# FDA's Financial Disclosure Regulations: Careful Compliance in a Changing Landscape—Part II

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This two part series reviews US Food and Drug Administration (FDA) financial disclosure regulations set forth in 21 CFR Part 54. Part I, published in the November issue of *Regulatory Focus*, presented the general requirements of the FDA financial disclosure regulations and actions the agency may take. It also discussed the challenges many sponsors face in interpreting the regulatory requirements relating to "significant payments of other sorts", or SPOOS. This article delves further into SPOOS to investigators' institutions using the scenario of a knee study sponsor with an investigator who is a knee surgeon in a large institution's orthopedics department. It then reviews the three other types of financial arrangements covered by the regulations: outcome-dependent compensation, proprietary interests in the product and equity interests in the sponsor. The article also discusses the changing landscape within and outside FDA regarding transparency of financial interests, and concludes with proactive steps companies can take to help stay under the radar.

## SPOOS to the Investigator's Institution

***Training and Workshops***

Sponsors often provide monetary support to institutions for device training or workshops. These workshops might provide instruction on the study device, on other approved sponsor products or for other purposes. Payments might cover faculty honoraria, space rental and provision of cadavers, lab supplies or equipment. An investigator might serve as faculty or simply attend the program.

The sponsor does not have to track as SPOOS any compensation to the investigator's institution that supports the clinical trial,[1] such as surgeon training for the study device or lab equipment for the clinical study. However, the sponsor must track payments earmarked as faculty honoraria if the investigator is part of the program's faculty.[2]

The regulations and guidance do not indicate whether the sponsor should track payments to the institution if the investigator is a participant at a training session or workshop supported by the sponsor. In addition, it is unclear how much, if any, of the payment to the investigator's institution for training or workshops should be attributed to the investigator, particularly if the program involves large numbers of participants or faculty.

Considerations may include the number of faculty members, the nature of the investigator's role and the number of program attendees. The determination becomes more challenging if one method of allocation would bump the investigator from the "no financial interests" to the "disclosable financial interests" group, but another allocation method would not.

***Research Support***

Institutions frequently look to industry for research support. Sponsor accounting systems typically describe such payments simply as "research support." The sponsor must determine whether the payment was for "direct support of the investigator." As noted above, sometimes the sponsor can quickly rule out the payment because it covers research in a different specialty, such as mechanical testing in the foot and ankle field.

In another example, the funding covers research by the knee group but the records do not indicate how directly the investigator benefits. The sponsor should determine who performs the work under the contract, such as the investigator, other knee surgeons or a research assistant. If the research involves the investigator but the project budget allocates little or no money to the investigator, the sponsor must decide whether and how much of the project budget to allocate to the investigator as SPOOS.

***Educational Symposia, Continuing Medical Education (CME)***

Many sponsors provide educational grants to help support institutions' symposia or CME. An investigator might be a speaker or participant at one of these events. The sponsor may have no control over speaker selection and may be surprised to learn that an investigator is an honoree or speaker. Alternatively, a sponsor may earmark part of its grant as honoraria for faculty speakers, some of whom may be investigators.

The sponsor must track as SPOOS all payments earmarked for the investigator's presentation at a symposium, industry conference or CME. Should the sponsor track a payment if the investigator was a speaker but the sponsor was not aware of this when making the grant? If so, how much should the sponsor allocate to the investigator if the grant was general and did not contain a specific earmark for speakers? As with training and workshops, how should the sponsor handle the payment if the investigator attended the program? Considerations include the number of attendees, the nature of the program and the intended audience. As with other SPOOS payments, resolution often involves a judgment call by the sponsor.

Many sponsors, institutions and industry organizations have policies prohibiting sponsors or manufacturers from selecting content or speakers.[3] A documented practice of following these policies can make it easier for the sponsor to justify its decision of whether to track sponsorship of an industry conference or educational program as SPOOS.

***Charitable Donations***

Many hospitals host annual dinners or other charitable events to raise money. They typically look to industry for support. The dinners may honor members of the medical community. If supporting an event where the investigator is an honoree, the sponsor will need to consider whether and how to disclose part or all of its charitable donation. As with other potential SPOOS, there is no bright line rule. If the sponsor purchases tickets to the event and gives them to the investigators, the sponsor will need to track the payments as SPOOS.

***Endowments***

To attract top professors, many universities endow chairs or professorships. Funds often come from the university and from the community. The chair may honor a retiring professor or other prominent individual. Prior to contributing to an endowment, a sponsor should consider the financial disclosure ramifications if the endowed chair is named for an investigator or if an investigator might hold the endowed professorship down the road.

## Outcome-dependent Compensation, Proprietary Interests and Equity Interests

The three remaining types of disclosable interests—compensation affected by the outcome of clinical studies, proprietary interests in the device and equity interests in the sponsor—are arguably more insidious than SPOOS because the value of the investigator's financial interest has the potential to grow exponentially with the success of the clinical trial or of the company.

Lacking cash, early-stage companies commonly barter for services. These companies often compensate people with stock, royalties or interests in their products under development. In most industries, company founders receive company stock. Likewise, doctors who help develop a product or who serve on scientific advisory boards may receive company stock options, royalties or other incentives. A doctor who helped invent a product may own part of its intellectual property.

Motivation is another reason for compensation with stock, options or other interests in the company or in the product. In FDA's view, doctors who have these kinds of financial arrangements may have more of a vested interest in the company's success than doctors who receive cash compensation on a fair market value basis. Creating this motivation may not have been the intent of the sponsor when it initially provided the financial interest to a specific doctor. However, when that doctor later becomes an investigator, the sponsor will have a harder time denying that the potential for bias exists.

For example, product royalties become worthless if FDA denies approval or clearance of the product. The product, and any proprietary interest in it, will not be of much value if study results fail to support regulatory approval. Similarly, the value of an investigator's equity interest in the company will rise or fall with the success or failure of the study. If poor study results cause the company's value to crash, the investigator may be left with an equity interest that is worthless. This is especially true where there is no public market for the investigator's equity interest and, therefore, no readily available exit strategy.

Because good study results can boost the investigator's financial interests exponentially, these financial arrangements may raise FDA concern that the investigator may be tempted to influence the outcome of the trial data rather than to remain impartial. Rooting out this motivation is a primary purpose of the financial disclosure regulations.

The following is more detail on these three categories of financial disclosure.

***Compensation Affected by the Outcome of the Study***

Compensation affected by the outcome of clinical studies include stock, stock options, other equity interests in the sponsor, royalties from product sales and other compensation tied to sales of the product being studied.[4]

When disclosing compensation in this category to FDA, sponsors should take care to review all arrangements with their investigators, including contracts not related to the clinical trial of the product. For example, sponsors often have consulting or product development agreements with physicians who eventually become investigators. These preclinical agreements may

provide the investigator with royalties tied to product sales, company stock or stock options.

***Proprietary Interest in the Tested Product***

A sponsor must disclose all proprietary interests that its investigators have in the product being tested, including patents, trademarks, copyrights and licensing agreements.[5]

To determine who has proprietary interests in the product, sponsors need to review contracts relating to intellectual property. These contracts typically are signed before the clinical trial in circumstances unrelated to the trial. The contracts may include employment, independent contractor, consulting and licensing agreements. While at many companies, one person has an institutional memory of these arrangements, as a company grows, it becomes increasingly important to keep track centrally of the intellectual property rights in the company's products.

***Significant Equity Interest in the Sponsor of a Covered Study***

Broadly speaking, the requirement to disclose significant equity interests in the sponsor addresses public and private stock differently. Public companies must disclose equity interests of investigators who own more than $50,000 of publicly traded company stock. Sponsors must also disclose all investigator ownership interests, stock options and other financial interests whose value cannot be readily determined through reference to public prices. While these will generally be interests in non-publicly traded corporations,[6] a public corporation may have private financing arrangements that fall into this category.

The sponsor should describe the specific details of the financial interest, including size and nature.[7] Even if the value of the investigator's' stock or stock options is negative, these interests must be disclosed to FDA.

## Changing Landscape

Financial conflicts of interest make the news almost every day. This section highlights recent activity in this area, ranging from federal and state governments to industry to academia. As reflected below, transparency, particularly relating to financial conflicts of interest, has become a common buzzword across the spectrum.

The consequences of failing to properly disclose investigator financial interests in the sponsor can go beyond penalties such as an FDA audit or rejection of the study data. Federal and state governments, trade associations, manufacturers, academia and medical journals are among those weighing in on ties between physicians and industry. At least partly in response to this pressure, FDA began increasing its attention to financial disclosure and is more likely to do so after receiving a so-called "Grassley letter," which was released after the first article in this series went to press.[8] A prudent company will recognize the likelihood of stricter FDA scrutiny of its financial disclosures and take a conservative approach.

***OIG, Senator Grassley and FDA***

**OIG**

In January 2009, the Department of Health and Human Services Office of Inspector General (OIG) issued a report criticizing FDA's oversight of financial disclosure for clinical investigators.[9] The report contains five findings: (1) 1% of clinical investigators disclosed a financial interest, (2) FDA cannot determine whether sponsors have submitted financial information for all clinical investigators because it does not maintain a complete list of the investigators, (3) 42% of FDA-approved marketing applications were missing financial information, (4) FDA did not document a review of any financial information for 31% of marketing applications, and (5) in 20% of the marketing applications with disclosed financial interests where the sponsor did not indicate that it had minimized potential bias during the clinical trials, FDA did not take any action, such as conducting its own analysis to identify potential bias or requesting additional analysis from the sponsor.[10]

In response to these findings, the OIG report recommends that FDA ensure sponsors have submitted complete financial information for all clinical investigators; FDA reviewers consistently review financial information and take action in response to disclosed financial interests; and sponsors submit financial information for investigators as part of the pretrial application process. FDA agreed with the first two recommendations but not the third one.[11]

In response to OIG's first recommendation, the OIG report indicates that FDA is considering requiring sponsors to provide a table listing all clinical investigators and indicating whether a certification form, a disclosure form or the due diligence exemption is provided. In addition, FDA may provide additional advice on the use of the due diligence exemption. Further, FDA indicated that its on-site inspection protocol has been updated to include a closer inspection of financial information.[12]

At a subsequent industry conference, an FDA official indicated that the agency is working on several new guidance documents, including financial disclosures for clinical investigators in response to the OIG study.[13]

A recent FDA outside panel review of a device marketing application was unusual in that it raised questions about whether the sponsor's payments to the trial sites may have influenced the trial results. According to this review, more than half of the patients in the trial were treated at 10 medical centers that received more than $100,000 in payments from the sponsor. Five of those sites received more than $500,000, and 20% of the patients in the study's investigational

arm were treated at two sites that each received almost $1.5 million.

In materials released prior to the panel meeting, FDA raised questions about potential investigator bias due to financial arrangements with the sponsor, but did not raise the financial ties issue during its presentation to the panel or include the matter is its questions to the panel. The panel voted to recommend against FDA approval of the device. Subsequently discussing the vote, FDA said as part of product reviews, companies should expect more scrutiny of financial payments, citing interest from Congress in ties between investigators and manufacturers.[14]

In transparency initiatives unrelated to the financial disclosure regulations, FDA created a transparency task force in June 2009 to provide more information about its operations and decision-making processes to the public.[15] In March 2010, FDA issued new draft guidance regarding financial ties to industry for members of FDA advisory panels.[16] While these initiatives are not related to the financial disclosure regulations, they reflect a transparency agenda for FDA.

**Senator Grassley Letter to FDA**

While comments by FDA after the OIG report suggest that FDA may increase its attention to financial interests, an October 2010 letter to FDA from Senator Grassley adds significant fuel to the fire. Senator Grassley has a long-standing record of investigations into physician-industry financial ties, and his letter to FDA remarks that the FDA regulations do not address how FDA should handle conflicts presented by investigator financial interests. The letter seeks FDA's response to the following questions: (1) how does FDA determine if the disclosed financial interests adversely affect the rights and welfare of the trial subjects and/or the reliability and integrity of the trial results? (2) should certain types of financial interests bar an individual from being a study investigator? and (3) does FDA advise companies how to minimize potential bias posed by financial interests, and does FDA expect manufacturers to take certain actions to manage potential conflicts of interest? FDA's response to this letter was due after this article went to press.[17]

***Congress***

In addition to his recent letter to FDA ,[18] Senator Grassley has sent letters to medical groups,[19] educational institutions,[20] manufacturers,[21] NIH[22] and others seeking to increase transparency of funding sources. As part of this transparency effort, Senator Grassley has also requested policies on ghostwriting from medical schools, medical journals and pharmaceutical companies,[23] and issued a Senate report (July 2010 Senate Report) focusing on medical ghostwriting.[24] Ghostwriting is the practice wherein drug and device companies have influential doctors sign on as authors for scientific journal articles that the companies paid third-party medical education companies to write. For ghostwritten articles, the journal does not disclose the company's role and financial support for the article.

In terms of legislation, Senator Grassley was co-author with US Senator Herb Kohl (D-WI) of the *Physician Payment Sunshine Act*, first introduced in 2007.[25] The recent healthcare reform legislation, signed into law on 23 March 2010,[26] contains "physician payment sunshine" provisions designed to promote transparency of payments by industry to physicians. These transparency provisions require disclosure of certain payments or other transfers of value by applicable manufacturers to physicians and teaching hospitals, and are derived from the *Physician Payment Sunshine Act*.

***State Governments***

New Jersey has been on the forefront of state action relating to physician-industry ties. The New Jersey attorney general launched a series of investigations into financial ties between manufacturers and the investigators conducting their clinical trials.[27]

In December 2009, a task force appointed by the attorney general issued a report recommending that the state adopt regulations governing financial relationships between doctors and the device and drug industries.

In addition to New Jersey, California, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia have conflict of interest and/or disclosure rules for drug and device manufacturers. However, if the New Jersey report is enacted into legislation, the state would be the first to impose the requirements directly on its physicians.[28]

***Industry***

**Associations**

The Institute of Medicine released a report last year recommending new regulations and voluntary practices to increase disclosure of physicians' and scientists' relationships with device and pharmaceutical companies.[29] In 2008, the Association of American Medical Colleges and the Association of American Universities issued a joint report with guidelines on conflicts of interest for all medical schools and major research universities.[30]

The Pharmaceutical Manufacturers Research Association of America (PhRMA) has new guidelines on conducting clinical trials. Effective 1 October 2009, these guidelines prohibit: tying compensation to the outcome of clinical trials; clinical investigators or their immediate family from having a direct ownership interest in the study drug; and investigators and institutions from being compensated in company stock or stock options for clinical trials work.[31] The Advanced Medical Technology Association (AdvaMed) updated its code of ethics for the device industry effective 1 July 2009.[32] The

updated AdvaMed code addresses topics beyond clinical trials, and further clarifies appropriate and inappropriate activity between health care professionals and AdvaMed member companies.

**Manufacturers**

Large companies are voluntarily announcing efforts to increase transparency of their payments to doctors. GlaxoSmithKline,[33] Merck,[34] Eli Lilly,[35] Pfizer,[36] Medtronic,[37] and Johnson & Johnson[38] are among the companies that disclose certain payments to physicians and other healthcare professionals on their websites. In early 2010, Cephalon became the first company to disclose physician payments for consulting and speaking services under a corporate integrity agreement.[39]

*Academia*

Large research centers such as Cleveland Clinic, Stanford University School of Medicine,[40] and Partners HealthCare[41] and Harvard Medical School[42] have adopted or revised policies in order to increase disclosure of relationships between their doctors and scientists and industry.

Institutional review boards (IRBs) are also under pressure. A recent study concluded that many academic institutions lack clear policies governing conflicts of interest for their IRB members.[43]

Continuing medical education is also attracting attention.[44] Universities such as Stanford have banned industry-directed funding of CME programs.[45] Early this year, Pfizer provided a $3 million grant to Stanford to develop a new continuing education program. Drawing some skeptical responses, the grant reportedly has no strings attached, and Pfizer will have no say in the content of the program.[46]

*Medical Journals*

In October 2009, the International Committee of Medical Journal Editors released a new form for investigators to disclose potential conflicts of interest. This form reflects an effort to standardize what researchers report to medical journals, as the current journal disclosure requirements vary.[47] Ghostwriting is another issue under attack by transparency proponents.[48] The July 2010 Senate Report found that while journals recently have strengthened their authorship and publication requirements, the prevalence of ghostwriting has not changed substantially in the past ten years.[49] The new PhRMA guidelines also largely ban ghostwriting.

## Conclusion

To comply with FDA financial disclosure regulations, companies should take a conservative approach. Well before their clinical trials, companies should consider what types of financial ties they want to establish with physicians or institutions that may eventually be involved in their trials.

Before companies are ready to conduct clinical trials, they can take proactive steps such as keeping SPOOS payments below the $25,000 threshold and having their consulting agreements end well before the commencement of a clinical trial. Where feasible, companies should compensate physician advisors and consultants on a fair market value for services basis, rather than with stock or stock options. When setting up advisory boards or consulting arrangements, companies should exclude some physicians who could later serve as investigators and should populate the boards with a sufficient number of independent members who have no other financial ties to the company.

At the clinical trials stage, prudent sponsors will set up their clinical trials with a sufficient number of non-interested investigators and research sites. Sponsors should also design their trials in a manner that minimizes the potential for bias.[50] Measures might include, for example, the use of an independent clinical events committee or the use of objective measures as part of the primary study endpoint.

Other practical measures include early establishment of internal systems, such as appropriate standard operating procedures and technology solutions to track financial arrangements and intellectual property ownership. As the company grows, the reporting task becomes more complex. It is becoming increasingly important to have a system in place to track these financial arrangements, not only for FDA regulatory purposes, but also for compliance with the recent federal transparency requirements as well as state laws, association and institutional conflict of interest policies and journal requirements.

While mid-size to large companies may be more obvious targets for an FDA or other investigation into financial ties with their investigators, small companies should think ahead. Transparency is now a buzzword, and large companies will be wary of purchasing small companies that do not have their financial disclosure house in order.

Sponsors should expect more scrutiny of their financial disclosures by FDA and should review FDA's forthcoming response to Senator Grassley's letter for indications of potential changes. It is also important for companies to familiarize themselves with the new federal transparency requirements and to stay up to date on the growing patchwork of other statutes, regulations, policies and requirements unrelated to the FDA regulations. Sponsors should keep careful records of their financial and other relationships with physicians and other key players in their clinical trials, as these relationships may have more far-reaching consequences both within and outside FDA than many sponsors anticipate.

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