CLIENT ALERT

ROPES & GRAY

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Increased Scrutiny of the Pharmaceutical Industry and its Relationship with Academic Medical Centers and Health Care Providers

Governmental and professional scrutiny over pharmaceutical and medical device companies' grant-making practices has steadily been increasing. Investigative letters sent by the Senate Finance Committee to 23 manufacturers on January 9th, and a set of recommendations published by ten prominent individuals in the January 25th issue of the *Journal of the American Medical Association* ("JAMA") are part — and certainly not the last part — of this trend. Indeed, the states are increasingly focusing on this issue, as well.

In light of these recent events, drug companies and device manufacturers, as well as hospitals and physician groups, would be well-served to revisit their policies and procedures regarding (among other things) educational grants and charitable donations, to ensure that they are consistent with the most current ACCME Guidelines and are responsive both to the heightened sensitivity in the academic community, as well as the government's concerns.

Senate Finance Committee Inquiry

On June 9, 2005, Senators Grassley and Baucus of the Senate Finance Committee sent letters to 23 pharmaceutical manufacturers, inquiring into their grant-making practices. Reflecting their continuing attention to this area, the Senators sent a second wave of letters on January 9, 2006.

While recognizing that many companies have implemented new policies and procedures in the past few years, the Senate Committee stated in its most recent letter that it continues to be "concerned that sales and marketing personnel may influence the awarding of grants in a way that favors those individuals or organizations that are known to advocate use of specific product(s) . . . [and that] professional and patient advocacy . . . organizations, many of which develop treatment or practice guidelines, may come to rely on such funding to an extent that may compromise their independence." These letters sought specific information, including the role of companies' marketing and sales agents in grant-making, and specific details regarding the recipients, amounts, and purposes of grants that the companies have made.

Journal of the American Medical Association Article

An article in the January 25, 2006, issue of JAMA urges academic medical centers to "more strongly regulate, and in some cases prohibit, many common practices . . . with drug and medical device companies." The article's ten authors reviewed existing guidelines — including the ACCME's guidelines and the Office of the Inspector General's

compliance guidance — and determined that they are insufficient to uphold the medical profession's "commitment to patient welfare and research integrity." In light of this deficiency, the authors concluded that "[t]he profession itself must exert much tighter control over the relationships between manufacturers and physicians."

Specific recommendations made by the authors include:

- Termination of manufacturers' direct educational grants to medical institutions, in favor of establishing a central repository that itself would receive company grants and distribute them to support educational events;
- A ban on all gifts to physicians from pharmaceutical companies, regardless of the value of such gifts;
- Replacement of free drug samples with drug vouchers for low-income patients;
- Exclusion of physicians with financial relationships to drug companies from hospital formulary and purchasing committees;
- Prohibition on medical school faculty members' participation in manufacturers' speaker bureaus; and
- Requirement that all consulting contracts include specific, scientific deliverables to demonstrate the bona fide nature of the contracts.

Although implementation of these recommendations is far from certain, some initial governmental reaction to them has been positive. On the other hand, they have also been criticized by some in the academic community.

Continuing Timeline of Developments

The Finance Committee's inquiry and the JAMA article continue growing scrutiny of the grants that many companies make to support medical education and advocacy groups.

2002	Pharmaceutical Research and Manufacturers of America releases PhRMA Code on Interactions with Healthcare Professionals, imposing voluntary restrictions on gifts that companies may make.
2003	Office of the Inspector General of the Department of Health and Human Services releases Compliance Program Guidance for Pharmaceutical Manufacturers, explicitly identifying educational grants as areas of potential risk.
2004	ACCME adopts revised Standards for Commercial Support, heightening restrictions designed to insulate CME programs from their corporate supporters.
2005	Senate Finance Committee begins inquiry into grant-making practices.
2006	Journal of the American Medical Association publishes article proposing more stringent treatment of pharmaceutical company grants.
Ongoing	U.S. Attorney's Offices' investigations of pharmaceutical manufacturers and hospitals regarding marketing and grant-making practices.
Ongoing	Pending legislation in various states that could require disclosure of financial relationships between pharmaceutical manufacturers and hospitals or physicians, including the amount, purpose, and terms of educational grants.

Further Information

This heightened attention suggests that, both as a matter of best practices and to withstand any focused regulatory scrutiny that might occur, companies and manufacturers that maintain grant programs must be certain to include strict eligibility standards coupled with clear assignments of responsibility, consistent procedures, careful ongoing oversight, and centralized on-line tracking of applications received and funds disbursed.

Similarly, hospitals and physician groups that receive funding from drug companies or device manufacturers should reconsider their own practices, to ensure compliance with current legal requirements, as well as evolving professional standards. For example, there should be careful adherence in all funded CME programs to ACCME standards, with full control over program content vested in the institution and its medical staff. "Unrestricted" research grants should be carefully scrutinized for anti-kickback concerns, and hospitals must remember that in most cases, unless strict criteria are met, unrestricted donations from suppliers must be taken as discounts on cost reports, rather than treated as charitable donations. Further, compensation amounts for sponsored research should be supported by a fair market value analysis of the activities being purchased.

Contact Information

Through its long-standing representation of large pharmaceutical companies, device manufacturers, hospitals, and academic medical centers, Ropes & Gray has developed significant experience in and sensitivity to the complexities that these issues raise for both medical centers and the pharmaceutical and medical device industry. For further information, please contact your Ropes & Gray lawyer or:

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