



The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research

A White Paper

by

The Center for
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& Policy

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INTRODUCTION

Financial relationships between the pharmaceutical and medical device industries and health care professionals and institutions have led to concern about commercial influences on medical practice, research, publication, and education.¹ Congressional investigations, prosecutions, press reports, and published studies have generated public awareness of the pervasive nature of these relationships.² Along with other dimensions of professional activity, public inquiry has focused sharply on the implications of conflicts of interest in clinical research for both the safety and welfare of research participants and the integrity of research results.³

A common response to the problem of conflicts of interest in clinical research has been to urge greater transparency about the relationships among industry, researchers, and academic medical institutions.⁴ In this White Paper, we argue that public policy should encourage researchers and institutions to make information about their financial relationships with industry available to the public, but—contrary to many other commentators’ recommendations—we conclude that disclosure of financial information should not routinely be required as part of the informed consent process. While we recognize the importance of transparency as an ethical value, incorporating financial issues into the informed consent process would provide few, if any benefits to research participants and could in fact cause significant harms. This White Paper also reiterates our prior recommendations for direct measures to eliminate, reduce, and manage problematic financial relationships in clinical research.

Financial Relationships in Clinical Research

Before 1980, the National Institutes of Health (NIH) funded most clinical trials. While NIH remains the single largest source of federal funding, between 2003 and 2007 NIH funding for biomedical research declined 8.6% when adjusted for inflation.⁵ Total federal funding for biomedical research increased during that period, but by less than 1%.⁶ By contrast, industry funding of medical research increased by 25% between 2003 and 2007.⁷ Today, pharmaceutical and medical device companies fund nearly 80% more clinical trials than NIH.⁸

Various financial arrangements between industry and investigators or research institutions are possible. Often, pharmaceutical and medical device companies pay investigators or their employers a per capita fee for each participant enrolled in a study.⁹ In academic medicine, payments for conducting clinical trials are made to the investigator’s department or institution. While there is typically no direct relationship between the number of participants enrolled and an academic investigator’s salary, physicians in academic medicine may find that, over time, their compensation reflects their overall success in obtaining clinical research funding for their institutions.¹⁰ Moreover, academic physicians have other incentives to conduct externally-funded research, including the potential for future funding, as well as publication of the results in the medical literature, a requirement for tenure and promotion.¹¹

In contrast to academic physicians, physicians in private practice are generally paid directly for conducting clinical research.¹² Compensation for clinical research can be a substantial part of a physician practice’s income, prompting some physicians to attend seminars on how to make money in clinical research.¹³

In some cases, research sponsors may pay so-called “finder’s fees” to individuals other than the investigator—including other physicians, nurses, medical students, or persons already enrolled in a trial—for identifying and referring potential study participants.¹⁴ Although find-

er's fees have been called unethical¹⁵ and at least one company represents that it has stopped using them,¹⁶ a 2006 survey of 300 clinical research coordinators revealed that nearly a third had worked in studies in which fnder's fees were paid.¹⁷ In our previous White Paper, *Conflicts of Interest in Clinical Trial Recruitment & Enrollment: A Call for Increased Oversight*, we recommended that the Department of Health and Human Services (DHHS) prohibit fnder's fees.¹⁸

Drug and device companies that sponsor research may also pay investigators bonuses for meeting certain benchmarks in recruiting or retaining research subjects in a trial.¹⁹ As we observed in our previous White Paper, such bonus payments "could influence investigators' decisions about prospective participants' initial or continuing eligibility, thereby potentially placing enrollees at risk or undermining the scientific integrity of the study."²⁰

Equity interests in the sponsoring company, which give physicians and research institutions a direct stake in the outcome of the research, are a highly controversial form of payment. Recent prosecutions have brought to light several such compensation arrangements.²¹ In our previous White Paper, we recommended that the federal government prohibit compensation for research in the form of equity interests in the sponsor of a clinical trial.²²

An increasingly common situation is when an investigator who owns the patent for the device or substance being tested, and/or the investigator's institutional employer, separately incorporates a for-profit subsidiary that owns and will develop the patent for commercial use, and in which the investigator and/or the institution holds significant equity interests. This for-profit subsidiary often brings in a large medical device or pharmaceutical company as an additional investor or joint venture partner as the invention comes closer to the clinical trial and market development stage, which may be another source of financial benefit to the investigator and institution. Once the product reaches the stage of Phase I trials, the subsidiary will seek relationships with one or more medical centers to host the trials, potentially including the institution with the equity stake. As we observed in our prior White Paper, this scenario is analytically comparable to compensation with an equity interest in the sponsor, and should preclude the patent holder or investor from serving as an investigator.²³

In addition to payments directly related to research, physician-investigators may receive money for consulting, speakers bureau and advisory board participation, and other activities.²⁴ These payments may influence physicians' decisions about prescribing,²⁵ the opinions they offer in the context of continuing medical education,²⁶ and the study results they report.²⁷

Finally, as highlighted by prominent prosecutions, companies sometimes design "trials" for products that are already on the market that are little more than guises for growing a new consumer base.²⁸ One such study enrolled 5,557 individuals in a head-to-head clinical trial of Vioxx and naproxen, with the stated purpose of evaluating Vioxx's gastrointestinal tolerability.²⁹ In fact, the trial was designed by the marketing department of Vioxx's manufacturer to familiarize primary care prescribers with the benefits of the drug.³⁰ When companies misleadingly characterize efforts to promote a new product as "scientific research," they deceive both physicians and the patients they recruit, thereby threatening to undermine the research enterprise as a whole. While anecdotal evidence suggests this practice is now less common in the pharmaceutical sector, it is unclear if it has been eliminated entirely, and whether it persists in the medical device context.

In sum, compensation arrangements between industry and physicians who oversee clinical trials raise conflict of interest issues that could expose participants to unacceptable risks, undermine the public's confidence in such trials, and affect the integrity of the research results. The shift of clinical trials from academic medical centers to the private practice setting, where trials are pursued as alternative revenue streams, exacerbates these dangers.

Disclosure of Financial Relationships: Existing Law and Guidance

A common response to the problem of conflicts of interest in clinical research has been to urge greater transparency about the relationships among industry, researchers, and research institutions. Calls for transparency have taken multiple forms, including mandated disclosure of the relationships to the government, to the researcher's academic home, to the public (often via company websites),³¹ or to individual trial participants as part of the process of informed consent.³² In this section, we summarize existing law and guidance on disclosure of financial interests in clinical research. In the remainder of this White Paper, we explain why we support public disclosure of conflicts of interest but oppose incorporating discussions about conflicts of interest into the process of informed consent. We also reaffirm our earlier conclusion that disclosure should not be seen as a panacea for conflicts of interest in clinical research. In itself, disclosure is likely to have only a minimal impact on the problems associated with conflicts of interest and must therefore be accompanied by direct regulation of the problematic financial relationships themselves.

1. Existing Law

Clinical trials of drugs and medical devices are regulated by the Food & Drug Administration (FDA), which has adopted conflict of interest regulations to ensure that steps are “taken in the design, conduct, reporting, and analysis of [clinical trials] to minimize bias.”³³ The FDA requires that sponsors submitting marketing applications for drugs and devices provide a list of the investigators who worked on “covered clinical studies,” as well as their financial interests, as defined by the FDA.³⁴ The FDA regulations require sponsors to disclose to the FDA the following financial interests: (1) financial arrangements where the value of the compensation could be influenced by the outcome of the clinical trial; (2) “significant payments of other sorts,” such as consulting or speaking fees, in excess of \$25,000 from the sponsor to the investigator; (3) any proprietary interest, such as a patent or trademark, in the tested product; and (4) any “significant equity interest in the sponsor,” defined to include equity in excess of \$50,000 in a publicly-traded corporation or any equity in an entity that is not readily valued by reference to public prices.³⁵ Notably, payments to cover “the costs of conducting the clinical study or other clinical studies” are expressly excluded from the definition of “significant payments of other sorts.”³⁶

In addition to disclosing information about financial ties, the FDA also requires research sponsors to report steps taken to minimize the potential for bias.³⁷ If an investigator's disclosure raises data integrity questions, the FDA may audit the investigator's data, require further analyses or studies, or decline to credit the entire study's results.³⁸ The FDA's conflict of interest regulations do not require or suggest disclosure to prospective participants of investigators' financial relationships with industry.

Researchers' compliance with these regulations is deficient. In a 2009 report, the DHHS Office of Inspector General (OIG) found that only 1% of clinical investigators disclosed any financial interest to the FDA, and that 42% of FDA-approved marketing applications were

missing financial information.³⁹ Even when financial information was disclosed, the FDA frequently did not document any review of it.⁴⁰ The OIG recommended that the FDA require sponsors to submit financial information for clinical investigators before clinical trials commence, which is not currently required, and again at the time a marketing application is filed. The OIG also recommended that the FDA take steps to ensure that sponsors submit complete financial information for all clinical investigators, and that reviewers consistently review financial information and take action in response to disclosed financial interests.⁴¹

In addition to the FDA regulations, DHHS has adopted regulations designed to promote objectivity in research funded by the Public Health Service (PHS). These regulations require institutions to maintain and enforce a written policy that reduces or eliminates financial conflicts of interest.⁴² Policies must include provisions for monitoring and reporting of all significant financial interests of any investigator involved in PHS-funded research.⁴³ Significant financial interests are defined to include, but are not limited to, salary, royalties, or other payments in excess of \$10,000, equity interests in excess of \$10,000 or that represent more than a 5% ownership interest in a single entity, and intellectual property rights such as patents and copyrights.⁴⁴ However, investigators must report only significant financial interests that “would reasonably appear to be affected by the research for which PHS funding is sought.”⁴⁵ A 2009 report by the DHHS Office of Inspector General found that 90% of grantee institutions “rely solely on researchers’ discretion to determine which of their significant financial interests are related to their research and are therefore required to be reported.”⁴⁶

Earlier this year, DHHS sought comments on proposed amendments to these regulations. The amendments would lower the threshold for a “significant financial interest” from \$10,000 to \$5,000⁴⁷ and would shift the onus of deciding whether a significant financial interest is related to PHS-funded research from the investigator to the institution itself.⁴⁸ Furthermore, in an effort to foster transparency, the proposed revisions would require institutions to post their compliance policies, as well as any known significant financial conflicts of interest of principal or key investigators, on a publicly available web site.⁴⁹

The recent health reform legislation, The Patient Protection and Affordable Care Act (PPACA), requires that, every 90 days beginning on March 31, 2013, pharmaceutical and medical device manufacturers notify the federal government of payments or “transfer[s] of value” made to physicians and teaching hospitals, including “stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment,” as well as “the name of the covered drug, device, biological, or medical supply” to which the payment is related.⁵⁰ The law requires the government to establish a searchable public web site with this information. Importantly, however, publication of payments or transfers of value that relate to “a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply,” or in connection with a clinical trial, shall be suppressed until the manufacturer obtains FDA approval of the product or four years following the date of the compensation.⁵¹

At least six states – California, Maine, Massachusetts, Minnesota, Vermont, and West Virginia – as well as the District of Columbia, have passed laws requiring disclosure of financial relationships between drug and device companies and physicians to an appropriate state agency.⁵² Massachusetts, Minnesota and Vermont require disclosure to the public as well.⁵³ However, when the reporting requirements under PPACA take effect, they will preempt state laws that require redundant reporting.⁵⁴

Most of these states' reporting laws do not require disclosure to research participants of an investigator's or institution's compensation for research, financial interests in the outcome of clinical trials, or other financial relationships between the sponsor and the investigator or institution. One exception is California, where the informed consent law expressly requires disclosure "both verbally and within the written consent form, in nontechnical terms," of "[t]he material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment."⁵⁵ The California law defines "material" as "ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned."⁵⁶ However, these requirements do not apply to research that is subject to DHHS' regulations on the protection of human research participants.⁵⁷

A more recent New Jersey statute covering medical research involving "persons with cognitive impairments, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases"⁵⁸ requires prospective research participants (or their guardians or authorized representatives) to be informed of "the material financial stake or interest, if any, that the investigator or research institution has in the research."⁵⁹ As in California, New Jersey defines "material" as "\$10,000 or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned or as otherwise determined by the research institution."⁶⁰ In addition, for the population of participants identified in the statute, New Jersey requires disclosure of "the name of the sponsor or funding source, if any, or manufacturer if the research involves a drug or device, and the organization, if any, under whose general aegis the research is being conducted."⁶¹

2. Other Guidance

In 2001, the Association of American Medical Colleges (AAMC) proposed that financial conflicts of interest be disclosed in the informed consent forms signed by research participants, stating, "[t]he precise wording of disclosure in the consent form should be determined by the IRB, but should include an explanation of the fact that the financial interest in question has been reviewed by the COI committee, approved subject to committee oversight, and determined by both the committee and the IRB not to pose any additional significant risk to the welfare of research subjects or to the integrity of the research."⁶² In 2008, the AAMC-Association of American Universities (AAU) Advisory Committee on Financial Conflicts of Interest in Human Subjects Research recommended that investigators report "all of their outside financial interests," no matter how small, as long as they were "directly or indirectly related to their professional responsibility to the institution."⁶³ This was a departure from the 2001 AAMC recommendations, pursuant to which investigators were instructed to report only their financial interests that were "significant" and "would reasonably appear to be affected by [their] research."⁶⁴

Various medical associations have also opined on disclosure of financial incentives to research participants and patients. For example, the American Medical Association (AMA) has stated that the "nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process."⁶⁵ Similarly, the American College of Physicians' ethics manual states that "[p]hysicians must disclose their financial interests in any medical facilities or office-based research to which they refer or recruit patients."⁶⁶

In addition, the trade association for pharmaceutical companies, the Pharmaceutical Research and Manufacturers of America (PhRMA), has revised its Principles on the Conduct of Clinical Trials to recommend that “[c]linical investigators should disclose to potential research participants during the informed consent process that the investigator and/or the institution is receiving payment for the conduct of the clinical trial.”⁶⁷ Like other codes that commend conflict disclosure, PhRMA’s recommendations require only disclosure of the existence of compensation, with no requirement of quantification.

The Institute of Medicine (IOM) Committee on Conflict of Interest in Medical Research, Education, and Practice’s 2009 report observes that public disclosures of conflicts of interest are beneficial if they lead physicians to avoid situations that could potentially compromise their professional independence, but that transparency can be harmful if researchers react by avoiding relationships “that promote important societal goals and that are accompanied by adequate measures to protect objective judgment.”⁶⁸ The IOM report calls on researchers to report all information potentially giving rise to conflicts of interest to a variety of entities, including their academic homes, and supports a requirement for companies to disclose their relationships with physicians and researchers on a public website (essentially the requirement adopted in PPACA).⁶⁹ A minority of the IOM Committee members would have gone further, proposing that academic physicians and researchers be required to publicly disclose their industry relationships via a website.⁷⁰ The majority of the Committee members opposed this obligation as redundant of company reporting requirements, invasive of researchers’ privacy, unnecessarily costly, and unfairly singling out principal investigators in academic settings.⁷¹ The IOM’s recommendations emphasized that “disclosure of individual and institutional financial relationships is a critical but limited first step in the process of identifying and responding to conflicts of interest.”⁷²

At the international level, the Declaration of Helsinki, issued by the World Medical Association, requires that the “sources of funding, any possible conflicts of interest, [and] institutional affiliations of the researcher” be disclosed to all potential participants in human research.⁷³ The Council for International Organizations of Medical Sciences (CIOMS), an international, non-governmental, non-profit organization representing the biomedical scientific community, recommends that “[b]efore requesting an individual’s consent to participate in research, the investigator must provide [information regarding]... the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research[.]”⁷⁴

THE INTENDED GOALS OF DISCLOSURE

Scholars, professional organizations, and policy institutes have advanced various justifications and goals for requiring disclosure of financial interests by investigators and research institutions. Briefly, these goals include the following:

Respecting Participants' Right to Know

The “right to know” is premised on the idea that there are certain kinds of information to which a person is morally entitled, based on the individual’s status as an autonomous moral agent. A core argument for requiring researchers to disclose their conflicts of interest is that, because research participants are the ones who will be exposed to the risks of the research, they have a moral right to know how the investigator and research institution stand to benefit from the trial.⁷⁵ As some respondents to a recent survey put it, participants “might feel morally wronged” if they learned of an investigator’s financial relationships in a study “after the fact.”⁷⁶

Establishing and Maintaining Trust in Physicians⁷⁷ and Clinical Research⁷⁸

A 2003 article on conflicts of interest in research observed that “there is virtual unanimity that the ultimate goal of reform is to promote public trust in the human research enterprise.”⁷⁹ This notion of public trust is reflected in almost every statement addressing conflicts of interest in clinical research. For example, in their 2008 report, the AAMC and AAU stressed that a central goal of conflict management strategies is to promote public trust in research.⁸⁰ Additionally, the AAMC in a separate report stated that its recommendations sought to maintain public trust in order to “retain the confidence of those who generously volunteer to participate in research.”⁸¹

Protecting the Integrity of Clinical Research Results

A significant concern about conflicts of interest is their potential to undermine the reliability of research data. Many calls for disclosure reflect these concerns. For example, in recommending disclosure of researchers’ financial interests, the AAMC emphasized that disclosures should be structured to avoid “any additional significant risk to... the integrity of the research.”⁸²

Deterring Troubling Financial Relationships

In some contexts, the ultimate goal of mandating disclosure is to change the discloser’s behavior.⁸³ It has been suggested that divulging investigators’ financial relationships will create pressure on researchers to eliminate “unproductive” conflicts.⁸⁴ This expectation “assumes that investigators dislike having to disclose their financial interests in clinical trials and will avoid relationships that might suggest a conflict of interest.”⁸⁵

Dispelling the Therapeutic Misconception

The “therapeutic misconception” refers to the mistaken belief that decisions about the type of interventions given to research participants are based primarily on an individualized

assessment of each participant's therapeutic needs, just as treatment decisions would be made for patients receiving care outside of a study.⁸⁶ The therapeutic misconception is widespread among both research participants and even many physician-investigators.⁸⁷ Some proponents of disclosure argue that highlighting the financial relationship between investigators and sponsors will alert prospective subjects to the fact that the primary goal of the study is to develop scientific knowledge, rather than to advance the medical best interests of the individual participants.⁸⁸

Protecting Research Participants' Welfare

It is possible that studies in which investigators or research institutions have financial conflicts of interest may pose greater risks of injury to participants than studies without such conflicts. If conflicts do in fact increase risks, requiring disclosure could protect individuals by making prospective participants more wary of enrolling, or by discouraging investigators and institutions from entering into the troubling arrangements in the first place.⁸⁹

This was essentially the argument made in the lawsuit brought by the father of Jesse Gelsinger, an 18-year old with ornithine transcarbamylase deficiency who died as a result of his participation in a Phase I gene transfer study at the University of Pennsylvania. The lawsuit against the University and investigators alleged that the investigators committed fraud by not revealing that an investigator, the University, and other officials had financial relationships with Genovo, the biotechnology company that would take the gene vectors being studied to market in the event of a successful trial.⁹⁰ Jesse's father learned that the "principal investigator, James Wilson, owned stock in... [the] company [he had] founded, which contributed \$4 million per year to human gene therapy research at the University... where the experiment took place," and claimed that had Jesse known about these financial interests, "he would not have agreed to take part in the research study."⁹¹ The suit ended in a confidential settlement in 2000, six weeks after it was filed. In 2005, the University of Pennsylvania and Children's National Medical Center agreed to pay over \$1 million in a False Claims Act settlement with the federal government to resolve allegations that the institutions failed to disclose necessary information and misled the government about the benefits of the treatment (the three physician-investigators—including Wilson—were also parties to the settlement).⁹²

THE LIMITS OF DISCLOSURE AS A RESPONSE TO CONFLICTS OF INTEREST IN RESEARCH

In our previous White Paper, *Drug and Device Promotion: Charting a Course for Policy Reform*, we concluded that conflicts of interest created significant risks to the integrity of the physician-patient relationship, medical education, and clinical research.⁹³ We proposed a variety of policy reforms to address these concerns, including banning industry-provided gifts, meals, and other perks to physicians; establishing clear guidelines for disseminating publications on off-label use of products; and creating new limits on industry funding of continuing medical education.⁹⁴

In that White Paper, we stressed the importance of increased transparency in industry-physician relationships.⁹⁵ While our primary focus was on public disclosure requirements, such as those contained in the recently-enacted health reform legislation,⁹⁶ we also suggested that financial support from industry should routinely be disclosed to participants in clinical trials as part of the informed consent process.⁹⁷ Based on further research and reflection, however, we have become increasingly skeptical that disclosure is likely to provide significant protections to research participants or the integrity of research. This skepticism has not led us to change our basic position on the need for transparency, but it has led us to reconsider our conclusion that discussions about financial relationships should be routinely incorporated into the process of informed consent. Rather than burdening the already dysfunctional informed consent process with mandatory disclosures that are unlikely to achieve most of their sought-after benefits, we propose that financial relationships in clinical research be disclosed under a system modeled on transparency initiatives undertaken in other areas of health and consumer affairs. We also reiterate our call for direct measures to eliminate, reduce, and manage conflicts of interest in research, as outlined in our White Paper, *Conflicts of Interest in Clinical Trial Recruitment & Enrollment: A Call for Increased Oversight*.

In this section, we revisit the goals of disclosure discussed in the previous section. We conclude that disclosure would promote participants' moral "right to know," but that it is unlikely to achieve most of the other sought-after benefits. In the next section, we explain why disclosure of conflicts of interest should not routinely be included in the process of obtaining informed consent from research participants.

The Right to Know

Empirical evidence of research participants' desire for information about financial relationships demonstrates that financial incentives matter to some potential research subjects. One study, consisting of in-person interviews of 253 participants in cancer-research trials, revealed that a large minority—40%—wanted to be informed about the oversight system for investigator financial conflicts of interest, and nearly a third wanted to be told about investigators' financial interests, regardless of the monetary value.⁹⁸ Another study surveying 259 participants in six clinical trials for non-acute conditions conducted at Royal Melbourne Hospital in Australia found that 57% wanted to be informed about the sponsor of the clinical trial and 34% wanted to know how much funding was accrued at study completion.⁹⁹ A third study consisting of 16 focus groups conducted in 2004 and 2005 similarly found that many participants wanted to know about financial interests in research, even those who did not think it would make a difference in their decision to enroll in a study.¹⁰⁰

In a qualitative study of 33 individuals with serious, life-threatening, or chronic conditions who had participated in NIH studies for extensive periods of time, most respondents wanted to be informed about physician financial interests.¹⁰¹ They thought that prospective participants should be informed about investigators' financial interests, but only a few said that they would want the full details. Similarly, a survey of over 5,000 individuals with chronic conditions who had indicated a willingness to participate in clinical trials revealed that most respondents wanted to be informed about potential conflicts of interest, even though only a minority (ranging from a low of 2% to a high of 32% depending the nature of the hypothetical financial tie) would actually decline to participate due to a perceived conflict.¹⁰² In both of these studies, the individuals who wanted information about financial relationships tended to be more highly educated.¹⁰³

While a subset of research participants is clearly interested in receiving information about financial incentives, it does not appear that the information is likely to affect many individuals' ultimate decision to participate.¹⁰⁴ In one study, for example, the authors surveyed a random sample of 470 adults diagnosed with coronary artery disease.¹⁰⁵ All respondents were presented with an informed consent document for a hypothetical clinical trial evaluating a new medication to treat their disease. For one group, the informed consent document provided no information about investigator financial ties. For a second group, the document stated that the investigator received a per capita payment that covered the costs of research, including the investigator's salary. For the third group, the document stated that the investigator was an investor in the company sponsoring the research. The informed consent documents shown to the second and third groups stated that an IRB and another committee had reviewed the financial interest and did not believe that it would affect the safety or scientific quality of the trial. They were also told that more information was available on request. The authors found that per capita payments had no effect on participants' willingness to enroll, although they did find that an equity holding by the investigator significantly decreased willingness.

Similarly, a 2006 survey study of 297 undergraduates found that various investigator conflicts of interest did not have a statistically significant effect on the students' willingness to participate in a hypothetical clinical trial.¹⁰⁶ The survey respondents were asked the importance of: (1) an investigator employed by the sponsor; (2) an investigator employed by the sponsor and paid a fee for each participant who completed the study; and (3) an investigator who developed the product under investigation and would receive royalty payments from all potential sales.¹⁰⁷ None of the three conflicts of interest affected the students' willingness to participate.¹⁰⁸

Whether disclosure of information is likely to affect an individual's decision may depend on whether the individual believes she has options or alternatives.¹⁰⁹ The importance of genuine choice cannot be understated: "the value of information nearly always depends on the potential for someone to act on it. Although creating a naked 'right to know' can be seductive in the heat of politics, lasting benefit from disclosure generally requires the availability of choice through entry and exit, ongoing control, political voice, or other forms of self-help through legal or extralegal mechanisms."¹¹⁰ In the financial context, for example, a would-be investor, once provided with information about an advisor's relationship with a company whose stock she is recommending, is likely to understand that he can choose not to invest at all or invest in something else.¹¹¹ Prospective participants in clinical trials, by contrast, often do not believe they have realistic alternatives outside the study. For some prospective participants, clinical trials offer the last hope when all other treatments have failed. Although it may be possible for these individuals to obtain investigational treatment outside of a study, either by obtaining an

off-label prescription (if the drug is already approved for another indication)¹¹² or by seeking a compassionate use exemption for an unapproved drug,¹¹³ many individuals do not have the knowledge, access, or resources to pursue these alternatives. And, even if alternative treatments are theoretically available outside the trial, patients who are uninsured or underinsured may not realistically have access to them. When the patient believes that enrolling in a clinical trial is the only viable option, mandated transparency does not improve choice.

Establishing and Maintaining Trust in Physicians and Clinical Research

The argument that disclosure will enhance trust is dubious on both empirical and ethical levels. As an empirical matter, it is simply not clear what impact disclosure of financial relationships will have on trust in physicians or research institutions. One study showed no statistically significant difference in investigator trust between potential research participants told of per capita payments made to the investigator and those told nothing at all.¹¹⁴ Participants who were told that the investigator had an equity interest, on the other hand, were less trusting than those who were told of per capita payments and those who were told nothing.¹¹⁵ Interestingly, trust in the sponsor and institution was not affected by disclosure at all.¹¹⁶ Other studies have found that disclosure of financial incentives could undermine trust in the physician,¹¹⁷ or could have no effect.¹¹⁸ One study found that when enrollees in a capitated managed care plan were told how the plan compensated participating physicians, their trust in their doctors increased.¹¹⁹

More importantly, as an ethical matter, it is not clear why promoting trust in researchers or research institutions is desirable. It is possible that, to the extent that disclosure enhances trust, potential participants will not exercise enough caution in weighing the risks and benefits of studies.¹²⁰ Unalloyed trust might also exacerbate the problem of the therapeutic misconception. For example, in one study, “[m]any volunteered that they trusted their physician and that he or she would not ask them to participate unless they were regarded as an appropriate candidate.”¹²¹ For these individuals, a healthy dose of skepticism might be more beneficial than measures to promote greater trust. One of the main goals of informed consent is, after all, to encourage individuals to behave as active decision-makers about treatment or research opportunities.

Protecting the Integrity of Clinical Research

To the extent that financial relationships between industry and researchers or institutions create a risk to data integrity, disclosure of those relationships is unlikely to eliminate that risk. Despite disclosure, conflicted investigators would still be in a position to influence study design, recruitment of subjects, the conduct of trials, or the reporting of results in a manner that is favorable to the investigators’ financial interests. The AAMC and IOM both outline a variety of appropriate responses when financial relationships create risks to research or data integrity, including eliminating the conflicts or managing them through techniques like independent data monitoring,¹²² asking the investigator to reduce the interest creating the conflict, changing the project design, or substituting a principal investigator without a conflict of interest.¹²³

Deterring Troubling Financial Relationships

There is little to no evidence that disclosure will, in fact, influence physician-investigators to modify problematic behavior by avoiding questionable relationships or deciding not

to participate in research. Indeed, it is possible that physicians will be more willing to enter into these relationships if they think that disclosure “sanitizes” them, thereby giving them a perceived “free pass.”¹²⁴ As some commentators have suggested, “by laying their cards on the table, investigators might adopt an attitude of caveat emptor and become less vigilant in policing their own judgmental biases with regard to enrolling patients, collecting data, interpreting results, and other research activities.”¹²⁵ It has also been argued that individuals may look at “compliance with disclosure as a moral license to follow their self-interest.”¹²⁶ One study demonstrated that

advisers are more biased when conflicts of interest are disclosed as opposed to suppressed.... [D]isclosure gives advisers moral license to exploit their informational advantage.... [A]dvises... are worse off when conflicts of interest are disclosed. Although disclosure affords a forewarning of biased advice, advisees do not adequately adjust for the bias—in fact, adjustment is woefully inadequate.... [D]isclosure is not always beneficial and is potentially harmful.¹²⁷

Disclosure of financial relationships may make both investigators and participants believe that the disclosed arrangements do not pose any risk because if there had been any concerns the arrangements would never have been approved.

Dispelling the Therapeutic Misconception

Although it has been posited that disclosure of financial relationships to potential research participants might reduce the therapeutic misconception by shedding light on the relationship between the investigator and the sponsor, we doubt that the therapeutic misconception can be so easily dispelled, particularly where physicians refer their own patients to participate in research. For example, in one study, 24% of participants who were a part of other ongoing clinical research trials reported no risks or disadvantages of their treatment, even though they had previously been explicitly told about such risks.¹²⁸ Some commentators note that disclosure might “paradoxically” reinforce the therapeutic misconception, explaining that “[d]ata suggest that some people place more faith in an experimental intervention when the investigator has a financial stake in the product being tested, believing that the investigator’s investments signal his or her confidence in the product.”¹²⁹ Other evidence suggests that participants might believe that a greater financial interest would make the investigator do a better job, due to his or her investment in the outcome of research and the product or drug being tested.¹³⁰

Protecting Research Participants’ Welfare

The danger that financial relationships between companies that sponsor research and investigators or institutions will lead to riskier studies is a serious concern. However, the proper remedy for this problem is the elimination or management of problematic conflicts, through the mechanisms outlined in our previous White Paper. Relying on disclosure to prospective participants on the theory that these individuals can then protect themselves by asking the right questions is unrealistic and may lead institutions to become lax in their oversight responsibilities. It is also unlikely to help those who need it most. As social scientists have observed, disclosure of financial incentives is most likely to have a beneficial impact on the “sophisticated estimator,” even though “unsophisticated estimators are exactly the ones who are most likely to need protection from exploitation.”¹³¹

DISCLOSURE OF CONFLICTS OF INTEREST SHOULD NOT BE INCORPORATED INTO THE INFORMED CONSENT PROCESS

The previous section explained why disclosure of financial conflicts of interest is unlikely to achieve most of the goals espoused by advocates of disclosure. In itself, that is not an argument against incorporating a discussion of conflicts of interest into the informed consent process; even if the potential benefits are small, disclosure might still be appropriate if the costs are equally low. In fact, however, adding discussions about conflicts of interest to the informed consent process would impose significant burdens that outweigh the limited expected benefits. For this reason, requiring routine disclosures of conflicts of interest to potential research participants would be unwise public policy.

First, informed consent documents are becoming increasingly long and complex, thereby confusing and overwhelming potential research participants.¹³² Evidence indicates that participants are often unable to sift through the morass of information to tease out the content they find salient or material.¹³³ Adding to the already lengthy document by including information that participants may be unable to process or absorb—and which is of less utility than information related to the risks, potential benefits, and alternatives to research—will simply exacerbate the problem. Indeed, evidence shows that information overload, particularly where it includes irrelevant or insignificant information, can cause decision-making that is worse than if the user had been provided less information or no information at all.¹³⁴ For example, disclosing financial relationships may cause participants to overemphasize the importance of the information, increasing the salience beyond its intended significance.¹³⁵

In recognition of the danger of information overload, one might suggest that the solution is to include brief statements regarding investor/industry financial relationships in the informed consent process. Yet, in one qualitative study, Kevin Weinfurt and colleagues found that brief, concise statements about financial interest within informed consent documents were rarely understood, and sometimes only served to confuse potential participants.¹³⁶ Other commentators have noted that “the cure for the mandated disclosure failure is not as simple as merely make-them-simple. Sometimes even a simple mandate to disclose simple information has undesirable consequences.”¹³⁷

These findings are unsurprising. Given the level of trust that pervades the relationships between participants and investigators, one would imagine that only highly sophisticated or skeptical individuals would intuit that disclosures of conflicts of interest are designed to alert participants of the risk the researcher is acting in a self-interested manner. Further, even if prospective participants understand why the information is being provided, they would have no context within which to evaluate the information. For example, most people would have no way of knowing whether a particular conflict is significant, or whether it has influenced the study design.

Theoretically, one response to this concern would be to provide longer descriptions, explanations, and context to disclosures of financial information in informed consent documents. However, Weinfurt and colleagues found that, even after longer descriptions about financial interests were provided, many participants required discussion with the group to understand the meaning of the descriptions. They explained, “[e]ven when participants did understand the definitions, they did not always understand why the information was relevant to them.”¹³⁸

Further, because an individual's level of education correlates with the level of concern about investigator financial interests,¹³⁹ commentators have cautioned that an unintended harm of mandated disclosure is that it can lead to inequity. Disclosure could very well help "most those who need help least and help least those who need help most," thereby increasing the disparity between educated and uneducated, or rich and poor.¹⁴⁰

Our conclusion that financial conflicts of interest should not routinely be disclosed as part of the informed consent process is not inconsistent with the California Supreme Court's decision in *Moore v. Regents of the University of California*.¹⁴¹ In that case, a physician removed the plaintiff's spleen as part of the plaintiff's treatment for hairy-cell leukemia. He then encouraged the plaintiff to return for several follow-up visits during which additional tissue was removed. Throughout this entire time, the physician was using the plaintiff's biological material in experiments that had considerable commercial potential, but he never disclosed this fact to the plaintiff.¹⁴² The research ultimately resulted in the production of a valuable commercial product, and the plaintiff sued for a share of the profits. Although the court concluded that the plaintiff did not have a "property interest" in the product developed from his biological material, it found that he had stated a valid claim for breach of fiduciary duty or, in the alternative, failure to obtain informed consent. The court reasoned that a reasonable person in the plaintiff's position would have wanted to know about the physician's research activities, because those activities created "a possibility that an interest extraneous to the patient's health has affected the physician's judgment."¹⁴³

While *Moore* creates the possibility that, in the right set of circumstances, a physician's failure to disclose research-related financial interests could give rise to liability, it does not mean that any and all financial relationships with industry must necessarily be disclosed. Rather, as in any informed consent claim, liability would depend on the plaintiff's ability to establish the element of causation—i.e., that, if the omitted information had been disclosed, a reasonable person in the plaintiff's position would not have consented to the procedure.¹⁴⁴ Such proof would be possible only in situations involving truly serious conflicts, and as we explained in our previous White Paper, studies with such conflicts should not be permitted to proceed.¹⁴⁵ In other words, our proposed approach to informed consent presumes that any conflict serious enough to affect a reasonable person's decision about enrollment has already been eliminated, and that the only conflicts that remain are relatively minor. For the reasons set forth above, we believe that requiring disclosure of these residual conflicts would not be good public policy; we also believe that the failure to disclose them would not be grounds for liability under *Moore*.¹⁴⁶

INFORMATION ABOUT FINANCIAL INTEREST SHOULD BE MADE AVAILABLE THROUGH OTHER MECHANISMS

Although we oppose the disclosure of financial conflicts of interest as part of the informed consent process, we recognize that some potential participants will want this information.¹⁴⁷ In order to accommodate these individuals, and to promote the inherent ethical value of transparency, we encourage the dissemination of information about financial relationships in research through other mechanisms, such as in pamphlets provided in doctors' offices and on physician and hospital web sites.¹⁴⁸ Consumer guides such as those released by the American Health Lawyers Association (AHLA) can aid potential enrollees in understanding the rights and responsibilities of research participants and suggest questions that participants can ask their physicians to put the information in context.¹⁴⁹

We should not, however, place too much faith in these methods as a means of changing behavior, as experience in other areas of health and consumer affairs has shown that the benefits of mandated disclosure are often quite limited. For example, laws mandating quality report cards for hospitals have not been as effective as originally hoped due to the limitations in the state of the art of quality measurement, ambiguity as to what information patients actually need, and an inadequate understanding of how consumers process disclosed information.¹⁵⁰ Moreover, research has shown low cooperation by healthcare workers and a failure to report or integrate information into communications with patients. Additionally, quality report cards have led to unintended harmful consequences. For example, report cards on bypass surgery reportedly caused some hospitals to "game" the system by rejecting sicker patients.¹⁵¹

CONCLUSION

Transparency is an important ethical value. Financial relationships between commercial sponsors of clinical research and investigators or research institutions should not be kept secret. It does not follow from this that information about such relationships should be incorporated into the informed consent process, however. Available empirical evidence suggests that doing so would provide few, if any benefits to research participants and could in fact cause significant harms. To the extent that financial relationships between sponsors and investigators are problematic, they must be directly regulated. Research participants cannot be expected to protect themselves against the risks that financial relationships pose to researchers' judgment.

ENDNOTES

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- 3 Consistent with our definition of conflicts of interest in our earlier White Paper, we adopt the IOM's definition as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." CENTER FOR HEALTH & PHARM. LAW & POLICY, SETON HALL UNIV. SCH. OF LAW, WHITE PAPER, CONFLICTS OF INTEREST IN CLINICAL TRIAL RECRUITMENT & ENROLLMENT: A CALL FOR INCREASED OVERSIGHT 9 (2009) [hereinafter OVERSIGHT WHITE PAPER]. See IOM Report, *supra* note 1, at 46. As noted, the term "conflict of interest" does not equate to compromised judgment or action but to the risk of such compromise. IOM REPORT, *supra* note 1, at 26.
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- 7 *Id.*
- 8 Joseph Loscalzo, *The NIH Budget and the Future of Biomedical Research*, 354 NEW ENG. J. MED. 1665 (2006).
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- 10 Norman G. Levinsky, *Nonfinancial Conflicts of Interest in Research*, 347 NEW ENG. J. MED. 759, 759 (2002); Alan R. Fleischman & Jason E. Klein, *Clinical Research in the Private Office Setting – Ethical Issues*, 113 TRANSACTIONS OF THE AM. CLINICAL AND CLIMATOLOGICAL ASS'N 126, 129 (2002) ("For years physician-investigators in academic settings have accrued substantial secondary gain to themselves or their departments from clinical trials, but as compared to the private practice setting, in academia direct personal financial gain has rarely been possible.").
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- 13 *Id.* See also Jason Roberson, *Dallas Area Sees Significant Growth in Clinical Trials*, DALLASNEWS.COM (Nov. 3, 2009, 7:54 AM), <http://dallasnews.com> (reporting that "Synergyst Research, a San Antonio-based company ... helps doctors land clinical trials for extra income," ranging from \$50,000 for a trial with 10 research participants on the low end to in excess of \$100,000 on the high end).
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- 15 See OVERSIGHT WHITE PAPER, *supra* note 3, at 39 n.76.

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- 18 See OVERSIGHT WHITE PAPER *supra* note 3, at 28.
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- 70 *Id.* app. F at 385-87.

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- 72 IOM REPORT, *supra* note 1, at 5 (emphasis added).
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- 89 Weinfurt, *Disclosure of Financial Relationships to Participants in Clinical Research*, *supra* note 32, at 919.
- 90 Complaint, *Gelsinger v. Trs. of the Univ. of Pa.*, No. 000901885 (Pa. Ct. Com. Pl. Sept. 18, 2000), available at http://www.sskrpplaw.com/Files/gelsinger_complaint.pdf. The Complaint also alleged that the investigators had failed to inform Jesse of the risks of the study, that they had failed to inform Jesse or the FDA of adverse events experienced by other participants in the same trial as well as the death of monkeys in an earlier animal study, and that the investigators had allowed Jesse to participate in the study despite not meeting the inclusion criteria due to the fact that his liver was not functioning within the study's 24-hour limit. *See also* Gerald R. Prettyman, Jr., *Ethical Reforms in Biotechnology Research Regulations*, 15 VA. J. SOC. POL'Y & L. 51, 69 (2007).
- 91 David Resnik, *Disclosing Conflicts of Interest to Research Subjects: An Ethical and Legal Analysis*, 11 ACCOUNTABILITY IN RES. 141, 142 (2004).
- 92 Associated Press, *Settlement is Reached in Fatal Experiment*, N.Y. TIMES, Feb. 10, 2005, at A18; *U.S. Settles Case of Gene Therapy Study That Ended With Teen's Death*, 51 UNIV. OF PA. ALMANAC 4, 4-5 (2005), available at http://www.upenn.edu/almanac/volumes/v51/n21/pdf_n21/021505.pdf.
- 93 PROMOTION WHITE PAPER, *supra* note 1, at 21.
- 94 *Id.* at 4-6.
- 95 *See generally* PROMOTION WHITE PAPER, *supra* note 1.
- 96 *See discussion supra* notes 50-51.
- 97 PROMOTION WHITE PAPER, *supra* note 1, at 4.
- 98 Lindsay A. Hampson et al., *Patients' Views on Financial Conflicts of Interest in Cancer Research Trials*, 355 NEW ENG. J. MED. 2330, 2334 (2006).
- 99 Anastasia Hutchinson & Abe R. Rubinfeld, *Financial Disclosure and Clinical Research: What is Important to Participants?* 189 MED. J. AUST. 207 (2008).
- 100 Weinfurt, *Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure*, *supra* note 78, at 904.
- 101 Christine Grady et al., *The Limits of Disclosure: What Research Subjects Want to Know about Investigator Financial Interests*, 34 J. L. MED. & ETHICS 592, 596 (2006).
- 102 Scott Y. Kim et al., *Potential Research Participants' Views Regarding Researcher and Institutional Financial Conflicts of Interest*, 30 J. L. MED. & ETHICS 73, 73, 75, 77 (2004).
- 103 Grady, *supra* note 101, at 594; Kim, *supra* note 102, at 77; *see also* Judith Hibbard et al., *Identifying Medicare Beneficiaries with Poor Health Literacy Skills: Is a Short Screening Index Feasible?* 1 (2005), available at http://assets.aarp.org/rgcenter/health/2005_01_literacy.pdf (“[i]nadequate health literacy skills prevent people from being involved and active participants in their care.”); Hutchinson & Rubinfeld, *supra* note 99, at 208.
- 104 *See* Adam Licurse et al., *The Impact of Disclosing Financial Ties in Research and Clinical Care: a Systematic Review*, 170 ARCHIVES INTERNAL MED. 675, 680 (2010). Some empirical evidence shows that, for a minority, information about an investigator's financial relationships would affect the decision to enroll in research. For example, a study consisting of in-person interviews of 253 patients in cancer-research trials revealed that approximately 15% of survey respondents reported that knowledge of any investigator financial tie would have prompted them not to participate in the cancer trial in which they were currently enrolled. Hampson, *supra* note 98, at 2336. Another study of 102 patients enrolled in cancer trials found that, while the majority would be willing to participate despite knowledge of a conflict of interest, 37% would either be unwilling or uncertain about participating. Stacy W. Gray et al., *Attitudes Toward Research Participation and Investigator Conflicts of Interest Among Advanced Cancer Patients Participating in Early Phase Clinical Trials*, 25 J. CLIN. ONCOL. 3488, 3492 (2007).
- 105 Kevin P. Weinfurt et al., *Effects of Disclosing Financial Interests on Participation in Medical Research: A Randomized Vignette Trial*, 156 AM. HEART J. 689, 689-91 (2008).
- 106 Jeffrey N. Gibbs & Gregory A. Guagnano, *Investigator Financial Disclosures and Its Effect on Research Subjects*, 62 FOOD & DRUG L. J. 727, 733 (2007).
- 107 *Id.* at 732.

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- 108 *Id.* at 733.
- 109 Weinfurt, *Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure*, *supra* note 78, at 903 (noting that some potential research participants “felt that if they were extremely ill and desperate for a cure, they would not care about financial interests” while others, in particular parents of children with leukemia or brain tumors, believed that disclosure was of paramount importance because “[w]e’ve got little folks with lives on the line”).
- 110 William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1827-28 (1999).
- 111 Bryan K. Church & Xi Kuang, *Conflicts of Interest, Disclosure, and (Costly) Sanctions: Experimental Evidence*, 38 J. LEGAL STUD., 505, 507 (2009).
- 112 Jerry Menikoff, *The Hidden Alternative: Getting Investigational Treatments Off-Study*, 361 LANCET 63, 66 (2003).
- 113 In August 2009, the FDA published new rules to clarify the methods by which patients can access investigational drugs. See 21 C.F.R. §§ 312.300 – 312.320, 316.40 (2009).
- 114 Weinfurt, *Effects of Disclosing Financial Interests on Participation in Medical Research: A Randomized Vignette Trial*, *supra* note 105, at 691.
- 115 *Id.*
- 116 *Id.*
- 117 Licurse, *supra* note 104, at 679; *see also* Tracy E. Miller & Carol R. Horowitz, *Disclosing Doctors’ Incentives: Will Consumers Understand and Value the Information?*, 19 HEALTH AFFAIRS 149, 150 (2000) (for comment on a similar decrease in trust seen in the managed care setting).
- 118 Studies have found that, although “[p]erceived trust of the investigator was significantly related to willingness to participate, [t]he perception of trust... was not correlated with the level of financial stake.... It is not clear whether subjects were more willing to participate because—on whatever basis—they had concluded that the investigator was trustworthy, or they first decided that they wished to participate and that influenced the way they responded to the question regarding trustworthiness, or due to some other mechanism. The basis for the means by which they formed trustworthiness evaluations is an area meriting further research.” Jeffrey N. Gibbs & Gregory A. Guagnano, *Investigator Financial Disclosures and Its Effect on Research Subjects*, 62 FOOD & DRUG L. J. 727, 736 (2007). *See also* Steven D. Pearson et al., *A Trial of Disclosing Physicians’ Financial Incentives to Patients*, 166 ARCHIVES INTERNAL MED. 623 (2006) (finding that disclosure either increased trust or did not affect it).
- 119 Mark A. Hall et al., *How Disclosing HMO Physician Incentives Affects Trust*, 21 HEALTH AFF. 197, 200 (2002). Enrollees in a second plan, which paid its physicians in a different way, experienced no change in trust levels after being told how their physicians were compensated. *Id.*
- 120 See Daylian M. Cain et al., *The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest*, 34 J. LEGAL STUD. 1, 5 (2005) (“[T]here is at least suggestive evidence that people tend to be naturally trusting and credulous toward their own advisors.”).
- 121 Finkel, *supra* note 32, at 2.
- 122 AAMC-AAU 2008 COI REPORT, *supra* note 31, at 29.
- 123 IOM REPORT, *supra* note 1, at 81.
- 124 Cain, *supra* note 120, at 18 (“Disclosure...benefited the providers of information but not its recipients”).
- 125 Weinfurt, *Disclosure of Financial Relationships to Participants in Clinical Research*, *supra* note 32, at 919.
- 126 *Id.* at 919; *see also*, Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252 (2003).
- 127 Church & Kuang, *supra* note 111, at 507.
- 128 Charles Lidz et al., *Therapeutic Misconception and the Appreciation of Risks in Clinical Trials*, 58 SOC. SCI. MED. 1689, 1693-94 (2004).

- 129 Weinfurt et al., *Disclosure of Financial Relationships to Participants in Clinical Research*, *supra* note 32, at 917.
- 130 Weinfurt, *Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure*, *supra* note 78, at 903. See also Jesse A. Goldner, *Childress Lecture: Regulating Conflicts of Interest in Research: The Paper Tiger Needs Real Teeth*, 53 ST. LOUIS L.J. 1211, 1225-26 (2009) (summarizing the “evidence that disclosure of conflicts of interest may actually encourage potential subjects to agree to participate in a study”).
- 131 Cain, *supra* note 120, at 20. “For disclosure to be effective, the recipient of advice must understand how the conflict of interest has influenced the advisor and must be able to correct for that biasing influence. In many important situations, however, this understanding and ability may be woefully lacking.” *Id.* at 4.
- 132 James Henry et al., *Reformed Consent: Adapting to New Media and Research Participant Preferences*, 31 IRB: ETHICS & HUMAN RESEARCH, March-April 2009, at 1; Ezekiel Emanuel, *Is Longer Always Better*, 38 HASTINGS CTR. REP., May-June 2008, at 10, 11 (“[I]nformed consent documents have become longer, more complex, exhaustive, and exhausting without clearly promoting subjects’ understanding.”).
- 133 See Henry, *supra* note 132, at 1 (“longstanding evidence that increased document length hinders participant comprehension of key information”); Nancy N. Dubler, *Remaining Faithful to the Promises Given: Maintaining Standards in Changing Times*, 32 SETON HALL L. REV. 563, 568-69 (2002) (describing “‘informed consent’ documents, which neither inform nor empower, but rather dump all of the possibly foreseeable - however remote - risks on the patient. How is a patient to distinguish the most important of these risks, those of serious impact and frequent occurrence, from the less significant? With the exception of possibly teratogenic drugs, which usually come with warnings in bold and capital letters - again for risk management reasons - the rest of the form disappears into the tombstone gray of endless, invariable discourse.”); Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure* 58 (Winter 2010) (preliminary draft) (on file with The Chicago Working Papers Series Index) (“[M]andated disclosure can crowd out useful information.”).
- 134 Dalley, *supra* note 83, at 1115. See also Ronald Epstein, *Withholding Information from Patients – When Less is More*, 362 NEW ENG. J. MED. 380, 380 (2010) (noting that cognitive overload may be compounded by the emotional nature of medical decisions).
- 135 Dalley, *supra* note 83, at 1114 (“The availability bias, for example, leads people to respond to information based on the ‘ease with which instances or associations could be brought to mind.’ Thus, people will overestimate the risk of an accident after seeing or hearing about such an accident.”) (citing Amos Tversky & Daniel Kahneman, *Availability: A Heuristic for Judging Frequency and Probability*, in *Judgment Under Uncertainty: Heuristics and Biases*, in JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 163-64 (Daniel Kahneman et al. eds., 1982)); Robert Prentice, *Whither Securities Regulation? Some Behavioral Observations Regarding Proposals for Its Future*, 51 DUKE L. J. 1397, 1469-70 (2002) (noting that “while making decisions, people tend to concentrate on facts that are ‘available’ in their memories”); Cass R. Sunstein, INTRODUCTION TO BEHAVIORAL LAW AND ECONOMICS 1, 3-5 (Cass R. Sunstein ed., 2000) (describing various kinds of biases, including the availability bias).
- 136 Kevin P. Weinfurt et al., *Developing Model Language for Disclosing Financial Interests to Potential Clinical Research Participants*, 29 IRB: ETHICS & HUMAN RESEARCH, January-February 2007, at 2.
- 137 Ben-Shahar & Schneider, *supra* note 133, at 62 (emphasis in original).
- 138 Weinfurt, *Developing Model Language for Disclosing Financial Interests to Potential Clinical Research Participants*, *supra* note 136, at 2.
- 139 Kim, *supra* note 102, at 76.
- 140 Ben-Shahar & Schneider, *supra* note 133, at 60, 61 (pointing to healthcare as the principal example of the inequity of mandated disclosure).
- 141 *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).
- 142 *Id.* at 481-482. Indeed, the physician actively misled Moore by telling him that the research team was “engaged in strictly academic and purely scientific medical research” and “there was no commercial or financial value to his Blood and Bodily Substances.” *Id.* at 486.
- 143 Moore, 793 P.2d at 484.
- 144 *Id.* at 520.
- 145 OVERSIGHT WHITE PAPER, *supra* note 3, at 13.
- 146 We note, however, that if a serious conflict—i.e., one significant enough that, if disclosed, would lead a reasonable person to refuse to participate in a study—slips through the IRB or Conflicts of Interest Committee and a participant is injured, the participant may well have a valid cause of action based on the failure to disclose. However, even if such a conflict had

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been disclosed, it is far from clear that the disclosure would be sufficient to insulate the investigator and/or institution from liability for the injuries.

- ¹⁴⁷ See, e.g., Hampson, *supra* note 98, at 2334; Weinfurt, *Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure*, *supra* note 78, at 904; Kim, *supra* note 102, at 77.
- ¹⁴⁸ Some academic medical centers already publish online databases to disclose the financial ties of their physicians to industry. See, e.g., Duke Clinical Research Institute, <http://www.dcri.org/research/coi.jsp>, (last visited April 27, 2010); Cleveland Clinic, <http://www.clevelandclinic.org>, (last visited April 27, 2010) (listing each staff physician's "industry relationships," including consulting fees, on his or her individual biographical page).
- ¹⁴⁹ American Health Lawyers Association (AHLA), *Medical Research: A Consumer's Guide for Participation* (2009), available at http://www.healthlawyers.org/Members/PracticeGroups/Documents/MedicalResearch_09.pdf.
- ¹⁵⁰ See Jason Ross Penzer, Note, *Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessment in Health Care Reform*, 12 YALE J. REG. 207, 254-56 (1995); Eric C. Schneider & Arnold M. Epstein, *Use of Public Performance Reports: A Survey of Patients Undergoing Cardiac Surgery*, 279 JAMA 1638, 1642 (1998) ("Without a tailored and intensive program for dissemination and patient education, efforts to aid patient decision making with performance reports are unlikely to succeed."); Ben-Shahar & Schneider, *supra* note 133, at 26 ("[D]espite decades of research, scholars have not found reliable indicia of medical quality, principally because it has proved impossible to factor out all the influences on medical success. And since exceptional doctors attract risky cases, success may not reflect skill."); see also Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 NW. U. L. REV. 1 (1999) (describing the application of the informed consent cause of action to disclosure of the relative risks associated with the providers who would perform medical procedures).
- ¹⁵¹ David Wessel, *Eatery Report Cards: A Model for Schools?*, WALL ST. J., May 29, 2003, at A2; see generally David Dranove, et al., *Is More Information Better? The Effects of "Report Cards" on Health Care Providers*, 11 J. POLITICAL ECON. 555 (2003).

APPENDICES

Appendix A

Center for Health & Pharmaceutical Law & Policy

The Center for Health & Pharmaceutical Law & Policy at Seton Hall University Law School advances scholarship and recommendations for public policy on cutting edge issues posed by pharmaceutical and health law. The Center also serves as a forum to convene leaders in government, industry, academia, medicine and consumer organizations to examine the issues posed by clinical and policy developments and explore potential solutions. The Center builds upon the nationally recognized scholarship in health law, conferences on key public policy questions, and an internationally recognized healthcare compliance training program that are part of the Health Law & Policy Program at Seton Hall Law School.

The Center

- Researches, reviews, and develops policy recommendations on key issues on health and pharmaceutical law to inform and shape policy at the state and national levels;
- Produces scholarship through journal publication and white papers on emerging legal, ethical, and social issues in health and pharmaceutical law;
- Provides a neutral forum to convene leaders in government, industry, academia, and medicine to engage in an informed dialogue, consider pressing policy questions, and explore potential solutions;
- Offers educational programs on health and pharmaceutical issues by leading experts from the public and private sectors to examine important policy and legal issues; and
- Holds compliance education and training programs on state, federal and international regulatory requirements that govern the research, approval, promotion, and sale of drugs and devices.
- The Center operates under the direction of Faculty Director and Professor of Law John Jacobi and Executive Director Simone Handler-Hutchinson, Research Fellows and Staff. In addition, the Center draws upon the intellectual strength of the Seton Hall Law School faculty. Faculty members bring to the Center's work nationally recognized expertise in pharmaceutical law, not-for-profit governance, intellectual property law and bioethics, among other areas.

Appendix B

Center Financial Disclosure Statement and Policies

The Center for Health & Pharmaceutical Law & Policy of Seton Hall Law School is committed to independent academic inquiry focusing on issues affecting health and pharmaceutical law and policy. As a part of Seton Hall University, the Newark-based Law School is a nonprofit 501(c)(3) organization. The University and Law School engage in fundraising from alumni and other contributors. Remaining committed examining divergent perspectives on policy issues related to health and pharmaceutical law and policy is critical to the mission of the Center.

Law School faculty members and Center Staff are devoted to academic independence in their research and transparency in their relationships. As such, funding sources are announced on all published materials and on the Law School Web site. Regardless of whether financial support is received in the form of an endowment, as unrestricted funds or for a specific project, Law School and Center donors are not involved in the academic work of Law School professors or Center Staff. Grants and donations are only accepted if they do not limit the faculty's or the Center's ability to carry out research free of outside influence and consistent with the Center's mission and values.

Seton Hall Law School funds the salaries of the faculty associated with The Center for Health & Pharmaceutical Law & Policy. Research and administrative support for the Center are jointly funded by Seton Hall Law School and by unrestricted funds provided by corporate donors, with the Law School currently providing the majority of the funding.

The Center for Health & Pharmaceutical Law & Policy and its faculty assume sole responsibility for the content of its publications and position statements. The Center does not issue publications or statements on behalf of any donor or other entity.

The corporate donors that have provided funding to the Center or to the Law School are listed below.

- In 2010, Ernst & Young provided \$15,000 to support the creation of a European healthcare compliance program, which was implemented in June 2010.
- Bristol-Myers Squibb provided a \$5 million endowment in 2005 in support of The Harvey Washington Wiley Chaired Professorship in Corporate Governance & Business Ethics. The Law School is recruiting candidates for this position.
- Johnson & Johnson provided \$100,000 in 2008 as seed funding for two projects (i) a program on "Strategies for Compliance Professionals: Honing Decision-Making Skills," and (ii) creation and implementation of an international compliance program. It provided an additional \$50,000 in unrestricted support in 2009. In 2007, Ortho-McNeil Janssen Scientific Affairs, a subsidiary of Johnson & Johnson provided \$49,900 in unrestricted funds. Johnson & Johnson provided \$50,000 in 2007 and \$100,000 in 2006 in unrestricted funds to support the Center. Two of Johnson & Johnson's subsidiaries, Centocor, Inc. and Ortho Biotech, provided \$125,000 in unrestricted funding to the Center in 2007.

The Center for Health & Pharmaceutical Law & Policy

- In 2006, sanofi-aventis provided \$500,000 to Seton Hall Law School in “support and development of the Center for Health & Pharmaceutical Law & Policy and the programs and activities associated with the Center.”
- In 2006, Schering-Plough Corporation made a \$2.5 million commitment to be paid over five years “to partially endow a tenured track/tenured faculty position dedicated to health care regulation.” In May 2010, Frank Pasquale was named the Schering-Plough Professor in Health Care Regulation and Enforcement.
- In 2008, Purdue Pharma provided \$25,000 in unrestricted funding for the Center for Health & Pharmaceutical Law & Policy.
- In 2008, Roche provided \$50,000 for a symposium sponsored by the Gibbons Institute of Law, Science & Technology, the Seton Hall Law Review, and the Center on “Preparing for a Pharmaceutical Response to Pandemic Influenza.” The symposium was held in October 2008.

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