-interest bias” has shown that it takes extraordinarily little to bias an individual’s interpretation and processing of information as well as one’s subjective judgments, including those dealing with ethics and fairness (Babcock 1997).

The fundamental question is whether the risk of bias from small commercially-oriented gifts is acceptable. Implicit in many guidelines is the recognition that marketing wares create a conflict of interest, but that the risk of bias from items of negligible value is small and, on net, worth taking because of the potential benefits offered product marketing information. Guidelines establishing thresholds, such as the arbitrary amount of \$100, are based on the belief that there is a direct “dose response” – that the risk of bias increases as the value of the gifted item increases. There is no level, however, below which it is guaranteed that marketing wares have no effect on the recipient.

The Need to Respond: Practical Considerations

Given that small gift giving can influence clinical judgment in ways that conflict with physicians’ fiduciary responsibilities, the question of how best to respond to the problem still remains. Changes in the standards of acceptable professional conduct and pharmaceutical marketing practices may be in order, ranging from disclosure of gift exchange to elimination of the practice altogether.

In June 2002, Vermont enacted legislation that requires pharmaceutical companies to disclose gifts worth more than \$25 to the state pharmacy board (State of Vermont 2002). Wisconsin, New York, and Maine are considering similar legislation (Review 2002). If gifts of all sizes are disclosed to federal or state regulators, valuable research can be conducted to

determine the extent to which gift acceptance is associated with physicians' prescribing practices. Disclosure policies can also take the form of requiring physicians to inform patients receiving prescriptions that they have received gifts from the drug's manufacturer. Considering the extent to which physicians' offices are adorned with drug company trinkets, it is likely that patients are already aware of the *de minimis* gifts physicians receive. What they may not know is that these inexpensive penlights and notepads may actually undermine physician objectivity in ways that clash with their own medical and financial interests. Full disclosure, therefore, could also require physicians to inform patients of this potential bias. Such disclosure, however, would not neutralize the bias, nor would it assist patients who have little choice but to rely on physicians' judgments and little or no ability to combat the bias.

One obvious and compelling policy option in response to the evidence of the power of small gifts is to restrict or eliminate gift giving or gift acceptance. Restrictions could take many forms, such as limiting the frequency of or settings for gift giving, such as conferences or to major holidays. Enforcement of restrictions or bans could take various forms, including FDA regulation or ties to state medical licensure through state anti-kickback and bribery laws. In light of the evidence that all gifts influence behavior, physicians and pharmaceutical firms could be sanctioned now for small gift exchange under current anti-kickback laws (Bulleit 1999). The federal government has already indicated that gift-giving practices may be criminalized because of the presumable effects on governmental drug expenditures (DHHS 2002).

On the other hand, some may argue that the regulation of gift giving in medicine should be no stricter than it is in any other business context. In response, we ask whether

physicians aspire to be viewed more like corporate salespeople or like professionals beholden to the public trust. Most journalists are not permitted to accept gifts from information sources and university professors are prohibited from accepting gifts from students before grades are issued (www.presswise.org.uk/Washington%20Post.htm). Judges, National Basketball Association referees and Major League Baseball umpires are all prohibited from accepting gifts of any size for any occasion from anyone with an interest in the outcomes of their judgments. Similarly, medical professionals ought to step up to the plate. When acting as patient advocates and trusted sources of information, physicians should carry out their professional activities in a way that minimizes the intrusion of avoidable conflicting interests.

We note that psychology research suggests that any imposed restrictions on physicians' professional behavior are likely to be ill received and viewed as an affront to their personal integrity and professional freedom. Because people tend to desire freedoms more when faced with the threat of losing them (Worchell 1973; Cialdini 245 1993). restrictions would not only irritate physicians who (over)value drug company gifts, but physicians who have historically been indifferent toward them may find themselves valuing the gifts more. The exaggerated desire for restricted behavior increases when the restrictions apply to one group and not another (Cialdini 1993, 245). Therefore, if physicians liken themselves to business professionals, restrictions on gift exchange would be viewed as unfair because medicine would seem the only sector of US business prohibited from exchanging small gifts. However, regulations barring the use of marketing wares would not, in actuality, regulate physician practices but only the sales practices of the pharmaceutical industry. To our minds, a ban on industry gift giving would be inherently fair in that it would put all firms, including generics, on a level playing field.

Nonetheless, we recognize that gift giving is the foundation of human interaction. If it engenders valuable social obligations that are definitional of relationships such as friendship and camaraderie, then regulating the gift relationship may compromise desirable, arguably essential, social relations. Government regulations may, indeed, be too crude and heavy-handed an approach for micromanaging the fine lines between geniality and commercial inducement. For example, company sponsored gifts to physicians clearly fall within the purview of government interest because they are ostensibly given for commercial purposes. In contrast, a true gift (one that is not subsidized by a company) that is given to a physician by a sales representative with whom a preexisting, interpersonal relationship or friendship is shared (not merely a professional acquaintance or courtesy) should generally fall outside the purview of government interest and regulation. It is the grey area in between that presents challenges with respect to the government's ability to enforce restrictions on gift giving while refraining from dictating the boundaries of social interaction.

We believe that, as a general rule, society ought not regulate the exchange of small tokens of courtesy in business or other social settings. Medicine is different, however, and limits placed upon pharmaceutical companies use of marketing wares within this context would not be unfair, but both appropriate and enforceable. The drug industry is highly regulated, and restrictions on marketing practices already are in place. If the distribution of marketing wares were prohibited, associated expenses would no longer be deductible as a cost of business, and the practices would cease.

The body of evidence reviewed above suggests that guidelines aimed at preserving professional objectivity by limiting the size of gifts physicians receive or companies distribute have thus far been short sighted. The practice of small gift giving occurs in an

environment where physicians interact heavily with industry sales representatives, have their CME courses industry funded, receive information from industry-funded studies, are deluged with print advertising, and see patients targeted by direct-to-consumer advertising. In an environment in which industry plays such a prominent role, it may be difficult to determine, even with rigorous research methods, which industry tactics wield the most influence and impossible to say with confidence that if the practice of small gift giving were to cease, prescribing practices would change.

That said, from a moral and regulatory perspective, policies that determine the acceptability of a gift according to its size are unsound. The power of gift giving, both large and small, must be acknowledged if appropriate regulatory policies are to be created and enforced.

Acknowledgements

Sponsored in part by an unrestricted gift from Pfizer, Inc. DK conducted research, analysis, and wrote all drafts of the manuscript. ALC guided the design and analysis and edited drafts of the manuscript. JFM contributed to the design and analysis and edited drafts of the manuscript. The authors thank David Casarett and David Doukas for their comments, Robert Goodman for his insight, and Donald Light, Lev Kalman, Jeffrey Blustein, Michelle Henry, Alex Kipp and Brad Berman for reading early drafts. Responsibility for the content is solely that of the authors.

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