
Because physician–drug industry exchanges have come under a regulatory spotlight, some common activities are now off-limits.

by Susan Chimonas and David J. Rothman

PROLOGUE: Consumer-driven health care, direct-to-consumer advertising, and broader access to health information via the Internet may be changing the way health conditions are diagnosed and medications are prescribed and dispensed. However, the battle to win the hearts and minds of physicians as the prima facie gatekeepers of prescription drugs has not been abandoned. Doctors write more than 2.2 billion prescriptions each year, and it’s critical that they have knowledge of and access to the latest information on what will best meet their patients’ health needs. Thus, protecting opportunities to inform physicians about products is a legitimate and serious goal of medical societies and pharmaceutical manufacturers. But how can patients be assured that drug manufacturers—whose ultimate goal, after all, is to increase product sales—do not unduly influence their doctors? When physicians are paid to learn about new products, and detailers share selective clinical trial results, patients’ interests are compromised. Who determines what protections are necessary and how much influence is too much?

Because ours is a democratic, pluralistic society, regulations are developed in a participatory process that is open to all interested stakeholders. The paper that follows explores the process by which stakeholders inform and affect guidelines regulating pharmaceutical industry contacts with physicians. Some stakeholders are particularly effective at communicating and protecting their interests. Are patients’ interests adequately protected?

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ABSTRACT: In October 2002 the federal government issued a draft “Compliance Program Guidance for Pharmaceutical Manufacturers.” The draft Guidance questioned the legality of many arrangements heretofore left to the discretion of physicians and drug companies, including industry-funded educational and research grants, consultancies, and gifts. Medical organizations and drug manufacturers proposed major revisions to the draft, arguing that current practices were in everyone’s best interest. To evaluate the impact of their responses, we compare the draft, the changes requested by industry and organized medicine, and the final Guidance document (issued in April 2003). We also explore the implications—some intended, others unanticipated—of the final document.

During the past several years, oversight of relations between the pharmaceutical industry and physicians has increased dramatically. Many medical organizations, including the American Medical Association (AMA) and the American College of Physicians (ACP), have promulgated guidelines addressing pharmaceutical company gifts, consulting fees, conference and travel grants, free samples, and dinners. The drug industry itself has issued guidelines. In 2002 the Pharmaceutical Research and Manufacturers of America (PhRMA) released the PhRMA Code on Interactions with Healthcare Professionals, modeled on the AMA’s 1998 “Ethical Guidelines for Gifts to Physicians from Industry.”

Even more important, physician-industry interactions have become the focus of intense regulatory oversight by federal and state agencies. Among the most active is the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services (HHS). Its mandate is to investigate and prosecute fraud and abuse in Medicare and Medicaid, including drug company kickbacks to physicians to influence their choice of drugs and drug companies’ submission of false pricing data to increase levels of reimbursement. In April 2003 the OIG issued a “Compliance Program Guidance for Pharmaceutical Manufacturers.” It addressed not only patently illegal practices but also the “gray areas” of physician-industry relations, including consultancies, conference grants, and gifts. Although these exchanges were not illegal, they carried “significant potential for abuse” under the anti-kickback statute.

The OIG Guidance represents an unprecedented effort by a federal body to regulate arrangements previously left to the discretion of physicians and companies. Given the special character and importance of this initiative, we first analyze the conditions that prompted the OIG to produce a draft of the Guidance in October 2002. We then examine the responses of medical organizations and pharmaceutical companies and evaluate their impact. Finally, we explore the implications—some intended, others unanticipated—of the final Guidance.

Origins Of The OIG Guidance

- Rise in drug spending. The OIG’s decision to issue the Guidance reflected, first, a dramatic rise in drug spending. The OIG identified pharmaceuticals as the single largest source of cost increases in federal health care programs and the great-
est threat to their solvency: “In fiscal year 2001, Medicaid expenditures for drugs were approximately $20 billion, or 9% of the Medicaid budget. From 1997 to 2001, Medicaid expenditures for prescription drugs grew at more than twice the rate of total Medicaid spending.”3 Indeed, the OIG’s findings are consistent with those of other researchers.4

**More successful prosecutions.** Second, the appearance of the Guidance reflected an increasing number of successfully prosecuted cases of Medicare and Medicaid fraud. Beginning in the late 1990s, investigations by the OIG and by the Food and Drug Administration (FDA) uncovered fraudulent marketing and billing practices by several prominent drug companies. In many of these cases, companies purposely provided inducements to physicians, health maintenance organizations (HMOs), and other health care providers to secure and protect market share for their drugs and to inflate their billings to public programs.5

One case that captured particular attention involved TAP Pharmaceuticals and the Lahey Clinic in Boston. To retain the Lahey market for its prostate cancer drug, Lupron, and prevent a switch to cheaper competitor drugs, TAP apparently held out the inducement of $100,000 in additional funding and support to the Lahey Clinic. Federal prosecutors filed charges against TAP, and in October 2001 the company settled the case, paying out $875 million.6 Prosecutors are now investigating allegations of kickbacks and the “sale” of free samples by TAP employees and several physicians at Lahey. TAP has already admitted that its salespeople helped physicians bill Medicare and Medicaid for free samples of Lupron dispensed to patients. A jury acquitted eight TAP employees of bribery charges in July 2004, but five urologists have been convicted of health care fraud (in light of their cooperation with government investigators, they were sentenced to probation). Investigations against physicians in the TAP case have added a potent dimension to enforcement.7

Since 2001, federal prosecutors have negotiated at least ten more major settlements by such industry giants as Bayer, GlaxoSmithKline, and AstraZeneca; these have ranged from $18.5 million to $600 million.8 Prosecutions continue, and more cases are in the pipeline.9 In 2004 Schering-Plough agreed to pay $345.5 million to settle claims that it overcharged Medicaid for the nonsedating antihistamine Claritin and illegally induced two HMOs to keep it on their formularies.10

Disclosures by whistleblowers often fuel the investigations. In fact, whistleblowers are the prime source of information for prosecutors and, in return, receive as much as 21 percent of the settlements.11 In the TAP case, two whistleblowers received a total of $95 million. In the AstraZeneca case, one received $47.5 million.12

**Need for preventive measures.** Although the prosecutions have been successful, the OIG was understandably eager to undertake preventive measures, as exemplified by the Guidance. The document does not constitute new administrative law; rather, it “represents the OIG’s suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and
program requirements.” Companies are not legally bound to follow them so long as they observe all existing regulations. However, it would be a foolhardy company that ignored the OIG’s “suggestions,” particularly when they represent the OIG’s method for assessing company behavior.

OIG Policy Formation: Involvement Of Medicine And Industry

Like all federal agencies, the OIG is governed by the Administrative Procedure Act of the U.S. Code of Federal Regulations. Under this act, the OIG is required to publish Guidance documents in draft form, so that it can then receive and consider comments from interested groups and individuals. This requirement is intended to promote administrative due process and ensure agency accountability and transparency. But it also provides policy analysts with a unique window into the rule-making process, documenting the exchange of views between regulated parties and government agencies.

The OIG received 142 responses to the draft. (The authors obtained copies through a Freedom of Information Act [FOIA] request.) Twenty-six came from medical associations and specialty societies; fourteen, from the pharmaceutical industry; and the remaining 102, from consumers, health care organizations and providers, pharmacy benefit managers (PBMs), and state health departments. The OIG also met privately with representatives of medical organizations, the pharmaceutical industry, private health plans, and PBMs.

To assess the influence of medical organizations and drug manufacturers in shaping the Guidance, we compared the provisions of the draft, the changes requested by medicine and industry, and the final Guidance. Although many aspects of the Guidance remained unchanged, medical organizations and drug companies persuaded the OIG to make some important amendments. The final product differed from the original in many crucial ways.

Provisions of the draft. The draft Guidance opened by specifying three illegal practices: (1) manufacturers’ inaccurate reporting of pricing data to federal and state governments for reimbursement through Medicare and Medicaid; (2) billing for or sale of free drug samples to federal health care programs by providers or companies; and (3) kickbacks and other illegal remuneration by which companies offer gratuities or benefits to providers with the explicit intent of generating business. The OIG also singled out so-called switching arrangements in which drug companies pay pharmacists, physicians, or others to switch patients from a competitor or generic drug to the company’s product.

The draft next addressed drug industry practices in that gray area with a “significant potential for abuse.” These practices include funding for education, research, and consulting, as well as gifts and gratuities. The draft explained that although liability turns on intent, the language of the anti-kickback statute is broad and goes beyond explicit, tit-for-tat arrangements. An exchange comes under the anti-kickback statute if it is “excessive” and involves “parties in a position to pre-
scribe or order products or to influence such prescriptions or orders.” Thus, all physician-industry exchanges potentially violate the anti-kickback statute should government prosecutors deem them excessive.

The draft specifically discussed the 2002 PhRMA Code. It noted that the code provides “minimum standards” for behavior; for example, it allows gifts of “modest” value ($100 or less) and specifies that they should not come with “strings attached.” However, the OIG went on to declare that “compliance with the relevant sections of the PhRMA Code will not necessarily protect a drug manufacturer from prosecution or liability for illegal conduct.”

The OIG encouraged manufacturers to avoid legal liability by using available “safe harbors”—regulations previously established by the OIG to offset the breadth of the anti-kickback statute. To allow businesses to make “non-abusive...beneficial and innocuous arrangements” with their customers, safe-harbor regulations specify practices “for which the government will not seek enforcement action despite a literal violation of the terms of the law.” Safe harbors exist for “personal services and management contracts, warranties, discounts, employees, group purchasing organization arrangements, and shared risk arrangements.” The draft emphasized that “activities that fit squarely in one of the safe harbors...are deemed immune from sanction under the anti-kickback statute.”

Consider the case of a company hiring a physician as a consultant to evaluate marketing materials. To avoid liability, the manufacturer should use the personal-services safe harbor, which requires a written, signed contract specifying the length of service, the consultant’s duties, and fair-market compensation. By this strategy, companies may continue all consultantcies in which physicians provide legitimate services in exchange for appropriate compensation.

In other instances, however, the OIG contended that so-called consultants were not performing bona fide services. Rather, manufacturers were rewarding physicians for merely attending meetings or promotional events. These arrangements did not meet the requirements of the personal-services safe harbor. Similarly, the OIG warned that common industry gifts to physicians fall outside safe-harbor protections and might violate the anti-kickback statute. Thus, the OIG draft invoked a strict interpretation of the anti-kickback statute. Given these clear and narrow parameters, drug companies would be hard pressed to continue many common physician-industry exchanges.

**Requested Changes To The Draft And OIG Responses**

The sweeping implications of the draft Guidance prompted pharmaceutical manufacturers and medical organizations to request major changes. The issues of greatest concern were funds for education, research, and consulting; gift giving; and payments for detailing.

- **Requested changes: funds for education, research, and consulting.** Twenty-five medical organizations, including the AMA, ACP, and Association of
American Medical Colleges (AAMC), protested that the Guidance would jeopardize drug-company funding of educational activities. According to the draft, the sponsoring or financing of "educational conferences and meetings attended or taught by physicians or others in a position to generate or influence referrals...[or the providing of] scholarships and educational funds...[and giving] grants for research and education" all might "potentially implicate the anti-kickback statute."

This formulation, medical organizations argued, put unnecessary and inappropriate restrictions on such funding. Referring to the policies of the Accreditation Council for Continuing Medical Education (ACCME)—particularly its requirement that educational activities be independent of commercial interests—they asserted that "organized medicine has taken steps to ensure that the financial support provided by industry does not compromise the integrity of educational programming or unduly influence physician attendees." The medical organizations then requested that special safe-harbor protection be provided for all educational activities.

To secure further immunity from the anti-kickback statute, medical organizations also urged the OIG to leave the oversight of industry-funded research grants and consulting arrangements to universities and medical centers. They argued that the OIG ought to be encouraging physicians to serve as advisers or consultants to drug companies and to accept grants from and conduct research for them because these arrangements promoted "new cures and treatments for diseases" and ensured "correct policy decisions." The organizations also argued that the evaluations and approval of research by university-based institutional review boards (IRBs) guaranteed "that the researcher has not received improper inducements from pharmaceutical manufacturers."

**OIG response: final Guidance.** In the final Guidance, the OIG refined and relaxed its position on grants for education, research, and consulting. It provided more detail on how safe harbors could reduce drug company liability and identified provisions likely to raise suspicion. Parties should make certain that research and educational services were not simply marketing activities in a different guise, it said, and that compensation to physicians was at fair market value. Furthermore, while bona fide consulting or advisory services were unlikely to prompt OIG concern, "compensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a passive capacity is suspect." The OIG also specified as unacceptable payments to physicians for papers or speeches that were ghostwritten by companies, as well as for "shadowing" or preceptor services, in which drug representatives observed physicians treating patients.

The OIG then added two new criteria for avoiding liability in grant making. First, to reduce the risks that a grant program is used improperly to induce or reward product purchases or to market products inappropriately, manufacturers should separate their grant-making functions from their sales and marketing functions. Second, grants for educational activities sponsored and organized by
medical associations raise “little risk of fraud and abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.”

Taken together, these revisions required alterations in how drug companies dispense funds. They must better separate marketing and education and set limits on physician compensation. But in the end, the OIG permits grants for education, research, and consulting to continue.

- **Requested changes: gifts and gratuities.** Both organized medicine and the pharmaceutical industry were acutely concerned about the draft’s potential impact on gifts and other gratuities. The draft read as follows:

  A good starting point for compliance purposes is the “PhRMA Code.” Arrangements that fail to meet the minimum standards set out in the PhRMA Code are likely to receive increased scrutiny from government authorities. [Issues to consider include the following:] Is the gift or benefit more than nominal in value and/or does it exceed the fair market value of any legitimate service rendered to payer?

Medical organizations took issue first with the OIG’s proposed standard that gifts should not “exceed the fair market value of any legitimate service rendered to payer.” The AMA, for example, argued that physicians often receive “nominal gifts” that “have no correlation to any service provided” and “are envisioned as giveaway items.” Dismissing these gifts as so insignificant that no underlying expectation of reciprocity exists, the AMA concluded that “giveaway items should not have to meet standards to indicate they are fair payment for a provided service.” So, too, the ACP, whose 2002 guidelines acknowledge the influence of giving gifts, nonetheless urged the OIG to protect gifts and other benefits from the pharmaceutical industry.

To obtain still more protection, medical societies and companies asked the OIG to defer to already existing codes of conduct, particularly those of PhRMA and the AMA. Drug companies objected to the OIG’s view of the PhRMA Code as a set of “minimum standards.” They wanted the code to serve as the benchmark for compliance: “[W]e urge the OIG,” PhRMA wrote, “to foster adherence to the Code by making clear that practices that are consistent with the Code are ‘low risk’ and that companies that take serious and sustained efforts to adhere to the Code will be granted the benefit of the doubt if their corporate intent is ever questioned.”

The industry went on to warn that “treating these guidelines as ‘minimum standards’ can only discourage future initiatives by industry groups to articulate higher standards.” Endorsing the PhRMA Code would preserve mutually beneficial relationships between medicine and industry.

- **OIG response: final Guidance.** In its final Guidance, the OIG continued to insist that gifts, regardless of value, “potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company.” However, it provided questions that drug companies (and, in turn, physicians) could use to identify dubious arrangements: “Does the arrangement or practice have a potential to interfere with, or skew, clinical decision making? ...to increase costs to the federal healthcare programs, beneficiaries, or enrollees? ...to
increase the risk of overutilization or inappropriate utilization? ... Does the arrange- ment or practice raise patient safety or quality of care concerns?” If the answers were “no,” the practice could continue.

The OIG’s response was equivocal, expressing suspicion of drug-company gifts even as it allowed the parties’ subjective denials of influence to justify them. In one crucial aspect, however, the OIG relented. Its draft language had identified the PhRMA Code as a “starting point” for compliance; now, the OIG explicitly endorsed it. According to the final Guidance, adherence to the PhRMA Code offered “substantial” protection to manufacturers and health care professionals. Although the OIG stopped short of giving blanket assurances to practices allowed by the PhRMA Code, its final Guidance read:

Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.

While liability under the anti-kickback statute still “depends on the particular facts and circumstances of the specific arrangement,” compliance with the PhRMA Code “should substantially reduce a manufacturer’s risk.”

- **Request for changes: payments for detailing.** Finally, the pharmaceutical industry raised an issue that the draft had not discussed: pay-to-detail arrangements in which physicians receive compensation for listening to sales talks or reading marketing materials. The industry asked the OIG to confirm the legality of this practice. One company suggested that “these arrangements merely buy access to physicians at a reasonable fee to provide information to the physician and are not intended to be an illegal inducement to prescribe the company’s products under the Federal anti-kickback statute.”

- **OIG response: final Guidance.** The final Guidance contained a new section that took a hard line on these arrangements:

  Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as “consulting” fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform “research.” All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged.

Although the OIG did not characterize this practice as patently illegal, the final Guidance offered no safe harbor or other protective conditions.

**Implications Of The Guidance**

The pharmaceutical industry and the medical profession reshaped the Guidance in several important ways. They weakened the OIG’s strict interpretation of the anti-kickback statute and won the OIG’s endorsement of the PhRMA Code and of grant making separated from marketing. As a result, the Guidance allows the continued flow of gifts and grants from the pharmaceutical industry to phys-
cians who prescribe its products.

Despite considerable research documenting the influence of industry gifts and funding (no matter how “modest”) on physicians’ beliefs and behavior, the practices will continue.28 Drug companies spend an average of $13,000 per physician per year on gifts and other promotional items, to an annual total of $12 billion, and the OIG Guidance will not reduce these.29 Moreover, given their responses to the Guidance, medical societies are not likely to encourage efforts to rein in industry-physician exchanges. Left to itself, organized medicine will not curb abuses.

Neither the final Guidance nor the PhRMA Code contains provisions for monitoring or reporting drug company–physician exchanges. Absent hard data, only anecdotal evidence is available, and it is contradictory. Some accounts describe disgruntled physicians lamenting that their free trips have disappeared and that their spouses are no longer invited to dinner meetings. But other stories tell of continuing violations. Janet Woodcock of the FDA, for example, reports that drug companies are still offering physicians free cruises and trips to resorts.30 Absent any monitoring system, however, conclusions about the impact of the final Guidance can only be tentative.

**Shifting resources to reduce risk.** Uncertainty conceded, the final Guidance may spark some important changes. Industry practices appear to be more sparing and conservative.31 Companies seem to be shifting resources away from lavish gifts and entertainment to areas such as medical education.32 ImpactRX, a company that analyzes pharmaceutical marketing, conducted a survey of 2,000 physicians. Six months after the PhRMA Code was instituted, the company found that drug company invitations for continuing medical education (CME) seminars nearly doubled, while entertainment events decreased 90 percent.33 In addition, manufacturers are almost certain to cease pay-to-detail practices.

**New procedures for grants.** The OIG’s insistence on separating grant making from sales and marketing is also compelling drug manufacturers to restructure their funding processes. Heretofore, most companies dispensed CME funding through “brand teams,” which are part of sales and marketing divisions. Now they must funnel requests for CME funding through a medical education or medical affairs unit.34 Whether the separation will better ensure that education is not subverted by marketing and sales interests remains an open question.

**Increasing industry emphasis on compliance.** The Guidance is also spurring a reorganization and strengthening of industry approaches to compliance. The Pharmaceutical Compliance Forum (PCF), an association for industry compliance officers, has convened several meetings to discuss the OIG Guidance; other industry associations have also organized conferences on compliance issues. These sessions, several of which we have attended, demonstrate that the pharmaceutical industry is reshaping practices in the risk areas identified by the OIG Guidance. Companies are developing and maintaining official compliance policies, procedures, and record keeping, including documentation of employee training in compliance policies.
The Guidance may elevate the position of compliance officers within the corporate hierarchy. Because senior management gives priority to compliance issues within corporate policy, compliance officers are likely to gain more resources, more personnel, more space, and more authority. An invigorated compliance department, at a minimum, creates new tensions within drug companies. To be sure, sales and marketing divisions will work even harder to develop increasingly novel ways to influence physicians. Nevertheless, compliance priorities will force greater conformity within the risk areas identified by the OIG.

**State enforcement of the Guidance.** Another outcome of the Guidance is the invigoration of state-level enforcement. State attorneys general—most prominently in New York, Vermont, and Massachusetts—are now using federal and state anti-kickback laws, consumer protection laws, and fair trade regulations to investigate and prosecute drug companies. Associations of attorneys general have also begun to collaborate. In August 2004 a nationwide coalition of state and federal attorneys general settled an antitrust case against two drug companies, Perrigo Company and Alpharma Inc. The companies will pay $10,000 to every state and $1 million to the National Association of Attorneys General (NAAG) to fund future enforcement. Collaborative efforts are likely to increase. In January 2005 NAAG held a summit to explore the most effective litigation strategies against the industry.

The Guidance has moved at least one state legislature to action. In September 2004 California enacted legislation, to take effect in July 2005, requiring pharmaceutical companies to establish compliance programs consistent with the OIG Guidance and the PhRMA Code. The legislation also requires companies to set an annual dollar limit on “gifts, promotional items or materials or activities” for individual providers. Companies must make public a description of their compliance program, including the dollar limit on gifts to providers, and a written declaration that they are in compliance with the new law and with their own policies. In this way, the law imposes some transparency on industry-physician relationships.

Because the California law covers all companies that manufacture, package, label, market, or distribute pharmaceutical products in California, it may apply to pharmaceutical suppliers everywhere. Manufacturers intend to challenge the law’s constitutionality on the grounds that it is more restrictive than federal regulations. But, should it survive this challenge, the implications would be substantial, and all the more so if other states follow California's lead.

In the absence of systematic monitoring, it is difficult to evaluate the Guidance’s immediate or potential long-term impact. Nevertheless, physician-industry exchanges have come under a regulatory spotlight, and some traditional activities are now off-limits. The drug industry is alert to government regulations and is altering its internal organization. Although the final Guidance still gives companies ample discretion, there is good reason to anticipate fundamental changes in industry-physician relationships.
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NOTES
10. Ibid.
11. Ibid.
14. To obtain information about these meetings, we filed a second FOIA request. This brought us materials of little use: a brief meeting agenda, letters from the American Association of Health Plans and the Pharmaceutical Care Management Association reiterating their initial comments on the draft, and the Academy of Managed Care Pharmacies’ published guidelines for drug formularies.
17. W. Goldstein and S. Snyder, “The OIG’s Draft Compliance Guidance for Pharmaceutical Manufacturers:


20. OIG, “Compliance Program Guidance.”

21. AMA’s comments on the draft.


23. OIG, “Draft OIG Compliance Program Guidance.”

24. PhRMA’s comments on the draft, submitted by Sidley Austin Brown and Wood LLP, obtained via FOIA.

25. Comments from nineteen pharmaceutical companies on the draft, submitted by Arnold and Porter and PriceWaterhouseCoopers LLP, obtained via FOIA.

26. OIG, “Compliance Program Guidance.”

27. Comments from an anonymous pharmaceutical manufacturer, submitted by Kleinfeld Kaplan and Becker LLP, obtained via FOIA.


