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Science in the Sunshine: Transparency of Financial Conflicts of Interest

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ABSTRACT: Beginning in 1995, the U.S. Department of Health & Human Services (DHHS) issued conflicts of interest (COI) regulations to all institutional recipients of Public Health Service grants, including grants from the National Institutes of Health. These regulations set requirements for the disclosure and management of researcher financial COIs (FCOIs). In 2010, the DHHS revised its FCOI regulations. This paper reviews the historical conditions leading up to the first FCOI regulations and its revisions, discusses the response of journals to author COIs, and examines how well the revised regulations respond to criticism that grantee institutions were not properly managing FCOIs.

KEY WORDS: conflicts of interest; scientific objectivity; NIH, journal policies

I. INTRODUCTION

In May 2010, the U.S. Department of Health & Human Services (DHHS) proposed revised regulations, applicable to all grantee institutions and investigators, which set requirements for the disclosure and management of financial conflicts of interest (FCOIs). The new rules would be the first major revisions promulgated since 1995, when investigator-FCOIs were first regulated. In this paper I review the historical events leading up to current policies adopted by journals and federal scientific funding agencies on FCOIs. I discuss the trends among science and medical journals toward full disclosure of FCOIs by contributing authors and examine the changes in the newly proposed federal policy. Finally, I explore some shortcomings in the new proposed policy for achieving the government's goal of ensuring unbiased publicly funded scientific research.

II. HISTORICAL TRENDS

Concerns of FCOIs in the public sphere have their origins in the U.S. Constitution. The Founding Fathers, who had justifiable concerns that elected officials of the new Congress could be influenced by gifts or special favors, wrote into the Constitution some explicit prohibitions against egregious FCOIs. Article 1 forbids any person holding an office from accepting gifts, holding employment, or accepting titles from foreign governments without the consent of Congress. Also, no former member of Congress can assume a federal post that was created during his or her term of office.

Nearly 200 years after the ratification of the Constitution, Congress passed its most comprehensive regulations on COIs of government employees. The Ethics in Govern-

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ment Act of 1978 established the Office of Government Ethics and created rules for financial disclosure for federal employees. Members of the upper levels of all three branches of government (including the president, vice president, members of Congress, federal judges, and certain staff members in each branch) must file annual public financial disclosure reports that list the sources and amount of all earned income; all income from stocks, bonds, and property; any investments or large debts; and the same information for spouse and dependent children. They must also report any positions or offices held in any business or nonprofit organization whether or not they are compensated.

Scientists serving on federal advisory committees were largely outside of federal oversight until 1972. In that year, the Federal Advisory Committee Act (FACA) was passed. Scientists serving on what currently amounts to about 1000 federal advisory committees are considered special government employees. According to FACA, no individual appointed to serve on an advisory committee can have a COI that is relevant to the functions to be performed, unless the conflict is promptly and publicly disclosed and the National Academies of Science determines that the conflict is unavoidable. It is now standard practice for scientists participating on federal advisory committees to disclose their competing interests at the start of their service. By the early 1980s, there was a significant cultural shift in academic science that brought COI concerns of the public and the scientific community to a new level.

At the start of the decade, a series of laws, executive orders, and tax policies designed to improve U.S. competitiveness in high technology were enacted and adopted. These policies were premised on the idea that if closer ties were developed between universities and industry, the rate of discovery would increase, technology transfer would expand rapidly, and the resulting innovations would create new industrial sectors and new wealth. Included in this new policy initiative were the enactments of the Bayh-Dole Act, the Stevenson-Wydler Technology Innovation Act, new tax policies, and Executive Order 12591 that stimulated university-industry partnerships. These policies gave universities and industry intellectual property ownership to discoveries funded by the government, tax credits to companies that contributed equipment to universities, tax incentives for limited partnerships between companies and universities, and funding for the formation of university-industry research centers at the National Science Foundation.

In 1980, *Nature* magazine asked a series of questions about the unintended consequences of those policies: "As industrial corporations become more involved in developing new biological techniques, where does this leave the scientist? How will university biology departments maintain their integrity and autonomy? How will individual scientists react to corporate demands?"[1] Journal editors, the so-called gatekeepers of certified knowledge, were among the first to respond.

III. MEDICAL JOURNALS: FIRST RESPONDERS TO AUTHOR COIS

By the mid-1980s, two leading medical journals introduced FCOI disclosures for authors. *The New England Journal of Medicine's* editor-in-chief, Arnold Relman, wrote an editorial in the journals titled "Dealing with Conflict-of-Interest," which was a path breaker for

the medical journal community. Relman explained the reasons behind the new policy:

> *...in recent years, as the commercial possibilities of the new biomedical discoveries have become increasingly attractive, these connections [between industry and academic medicine] have become more pervasive, complex and problematic. Now, it is not only possible for medical investigators to have their research subsidized by businesses whose products they are studying, or act as paid consultants for them, but they are sometimes also principals in these businesses or hold equity interest in them.*[2]

The very first journal policy was nothing more than a suggestion to authors that they list any funding or direct business interests that they considered to be related to the subject matter of their submitted article. Other types of FCOIs, such as patents and business consultancies, were a lower priority for the journal, which made a commitment to handling them on a case-by-case basis.

As the print media and Congress brought more attention to the links between academic scholars and industry, especially in drug research, the leading medical journals incrementally deepened and broadened their disclosure policies. Initially applied to original research, disclosure of FCOIs was extended in many journals to editorials, commentaries, meta-analyses, review articles, and book reviews. Some journals banned authors with FCOIs from publishing certain types of articles for which author bias was more difficult to detect, such as reviews of a field and commentaries.

For 6 years (1996–2002), the *NEJM* adopted a policy that prohibited editorialists and authors of review articles from having an FCOI with a company that could benefit a drug or medical device discussed in the article. In 2002, Editor-in-Chief Jeffrey Drazen withdrew the zero-tolerance policy and replaced it with a de minimis FCOI requirement applying a "significant conflict-of-interest standard" that was used to exclude certain authors from publishing in the journal.

Medical journals, more visible to the public through the eye of the media than journals in other fields, were the first to take FCOIs seriously. The general science journals followed their lead. After an initial resistance to requiring authors to make their FCOIs known to readers, the *Nature* journals were the last holdouts of the high-impact science journals to adopt a disclosure policy. In 1997, the editors of *Nature* wrote defiantly:

> *This journal has never required that authors declare such affiliations, because the reasons proposed by others are less than compelling. It would be reasonable to assume, nowadays, that virtually every good paper with a conceivable biotechnological relevance emerging from west and east coasts of the United States, as well as many European laboratories, has at least one author with a financial interest—but what of it? ... The work published (*Science and Engineering Ethics 2, *395; 1996) makes no claim that the undeclared interests led to any fraud, deception or bias in presentation, and until there is evidence that there are serious risks of such maipractice, this journal will persist in its stubborn belief that research as we publish it is indeed research, not business.*[3]

Four years later with the same editor-in-chief, the journal reversed itself and reached the decision to adopt a disclosure policy for author competing interests. Editor-in-Chief Philip Campbell wrote: "There is suggestive evidence in the literature that publication practices in biomedical research have been influenced by the commercial interests of authors.... There are circumstances in which selection of evidence, interpretation of results, or emphasis of presentation might be inadvertently or even deliberately biased by a researcher's other interests."[4] Campbell was referring to the growing evidence that private funding of science had a biasing influence on its outcome.[5] A study of 47 refereed toxicology and 180 medical journals found that 87% and 84%, respectively, had written COI policies for authors in 2009.[6]

IV. FEDERAL FUNDING AGENCIES ISSUE COI RULES

After a 10-year period during which scientific and medical journals were developing FCOI disclosure policies, two major federal science agencies, the Public Health Service (PHS), which includes the National Institutes of Health, in conjunction with the Office of the Secretary of DHHS and the National Science Foundation issued regulations after a year of public debate and input. The final rules were promulgated in 1995. In essence, this was a decentralized, locally managed system for addressing scientific COIs for investigators who received federal grants with federal walk-in rights to obtain information.[7] Under the 1995 rules, faculty were required to report external income to a designated agent at their university. Much of that information was not available to the general public, researchers, or the media, but could be accessed by federal funding agencies at their request. .

For the purpose of the FCOI rules the DHHS defined "significant financial interest" (SFI) as anything of monetary value including consulting fees, honoraria, equity interests, and intellectual property that exceeded $10,000 over a 12-month period.[7] The reporting requirement excluded any salary or royalties from the applicant's institution; income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and income from an applicant's service on advisory committees or review panels for public or nonprofit entities. The definition of SFI was designed to capture ancillary income from profit-making organizations that included the investigator's spouse and dependent children.

The institution's responsibility under the 1995 rules was to maintain and enforce a written policy and establish guidelines on COI, to ensure that investigators who receive PHS grants follow the policy and guidelines, to designate an official to solicit and review financial disclosures from those awarded these grants, and to take the appropriate action for managing, reducing, or eliminating significant FCOIs.

The institution must also report to the DHHS the "existence of a conflicting interest (but not the nature of the interest or the details) found by the institution...."[7] They must assure the DHHS that a significant COI is managed properly. While the institution must make information available to DHHS upon request, it is not obligated to disclose the SFIs to the press or the public.

The federal compliance mechanism is triggered when two conditions occur: first, when an investigator fails to comply with the institution's COI policy, and second, when an investigator's non-compliance "has biased the design, conduct, or reporting of the PHS-funded research...."[7] The burden is on the institution to show that both conditions apply before DHHS will undertake action on compliance. The system was based largely on the trust of institutions and investigators. NIH took little oversight responsibility.

V. THE INSPECTOR GENERAL: DEFICIENCIES IN OVERSIGHT

In January 2008 the inspector general (IG) of the DHHS completed his report on the number and nature of FCOIs reported by grantee institutions to the NIH, and on the extent to which NIH oversees its grantee institutions' FCOIs.[8] The investigation had two goals: first, to determine if NIH kept an accurate accounting of the reported FCOIs, and second, to ascertain the extent to which NIH oversees grantee institutions' FCOIs. The IG found two deficiencies in NIH's oversight of the rules on COIs at grantee institutions. First, the NIH could not give the IG an accurate account of the FCOI reports for FY 2004–2006. Nearly half of the institutes could not provide the IG with any financial disclosure reports for FY2004–2006. Second, the IG felt that there was insufficient information about the COIs that were reported: "NIH is not aware of the types of financial conflicts of interest that exist within grantee institutions because details were not required to be reported and most conflict-of-interest reports do not state the nature of the conflict."[8]

As previously noted, the 1995 rules did not require the grantee institutions to report on the specific nature of the FCOIs, so it was not surprising to learn that "at least 89 percent of financial conflict-of-interest reports did not state the nature of the conflicts or how they would be managed."[8] Only 30 of the 438 FCOI reports provided by NIH and reviewed by the IG included detailed information.

Another finding of the IG was that the individual institutes did not have a proactive method for ensuring that institutions had FCOI policies or for checking the accuracy and quality of the reporting by grantee institutions. It was based mostly on good faith. In response to the IG report, NIH did not agree that it should require grantee institutions to provide details on the FCOIs they report. The NIH director argued that such information should remain with the institution.[8]

VI. CONGRESSIONAL OVERSIGHT

In April 2007, Iowa Senator Charles (Chuck) Grassley hired Paul D. Thacker after Thacker had resigned as news reporter for *Environmental Science & Technology* (EST), an American Chemical Society magazine. While at EST, Thacker had written a number of articles about COIs in the biotechnology sector. It was after he honed his investigative journalistic techniques on the corporate influence on environmentally related science, fields such as energy and chemicals, that he began running into opposition from the EST board and editors. Thacker wrote a story in EST about the Weinberg Group, a scientific

consulting firm operating in Washington, DC hired by chemical companies to create uncertainty about scientific claims regarding the health and environmental effects of chemicals such as Teflon. He raised issues about whether environmental health science was for sale to the highest bidder. This brought Thacker criticism from EST for allegedly lacking proper training in investigative journalism and for failing to be balanced in his coverage of a story.[9] After his magazine editor limited his coverage of certain topics, Thacker submitted his resignation and accepted a position with Senator Grassley, a ranking member of the Senate finance and budget committees, to work on the senator's investigative oversight projects.

Thacker began investigating the reporting mechanism of universities in response to FCOIs. He discovered a number of cases where there was a significant discrepancy between what a university professor claimed to report and what drug companies disclosed that they had paid the individual for consulting services. Based on Thacker's investigations for Senator Grassley, in June 2008 the *New York Times* reported "Researchers Fail to Reveal Full Drug Pay."[10] The *Times* wrote that Senator Grassley found egregious violations in federal COI reporting requirements. They cited a Harvard child psychologist who promoted the use of antipsychotic medicines in children while earning at least $1.6 million over a period of seven years of consulting.

Grassley wrote on his website: "We all rely on the advice of doctors, and leading researchers influence the practice of medicine.... Taxpayers spend billions each year on prescription drugs and devices through Medicare and Medicaid. The National Institutes of Health distributes $24 billion annually in federal research grants. So the public has a right to know about financial relationships between doctors and drug companies."[11]

With the support of Paul Thacker's findings that prominent NIH awardees failed to disclose consulting or equity income and thus flagrantly violated federal regulations, Senator Grassley began a two-year campaign to tighten up the rules and improve their oversight both at the NIH and at the awardee institutions. He wrote to NIH Director Elias Zerhouni on June 4, 2008 expressing his concerns about the management of COIs in NIH-supported institutions. Director Zerhouni responded on June 20 in agreement that "we need to increase transparency and enhance NIH's system of oversight" and that he was hopeful "that we can significantly enhance identification and management of FCOIs to insure that undisclosed, and therefore unmanaged, conflicts do not bias the design, conduct, or reporting of NIH-supported research."[12]

On June 25, 2008, Grassley wrote to the chair (Robert C. Byrd) and ranking member (Thad Cochran) of the powerful Senate Committee on Appropriations alerting them to the problems at NIH and the need for accountability and greater transparency. Grassley wrote, "As you know, institutions are required to manage a NIH's grantee's conflicts of interest. However, I am discovering that these regulations may be nothing more than words with little if any teeth." Citing the 2008 DHHS Inspector General report (see next section), Grassley teamed up with Senator Herb Kohl and on July 7, 2009 issued a press release urging NIH to take steps to increase transparency of federally funded biomedical research. They filed amendments into new legislation that would have placed new

requirements on institutions receiving NIH grants.

As a ranking member of the Senate Committee on Finance, Grassley issued press releases supporting changes in the NIH's COI policies. In one release he was quoted: "Letting the sun shine in and making information public is basic to building people's confidence in medicine. And with the taxpayer funding that's involved, people have a right to know. Public trust and the public dollars are at stake."[13]

During the confirmation hearings of Governor Kathleen Sebelius, seeking to be secretary of Health and Human Services, Grassley posed a series of queries to the candidate outlining the problems that he had identified and requesting her response. Sebelius' answers, while expectedly somewhat vague, did agree with the principles that Grassley had raised. "I support NIH's efforts and agree that it is time to reevaluate the existing FCOI regulation to assure that PHS supported research is conducted without bias."[14]

While building support from members of the Senate and keeping the pressure on DHHS and NIH by requesting data and urging policy change, Grassley continued to request information from universities in those cases where awardees had neglected to make proper disclosures. His efforts to raise visibility on COIs were greatly reinforced by two investigations of the IG.

VII. IG REVIEWS DHHS RULES ON COI

In January 2008, the IG issued the final report of its investigation on the number and nature of financial COIs reported by grantee institutions to the NIH, which sought to ascertain the extent to which NIH plays an oversight role in ensuring that its grantee institutions abide by the 1995 rules of reporting, managing, and mitigating FCOIs.[15] The IG reviewed 438 reports and found a number of deficiencies in FCOIs in NIH grantee institutions. Prominent among them is that the IG could not obtain an accurate count of the FCOI reports for FY2004–2006; 93% did not state the nature of the conflicts; 89% did not state how the conflicts would be managed, reduced, or eliminated.

This latter point about whether the NIH should require detailed records of the types of COIs occurring at its grantee institutions became contentious between the agency and the IG. The 1995 rules did not require any level of detail in the reporting by grantee institutions to the NIH. The IG wrote: "At least 89 percent of financial conflict-of-interest reports did not state the nature of the conflicts or how they would be managed."[15]

The IG also found that individual institutes did not have a proactive method of ensuring that grantee institutions had FCOI policies, or if they did, the accuracy and quality of the FCOI information. Nearly half of the institutes could not provide the IG with any financial disclosure reports for FY 2004–2006. According to the IG report, the quality of the information was based mostly on "good faith." NIH responded to the IG report by disagreeing that it should require grantee institutions to provide details on the FCOIs they report. In essence, by demurring, NIH refused to take on a policing role of its grantee institutions, but rather preferred that the information be decentralized and based on trust.

The IG issued a follow-up report in 2009 titled "How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health."[16] The IG

cited inquiries of the Senate Finance Committee into payments from drug and device manufacturers to academic researchers and physicians. In nine cases, they found five awardees who allegedly failed to report that they received payments of $1 million or more. In this investigation the IG reviewed 41 grantee institutions that submitted 225 FCOI reports to the NIH in FY2006. These institutions were surveyed on how FCOIs were managed, reduced, or eliminated and how grantee institutions ensured that their researchers complied with federal regulations. After excluding 41 grantee institutions from its analysis, the study was left with 184 reports involving 165 researchers. The most common type of conflict that the IG found among researchers (67%) was "holding an equity ownership" in companies whose financial interests were related to the investigator's research, while 40% of the grantees consulted for an outside company. Sixty-five grantees had some type of position with outside companies including executive office and membership on the board of directors, advisory board, or medical review board.

Of the 184 reports, 136 indicated that the researchers' conflicts were managed, six indicated that the conflicts were reduced, and a mere six were eliminated.[16] The most cited method for managing COIs was disclosure. And for one-third of the reports (n = 60), there was no evidence in the submitted documentation to show that management methods were fulfilled.

Once again, the IG report confirmed that "researcher discretion" in deciding what to report guided the management plans. "Ninety percent of the grantee institutions rely solely on the researchers' discretion to determine which of their significant financial interests are related to their research and are therefore required to be reported."[16] The IG also reported that none of the grantee institutions have a policy of full disclosure of SFIs, but rather allow the researcher to make the determination of whether disclosure is appropriate. Most of the institutions do not make an effort to verify information submitted by researchers.

The IG recommendations in the second report once again focused on the lack of detail in the information sent to NIH from grantee institutions. The IG recommended that "after a grantee submits a report identifying the existence of a conflict, NIH use [its authority] to request details about the conflict and how it was managed, reduced or eliminated."[16] The IG also criticized the investigator "trust standard" in the reporting of FCOIs and recommended that "NIH require grantee institutions to collect information on all significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research."[16] Under these criteria, all external income that exceeds the threshold would be reported.

VIII. REVISED PHS RULE ON REPORTING FCOIS.

The DHHS issued a new set of proposed rules pertaining to COIs in academic research on May 21, 2010.[17] The goal set forth by DHHS in this proposed rule was to ensure objectivity in funded research. To fulfill this goal, institutions and investigators had to completely disclose COIs, develop appropriate review of faculty with FCOIs, and aggressively manage the conflicts that are disclosed. DHHS stated that the 2010 proposed

rules represent "substantial revisions to the current regulations."[17] Many of the proposed revisions were direct responses to the IG recommendations and to Grassley's campaign for change.

The proposal changed the definition of "financial interest" from "anything of monetary value" to "anything of monetary value or potential monetary value." The new rules would require awardees to report intellectual property and equity in a startup company, which currently may have no monetary value. The new rules broaden the meaning of *investigator* to include anyone who is responsible for the design, conduct, or reporting of research, including sub-grantees and contractors, and *research* as any activity for which research funding is available, including PHS awards, grants, cooperative agreements, contracts, or career development funds.[17]

The definition of an SFI in the document is "a financial interest consisting of one or more of the [financial] interests of the Investigators (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities."[17] The interests include stock holdings, remunerations from companies that aggregate within 12 months to more than $5000, and intellectual property such as patents and royalties.[17] Thus, the new rules cut the reporting threshold for external funding in half, from $10,000 to $5000. If an investigator holds an equity interest in a non-publicly traded company (i.e., a startup) then an SFI would exist regardless of the value. Also, there was a change in the time period under which the SFIs aggregate. Under the 1995 rule, aggregated payments were supposed to be calculated "over the next 12 months," whereas under the new rules, they are calculated over the past 12 months. If investigators receive external monies that meet the SFI threshold after their disclosure statement has been made, they are required to update their statement within 30 days.

The new definition of SFI also introduces new criteria for disclosing some activities as SFI. In the past rules, the external funding had to be related to the current PHS grant. The new rules state that disclosure is required for any external funding classified as SFI that would "reasonably appear to be related to the Investigator's 'institutional responsibilities'."[17] This means that institutions must disclose external funding classified as SFIs that relate to any aspect of an investigator's scientific life, including teaching at the institution.

In what is likely to be the most controversial changes to the current federal COI policy are the institutional requirements for record keeping and reporting of FCOIs. Institutions will be required to post their COI policies on a publicly accessible website, to develop and implement training programs on their policies, and to require all PHS investigators to complete the training. Up to now, the investigator bore the responsibility for determining the relatedness of the SFI to his or her PHS-funded research. Under the proposed rules, it is the institution's responsibility, through a pre-designated office, to make the relatedness determination. When a determination of SFI and its relatedness to an investigator's work has been made, the past rules required the institution to manage the conflict, while the new rules would require the institution to create a management

plan to be submitted to the awarding agency.

Standing out among the institutional changes is the new public disclosure provision. When an institution has determined that an SFI of a senior investigator or key personnel of a PHS-funded project is related to the research, and that it involves an FCOI, then the institution is required to post information describing the FCOI on a publicly accessible website. This means that some investigators will have personal information about earnings and their (and their family's) financial relationships with private companies made public. The publicly accessible website would be updated annually or within 60 days of a change in the SFI status of an investigator. The DHHS discussion of the proposed guidelines noted the significance of the change to personal privacy. "We recognize that the proposed public disclosure requirement would place an additional administrative burden on institutions, and would also impact the privacy of Investigators who have information related to their personal financial interests posted publicly to the extent such interests are determined to the FCOI."[17] In balance, DHHS noted, the publicly accessible website has the advantage of offering the public more complete information; it is also consistent with public disclosures in journals and at professional meetings.[17]

The problem associated with poor compliance of the regulations was a major factor in bringing public attention to the 1995 COI policy. Under the old rules, if an investigator failed to comply, the institution was required to inform PHS of the action it planned to take or had taken. The new rules expand the power of investigation of the awarding agency. The agency would be able to undertake a site review before, during, or after the award period, gain access to all relevant records of the awardee institution, and exercise enforcement action that includes suspension of funding or imposing special award conditions. The new rules stipulate that greater enforcement attention is given to research that evaluates the safety or effectiveness of drugs, medical devices, or treatment.

While remaining within the same general framework as the existing rules, the proposed rules on COI provide greater detail, close up loopholes in reporting, provide greater transparency to the public, shift responsibility from the investigator to the institution, and establish higher accountability standards for the awarding institution.

IX. CONCLUSION

The 2010 proposed DHHS rules on COIs have responded to most of the criticisms and recommendations issued by public critics, Senate oversight committees, and the IG. Some highly visible cases have illustrated the extent to which some academic scientists and their institutions treated the 1995 rules as burdensome and intrusive. Some members of this group of scientists felt emboldened to flaunt the rules, which they viewed as needless regulatory impositions on science that erodes their established tradition of "academic freedom and autonomy."

Under the newly proposed rules, Senator Grassley's idea of "science in the sunshine" is extended from journal disclosure to all grantees of PHS awards. Transparency is now required, at least for publicly funded research, at the outset of receiving an award and not just at the time of publication. This gives the university an opportunity to raise

the question of whether the investigator's significant FCOI could bias the results of the research. However, even with the revised rules, there remain significant omissions in addressing FCOIs in science.

First, we have to acknowledge that a significant funding of science, particularly as applied medical research, comes from the private sector. Investigators who do not receive public funds are not bound by the DHHS rules. Private funding of academic research has introduced systemic bias, perhaps more directly than public funding.[18] The bias is often introduced at the outset in the contract of the study. For example, recently it was disclosed that the international energy corporation BP proposed to contract out research to scientists at the University of Alabama, which would have given the company rights over publication. According to a report in the *Press Register* of Mobile, Alabama, BP attempted to hire the entire marine sciences department at one Alabama University under a contract that "prohibits the scientists from publishing their research, sharing it with other scientists or speaking about the data that they collect for at least the next three years."[19]

Second, improving the management and disclosure of COIs does not solve the problem of prevention.[20] The introduction of bias in research can be very subtle. It is not easy to determine whether an SFI biases the outcome of research unless there are telltale clues. The policy sets no boundaries on preventing an FCOI, such as by prohibiting a clinical investigator supervising a clinical trial from holding an FCOI.

Third, the DHHS's proposed rules do not address the problem of institutional COIs, which the agency has thus far found intractable. It is the universities who may negotiate contracts with secret covenants that trade off scientific autonomy in exchange for large grants or other largesse to the institution (including equity interests in the funder) that makes this issue so visible yet beyond the management of investigator COIs.

Finally, the newly proposed DHHS guidelines would replace the original guidelines, which have been in effect for 15 years. The new guidelines herald a new age of science, one in which "disinterestedness" as formulated by Robert Merton in his norms of science, is replaced with "managed bias," namely, an acceptance that science is largely influenced by entrepreneurship and that all there is left is to maximize the use of "organized skepticism" and transparency to ensure the publication of reliable knowledge. It broadens the responsibility from journals and the community of scientists to officers at the university who must decide whether "there is any reasonable expectation that the design, conduct, or reporting of PHS-funded research, by any investigator FCOI will be biased by the financial interest of that investigator."[17]

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