

Feature Article Reprint # 52-01

Free Gifts to Physicians: What's the Big Deal?

By John Mack

I must admit that I am a little creeped out every time I visit my primary care physician. Her office is cluttered with pharmaceutical company trinkets such as note pads, pens, wall charts, etc. Also, more often than not, there's a pharmaceutical sales rep sitting in the waiting room or trying to blend into the wall paper waiting for the doctor to give him or her a minute.

It is at these times that the advice from Marcia Angell, MD, former editor in chief of the *New England Journal of Medicine* (NEJM), and author of the book "The Truth About the Drug Companies" (see the [PMN review of this book](#)) comes to mind. She urges readers to ask their doctors this question: "Do you make time for visits from drug company representatives?" If the answer is yes, Angell says you should consider changing doctors.

Despite my doctor's proclivity to accept trinkets and pizza from pharma sales reps, I am not considering changing doctors. After all, she literally saved the lives of at least two people in my town—one of them a neighbor and friend of mine. I also think she was as helpful as my cardiologist in lowering my cardiovascular risk factors (and she didn't even prescribe a brand drug!).

JAMA Article Calls for Ban on Gifts

You can understand, therefore, why I am a little bit ambivalent about claims that pharma gifts to physicians have a negative impact on patient outcomes. That is one of the claims made by "a group of influential doctors" in a recent article in the *Journal of the American Medical Association* (JAMA, January 29, 2006. Vol. 295, No 4; also see the story in the NY Times, January 24, 2006: "Doctors Urge Ban on Gifts From Drug Makers").

The authors cite the following types of gifts that they wish banned:

- meals
- payment for attendance at lectures and conferences, including online activities
- CME for which physicians pay no fee
- payment for time while attending meetings

- payment for travel to meetings or scholarships to attend meetings
- payment for participation in speakers bureaus
- the provision of ghostwriting services
- provision of pharmaceutical samples
- grants for research projects
- payment for consulting relationships

In some cases, the authors recommend a "zero dollar limit." This should apply, according to the authors, "to free meals, payment for time for travel to or time at meetings, and payment for participation in online CME..." In other cases, such as free drug samples to physicians, alternatives are offered: "The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician."

According to the JAMA authors, a "ban" of pharma gifts to physicians—if it were possible—would cure all that ails the delivery of healthcare in the US. For one thing, physician decisions would become more "evidence-based" and result in better patient outcomes.

Time to Ask the Experts

How do pharma marketing experts feel about the issue of free gifts to physicians? Opinions from 65 experts were collected in the recent online *Pharma Gifts to Physicians Survey* sponsored by Pharma Marketing News and hosted on the Pharma Marketing Network Web site from 27 January 2006 through 16 February 2006. The issue was also discussed at a [Pharma Marketing Roundtable](#) conference call on 9 February 2006.

The online survey asked: "In your opinion, to what degree may EACH of the following pharmaceutical industry gifts to physicians present a potential conflict of interest?" For each of the "gifts" mentioned above, respondents could select "High Degree of Conflict," "Moderate Degree of Conflict," "Not Much Conflict," or "Very Low Degree of Conflict." They could also check "Neutral/Don't Know." Further, respondents were instructed to

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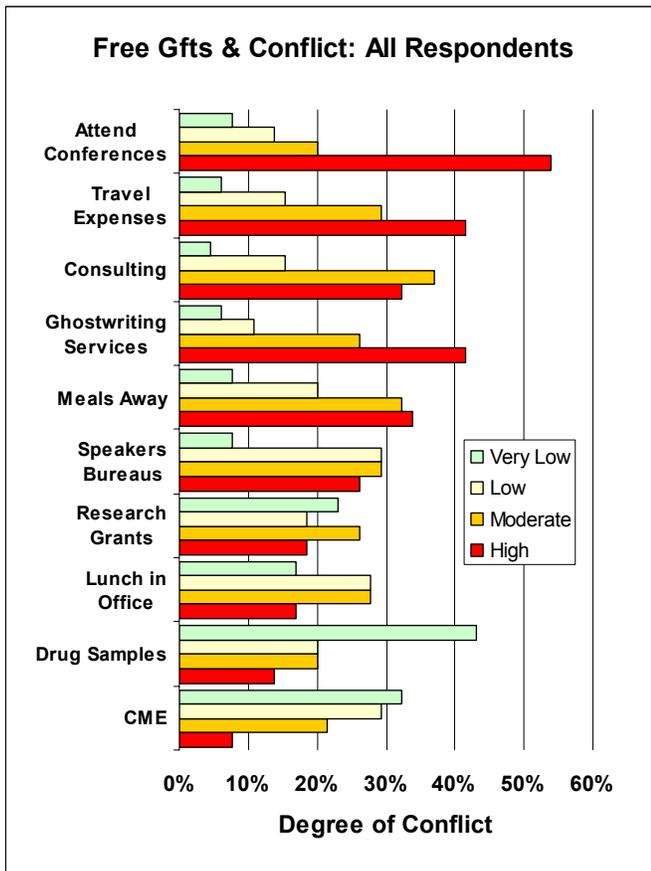


FIGURE 1: Pharma Gifts to Physicians Survey results from all respondents.

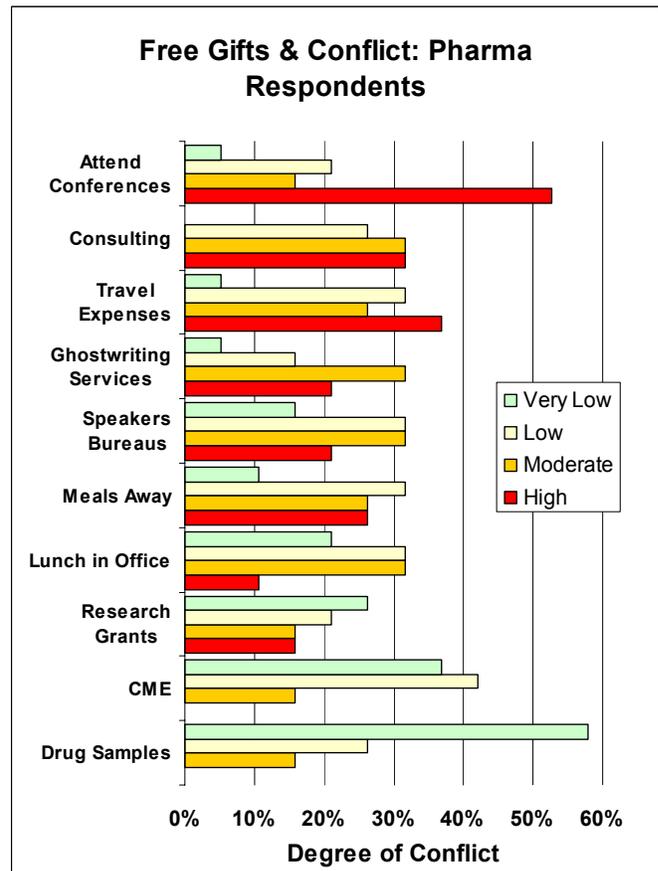


FIGURE 2: Pharma Gifts to Physicians Survey results self-identified pharma respondents.

Abbott - going to the dogs!

Gifts to physicians can get out of hand and become grist for critics' mills as demonstrated by the following [snippet](#) from a UK blog site.

Poor Abbott UK. More has now been revealed about their breaches of the [UK Code of Practice for Big Pharma](#) that led to their recent six month suspension.

The judgment was triggered by a "concerned member of the industry." It was found that in January and September 2004, Abbott employees inappropriately invited groups of doctors to a Grayhound stadium in Manchester while racing was taking place.

It also criticised an event in February, when an Abbott manager borrowed £1,000 from a company drug representative to pay for their attendance along with a doctor at a lap dancing club at the end of a two-day medical workshop.

It also found in breach of its code an invitation over the summer by an Abbott manager to senior London hospital consultants to centre court at Wimbledon and full hospitality and two managers' invitations for a Christmas dinner for a hospital department at which both arrived late and drunk.

Insiders' view: The timing of this is unfortunate as a stricter code has just been launched! It shows the whole "[voluntary code](#)" thing up for the farce it really is.

vote “High Degree” if they favored banning the practice and “Very Low Degree” if they favored continuing the practice as is. Realizing that the issues are complex, respondents also had an opportunity to submit comments to further explain their choices. Survey results are presented in FIGURES 1 and 2 (see pg. 2) and comments from respondents are included throughout this article.

Gifts with High Conflict Potential

Two-thirds to three-quarters of respondents indicated that the following practices represented a moderate or high degree of conflict of interest for physicians accepting them as gifts from pharmaceutical companies:

- Pay to attend conferences (**74%** all respondents vs. 68% pharma respondents)
- Travel scholarships (**71%** all respondents vs. 63% pharma respondents)
- Consulting (**69%** all respondents vs. 63% pharma respondents)
- Ghostwriting services (**68%** all respondents vs. 53% pharma respondents)
- Meals at restaurants (**66%** all respondents vs. 53% pharma respondents)

The percentages refer to respondents who selected high or moderate degree of conflict. In all cases, a smaller percentage of pharma respondents felt the practice represented a high or moderate degree of conflict.

Ghosts in the Machine

The JAMA authors felt that Academic Medical Center (AMC) faculty should be “prohibited from publishing articles and editorials that are ghostwritten by industry employees.” Surprisingly, most respondents to the survey (68%) agreed that ghostwriting could result in a moderate to high conflict of interest for physician authors.

“The ghostwriting thing is a red herring,” said Pharma Marketing Roundtable member Harry Sweeney. “Every academic center or teaching hospital—in fact nearly everyone who does clinical research—uses ‘ghostwriters’ who write the papers.

The researchers produce the data, the data are compiled by biostatisticians, and then writers sit down and write. The ghostwriters may be

residents, junior investigators, etc. But, I believe that it’s a very rare case today where the senior investigator actually writes the paper. Editing? That may be a different story.”

But who pays the piper? is the real question. “I think there should be more disclosure,” said Pharma Marketing Roundtable member John Kamp, “but let’s not pretend that’s it’s a big nefarious activity.”

Response to this issue may have been influenced by the NEJM recently published “Expression of Concern” regarding a last minute deletion of critical data from a manuscript reporting on a Vioxx clinical study. The NEJM editor cited proof that the changes were made by somebody using a Merck computer. I’m guessing it was probably an employee of Merck rather than a “resident” or “junior investigator.” For more on this, see Pharma Marketing Blog (“[Merck’s Hand in the Cookie Jar](#)”).

Speakers Bureaus Are on the Cusp

The JAMA authors had this to say about speakers bureaus: “Faculty at AMCs should not serve as members of speakers bureaus for pharmaceutical or device manufacturers. Speakers bureaus are an extension of manufacturers’ marketing apparatus. Because AMC faculty have a central role in the training of new physicians and represent their own institution, they should not function as paid marketers or spokespersons for medicine-related industries.”

Speakers bureaus are often comprised of key opinion leaders (KOLs)—respected individuals, such as college professors—who influence physicians through their professional status. Speakers bureaus without AMC faculty members would be much less effective at opening doors to other physicians and enabling pharma companies to disseminate new product information and clinical trial results to the medical community through these trusted sources. (For more on this, see “[Developing Win-Win Key Opinion Leader Relationships](#).”)

A slim majority (55%) of respondents to the Pharma Marketing survey felt that participating as paid members in

pharmaceutical speakers bureaus represented a moderate to high degree of conflict of interest for physicians.

“I wouldn’t categorize payments to physicians for consulting or participating in speakers bureaus as ‘gift giving.’ That’s simply payment for services.” -- Joe Orsini, survey respondent

“Speaker Bureaus serve a valuable purpose. This is based on the assumption that the MD does indeed ‘use’ and ‘prefer’ the drug over the competition.” -- Michael Bishop, survey respondent

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Gift with Low Conflict Potential

Less than 50% of respondents to the Pharma Marketing survey indicated that the following practices represented a moderate to high degree of conflict of interest for physicians accepting them as gifts from pharma companies:

- Free Lunch (**45%** all respondents vs. **42%** pharma respondents) *Continued on next page...*
- Research grants (**45%** all respondents vs. **32%** pharma respondents)
- Free drug samples (**34%** all respondents vs. **16%** pharma respondents)
- Pharma-supported CME (**29%** all respondents vs. **16%** pharma respondents)

Again, a much smaller portion of pharmaceutical respondents felt these practices were questionable, especially with regard to free drug samples and pharma-supported CME, two activities that pharmaceutical companies spend billions of dollars on annually.

Many survey respondents and Pharma Marketing Roundtable experts felt that the above practices were a normal aspect of doing business. As one anonymous survey respondent so eloquently said:

“It seems that we have lost focus on the fact that pharmaceutical companies are in business. In no other industry that I am aware of, no matter how highly regulated, is it considered unethical to buy lunch for a potential customer, fund education in the area of interest, seek advice from a target audience, or to present the pros and cons of ones product over lunch. I feel that the research related services should not even be a part of this conversation. If drug companies stop providing grants for research or the writing services that allow research findings to be published in an expedient time frame, then we all suffer. The idea that physicians and other healthcare providers are influenced by free lunches, payments to participate in speakers bureaus, or drug samples is ludicrous. If that is the case, we have a much bigger problem in our healthcare system than pharmaceutical spending. We have a system filled with dimwitted, naive, and unintelligent physicians. I do not think that is the case.”

Jerry Mauder, Sr. Marketing Executive at Custom Promotions, Inc., a company that provides promotional items to the pharmaceutical industry, also feels that these activities are normal business functions “I don’t know too many people who will

swing their business for a BLT and a beer,” Mauder said.

The JAMA article authors think otherwise. “Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people’s behavior. Individuals receiving gifts are often unable to remain objective; they reweigh information and choices in light of the gift. So too, those people who give or accept gifts with no explicit ‘strings attached’ still carry an expectation of some kind of reciprocity. Indeed, researchers suggest that the expectation of reciprocity may be the primary motive for gift-giving.”

At least one anonymous survey respondent agreed. “If a pharma company provides some tangible asset to [physicians] they will react favourably to that company’s products when future decisions about prescribing are to be made. They may unknowingly be compromising patient care because of their favoritism.”

Educational vs. Promotional Grants

Pharmaceutical companies claim that “unrestricted” educational grants help physicians keep up with clinical research and new drug products. In most cases, these grants are used to provide free CME programs to physicians (see box, “CME vs. Non-CME Grants,” pg 7). Sometimes, however, grants are given to medical communications companies or medical associations to publish non-accredited “highlights” of medical meetings, especially if the company’s drug trials will be presented at those meetings. In these cases and others, the line between education and promotion can get blurred.

The FDA does not regulate truly independent and non-promotional activities supported by the pharma industry. In 1997, FDA issued its “Guidance for Industry, Industry-Supported Scientific and Educational Activities.” The FDA guidance lists 12 factors the agency will consider when evaluating activities and determining independence. In general, the pharma grantor should have no editorial control over the content of the program and the program should not be promotional.

The Senate Finance Committee, under the leadership of Sen. Chuck Grassley (R-Iowa) and Max Baucus (D-Montana), is investigating educational grants made by the industry. According to a letter sent last June to major

“Buying lunch, providing samples, and utilizing a ‘lunch & learn’ program to educate your clientele are normal functions in many industries.” – Jerry Mauder

pharmaceutical companies, the senators said they want to know more about the practice to ensure that it's not just a "backdoor way to funnel money to doctors and other individuals who can influence prescribing and purchasing of particular prescription medicines, including off-label prescriptions. We need to know how this behind-the-scenes funneling of money is influencing decision makers," Grassley said. "The decisions result in the government spending billions of dollars on drugs. The tactics look aggressive, and the response on behalf of the public needs to be just as vigorous."

The JAMA authors cited several activities that might be considered "aggressive," including paying physicians to attend lectures and conferences, paying for time while attending meetings, and payment for travel to meetings or scholarships to attend meetings.

To reform CME, the JAMA authors suggest that "manufacturers wishing to support education for medical students, residents, and/or practicing physicians should contribute to a central repository (eg, a designated office at an AMC), which, in turn, would disburse funds to ACCME-approved programs."

The pharma industry may have already received and acted upon this message. Support for CME provided by independent medical education companies (MECCs) is decreasing, while support for CME programs provided by medical schools continues to increase (see FIGURE 3, pg, 8). For more about partnerships between academic CME providers and pharma companies, see ["Provider-Pharmaceutical Partnerships - Are They Possible Without Conflict of Interest?"](#)

Mario Cavallini, member of the Pharma Marketing Roundtable, wondered what actual harm was being done by the promotional activities. The writers of the current JAMA article answer that by citing another JAMA article from 2000, which stated in the abstract "Attending sponsored CME events and accepting funding for travel or lodging at educational symposia were associated with increased prescription rates for the sponsor's medication."

"Either these doctors were really impressed with the 'gift,'" said Cavallini, "or maybe information was conveyed that made a stronger case for the product."

"Education in a technology field is a benefit to the physician and ultimately to the patient," said Mauder. "Physicians have high fixed costs. They

need to be compensated for attending continuing education programs, whether pharma sponsored or not."

Grassley and Baucus, however, seem more concerned when grants are made to help promote off-label use of products. In a January 11, 2006, letter to Johnson & Johnson, for example, the senators cited a case involving the heartburn drug Propulsid, which some have advocated for use in children to treat gastroesophageal reflux disorder and colic, although it has not been approved for pediatric use. Documents and information provided to the committee show that Johnson & Johnson gave out hundreds of thousands of dollars in research and education grants related to Propulsid, including \$150,000 to a pediatric gastroenterologist, then associated with a children's hospital, who was a strong advocate for the pediatric use of Propulsid.

"It's hard to see how you could call some of these grants 'educational,'" Grassley said.

"Some groups have learned that their very survival depends on drug company money. In that case, it seems pretty obvious that their independence may be compromised. We need to look at just how beholden these groups are to the money they're getting."

Given the attention by Senate investigators, the OIG and the media on off-label promotion, it's no wonder that the industry is skittish about educational grants, especially grants given directly to physicians and non-ACCME accredited organizations.

Drug Samples: The "Mere Ownership Effect"

According to the JAMA authors, "the availability of free samples is a powerful inducement for physicians and patients to rely on medications that are expensive but not more effective. Samples also provide company representatives with access to physicians."

There is no doubt that samples are an effective means of gaining access to physicians (see, for example, ["Intelligent Online Sampling Strategies"](#)). Why? Because physicians want them and find samples useful to get patients started on treatment and even depend on samples to treat patients that can't afford the medication.

"Of course samples work!" says Kamp. "But if the drug doesn't work – and you can look at the ED market for a good case study of this – patients are not going to fill the prescription when the sample runs out. Let's not be hysterical about the use of samples."

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However, do samples unduly sway doctors' decisions about which drugs to prescribe? One way to examine this question is to compare the psychological effect of free samples upon physicians vs. the effect of free coupons or trials offered directly to consumers, an issue of possible interest to the FDA.

FDA recently proposed a study on the effect of coupons and "free trial" offers in DTC ads for drugs (see "[FDA, Coupons, and Sleep Aid DTC Ads](#)"). In its proposal, which was published in the Federal Register on February 6, 2006, and later withdrawn (see "[FDA Backs Down on Coupon Study](#)"), the FDA cited the following results of consumer research studies: "People tend to rate owned objects more favorably than those they do not own, even when those objects have been assigned to them at random (Beggan, James K., "On the social nature of nonsocial perception: The mere ownership effect," Journal of Personality and Social Psychology, 62(2), 229-237, 1992.) This has been termed the 'mere ownership' or 'mere possession' effect. [Other] research ... has shown that consumers rate a product more favorably when they are simply given a gift certificate or a coupon for that product or service."

Free drug samples could also trigger a "mere ownership" effect on physicians, causing them to look more favorably on the sampled products and prescribe them more often.

Whatever the mechanism by which samples do their "magic," the real issue for critics is inappropriate prescribing of more costly drugs,

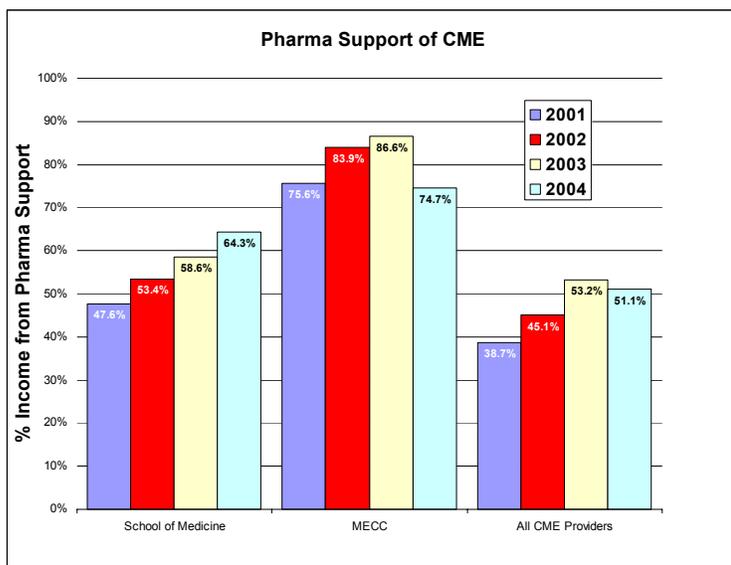


FIGURE 3: Pharma support for CME decreased overall, but continued to increase as a percentage of total support for medical school CME programs. [Source: ACCME Annual Reports]

Greasing Access

The use of samples by sales reps is often abused and well-documented (see, for example, "Hard Sell: The Evolution of a Generation X Salesman" in this issue). "The problem," said Pharma Marketing Roundtable member Jack Barrette, "is when samples are inappropriately used by reps and more importantly when the physician facilitates that by refusing to even see the rep and just sends out the signed voucher."

"I am a former pharma rep. My views are based on what I would see in the field. When I first got into the business there were fewer reps and more no access issues. Too many reps too many dinner functions and too many "speaker arrangements have caused physicians to close up shop to reps. Cut the number of reps and you will see a change in the way Dr. view samples, reps and giveaways." – survey respondent

The proliferation of free drug samples and pizza as physician access tools is a sad testimony to the failure of physician marketing in general. Often, the sales rep does not or cannot deliver any useful, believable evidence-based information to doctors.

Sales reps are being devalued confirms Sweeney. "Physicians have other sources of information such as the Internet. Consequently, there's been a devaluation of sales reps, many of whom are not as versed in the background and knowledge of products as they need to be. Yes, they bring pizzas and samples, but in terms of bringing useful information to the physician there's a consensus that they're not bringing that to the party any more."

"Thirty years ago 20 minutes face time with MD was typical. Today 20 minutes face time is rare and is likely to cost hundreds of dollars in free lunches to the entire MD's office staff and practice partners, if it happens at all. The ability to influence probably hasn't changed much, but the cost of access to that influence is big and will continue to develop new creative venues." – survey respondent

Drug companies need to wean themselves away from door-opener gifts to physicians and their staffs and think of new ways to gain access. "Docs shouldn't make any time to see reps unless they have something new to say," says Richard Vanderveer, Pharma Marketing News Advisory Board member. "And industry executives should stop running to conferences on improving physician access and should think more about how rep visits can be more valuable to docs." [See "[The](#)

[Truth About the Drug Companies: What To Do About It.](#)]

Culpability on the Other Side

“The criticism seems so one-sided. Where is the culpability on the physician side?” asked Vince DeChellis, member of the Pharma Marketing Roundtable. Barrette agreed. “The question is who’s requesting incentives? That’s a question, however, that no pharmaceutical company can raise about its own customers. We’ve all been in the position where a company is facing a competitor and the physician would say ‘whoever installs a new video conferencing center in our practice will get my business’. The company that complies gets the business whereas the one that sticks to the PhRMA guidelines doesn’t.”

Suggestions for Change: Ethics and Best Practices

While most experts I talked to feel that much of the criticism of the industry is misplaced and that there has been significant improvement in industry self-regulatory efforts to reign in abuses since 2000, there is more that could be done.

Some experts suggested a more ethical and open approach. “This is ultimately an ethical issue,” said Pharma Marketing Roundtable member Neil Gray, “and you can’t legislate ethics. You can, however, reward cultures that are ethical.”

“While all of these practices might be implemented in an ethical and open manner, the risk is that these practices might be misused and will give evidence to government and public that the industry does not promote drugs and services ethically.” – survey respondent

Gray suggested that a different kind of leadership is necessary. “Where’s the ethical backbone and leadership within the industry?” he asked. “Perhaps we are approaching a time where there’s going to be a leadership opportunity for some drug company if they are watching the headlines and the academicians who are shaking the bushes. There may be an opportunity to say we are not doing business that way. The only thing we are giving away is information and better direct-to-patient activities that will help physicians in the delivery of care. I don’t see, however, a lot of companies jumping on that bandwagon yet.”

“Best practices and standards need to be set, followed and enforced,” said DeChellis. “With ground rules in place ‘both parties’ can be held responsible. I can think of no other situation where the individual who accepts a kick-back is

considered the victim. Pharma needs access to the medical community. I would think an ethics committee would be able to reach some common ground that could set a level playing field.”

“Obviously, there’s a strong belief that too many lines have been crossed and it’s time that industry pushes the pendulum back in the other direction. I believe that the Ivory-Tower takes-all model proposed by the authors of the cited JAMA article is a particularly polarizing and troublesome one. A more moderate and responsible view, in my opinion, would be to judge each activity on its own merits and prescribe appropriate sanctions accordingly, not blanket prohibitions. Having said that, I think we are at a stage where the burden of proof has shifted to industry to establish that ANY payment to a doctor is for legitimate services rendered, and further, that the legitimacy will be determined not by the members of the industry, but by members of the legal and regulatory systems, and industry critics within and without the professions. Industry failure to respond adequately to legitimate criticism has led us to catastrophic losses of reputation in the court of public opinion.” – survey respondent

“If the industry has changed, the change has been poorly promoted,” said Gray. “I am waiting for the day when some company says we’ve decided the whole gift to physician thing is not a good way to go and we are going to take this money and put it somewhere else. I think that would get mileage until the cows come home.”

Pharma Marketing News

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