

Confronting Conflict of Interest

By Bryan A. Liang and Tim K. Mackey

On March 31, 2010, Pfizer, the world's largest drug maker, announced that it had paid some \$35 million dollars in the last six months of 2009 to health care practitioners, academic medical centers and other research groups. This included amounts given to over 4,500 physicians and other medical professionals for consulting, speaking engagements, meals and business expenses.

Pfizer's public disclosure is part of a larger movement to bring more transparency to the extensive relationship between the industry and health care providers. This relationship is often fraught with financial conflicts of interest that occur both on an individual level with physicians and at the institutional level with academic and research organizations and may raise serious ethical concerns.

Some conflicts of interest stem from marketing and promotion, which are aimed directly at individual health care practitioners. These include overt forms of remuneration such as meals, gifts and entertainment, expensive travel, lucrative consulting and speaking arrangements, no-fee continuing medical education, and other direct payments. In fact, studies have shown that more than 90 percent of physicians have some relationship with the pharmaceutical industry.

Other forms of marketing and promotion are aimed at influencing physicians to prescribe certain prescription drugs that are more expensive despite offering limited or no benefit to existing treatment options. These efforts are extensive and varied, and include pharmaceutical detailing and ghostwriting of scientific articles to sponsorship of medical education events.

Much attention has focused on these individual conflict of interest circumstances. But still more difficult to detect and regulate are the insidious institutional conflicts of interest in research entities such as academic medical centers. These occur when an institution, or an individual acting on the institution's behalf, has an external relationship or financial interest in research being conducted at or by the institution. These types of conflicts most commonly include equity holdings or royalty arrangements and intellectual property transfer agreements held by the entity, as well as university officials who have both individual financial conflicts of interest while participating as a member of the board of a corporation with a conflict of interest. At present, there are no laws or regulations addressing institutional conflicts of interest.

These institutional forms of conflict may result in academic and research institutions basing their activities on potential financial rewards and industry funding instead of patient safety and public benefit. The 1999 death of a teenage clinical study participant, Jesse Gelsinger, at the University of Pennsylvania highlights these risks. In that case, both the lead researcher and university stood to benefit financially from the commercialization of therapy being investigated through ownership of patents and equity in a biotechnology company collaborator. This led to revelations regarding inappropriate investigator consent methods, subject disclosures and oversight, suspension of research activities at the university, investigations by the U.S. Food and Drug Administration and a Senate subcommittee, enforcement action by the Department of Justice, and a wrongful death lawsuit.

Fueling these activities is the Bayh-Dole Act, which sought to facilitate cooperation between private industry and research institutions by allowing them to enter into technology transfer arrangements to better accelerate commercialization of academic research. The Act may contribute to over dependence of public institutions on industry funding and promote institutional conflicts of interest above research integrity and social benefit. Commentators have expressed doubts regarding the effectiveness and cost to society, as well as possible reforms to the law.

These pharmaceutical efforts are a multi-billion dollar strategy, with expenditures having tripled between 1996 and 2004. The pharmaceutical industry argues that payments to health care providers help encourage research and development and lead to better treatment options for patients. However, industry-funded marketing and promotion may unduly influence health care providers through financial incentives and may not accurately represent the risks and benefits of products by presenting false or misleading data to prac-

tioning physicians and their patients. Pushing research activities at academic centers in the current self-regulatory institutional conflict of interest regime may also lead to study activities in research institutions that compromise patient safety. Both may result in rapidly increasing expenditures in national health care related costs.

rate Web site. Eli Lilly, Merck and GlaxoSmithKline have also made such information available to the public on their Web sites. Yet all four companies make it difficult to download and analyze such data and questions have been raised regarding the accuracy of voluntarily disclosed industry data.

However, this will all be changing in 2012 with the implementation of the Physician Payment Sunshine Act that was passed as part of the health care reform bill. The law will require all drug and medical device companies to disclose certain payments worth more than \$10 made to physicians and teaching hospitals on an annual basis to a national public database.

Proponents of the Physician Payment Sunshine Act hope that it will lead to greater patient awareness, reassessment by physicians regarding involvement with pharmaceutical marketing and promotion, as well as increased scrutiny of industry-health care provider relationships by the public and policy makers. In conjunction with the passage of the law, or perhaps to stave off additional scrutiny, the pharmaceutical industry is being proactive in adopting disclosure initiatives.

Disclosures of payments made to health care providers are an important first step in addressing conflicts of interest in the individual case. Yet these efforts are deficient as they do not address the medical and research settings and institutional conflicts that still rely upon the industry, researchers, and institutions to take proactive steps in self-policing.

Due to these limitations, a more comprehensive and uniform solution may be necessary for institutions, integrating the current fragmented framework of self-regulation into a mandatory system. Possible solutions include the establishment of independent "centralized systems" within health care institutions that manage conflicts of interest. These systems would include mandatory adoption of a uniform policy on industry interactions by health care providers, random federal audits to compel compliance by health care providers and their institutions, and wider adoption of evidence-based educational activities replacing pharmaceutical sales, such as academic detailing, to break the chain between research institutions, their workers/trainees, and industry. This kind of system can create and/or reinforce a culture of neutrality and academic rigor, replacing the standard industry presence that results in overt individual conflicts and less obvious institutional ones.

As research and development costs continue to increase and new drugs in drug discovery pipelines continue to decrease, the pharmaceutical industry will continue to seek ways to generate products and sell them. But the risks are significant, as research institutions concomitantly are seeing their operational funds dwindling. Industry represents a large potential source of funds. But in order to ensure patient safety and public trust, institutional conflicts of interest must be addressed. The lessons of Jesse Gelsinger should always be remembered, and the focus of institutional activities must be on the ethical advancement of science for the betterment of society, not individual or institutional profits.

On March 31, 2010, Pfizer, the world's largest drug maker, announced that it had paid some \$35 million dollars in the last six months of 2009 to health care practitioners, academic medical centers and other research groups.

However, emphasis on conflict of interest issues has become increasingly focused. Pfizer's recent disclosure of payments was required as part of a corporate integrity agreement it entered into with the Office of Inspector General of the U.S. Dept. of Health and Human Services as part of the Department of Justice settlement regarding illegal off-label promotion (i.e., when a pharmaceutical manufacturer promotes its product for any non-FDA approved indication, population, dosage, administration or treatment duration).

Pfizer's settlement included a record setting \$2.3 billion dollar civil and criminal penalty and a guilty plea to a felony charge for illegal marketing of several drugs by Pfizer and a subsidiary. Included in this settlement was the largest criminal fine ever imposed in the U.S.

However, Pfizer's recent settlement is not the first against drug companies. Past Department of Justice enforcement actions include Eli Lilly's \$1.415 billion dollar civil and criminal fine, and other multi-million dollar fines against Warner-Lambert, Serono, and Purdue Pharma for illegal drug promotion and marketing, representing some of the largest cases of fraud and abuse in U.S. jurisprudence.

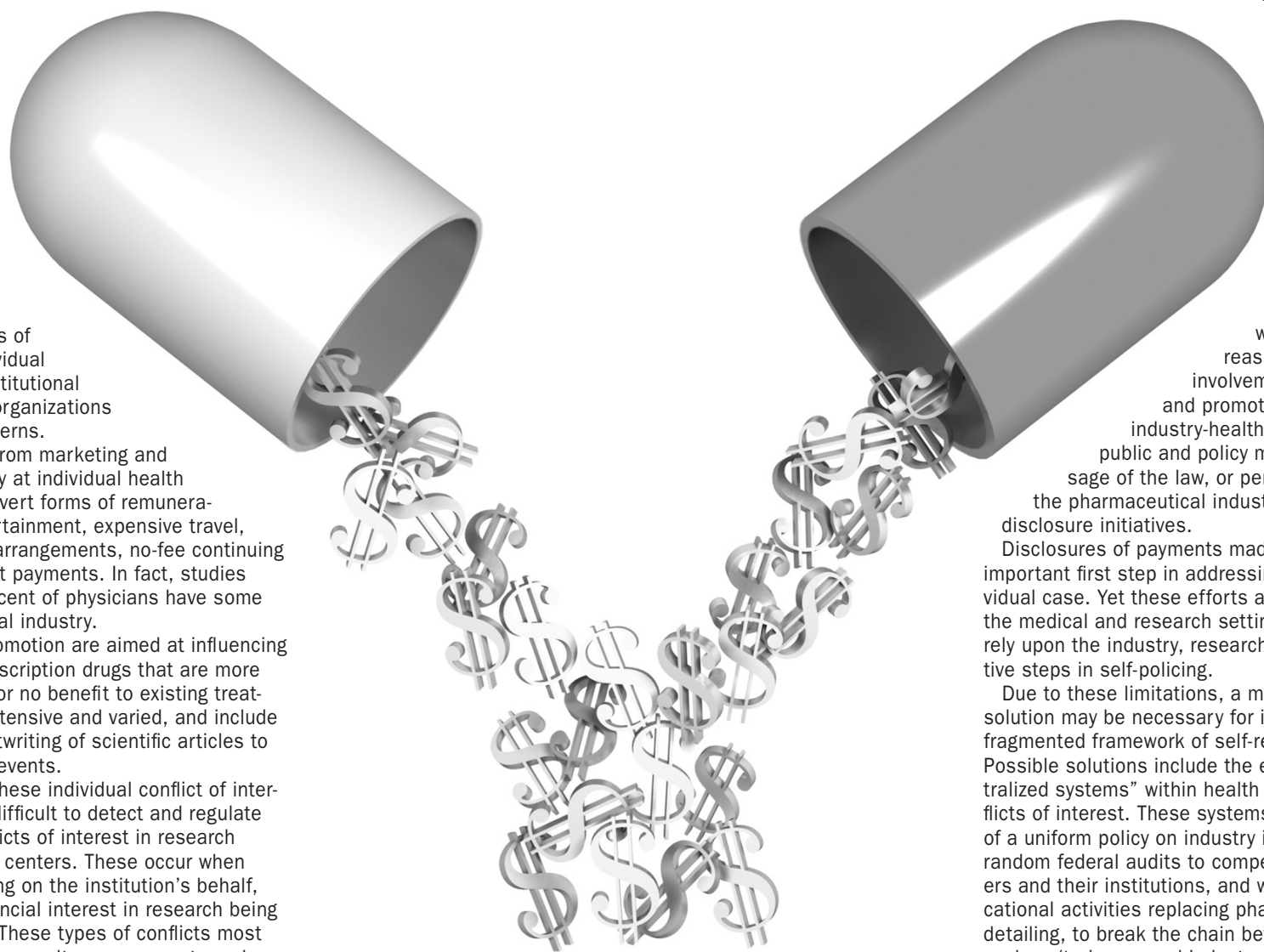
Pfizer's compelled disclosure of payments is available on its corpo-

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