

Kline and French once did in Australia (Harvey 1990). (The company later withdrew its resignation.) Furthermore, none of these codes mandate sanctions that would seriously impinge on a company's ability to promote its products. An example of such a sanction would be a requirement that if an advertisement that had breached the code had run for three months on the back page of five medical journals, then a correction of similar prominence should also run for three months in the five journals.

In some respects PhRMA's code is even worse than the ones from Australia, Canada, and the United Kingdom. It has no provisions for any kind of monitoring, proactive or reactive; there is no complaints procedure for alleged breaches; and there are no sanctions for companies that violate the code. Under the heading "Adherence to Code" there is only the single statement that "Each member company is strongly encouraged to adopt procedures to assure adherence to this Code" (PhRMA 2002, 5).

The weaknesses of industry self-regulatory codes should not come as any surprise when we remember that the primary allegiance of pharmaceutical companies is to their shareholders. That allegiance translates into an obligation to be as profitable as possible. Codes that would genuinely restrict the ability to make money simply do not fit into this commercial ethic. ■

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Small Gifts, Conflicts of Interest, and the Zero-Tolerance Threshold in Medicine

Sheldon Krimsky, Tufts University

In their paper "All Gifts Large and Small," Dana Katz, Arthur L. Caplan, and Jon F. Merz (2003) tackle an issue that has been percolating for decades within circles of bioethicists and medical opinion makers; namely, can small gifts to physicians fall below a threshold of ethical, professional, and public concern. It is noteworthy that this paper was funded, in part, by Pfizer, Inc., a leading pharmaceutical company, through an unrestricted gift to the University of Pennsylvania Center for Bioethics. Of course, it should be obligatory for bioethicists, no less than

biomedical and clinical researchers, to disclose their sources of funding and potential conflicts of interest. As a preface to my comments on the substance of their paper, I should underscore an inescapable psychological insight about perceived conflict of interest. If the results of their paper were consistent with the sponsor's position on small gifts, some indeterminate but consequential number of readers would be inclined to infer, without seeking further evidence, that the funding, however small, was related to the outcome of the study. Because the study is more like a

legal brief (a compilation of evidence in support of an argument) than a test of an empirical hypothesis, which involves original data, the opportunities for a sponsor's funding to influence the outcome, through, let us say the selection of studies, is heightened.

As it happens, the conclusion of the Katz, Caplan, and Merz study—namely that “from a moral and regulatory perspective, policies that determine the acceptability of a gift according to its size are unsound”—appears to be at odds with the values and practices of large pharmaceutical companies such as the one that provided unrestricted support for the study. Thus, our suspicions of a funding effect are immediately put to rest. Moreover, when researchers publish results that are antithetical to the values or practices of their sponsor, we are inclined to assign higher credence to their findings. This is exemplified in the case of Dr. Dong, the pharmacologist at the University of California, San Francisco, who reported that her sponsor's drug exhibited no greater efficacy than a generic agent (Rennie 1997). When the public learned that Dr. Dong refused her sponsor's request to suppress her findings, her results achieved a higher a priori standing than they might have were they consistent with the sponsor's interests.

Readers' suspicions about the influence of funding on research outcome (of which Katz, Caplan, and Merz's paper is a countervailing instance) does not depend on the amount of funding but on the mere existence of it. That is the psychological reality in regard to publications. There is growing evidence of a “funding effect” on the outcome of studies in certain areas of biomedical research (Stelfox et al. 1998; Krinsky 1999; 2003). By this I mean that the for-profit sponsor's interests are a potential biasing factor in the execution and interpretation of research. The general psychological factors at play in the funding effect also apply to gift-giving.

“All Gifts Large and Small” calls attention to two issues about gift-giving to physicians. The first is the voluntary code issued by the Pharmaceutical Research and Manufacturers of America that permits gifts when they amount to less than \$100. The second relates to the potential consequences of adopting a low-threshold norm for gift-giving. Little is known about the effectiveness of the voluntary code. If small gifts matter, then large gifts matter more. It is, therefore, of some significance that we understand so little about whether the voluntary code will be effective in stopping the flow of large gifts to physicians. While the issue of large gifts falls outside the scope of Katz, Caplan, and Merz's paper, it should not be lost upon us, even as we evaluate the effects of small gifts on prescribing behavior, that large gifts to physicians remain a significant ethical problem.

Drawing from over 60 years of medical and social science (psychological, sociological, and anthropological) re-

search, Katz, Caplan, and Merz have given us a new perspective on small gifts and behavior change. In cases where physicians have not taken strong positions on the efficacy and safety of certain drugs, small gifts may be all that's needed to influence clinical judgment and to create an allegiance between the physician and the gift giver. The influence can function subliminally. Katz, Caplan, and Merz correctly position gift-giving in its larger cultural context, its capacity to “engender valuable social obligations” such as “friendship and camaraderie.”

In a study not cited in Katz, Caplan, and Merz's paper, researchers surveyed chief residents at 87 emergency medicine residency programs in the United States. With 72 responses, the authors of the study learned that the “interaction of pharmaceutical representatives with emergency medicine residents and residencies is widespread” and also that “more than half of the institutions with emergency medicine residency programs have no formal guidelines on the interaction of residents with pharmaceutical representatives.” Twenty percent of the respondents reported that “accepting gifts from pharmaceutical companies could affect their own prescribing habits,” even while the most frequent gift types cited were small gifts (pens and notepads) and meals during department functions” (Reeder, Dougherty, and White 1993, 1593). These results are consistent with Katz, Caplan, and Merz's analysis of the effects of small gifts.

“All Gifts Large and Small” makes a strong case for a zero-tolerance threshold on gift-giving to physicians, while at the same time acknowledging the practical limitations of eliminating the practice of accepting such favors. Stark (2000) notes that prior to any untoward behavior certain antecedent acts condition the state of mind of an individual toward partiality, thereby compromising the potential of that individual to perform his or her responsibility on behalf of public rather than personal interests. There are perhaps some institutions whose fiduciary responsibility to the public is of such importance that it makes sense to establish a zero-tolerance for gifts of any value. These might include journalists, judges, professors, and physicians. ■

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Cheap Trinkets, Effective Marketing: Small Gifts from Drug Companies to Physicians

Allan S. Brett, University of South Carolina School of Medicine and Center for Bioethics and Medical Humanities

Dana Katz, Arthur L. Caplan, and Jon F. Merz (2003) argue that gifts of negligible monetary value given by pharmaceutical companies to physicians are ethically problematic. I first read their essay during a break in the action while I was precepting medical residents in a hospital-based outpatient clinic. I was seated in a shared office used by multiple physicians who supervise in the clinic. After reading several pages of the manuscript, I looked up and quickly took in the following items: a Norvasc-labeled pen, a Viagra-labeled mouse pad, a Zithromax-labeled desk clock, a Celebrex-labeled notepad (ironically, all of these drugs are products of Pfizer, a company that provided an “unrestricted gift” supporting Katz, Caplan, and Merz’s research). I provide this anecdote for readers who doubt the extent to which the small gifts discussed by Katz Caplan, and Merz saturate the medical practice environment.

Katz, Caplan, and Merz note that gift-giving by the pharmaceutical industry to physicians is increasingly under scrutiny. In recent years medical professional organizations have issued statements criticizing the exchange of expensive or extravagant items but permitting gifts of minimal value that “entail a benefit to patients” or “are related to the physician’s work,” such as pens and notepads (Coyle 2002; American Medical Association 2003). In a recent survey study, my colleagues and I examined whether physicians themselves support these distinctions between large and small gifts. Physicians did make such distinctions. Only a small minority (15%) found pads and pens to pose major ethical problems (Brett, Burr, and Moloo 2003). So it seems that the recently stated positions of professional organizations reflect the views of their constituents.

Katz, Caplan, and Merz believe that distinctions between the acceptability of small and large gifts are morally dubious. Their argument rests primarily on the “social rule of reciprocity” in which any gift, large or small, tends to impose upon the recipient an obligation to return the favor. Those obligations might be experienced consciously

or subliminally. In either case the pharmaceutical company counts on reciprocation by physicians in the form of favoring the company’s products.

The argument of Katz, Caplan, and Merz is convincing, as far as it goes. However, in focusing almost exclusively on the idea of social reciprocity, the authors pay insufficient attention to two other important issues. First, the brand-name recognition fostered by small gifts—which are labeled conspicuously with names of drugs—has a greater impact on drug prescribing than the authors acknowledge. Second, small gifts facilitate the transmission of potentially-biased information about new drugs during an interval when physicians might have difficulty obtaining unbiased information from other sources.

Small gifts such as notepads and pens frequently are not distributed during face-to-face encounters between drug representatives and physicians. Rather, these items simply appear in places where they will be seen and used by physicians. In my previous example of the hospital outpatient clinic, my colleagues and I virtually never see the drug company representatives who bring the items. Rather, the representatives leave the items with nurses and secretaries who distribute them throughout the office. In other words, the medical environment becomes saturated with drug names, independent of direct contacts between physicians and drug representatives. As a matter of principle I do not accept small gifts from (nor do I meet with) pharmaceutical representatives. Thus, I do not incur the social obligation to return favors. But that doesn’t protect me from seeing drug names wherever I turn, and that probably influences my prescribing.

Consider the following example. In February 1998 a drug called Trovan (trovafloxacin) became available. Trovafloxacin is a quinolone antibiotic similar to ciprofloxacin (the drug that became famous during the anthrax scare) and several others. Trovafloxacin had some advantages over its predecessors for certain specific types of infections, but for most clinical indications its expected activity was similar to that of other quinolones. As soon as