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CONFLICTED RESEARCH: MEDICAL SCIENTISTS ON THE PAYROLL

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I. INTRODUCTION

The purpose of this case is to explore the recent and eye-opening revelations of pervasive conflicts of interest throughout the United States medical industry, and to provide a framework within which the revelations can be examined and better understood. These revelations should provide rich, pedagogical fodder to professors of legal and ethical responsibilities of business executives, and enable those professors to demonstrate clearly the nature of conflicts of interest and the significant impact they play in the executives' ability to meet their obligations to stakeholders.

Conflicts of interest arise whenever executives have a private interest in the outcome of the task or responsibility they carry out on behalf of their employers. As a company employee, the executive owes his employer the duty to act solely for the benefit of his or her employer and not in the interest of the employee or third party; the employee's loyalty must be undivided.¹ As an officer of the company, the executive is an agent of the corporation, and owes the corporation the same fiduciary duties as those imposed on employees, including the duty to act solely for the benefit of the corporation.²

Whenever a conflict of interest exists, the executive cannot be said to act solely for the benefit of the employer. The conflict of interest may cause the executive to engage in a course of action that is not in the best interest of the company, or to fail to exercise independent judgment on behalf of the company, thereby breaching the duty of loyalty the executive owes to his

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¹ FRANK B. CROSS AND ROGER LEROY MILLER, *THE LEGAL ENVIRONMENT OF BUSINESS: TEXT & CASES* 486 (7th ed. 2009).

² *Id.* at 455.

employer. For example, a business executive has a conflict of interest if she owns stock in a company submitting a bid to the executive's employer: the executive may be tempted to enhance the value of stock she owns in the bidding company by approving its bid. Likewise, a business executive who enters into a contract on behalf of his employer to purchase consulting services from company owned by his daughter has conflicting interests: the executive may be more interested in benefiting his daughter than in obtaining the best terms for the employer. Similarly, a business executive who serves as a consultant to a third party and negotiates a lease or purchase agreement between the third party and his employer cannot be said to be acting solely in the interest of his employee.³

Unfortunately, the importance of conflicts of interest in examining the legal and ethical obligations of executives is frequently understated, because the explanation normally accorded them is couched in singular instances, such as the three examples cited above, all of which involve a single contract and none of which posed a significant impact beyond the immediate parties to the contracts in question. Such is not the case, however, in the conflicts of interest pervading the medical industry. Indeed, because these conflicts of interest threaten the public interest in safety and effectiveness of medical treatments and devices, they elevate the importance of addressing conflicts of interest in legal and ethical responsibility courses. Further, the professor teaching in these areas occupies the unique position of addressing ethical issues residing in her own or similar academic institutions, rather than critiquing ethical issues in outside business organizations. In effect, the professor is charged with putting his own house in order, rather than critiquing the activities of unrelated parties.

This case examines: (1) the extent and purpose of payments routinely made by the medical industry to physicians employed by academic organizations or engaged in private practice; (2) the failure of physicians to comply with regulations requiring them to disclose their conflicting financial interests; (3) the inability of the medical and research system to effect compliance with disclosure requirements; (4) forces inherent in the medical research system which have increased the incidence of conflict of interest, namely vertical integration of the pharmaceutical industry, the 1980 Bayh-Dole Act, and the accelerating need of the medical industry to conduct human experiments; (5) changes in medical research spawned by the increased dependence of drug and medical device companies on private industry medical research, namely industry contributions to physicians' nonprofit foundations, ghost written medical research, and the rise of the celebrity medical expert; (6) responses of medical institutions and academic organizations to the conflict of interest revelations; and (7) the three major

³ MANUEL G. VELASQUEZ, *BUSINESS ETHICS: CONCEPTS AND CASES* 430-31 (4th ed. 1998).

solutions proposed to combat conflicts of interest in the medical research industry: mandatory disclosure of financial conflicts, instituting independent, federal testing of medical research results, and the AMA conflict of interest policy proposal.

II. MEDICAL INDUSTRY PAYMENTS TO PHYSICIANS

The relationships between physicians and medical related companies in the United States, generally acknowledged to be cozy given their mutual interest in patient care, also turn out to be quite pervasive and lucrative. A survey of U.S. doctors undertaken by Harvard University in 2003 and 2004, in which nearly half of the 3,167 practicing anesthesiologists, cardiologists, family practitioners, general surgeons, internists and pediatricians responded, demonstrates that one-quarter of the respondents acknowledge receiving payments from medical industry companies.⁴ Similarly, a study published in the *New England Journal of Medicine* revealed that 80% of the responding doctors accepted free food or drug samples, one-third admitted being reimbursed for travel expenses to attend professional meetings or continuing medical education, and 28% reported they were paid for consulting, giving lectures, or signing up patients for clinical trials.⁵

Physicians serving as department heads in medical schools and teaching hospitals are also financially tied to the medical industry. In a survey published in the *Journal of the American Medical Association*, two-thirds of department heads acknowledge they have financial or other ties to the

⁴ *Survey finds doctor links with industry*, UPI (Apr. 26, 2007),

<http://it.moldova.org/news/survey-finds-doctor-links-with-industry-44482-eng.html>.

⁵ Christopher Lee, *Drugmakers, Doctors Get Cozier: Gifts Continue, Contacts Increase Despite Guidelines*, WASH. POST (Apr. 29, 2007),

<http://pqasb.pqarchiver.com/washingtonpost/access/1262426781.html?FMT=ABS&FMTS=A BS:FT&date=Apr+29%2C+2007&author=Christopher+Lee+->

[+Washington+Post+Staff+Writer&pub=The+Washington+Post&edition=&startpage=A.3&desc=Drugmakers%2C+Doctors+Get+Cozier%3B+Gifts+Continue%2C+Contacts+Increase+Despite+Guidelines; Robert Cohen, Doctors routinely receive perks from pharmaceutical industry](http://pqasb.pqarchiver.com/washingtonpost/access/1262426781.html?FMT=ABS&FMTS=A BS:FT&date=Apr+29%2C+2007&author=Christopher+Lee+-+Washington+Post+Staff+Writer&pub=The+Washington+Post&edition=&startpage=A.3&desc=Drugmakers%2C+Doctors+Get+Cozier%3B+Gifts+Continue%2C+Contacts+Increase+Despite+Guidelines; Robert Cohen, Doctors routinely receive perks from pharmaceutical industry), STAR-LEDGER, Apr. 26, 2007, at 79.

Family practitioners reported the highest number of meetings with drug company representatives (sixteen per month), followed by internists (nine per month), and cardiologists (ten per month). Doctors in group practices were three times as likely to receive gifts and nearly four times more likely to be paid for professional services than physicians practicing in hospitals. Eric G. Campbell et al., *A National Survey of Physicians – Industry Relationships*, NEW ENG. J. MED. (Apr. 26, 2007), <http://content.nejm.org/cgi/content/full/356/17/1742>. The drug industry has collectively decided to terminate the small gifts (e.g., pens, notepads, staplers, clocks, calculators, stethoscope lights, and other trinkets and knickknacks) pharmaceutical companies give to doctors effective January 1, 2009. See Alan Bavley, *Drug industry, government, schools tackle conflicts*, CHATTANOOGA TIMES FREE PRESS, Oct. 12, 2008, at A8.

industry (e.g., received research equipment or money to support residency and fellowship training, continuing medical education and research seminars from companies), 27% report that they worked as paid consultants, 27% report they served on companies' scientific advisory boards, 9% report they founded companies, and 7% report they served as company officers or executives.⁶

These types of financial relationships constitute conflicts of interest, which "occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised," and which pose a "serious threat . . . for professionalism and for the trust that patients have in physicians."⁷

III. FAILURE TO REPORT SIGNIFICANT CONSULTING COMPENSATION AND EQUITY HOLDINGS

While the above noted survey results standing alone do not indict the relationships between doctors and the medical industry, extensive information unearthed by Senator Charles E. Grassley (R. Iowa), ranking member of the United States Senate Committee on Finance, reveals multifaceted relationships between U.S. physicians and the medical industry, which have attracted significant attention and raise ethical concerns. Four recent revelations show that leading academic researchers at major universities have received, but failed to fully report, significant consulting fees from the medical industry.

First, the Senate Finance Committee reported that Psychiatry Professor Alan Schatzberg, a renowned and highly respected member of the Stanford University School of Medicine and President of the American Psychiatric Association, failed to report a \$22,000 payment from Johnson & Johnson for consulting services, ownership of stock worth \$6 million in Corcept

⁶ Katherine Mangan, *Medical Schools See Many Ties to Industry*, CHRON. HIGHER EDUC. (Oct. 26, 2007), at <http://chronicle.com/weekly/v54/i09/09a03103.htm>. See Charles Huckabee, *Another Academic Physician's Tied to Industry Come Under Senator's Scrutiny*, CHRON. HIGHER EDUC. (July 28, 2009), at http://chronicle.com/article/Another-Academic-Physicians/47484/?utm_source=at&utm_medium=en. (Medtronic, a medical device company, made \$1.14 million in payments to a University of Minnesota medical professor who receive research funds from the Pentagon to undertake a study involving one of the company's products and failed to disclose his consulting relationship with the company when he appeared before a Senate panel to urge the Defense Department to support research into combat relate injuries.)

⁷ Troyen A. Brennan, MD, MPH, et. al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, J. AM. MED. ASS'N, Jan. 25, 2006, at 430.

Therapeutics which he cofounded in 1998 and which recently developed the drug Mifepristone (RU-486) for the treatment of depression, and \$109,179 profits from sales of Corcept stock in 2005.⁸ As a consequence of these disclosures, Professor Schatzberg was forced to resign as principal investigator on his grant from the National Institutes of Health (NIH) to investigate the biology of psychotic depression and to determine the effectiveness of Mifepristone as an antidepressant.⁹ The results of that research are clearly capable of affecting the value of his Corcept stock.

Second, Senator Grassley accused Professor Jeffrey C. Wang, chief of UCLA's Orthopedic Spine Service, of violating university procedures by failing to inform UCLA that he received payments in the approximate amount of \$459,000 during the period 2004 to 2007 from Medtronic, Johnson & Johnson, and FzioMed for royalties, consulting fees, and speaking fees.¹⁰ In response to these accusations, UCLA removed Dr. Wang from his position as chief of the spine-surgery center.¹¹

Third, Senator Grassley accused Harvard University Medical School Psychiatrist Joseph Biederman of failing to report consulting income received from drug companies in the amount of \$1.6 million during the period 2000 to 2007.¹² Dr. Biedermann, a widely recognized expert on the use of antipsychotic drugs in children, whose studies are often financed by the drug makers and contributed to a 40-fold increase in the diagnosis of pediatric bipolar disorder,¹³ persuaded Johnson & Johnson, the manufacturer

⁸ Ryan Mac, *Iowa senator targets Stanford Prof for conflict of interest*, STANFORD DAILY (July 10, 2008), <http://www.cbsnews.com/stories/2008/07/10/politics/uwire/main4250153.shtml>; Arlene Weintraub, *Drugmakers and College Labs: Too Cozy*, BUS. WEEK (June 26, 2008), http://www.businessweek.com/print/technology/content/jun2008/tc20080626_630542.htm; and Kent Garber, *Committee Questions a Top Psychiatrist*, U.S. NEWS & WORLD REPORT (June 26, 2008), <http://politics.usnews.com/news/national/articles/2008/06/26/committee-questions-a-top-psychiatrist.html>.

⁹ Maria Jose Vinas, *Stanford Researcher, Accused of Conflicts, Steps Down as NIH Principal Investigator*, CHRON. OF HIGHER EDUC. (Aug. 1, 2008), <http://chronicle.com/article/Stanford-Researcher-Accuse/41395/>.

¹⁰ Paul Basken, *UCLA Surgeon Accused of Hiding Medical Company's Payments*, CHRON. OF HIGHER EDUC. (May 28, 2009), <http://chronicle.com/article/UCLA-Surgeon-Accused-of-Hid/47658/>.

¹¹ Paul Basken, *UCLA Investigates Corporate Payments to a Surgeon at Its Medical School*, CHRON. OF HIGHER EDUC. (July 21, 2009), <http://chronicle.com/article/UCLA-Investigates-Corporate/47423>.

¹² *Harvard Psychiatrists Underreported Earnings from Drug Companies, Investigators Say*, CHRON. OF HIGHER EDUC. (June 8, 2008) <http://chronicle.com/article/Harvard-Psychiatrists-Under/41117/>; KAISER DAILY HEALTH POLICY REPORT, THE HENRY J. KAISER FAMILY FOUNDATION (June 9, 2008), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=52614.

¹³ Gardiner Harris and Benedict Carey, *Researchers Fail to Reveal Full Drug Pay*, N.Y. TIMES (June 8, 2008),

of Risperdal, to establish and fund the Johnson & Johnson Center for the Study of Pediatric Psychopathology at Boston's Massachusetts General Hospital to conduct clinical trials to determine appropriate use and dosing of Risperdal in children.¹⁴ Dr. Biedermann and his colleagues published the results of that research in many articles favorable to the drug,¹⁵ even though those clinical trials were apparently conducted contrary to restrictions imposed by Harvard University and Massachusetts General prohibiting researchers from conducting clinical trials if they receive payments of more than \$20,000 from a drug maker.¹⁶

Finally, Senator Grassley accused Charles B. Nemeroff, a prominent Emory University psychiatrist, of failing to report at least one third of the \$2.8 million in consulting fees he received from GlaxoSmithKline between 2000 and 2007, while he was the principal investigator on a \$3.9 million grant from NIH to study five Glaxo drugs for treatment of depression.¹⁷ While Emory University regulations prohibit the acceptance of more than \$10,000 per year from any one company, Dr. Nemeroff exceeded that threshold each year between 2003 and 2006 but lied about it to Emory.¹⁸ Dr. Nemeroff resigned as the principal researcher of the NIH grant on October 24, 2008, pending an investigation into his relationship with the drug company.¹⁹ Upon completion of the investigation, Emory University

http://www.nytimes.com/2008/06/08/us/08conflict.html?_r=1&scp=1&sq=Researchers%20Fail%20to%20Reveal%20Full%20Drug%20Pay&st=cse.

¹⁴ David Armstrong and Alicia Mundy, *J&J Emails Raise Issues of Risperdal Promotion*, WALL ST. J. (Nov. 25, 2008),

<http://online.wsj.com/article/SB122755237429253763.html?KEYWORDS=JJ+Emails+Raise+Issues+of+Risperdal+Promotion;Gardiner+Harris,+Research+Center+Tied+to+Drug+Company>, N.Y. TIMES (Nov. 25, 2008),

<http://www.nytimes.com/2008/11/25/health/25psych.html?scp=1&sq=Research%20Center%20Tied%20to%20Drug%20Company&st=cse>.

¹⁵ Armstrong, *supra* note 14.

¹⁶ *Id.* See *For Harvard Psychiatrist, Professorliness Is Next to Godliness*, CHRON. OF HIGHER EDUC. (Mar. 20, 2009), <http://chronicle.com/article/For-Harvard-Psychiatrist-P/42600/> (In advance of his research, Dr. Biederman promised Johnson & Johnson that the proposed drug trial "will clarify the competitive advantages of risperidone vs. other neuroleptics.").

¹⁷ Denise Gellene and Thomas H. Maugh II, *Doctor Accused in Congress' Probe*, LOS ANGELES TIMES (Oct. 4, 2008)

<http://pqasb.pqarchiver.com/latimes/access/1567238281.html?FMT=ABS&FMTS=ABS:FT&type=current&date=Oct+4%2C+2008&author=Denise+Gellene%3BThomas+H.+Maugh+II&pub=Los+Angeles+Times&edition=&startpage=A.19&desc=Science+File%3B+Doctor+accused+in+Congress%27+probe%3B+An+Emory+University+psychiatrist+allegedly+failed+to+report+much+of+the+income+he+got+from+firms+whose+drugs+he+was+evaluating>.

¹⁸ *Emory U. Psychiatrist Failed to Report Income from Drug Makers*, CHRON. OF HIGHER EDUC. (Oct. 4, 2008), <http://chronicle.com/article/Emory-U-Psychiatrist-Faile/41743/>.

¹⁹ Chrissie Cole, *NIH Suspends Emory University Grant*, THE INJURY BOARD NATIONAL NEWS DESK (Oct. 14, 2008), <http://news.injuryboard.com/nih-suspends-emory-university-grant.aspx?googleid=249420>.

announced that Dr. Nemeroff relinquished his post as Department Chair, a position he held for 17 years, that it would not submit a NIH or other sponsored grant or contract requests listing Dr. Nemeroff as an investigator or in any other role for a period of at least two years, and that Dr. Nemeroff must submit any compensation requests for speaking engagements to the dean's office for review.²⁰

While those actions penalized Emory University, they did not deter Dr. Nemeroff. NIH continued his eligibility to serve on NIH advisory panels providing recommendations on who received grant funding.²¹ One year later, Dr. Nemeroff accepted the position of professor and chairman of the department of psychiatry and behavioral sciences at the University of Miami.²² Dr. Nemeroff landed the job shortly after Thomas R. Insel, Director of the National Institute of Mental Health, responding to the inquiry of the dean of the University of Miami's medical school, confirmed that Dr. Nemeroff was NIH grant eligible and could begin applying for NIH grants as soon as he arrived on campus.²³ Dr. Insel also gave the dean a positive recommendation of Dr. Nemeroff in an ensuing telephone conversation, NIH rules prohibiting a formal, written recommendation.²⁴ Dr. Insel's assistance reportedly was pay-back for earlier help given to him by Dr. Nemeroff. When Dr. Insel faced nonrenewal of his research position at NIH in 1994, Dr. Nemeroff hired him as professor of psychiatry and research director, and later lobbied in favor of Dr. Insel's appointment as Director of NIMH in 2002.²⁵

²⁰ *Emory U. Scientist Penalized for Hidden Payments From Drug Company*, CHRON. OF HIGHER EDUC. (Dec. 29, 2008), <http://chronicle.com/article/Emory-U-Scientist-Penalize/42166/>. Emory University publicly disclosed another psychiatrist's conflict of interest, when its medical school dean issued a letter of reprimand to Zachary N. Stowe, a professor of psychiatry, for failure to reveal he was paid by GlaxoSmithKline, a manufacturer of antidepressants, at the same time Dr. Stowe conducted a federally financed study of the use of the drugs in pregnant women. Paul Baskin, *Emory U. Penalizes Another Psychiatrist With Hidden Financial Conflicts of Interest*, CHRON. OF HIGHER EDUC. (June 10, 2009), <http://chronicle.com/article/Emory-U-Penalizes-Another-/47727/>.

²¹ Paul Baskin, *NIH Director Says New Rules on Conflicts May Need to Be Toughened Further*, CHRON. OF HIGHER EDUC. (June 11, 2010), http://chronicle.com/article/NIH-Director-Says-New-Rules-on/65905/?sid=at&utm_source=at&utm_medium=en.

²² Paul Baskin, *As He Worked to Strengthen Ethics Rules, MIMH Director Aided a Leading Transgressor*, CHRON. OF HIGHER EDUC. (June 6, 2010), http://chronicle.com/article/While-Revising-Ethics-Rules/65800/?sid=at&utm_source=at&utm_medium=en.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

IV. IMPOTENCE OF NIH, FDA, AND UNIVERSITIES TO UNCOVER CONFLICTS OF INTEREST

The four cases discussed above underscore the significance of the conflicts of interest uncovered by Senator Grassley and the impotence of NIH and the physicians' academic institutions to prevent them. While federal regulations require that researchers receiving NIH grants remain free of financial conflicts of interest (defined as receiving more than \$10,000 per year or owning more than 5% of an entity that might bias their work), NIH relies on the academic institutions to gather financial information from grant investigators and to manage or eliminate conflicts of interest, but does not require universities to provide information about the conflicts or how they are resolved.²⁶ Indeed, a report of the inspector general of the Department of Health and Human Services concedes NIH does not know the number or nature of conflicts of interest and does not track how universities and other institutions resolved them.²⁷ Perhaps prompted by the steady stream of financial conflicts of interest in scientific research, NIH recently published a notice in the *Federal Register* announcing it would initiate formal rule making procedures to control how institutions better guarantee their research scientists are not biased by outside company payment.²⁸

The FDA may be faring no better than NIH. The Office of Inspector General of the U.S. Department of Health and Human Services audited the financial disclosures made by researchers in "all 118 marketing applications approved by the FDA in the 2007 fiscal year," determined that "[o]nly 1

²⁶ Jeffrey Brainard, *NIH Turns Blind Eye to Academics' Financial Conflicts, Audit Says*, CHRON. OF HIGHER EDUC. (Feb. 1, 2008), <http://chronicle.com/weekly/v54/i21/21a00801.htm>; Richard Monastersky, *Hidden Payments to University Researchers Draw New Fire*, CHRON. OF HIGHER EDUC. (Oct. 31, 2008), <http://chronicle.com/weekly/v55/i10/10a01301.htm>; Jeffrey Brainard, *Senator Grassley Pressures Universities on Conflicts of Interest*, CHRON. OF HIGHER EDUC. (Aug. 8, 2008), <http://chronicle.com/weekly/v54/i48/48a01201.htm>.

²⁷ Gardiner Harris, *Researchers Go Unchecked, Report Says*, N.Y. TIMES (Jan. 19, 2008), http://www.nytimes.com/2008/01/19/us/19conflict.html?_r=1&scp=1&sq=Researchers%20Go%20Unchecked,%20Report%20Says&st=cse.

²⁸ Paul Basken, *NIH Plans New Rules to Police Researchers' Financial Conflicts of Interest*, CHRON. OF HIGHER EDUC. (May 11, 2009), http://chronicle.com/news/article/6456/nih-plans-new-rules-to-police-researchers-financial-conflicts-of-interest?utm_source=at&utm_medium=en. In response to NIH's request for public comment, two academic organizations, the Association of American Universities and the Association of American Medical Colleges, submitted a joint letter urging NIH to increase its oversight over research conflicts of interest and recommending that all research investigators report all financial conflicts of interest to their academic institutions related directly or indirectly to their research regardless of the amount of money involved. Katherine Mangan, *2 Academic Associations Urge the NIH to Increase Oversight of Research Conflicts*, CHRON. OF HIGHER EDUC. (June 11, 2009), http://chronicle.com/daily/2009/06/19810n.htm?utm_source=at&utm_medium=en.

percent of clinical investigators disclosed a financial interest in the products they studied,” and concluded that “[c]linical investigators may not be disclosing all financial interests.”²⁹ In contrast, and as noted above, the Harvard University survey of U.S. doctors determined that 28% of doctors were paid for consulting, giving lectures, or signing up patients for clinical trials, and the AMA survey determined that 27% of medical school department heads worked as paid consultants.

Further, most universities rely on their professors to report financial information, but lack the wherewithal to verify the information they submit.³⁰ Only a handful of states (Minnesota, Vermont, Maine, West Virginia, and California) and the District of Columbia require some level of disclosure of pharmaceutical company payments to physicians.³¹ Hence, there is no database which universities can use to check the disclosures made by physicians to their academic institutions or which informs the public of the fees paid by drug companies to physicians for consulting, speeches, and clinical trials.³² Moreover, the information submitted by universities to NIH about conflicts of information is not helpful: two-thirds of the reports failed to provide basic information describing the conflict and 90% failed to

²⁹ Paul Basken, *FDA Is Not Doing Enough to Thwart Conflicts of Interest in Research, Audit Finds*, CHRON. OF HIGHER EDUC. (Jan. 12, 2009), http://chronicle.com/news/article/5782/the-fda-is-not-doing-enough-against-conflicts-of-interest-audit-finds?utm_source=at&utm_medium=en. The Inspector General’s report caused Senator Grassley to remark: “It looks like the ability of the Food and Drug Administration to track financial ties is just as broken down as that of the National Institutes of Health.” See Press Release, Grassley Comments on FDA Tracking of Clinical Investigators’ Financial Ties (Jan. 12, 2009) (http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=18741).

³⁰Basken, *supra* note 29.

³¹ Gardiner Harris and Janet Roberts, *A State’s Files Put Doctors’ Ties to Drug Makers on a Close View*, N.Y. TIMES (Mar. 21, 2007), <http://www.nytimes.com/2007/03/21/us/21drug.html?scp=1&sq=A+State%92s+Files+Put+Doctors%92+Ties+to+Drug+Makers+on+a+Close+View&st=nyt>. The Vermont legislature recently approved a law requiring the disclosure of financial conflicts of interest involving drug and medical device makers and physicians, nurses, pharmacists, and other health-care providers. The law also bans industry-sponsored meals and nearly all other gifts to health-care providers. Katherine Mangan, *Vermont Legislature Cracks Down on Drug Company Gifts*, CHRON. OF HIGHER EDUC. (May 19, 2009), http://chronicle.com/news/article/6504/vermont-legislature-cracks-down-on-drug-company-gifts?utm_source=at&utm_medium=en. A Massachusetts statute bans all gifts from pharmaceutical and medical device companies to physicians. David Armstrong, *Two States Restrict Firms’ Gifts to Doctors*, WALL ST. J. (July 1, 2009), <http://online.wsj.com/article/SB124640634767976599.html>.

³² See, e.g., Maura Lerner et al., *Doctors’ ties to drug firms raise concern*, STAR TRIBUNE (Mar. 23, 2007),

<http://www.prescriptionproject.org/assets/pdfs/StarTribune%20March%2023.pdf> (detailing the income earned by Minnesota physicians and reported by medical companies to the Minnesota Pharmacy Board).

describe how the conflict was resolved.³³ Indeed, a recent survey led by the Association of American Medical Colleges found that fewer than 40% of medical schools have policies governing institutional conflicts of interest,³⁴ and the results of a recent survey of 211 chairmen of institutional review boards at research-intensive medical institutions in the United States demonstrate that one-third of the review boards did not require voting members to disclose any financial relationships with outside companies.³⁵ Further, a recent audit conducted by the inspector general of the Department of Health and Human Services demonstrated that “[u]niversities involved in federally sponsored medical research rarely take steps to investigate, reduce, or eliminate financial conflicts of interest among their scientists,” that universities rarely direct the scientists to alter their financial relationships when conflicts are acknowledged, and that “the NIH does little, if anything, to police the matter.”³⁶

V. INHERENT FORCES FOMENTING CONFLICTS OF INTEREST

Several forces have coalesced to increase the incidence of conflicts of interest in the medical industry: the vertical integration of the pharmaceutical industry, the 1980 Bayh-Dole Act, and the rapidly accelerating need of the medical industry to conduct human experiments.

A. Vertical Integration of Pharmaceutical Industry

The pharmaceutical industry has become increasingly vertically integrated, giving drug companies control over the entire chain of production.³⁷ Drug companies develop new products, hire university and private-sector researchers to conduct drug trials, contribute to the design and pay for the study, and control which study results get published.³⁸ Drug

³³ Brainard, *supra* note 26.

³⁴ Monastersky, *supra* note 26 (“A recent survey led by the Association of American Medical Colleges found that less than 40 percent of medical schools have policies governing institutional conflicts of interest, such as might arise when a company provides money directly to a university or to its senior officials. Over two-thirds of the medical colleges have more-limited policies governing payments to senior officials, but more than 20 percent of the institutions did not have even those narrow policies.”).

³⁵ Paul Basken, *Campus Medical-Review Boards Often Fail to Police Themselves, Survey Finds*, CHRON. OF HIGHER EDUC. (Mar. 26, 2009), http://chronicle.com/daily/2009/03/14555n.htm?utm_source=at&utm_medium=en.

³⁶ Paul Basken, *Federal Audit Faults Universities Over Researchers' Financial Conflicts of Interest*, CHRON. OF HIGHER EDUC. (Nov. 19, 2009), http://chronicle.com/article/Federal-Audit-Faults/49220/?sid=pm&utm_source=pm&utm_medium=en.

³⁷ Sheldon Krimsky, *A Dose of Reform*, STAR LEDGER, Feb. 20, 2005, at 1.

³⁸ *Id.*

companies also market prescription drugs directly to consumers and physicians,³⁹ support medical journals and conferences through advertising and contributions, fund physician continuing education⁴⁰ and medical symposia, pay consulting fees to physicians for giving presentations and serving on committees and boards,⁴¹ have financial relationships with the authors of guidelines establishing standards for prescribing medicines,⁴² and provide financial incentives to physicians to promote off-label prescriptions of drugs to provide data justifying the alternative uses of pharmaceutical products.⁴³ Using their increased vertical control, as will be discussed more

³⁹ Some legislators have responded to the direct marketing of drugs to consumers by introducing legislation to ban ads for prescriptions such as Viagra and Levitra in prime time television on decency grounds and to empower the FDA to prohibit tax deductions for drug advertisements directed to consumers. Natasha Singer, *Lawmakers Seek to Curb Drug Commercials*, N.Y. TIMES (July 27, 2009), http://www.nytimes.com/2009/07/27/business/media/27drugads.html?_r=1&scp=1&sq=Lawmakers%20Seek%20to%20Curb%20Drug%20Commercials&st=cse.

⁴⁰ A recent study of continuing-medical-education courses at the University of Wisconsin at Madison concluded that industry-sponsored continuing education courses offered without charge to physicians at Wisconsin “frequently advocate prescription medications over drug-free therapies and omit important information about potentially deadly side effects.” Katherine Mangan, *U. of Wisconsin’s Industry-Backed Courses Mislead Doctors and Could Hurt Patients*, CHRON. OF HIGHER EDUC. (Mar. 30, 2009), <http://chronicle.com/article/U-of-Wisconsins-Industry-/42653/>.

⁴¹ *Id.*

⁴² Nicholas Bakalar, *Potential Conflicts Cited in Process for New Drugs*, N.Y. TIMES (Oct. 25, 2005), <http://www.nytimes.com/2005/10/25/health/policy/25drug.html?scp=1&sq=Potential+Conflicts+Cited+in+Process+for+New+Drugs&st=nyt> (“more than one-third of the guideline authors acknowledged some financial interest in the drugs they recommended, including owning stock and being paid by the company to speak at seminars”; and “in half of the more than 200 guidelines examined, at least one author had received research financing from a relevant company, and 43 percent had at least one author who had been a paid speaker for the company.”).

⁴³ Miriam Hill, *Casting a light on ‘off-label’ medical devices*, PHILADELPHIA INQUIRER, June 23, 2009, p. C1. Pfizer recently pleaded guilty to a felony violation for “misbranding Bextra with the intent to defraud or mislead,” entered into a \$2.3 billion settlement with the Justice Department for illegally marketing of the antibiotic Zyxov, the painkiller Bextra, epilepsy and nerve pain drug Lyrica, and the antipsychotic Geodon, and “agreed to an ‘expansive corporate integrity agreement’ with the Office of Inspector General of the Department of Health and Human Services” to avoid similar matters in the future. Shirley S. Wang, *It’s Official: Pfizer Pleads Guilty to Illegal Marketing of Bextra*, WALL ST. J. (July 18, 2010), <http://blogs.wsj.com/health/2009/09/02/its-official-pfizer-pleads-guilty-to-illegal-bextra-marketing/tab/print>; Ashley Jones, *Pfizer Makes History With \$2.3 B Fraud Settlement*, WALL ST. J. (Sept. 2, 2009), <http://blogs.wsj.com/law/2009/09/02/pfizer-makes-history-with-23b-fraud-settlement/tab/print>; and Miriam Hill, *FDA: Pfizer ignored warnings, gets record fine*, PHILADELPHIA INQUIRER, September 3, 2009, at C1. More recently, on January 15, 2010, Eli Lilly & Co. entered a guilty plea to charges it illegally marketed the anti-psychotic drug Zyprexa, and agreed to pay \$1.42 billion to settle civil lawsuits and the criminal investigation.

fully below, drug companies seek to speed products to market as quickly as possible.⁴⁴

The efforts of the pharmaceutical industry to promote drugs for the treatment of kidney disease typify the first cause. Pharmaceutical companies Gambro Healthcare and Amgen paid consulting fees to David Van Wyck, a University of Arizona College of Medicine professor, while he chaired a National Kidney Foundation panel charged with updating physician guidelines for treating anemia in kidney patients during 2004 and 2005.⁴⁵ Indeed, 12 of the 18 members of the panel chaired by Van Wyck disclosed financial ties to Amgen, Johnson & Johnson, or other manufacturers or marketers of antianemia drugs.⁴⁶ After the more liberal prescribing guidelines for the drug were finalized, Van Wick became a paid consultant to DaVita Inc., which acquired Gambro in 2005, is the nation's second-largest dialysis chain, and profits from the use of the drugs in more than 1,200 clinics.⁴⁷

Likewise, in 2004, the pharmaceutical company Amgen underwrote more than \$1.9 million worth of research and educational programs led by Dr. Allan Collins, the president-elect of the National Kidney Foundation. Amgen made the payments to the Minneapolis Medical Research Foundation (MMRF) pursuant to its research contract with MMRF, for which Dr. Collins served as senior researcher. The payments triggered concerns, because they represented a substantial financial connection to an individual closely associated with the National Kidney Foundation at a time the Foundation was considering revisions to its guidelines on treating anemia in kidney patients.⁴⁸

Similarly, in 2006 the pharmaceutical industry accounted for about 30% of the annual \$62.5 million budget of American Psychiatric Association, the

Eli Lilly settles Zyprexa lawsuit for \$1.42 billion, MSNBC (Jan. 15, 2009), <http://www.msnbc.msn.com/id/28677805/>.

⁴⁴ Alice Dembner, *Research Integrity Declines*, BOSTON GLOBE, Aug. 22, 2000, at E2.

⁴⁵ Christopher Rowland, *Researchers' advice stirs issue of conflict dispute over care of kidney patients*, BOSTON GLOBE (Dec. 8, 2006), http://www.boston.com/business/globe/articles/2006/12/08/researchers_advice_stirs_issue_of_conflict.

⁴⁶ *Id.*

⁴⁷ *Id.* Similar tactics were used by the five largest U.S. orthopedic firms who manufacture artificial knees and hips. In September 2007, four of those firms (Zimmer Inc., DuPuy Orthopaedics, Biomet Inc., and Smith & Nephew) reached a settlement with the Department of Justice and agreed to pay \$311 million in fines and to release the list of their consultants and the payments they received. The fifth company, Stryker Orthopaedics, also released a list of its paid consultants, but was not named in the criminal complaint, because it cooperated with the federal investigators in the probe. According to the data they released, the five companies paid more than \$200 million to doctors, clinics and university health systems across the country in 2007, for royalties, clinical trials, and consulting fees. Bill Toland, *Are Doctors Getting Fees or 'Bribes'?*, PITTSBURGH POST-GAZETTE (Nov. 7, 2007), <http://www.post-gazette.com/pg/07311/831621-28.stm>.

⁴⁸ Harris, *supra* note 31.

field's leading professional organization, which publishes the field's major journals and its standard diagnostic manual. One half of those contributions purchased drug advertisements in psychiatric journals and exhibits at the Association's annual meeting.⁴⁹ Many psychiatrists earn consulting fees from the pharmaceutical industry to give dinner talks about drugs to other physicians for fees ranging from \$750 to \$3,500 per event.⁵⁰ Minnesota and Vermont, which require pharmaceutical companies to disclose their payments to physicians in those states, report drug makers gave more money to psychiatrists than other specialties and that psychiatrists who received at least \$5,000 from drug makers of newer-generation antipsychotic drugs wrote three times as many prescriptions to children for the drugs as psychiatrists who received less money.⁵¹ Studies have also demonstrated that researchers who are paid by drug companies are more likely to report positive findings when evaluating that company's drug.⁵² Further, 19 of the 27 members of the panel developing the Diagnostic and Statistical Manual of Mental Disorders ("DSM-V") prepared by the American Psychiatric Association and scheduled for publication in 2012, reported direct industry ties to the pharmaceutical companies, an increase of 14% over the percentage of DSM-IV task force members.⁵³ DSM-V is the APA's reference book, "the mental health bible," which recommends "treatment for known types of mental disorders, including what treatments are covered by health-care providers."⁵⁴ These financial conflicts are dangerous, because:

[D]iagnosis informs treatment decisions. Hence, pharmaceutical companies have a vested interest in the structure and content of DSM and in how the symptomatology is revised. Even small changes in symptom criteria can have a significant impact on what new (or off-label) medications may be prescribed. Public trust in the independence of clinical psychiatry is undermined if former DSM panel members are using - or a perceived as using - their participation on DSM to leverage lucrative consulting arrangements with the Pharmaceutical industry or to funnel

⁴⁹ Benedict Carey and Gardiner Harris, *Psychiatric Association Faces Senate Scrutiny Over Drug Industry Ties*, N.Y. TIMES (July 18, 2008),

<http://www.nytimes.com/2008/07/12/washington/12psych.html?scp=1&sq=Psychiatric%20Association%20Faces%20Senate%20Scrutiny%20Over%20Drug%20Industry%20Ties&st=cse>.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ Lisa Cosgrove and Harold J. Bursztajn, *Toward Credible Conflict of Interest Policies in Clinical Psychiatry*, PSYCHIATRIC TIMES (Jan. 1, 2009),

<http://www.psychiatrictimes.com/display/article/10168/1364672>.

⁵⁴ Paul Basken, *Do Drugs Help Psychiatrists Tune Out Patient Voices?*, CHRON. OF HIGHER EDUC. (Jan. 15, 2009), <http://chronicle.com/article/Do-Drugs-Help-Psychiatrists/42250/>.

industry funding to their departments, associates, and programs (e.g., exerting their influence on prescription practices through public speaking arrangements, such as industry-sponsored CME symposia).⁵⁵

Perhaps recognizing the dangers posed by medical industry sponsorship of conferences and association activities, past and current leaders of several professional medical associations recently advocated ending medical industry financial support for their conferences in a joint statement published in *The Journal of the American Medical Association*, because "such practices compromise health-care decisions and undermine public trust."⁵⁶ The leaders endorsing the statement were associated with the American Psychiatric Association, American College of Obstetricians and Gynecologists, American College of Physicians, American Academy of Pediatrics, American College of Cardiology, and Council of Medical Specialty Societies.⁵⁷

B. *The 1980 Bayh-Dole Act*

The second force contributing to the increase of conflicts of interest in the medical industry is the 1980 Bayh-Dole Act. The Bayh-Dole Act foments the commercialization of new medical products by creating a uniform patent policy among the many federal agencies funding research, and gives academic researchers and their institutions the right to products developed with government money. This permits them to license the inventions to other parties, thereby encouraging them to develop financial ties to the biotechnology or pharmaceutical industries.⁵⁸ Doctors quickly learned that they could go into business while continuing to practice medicine.⁵⁹

The second force is illustrated by Isador Lieberman, a leading Cleveland Clinic orthopedic surgeon, who pioneered and promoted a new treatment known as kyphoplasty for spinal fractures, and simultaneously enjoyed a

⁵⁵ Cosgrove, *supra* note 53. In their "Counterpoint" to Dr. Cosgrove, Drs. David Kupfer and Darrel Begier eschew any such danger, because no wrongdoing has been proved, the relationships among academic institutions, the government, and the pharmaceutical industry are collaborative, and the drug industry is regulated by the government. *Id.*

⁵⁶ Paul Basken, *Medical-Group Leaders Call for End to Industry Role at Meetings*, CHRON. OF HIGHER EDUC. (Apr. 2, 2009),

http://chronicle.com/daily/2009/04/14971n.htm?utm_source=at&utm_medium=en.

⁵⁷ *Id.*

⁵⁸ Dembner, *supra* note 44; Arlene Weintraub and Amy Barrett, *Medicine in Conflict*, BUS. WEEK (Oct. 23, 2006),

http://www.businessweek.com/magazine/content/06_43/b4006081.htm.

⁵⁹ Weintraub, *supra* note 58.

decade-long professional association with Kyphon Inc., a Sunnyvale, California, kyphoplasty equipment manufacturer. Kyphoplasty competes with its predecessor treatment, vertebroplasty, in spine surgeries primarily on patients with osteoporosis-related spinal fractures. While both procedures inject cement into the broken spinal column, kyphoplasty inserts a balloon device into the compressed vertebra to try to restore its original height, and then inserts the cement into the cavity. Vertebroplasty is routinely performed on an outpatient basis with local anesthesia; kyphoplasty requires more expensive equipment, general anesthesia and overnight hospital stays, and hence is considerably more expensive than vertebroplasty. Dr. Lieberman began offering advice to Kyphon shortly after arriving at the Cleveland Clinic in 1997. He initiated the inaugural work on kyphoplasty in the Cleveland Clinic in 1999, using equipment provided by Kyphon, and reported the results of the first 30-patient trial of kyphoplasty in a medical journal.⁶⁰ Working with Dr. Mark Reiley, an orthopedic surgeon who developed the use of a balloon in spinal surgery and co-founded Kyphon Inc. to develop the instruments used in kyphoplasty, Dr. Lieberman praised the favorable results obtained in their initial use of kyphoplasty on 26 patients on the web and permitted data generated from his Clinic procedures to be used for commercial purposes before being published in medical journals. Dr. Lieberman accepted Kyphon's invitation to serve on its scientific and clinical advisory board, and, during his first kyphoplasty trial at the Cleveland Clinic, was offered stock options in the company, permitting him to purchase Kyphon stock for \$1 per share before the company went public at \$15 a share.⁶¹ Lieberman exercised those options in June 2002, subsequently selling the stock at several intervals between then and January 2005.⁶² In 2004, when questions about the safety of the kyphoplasty procedure arose, largely related to the danger of subjecting elderly patients to trauma and general anesthesia and the attempts to treat three or more vertebrae at once because of the higher cost of the procedure, Dr. Lieberman led the rebuttal for kyphoplasty.⁶³ While promoting and defending kyphoplasty, Lieberman did not tell his patients about his financial interest in Kyphon unless asked, and did not reveal his Kyphon stock ownership in the numerous articles he wrote about kyphoplasty or in his Spring 2005 testimony touting the benefits of kyphoplasty at a Centers for Medicare and Medicaid Services committee hearing.⁶⁴

⁶⁰ Joel Rutchick, *Surgeon kept quiet about stake in company*, PLAIN DEALER, Dec. 10, 2006, p.

A1.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

C. *The Rapidly Accelerating Need of the Medical Industry to Conduct Human Experiments*

The third force contributing to an increase in conflicts of interest in the medical industry is the rapidly accelerating need of the medical industry to conduct human experiments as part of the drug and medical device approval process. In the early 1990s, managed care squeezed drug prices, leaving drug companies with one option: increasing the number of drugs they were selling. When the drug companies tried to hasten drug development, the academic world was unable to adapt rapidly, and drug companies began to recruit private practice doctors to mine their patient base for research subjects.⁶⁵ In short order, the medical industry changed providers of human subject experiments required as part of the approval process. In 1991, nearly 80% of human experiments were conducted by nonprofit academic medical centers; by 2000, 40% of the 60,000 human subject studies were conducted by nonprofit academic medical centers, and 60% were conducted by for-profit companies, moving more research to "private settings and even storefront clinics."⁶⁶ Likewise, there has been a significant increase in private industry funding of medical research that takes place in U.S. universities. According to a *New England Journal of Medicine* study, private industry funds more than two-thirds of medical research at U.S. universities; two decades ago, the main contributor to medical research was the federal government.⁶⁷

The pressure to accelerate the pace of human experiments is seen most clearly in two ways: the pharmaceutical industry has increased the bounty it pays to physician to recruit volunteers for sponsored studies, and physicians themselves have increasingly engaged in the business of conducting human experiments. An investigation published by *The New York Times* reveals:

- Drug companies and their contractors offer large payments to doctors, nurses and medical staff to encourage the recruitment patients to enroll in the trials and offer finder fees to physicians who refer their patients to other doctors for research; fees paid to physicians for an enrolled patient ranged from \$3,500 to

⁶⁵ Kurt Eichenwald and Gina Kolata, *Drug Trials Hide Conflicts for Doctors*, N.Y. TIMES (May 16, 1999), <http://www.nytimes.com/1999/05/16/business/drug-trials-hide-conflicts-for-doctors.html>.

⁶⁶ Dembner, *supra* note 44.

⁶⁷ Alicia Chang, *Study identifies conflicts in med school research*, STAR LEDGER, May 26, 2005, at 63.

\$5,000, enabling some physicians to net between \$500,000 and \$1 million per year doing clinical research.

- Physicians who successfully recruit the most patients are offered the opportunity to ghost write the papers published about the research.
- Testing companies frequently use physicians as clinical investigators regardless of their specialty, leaving the patient volunteers in the study to the care of a physician who is not knowledgeable about the patient's condition.
- Physicians conducting clinical investigations increasingly have little experience as clinical investigators.⁶⁸

The shift to private industry providers of drug studies is demonstrated by the following *New York Times* data: in 1997, 11,662 private doctors conducted drug studies, a threefold increase since 1990, when 4,307 doctors conducted such studies.⁶⁹ Satisfied with the responsiveness and flexibility of private physicians who “sign contracts overnight, advertise widely, offer financial incentives for patients and open their offices at unusual times to accommodate patient schedules,”⁷⁰ the drug industry has begun to aggressively recruit doctors to “grab their piece of the research pie.”⁷¹ As the number of physicians conducting research has increased, the average number of studies conducted by physicians has decreased (e.g., during the 1990s, 70% of the doctors conducting human experiments were involved in three or fewer drug studies; in 1997, one-quarter of the doctors conducted only one experiment).⁷² This means that an increasing number of physicians conducting drug testing have little or no experience in doing so, and, with the increase in the number of generalist physicians engaged in research, doctors conducting clinical trials often have no expertise in the disease they are investigating.⁷³ Nonetheless, they receive several thousand dollars in compensation per patient for examining and monitoring as many as 24 trial participants over the course of several months.⁷⁴

⁶⁸ Eichenwald, *supra* note 65.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Keith Darci, *Drug companies rely on volunteers to test their wares*, SAN DIEGO UNION-TRIBUNE, May 19, 2008, Today's Scene.

While the pressure to increase the pace of human experiments has increased, a study of the institutional review board policies at medical schools that receive funding from the National Institutes of Health demonstrates that fewer than half of those policies cover the topic of using finder fees or bonus payments to help recruit study participants.⁷⁵ In the absence of those policies, researchers “might otherwise be tempted to enroll ineligible study participants.”⁷⁶

VI. RELATED CHANGES IN MEDICAL RESEARCH

The significant increase in private industry drug studies has spawned three other changes in medical research: medical company contributions to nonprofit foundations associated with for-profit medical practices, ghost writing in medical research, and the celebrity medical expert.

A. Contributions to Physicians' Nonprofit Foundations

Physicians in private practice have begun to establish tax-exempt charities to engage in medical research or education, and drug and medical device companies are making significant contributions to these nonprofit organizations.⁷⁷ While the nonprofit organizations are separate entities, they are closely linked to physicians' medical practices. Typically, medical companies contribute funds to the nonprofit organizations to support medical research and educational programs. For example:

- CHF Solutions, a medical device company, contributed \$180,000 to the Midwest Heart Foundation, a charitable organization associated with a thriving for-profit medical group outside of Chicago, which uses many of the products made by CHF Solutions. CHF Solutions' contribution represented about 10% of the contributions received by the Midwest Heart Foundation during 2004.
- Orthopedic device company Stryker contributed \$200,000 to the Arizona Orthopedic Education Foundation. Its founder, Anthony K. Hedley, uses mainly Stryker devices with his own patients.

⁷⁵ Paul Basken, *Universities Face Conflict-of-Interest Questions Over Finder Fees for Study Participants*, CHRON. OF HIGHER EDUC. (Mar. 19, 2009), <http://chronicle.com/article/Universities-Face/42592/>.

⁷⁶ *Id.*

⁷⁷ Reed Abelson, *Charities Tied to Doctors Get Drug Industry Gifts*, N.Y. TIMES (June 28, 2006), <http://www.nytimes.com/2006/06/28/business/28foundation.html>.

- DePuy Orthopaedics, a unit of Johnson & Johnson, contributed \$75,000 to the Blue Ridge Bone and Joint Research Foundation, headed by Joseph T. Moskal, an orthopedic surgeon in Roanoke, Virginia. Those funds were used to offset the costs of a fellowship program permitting physicians to train in orthopaedic surgery performed in his medical practice.
- Medical device makers Guidant and Medtronic contributed funds to the Vascular Specialists Education Foundation headed by Marc H. Glickman, which uses those funds to support training of physicians and fellows on vascular disease procedures.⁷⁸

To the extent these contributions are actually used for the foundation's charitable purpose (research and education), there would appear to be no problem. To the extent, however, these funds are used to subsidize or offset expenses of the medical practice (e.g., using fellowship funds to underwrite medical practice salary expenses), significant tax and conflict of interest issues and problems are created.

B. *Ghost Writing Scientific Research*

Senator Grassley described the practice of medical ghost writing in his inquiry to Wyeth Laboratories and press release dated December 12, 2008:

Over the last year, the Committee has been examining a practice used by drug companies referred to as "medical ghostwriting." I have been informed that this practice involves marketing and/or medical education companies that draft outlines and/or manuscripts of review articles, editorials, and/or research papers. This information is then presented to prominent doctors and scientists, particularly those affiliated with academic institutions, to review, edit and sign on as authors, whether or not they are intimately familiar with the underlying data and relevant documentation. In addition, it is not always apparent in the publication that individuals and companies other than the listed authors were deeply involved in the study and/or drafting of the final manuscript. Articles published in medical journals are widely read by practitioners, and relied upon as being unbiased and scientific in

⁷⁸ *Id.*

nature. Concerns have been raised, however, that some medical literature may be subtle advertisements rather than publications of independent research. The information in these articles can have a significant impact on doctors' prescribing behavior and, in turn, on the American taxpayer, because the Medicare and Medicaid programs pay billions of dollars for prescription drugs. Thus, any attempt to manipulate the scientific literature, that can in turn mislead doctors to prescribe drugs that may not work and/or cause harm to their patients, is very troubling.⁷⁹

In his letter to Wyeth, Senator Grassley notes that documents uncovered in recent litigation involving Wyeth's hormone therapy products raise questions about the role of DesignWrite Inc. in devising, writing and obtaining academic investigators to sign on as the primary authors of articles appearing in *American Journal of Obstetrics and Gynecology*, *Obstetrics and Gynecology*, and *Primary Care Update for OB/GYNs*.⁸⁰

This is not the first venture of Wyeth in medical ghost writing. Wyeth paid Excerpta Medica Inc. \$40,000 to write ten articles supporting the use of the "fen" half of the "fen-phen" drug combination. Excerpta retained well-known university researchers to edit drafts and lend their name to the final work in exchange for \$1,000 to \$1,500 honoraria.⁸¹ Two of the ten articles were published in the *American Journal of Medicine* and *Clinical*

⁷⁹ Letter from U.S. Senator Charles Grassley, to Bernard J. Poussot, Chairman, President and Chief Exec. Officer, Wyeth from (Dec. 12, 2008) (<http://finance.senate.gov/newsroom/ranking/download/?id=d80f46b5-d896-41b8-a7ae-136d7ec5a431>); See Paul Basken, *Ghostwriters Haunt the Integrity of Medical Journals*, CHRON. OF HIGHER EDUC. (Sept. 14, 2009), http://chronicle.com/article/Ghosts-Haunt-the-Integrity-of/48365/?sid=at&utm_source=at&utm_medium=en ("The practice raises the specter of hidden bias in published papers that favor the effects of the company's drugs. Doctors rely on such papers when making life-or-death choices about treating their patients.")

⁸⁰ Grassley, *supra* note 79. Citing three Columbia University researchers who signed their names to articles financed by Wyeth, Senator Grassley subsequently recommended that NIH combat the practice of university researchers engaging in ghostwriting of drug company research articles. *Sen. Grassley Presses NIH Over Ghostwritten Research Reports*, CHRON. OF HIGHER EDUC. (Aug. 19, 2009), http://chronicle.com/blogPost/Sen-Grassley-Presses-NIH-Over/7741/?sid=pm&utm_source=pm&utm_medium=en. Wyeth also recruited a McGill University professor to contribute a ghostwritten article to the *Journal of the American Geriatrics Society*. In her article, Professor Barbara Sherwin "argued that estrogen could help treat memory loss in older patients." Lawyers representing clients suing Wyeth for harms caused by its hormone drugs have discovered 26 ghostwritten research papers in 18 medical journals. Paul Basken, *Professor at Canada's McGill U. Admits Signing Research Generated by Drug Maker*, CHRON. OF HIGHER EDUC. (Aug. 11, 2010), http://chronicle.com/article/McGill-U-Professor-Admits/48164/?sid=at&utm_source=at&utm_medium=en.

⁸¹ *Research Ethics: Paying MDs to 'Write' Fen-Phen Articles*, AM. HEALTH LINE (May 24, 1999), <http://www.americanhealthline.com/archives/1999/05/m990524.9.html>.

Therapeutics. The remaining eight articles were never published, because the fen-phen drugs were pulled from the market after studies linked them to heart-valve damage and an often-fatal lung disease.⁸²

Martin Keller, Professor of Psychiatry and Human Behavior and chairman of the psychiatry department at the Alpert Medical School of Brown University, and his coauthors were accused by doctors, lawyers, and journalists of permitting their names to be added as authors of the 2001 ghostwritten study of the antidepressant drug Paxil that concluded the drug was safe and effective in adolescents.⁸³ Their article became one of the most cited medical articles supporting the use of antidepressants in adolescents, and prompted Paxil manufacturer GlaxoSmithKline to promote the use of the product among children, an untapped market for antidepressants.⁸⁴ More recent studies, however, demonstrate Paxil can lead to increased suicidal tendencies in children, and Keller subsequently acknowledged receiving consulting fees in the tens of thousands of dollars from GlaxoSmithKline.⁸⁵

Further, because of the increase in private industry funding of medical research at U.S. universities - private industry funds more than two-thirds of medical research at U.S. universities - concerns have also been raised about the control ceded by universities to private companies sponsoring the research over the results attained in the study. A recent survey shows many of the top medical school in the United States have no clear policies prohibiting medical ghostwriting; only thirteen of the top fifty medical schools have such policies.⁸⁶ A study conducted by the Harvard School of

⁸² Charles Ornstein, *Evidence in fen-phen suit claims drug maker had hand in journal articles*, THE DALLAS MORNING NEWS, May 22, 1999.

⁸³ Chaz Firestone and Chaz Kelsh, *Senator targets Brown U. professor's ties to big pharma*, CBS NEWS (Sept. 23, 2008), <http://www.cbsnews.com/stories/2008/09/24/politics/uwire/main4473367.shtml>.

GlaxoSmithKline instructed its salespeople to offer assistance to physicians to write and publish articles about the helpfulness of Paxil. The offered assistance covered all facets from selecting a topic, writing the report, and submitting the article for publication. Matthew Perrone, *Glaxo used ghostwriting program to promote Paxil*, PHILADELPHIA INQUIRER, (Aug. 20, 2009), <http://abcnews.go.com/Health/Business/wireStory?id=8366574>.

⁸⁴ *Id.*

⁸⁵ *Id.* GlaxoSmithKline also paid consulting fees to a reviewer of an article submitted to *New England Journal of Medicine* reporting a link between heart attacks and the drug Avandia manufactured by GlaxoSmithKline. The reviewer faxed an advance copy of the manuscript to GlaxoSmithKline, prompting Senator Charles Grassley to request information from GlaxoSmithKline describing what it did after receiving the advanced copy. Letter from Senator Charles Grassley, to GlaxoSmithKline (Jan. 30, 2008) (<http://finance.senate.gov/newsroom/ranking/release/?id=33317a8c-ad81-43bb-8ed6-2acff4e45a46>).

⁸⁶ *Few Top Medical Schools Ban Ghostwriting by Researchers, Survey Finds*, CHRON. OF HIGHER EDUC. (Feb. 1, 2010), http://chronicle.com/blogPost/Few-Top-Medical-Schools-Ban/20990/?sid=at&utm_source=at&utm_medium=en.

Public Health and appearing in the *New England Journal of Medicine*, demonstrates that, while medical schools overwhelmingly agreed they would not enter into contracts that would allow companies to edit research articles or suppress negative results, 50% would permit companies to draft research papers and 25% would permit them to provide the data.⁸⁷ Indeed, a recent study indicates that ghostwriting research articles “is distressingly common in top medical journals.”⁸⁸ The study, presented at the Sixth Annual Conference on Peer Review and Biomedical Publication, “found the prevalence of ‘ghost’ authors at top-ranked medical journals ranged last year from 2 percent at *Nature Medicine* to 11 percent at *The New England Journal of Medicine*,” and that 7.8% of all articles from 2008 published in *Nature Medicine*, *The New England Journal of Medicine*, *Annals of Internal Medicine*, the *Journal of the American Medical Association*, *The Lancet*, and *PLoS Medicine* had at least one ghost author.⁸⁹ Perhaps stung by the negative publicity about ghostwritten articles, *The New England Journal of Medicine*, *The Lancet*, and the *Journal of the American Medical Association* have announced that they plan to require the disclosure by authors of possible conflicts of interest in their research by utilizing a uniform disclosure form of all actual and potential financial conflicts of interest.⁹⁰

C. The Rise of the Celebrity Medical Expert

The rise of the celebrity medical expert is the third offshoot stemming from the increase in private industry drug studies. For example, Lisa Hark parlayed her work in the nutrition education program at the University of Pennsylvania medical school, her experience as host of television nutrition programs, and her authorship of a widely used and award winning nutrition textbook into a successful consulting practice in the field of nutrition. The Florida orange industry hired her to promote the health benefits of orange juice in a six-month, \$24,800 contract that produced “more than 132 million media impressions,” including a *Forbes* magazine quote in which Hark touts

⁸⁷ Alicia Chang, *Drug Companies Influence Medical Research*, EXCITE NEWS (May 25, 2005), <http://www.biopsychiatry.com/bigpharma/influence.html>; See Michelle M. Mello et al., *Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry*, NEW ENG. J. MED. (May 26, 2005), <http://content.nejm.org/cgi/content/full/352/21/2202>.

⁸⁸ Paul Basken, *Medical 'Ghostwriting' Is Still a Common Practice, Study Shows*, CHRON. OF HIGHER EDUC. (Sept. 10, 2009), http://chronicle.com/article/Medical-Ghostwriting-Is-a/48347/?sid=at&utm_source=at&utm_medium=en.

⁸⁹ *Id.*

⁹⁰ *Medical Journals Tighten Rules on Author Conflicts*, CHRON. OF HIGHER EDUC. (Oct. 14, 2009), http://chronicle.com/blogPost/Medical-Journals-Tighten-Rules/8448/?sid=pm&utm_source=pm&utm_medium=en; The uniform disclosure form was accessed on July 21, 2010, at http://www.icmje.org/coi_disclosure.pdf.

the benefits of orange juice for preventing colds and the flu.⁹¹ Hark also provided a helpful comment to Tyson Foods campaign to promote its chickens as being “raised without antibiotics,” saying “This is great news for American consumers who have made it clear they pay attention to the use and presence of all sorts of antibiotics in the environment.”⁹² The U.S. Department of Agriculture later ordered Tyson Foods to stop using the “raised without” label after Tyson Foods admitted it injected eggs with antibiotics. Working for the National Dairy Council, Hark advocated the benefits of consuming three servings of low-fat dairy a day.⁹³ Hark’s website invites companies to engage her services as a nutritionist with the words:

Are you looking for a media expert to help promote and market your company? Do you want to add credibility to your brand, consult with a nutrition expert, hire a spokesperson or develop an Advisory Board? Dr. Lisa Hark has the academic background and media experience to help your company successfully reach both consumers and health professionals.⁹⁴

Similarly, psychiatrist Frederick K. Goodwin, the host of NPR’s popular program “The Infinite Mind,” admitted earning at least \$1.3 million from 2000 to 2007 giving marketing lectures for drugmakers.⁹⁵ “The Infinite Mind” has won more than 60 journalism awards and generated over one million listeners in more than 300 radio markets.⁹⁶ Goodwin’s weekly radio program frequently addressed topics important to the financial interests of companies for which he consulted.⁹⁷ For example, on September 20, 2005, Goodwin advised his audience that children with bipolar disorder who were not treated could suffer brain damage and that mood stabilizers have proven to be safe and effective in bipolar children. That same day, GlaxoSmithKline paid him \$2,500 to give a promotional lecture for GlaxoSmithKline’s mood stabilizer drug, Lamictal, at the Ritz Carlton Golf Resort in Naples, Florida, part of the \$329,000 it paid him during 2005 to promote Lamictal.⁹⁸ In another segment of his show, Goodwin denied the existence of scientific evidence of a link between antidepressants and increased risk for suicidal

⁹¹ Tom Avril, *Corporate money, expert opinions*, PHILADELPHIA INQUIRER (Nov. 25, 2008), <http://www.healthobservatory.org/headlines.cfm?refID=104580>.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Gardiner Harris, *Drug Makers Paid Radio Host \$1.3 Million for Lectures*, N.Y. TIMES (Nov. 21, 2008), <http://www.nytimes.com/2008/11/22/health/22radio.html>.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

behavior, while receiving \$20,000 from GlaxoSmithKline for a promotional lecture for Lamictal.⁹⁹ While Goodwin claimed he informed Bill Lichtenstein, the program producer, of his financial ties to drugmakers, Lichtenstein denies being aware of those ties.¹⁰⁰ When the drug industry consulting arrangements with Goodwin became public, Margaret Low Smith, vice president of NPR, announced that the show would be removed from its satellite radio service the following week, the earliest date possible, and NPR would never have broadcast the show if it had known of Goodwin's conflicting financial interests.¹⁰¹

VII. RESPONSE OF MEDICAL INSTITUTIONS AND ACADEMIC ORGANIZATIONS

The vast array of conflict of interest revelations uncovered by Senator Grassley produced swift responses from medical institutions and academic organizations. Harvard Medical School and Massachusetts General Hospital announced they would investigate doctors' disclosure and conflict of interest forms and re-examine their policies on the relationships between physicians and industry.¹⁰² Harvard Medical School faculty and students subsequently formed a nineteen member committee to re-examine the school's conflict of interest policies, and engaged David Korn, the former dean of Stanford University, who assisted the American Medical Association in drafting a conflict-of-interest policy for medical schools, as a consultant to the committee.¹⁰³ The University of Minnesota approved a tougher financial conflicts of interest policy, which requires faculty and staff to disclose all financial interests, which "an independent observer might reasonably question whether the individual's objectivity in the performance of

⁹⁹ *Id.*; *NPR Radio Host Failed to Disclose Payments*, AM. HEALTH LINE (Nov. 24, 2008), <http://www.americanhealthline.com/search.aspx?query=NPR+Radio+Host+Failed+to+Disclose+Payments&topic=&>.

¹⁰⁰ Harris, *supra* note 95; *Am Health Line*, *supra* note 99.

¹⁰¹ Harris, *supra* note 95.

¹⁰² *Harvard doctors' studies tainted*, PITTSBURGH TRIB. REV. (June 9, 2008), http://www.pittsburghlive.com/x/pittsburghtrib/news/breaking/s_571718.html; June Q. Wu, *Harvard medical school to reexamine conflicts of interest policy*, HARVARD CRIMSON (June 16, 2008), <http://www.thecrimson.com/article/2008/6/16/harvard-medical-school-to-reexamine-conflicts/>.

¹⁰³ Katherine Mangan, *Harvard Medical Students and Faculty Members Work to Expose Conflicts of Interest*, CHRON. OF HIGHER EDUC. (Mar. 3, 2009), <http://chronicle.com/article/Harvard-Medical-Students-an/42501>. See Charles Huckabee, *Sen. Grassley Asks Pfizer About Payments to Faculty Members at Harvard Medical School*, CHRON. OF HIGHER EDUC. (Mar. 3, 2009), <http://chronicle.com/article/Sen-Grassley-Asks-Pfizer/42505> ("The Iowa senator is asking the drug maker Pfizer to provide details of its payments to at least 149 faculty members at Harvard Medical School").

University responsibilities could be compromised by considerations of personal gain," and prohibits those individuals from engaging in University-related activities in which a conflict of interest exists.¹⁰⁴ Michigan Medical School has announced that it will stop taking money from drug or medical-device manufacturers to pay for the refresher courses that doctors must take to renew their licenses.¹⁰⁵ *The Journal of the American Medical Association* published a correction listing sixty-four financial ties between the authors of published articles and manufacturers of antidepressant drugs, and revised its conflict of interest policy to require authors to divulge any financial ties they may have to the medical industry in an acknowledgement section.¹⁰⁶ The Federation of American Societies for Experimental Biology, which represents 84,000 research scientists, issued a report containing a suggested set of voluntary guidelines to assist scientists identify and manage conflicts of interest.¹⁰⁷ Two medical organizations, the Institute on Medicine as a Profession (IMAP) and the Association of American Medical Colleges, announced they would launch websites detailing conflict of interest policies instituted by academic medical centers.¹⁰⁸ IMAP's website is up and running, contains the conflict of interest policies of over 125 medical institutions, and can be accessed at <http://www.imapny.org/policy/>. The Cleveland Clinic announced that the financial links between its 1,800 physicians and researchers will be published on the clinic's website as part of its effort to minimize conflicts of interest.¹⁰⁹ The University of Pennsylvania School of

¹⁰⁴ Paul Basken, *Minnesota Regents Outline Policy to Toughen Rules on Financial Conflicts of Interest*, CHRON. OF HIGHER EDUC. (Mar. 12, 2010), http://chronicle.com/article/Minnesota-Regents-Outline/64668/?sid=at&utm_source=at&utm_medium=en. The text of the policy approved by the Board of Trustees on March 12, 2010, appears in the minutes of their meeting accessed on July 20, 2010, at <http://www1.umn.edu/regents/docket/2010/march/board.pdf>.

¹⁰⁵ *Medical School Bans Industry Contributions for Continuing-Medical-Education Courses*, CHRON. OF HIGHER EDUC. (June 23, 2010), http://chronicle.com/blogPost/Medical-School-Bans-Industry/25050/?sid=at&utm_source=at&utm_medium=en.

¹⁰⁶ Katherine Mangan & Jeffrey R. Young, *Medical Journal Toughens Its Conflict-of-Interest Policy*, CHRON. OF HIGHER EDUC. (July 21, 2006), <http://chronicle.com/article/Medical-Journal-Toughens-Its/19274>.

¹⁰⁷ Jeffrey Brainard, *Biomedical Group Will Suggest Ways for Scientists to Handle Potential Conflicts of Interest*, CHRON. OF HIGHER EDUC. (July 28, 2006), <http://chronicle.com/article/Biomedical-Group-Will-Suggest/7728>.

¹⁰⁸ Shawn Rhea, *AAMC, institute ready online guides to centers' conflict-of-interest policies*, MODERN HEALTHCARE (Sept. 8, 2008), http://webcache.googleusercontent.com/search?q=cache:YxV_3dW1YuQJ:www.modernhealthcare.com/article/20080908/SUB/809059963%26Template%3Dprintpicart+Shawn+Rhea+AA+MC,+institute+ready+online+guides+to+centers%E2%80%99+conflict-of-interest+policies&cd=1&hl=en&ct=clnk&gl=us.

¹⁰⁹ Katherine Mangan, *Cleveland Clinic to Divulge Scientists' Industry Ties*, CHRON. OF HIGHER EDUC. (Dec. 2, 2008), http://chronicle.com/news/article/5594/cleveland-clinic-to-divulge-scientists-industry-ties?utm_source=at&utm_medium=en; Reed Abelson, *Cleveland*

Medicine and health system announced it would launch a website disclosing searchable information on all outside activities of its doctors and scientists.¹¹⁰ The American Psychiatric Association announced that it will no longer permit drug companies to provide education seminars and meals at its annual meeting.¹¹¹ The National Academies' Institute of Medicine issued a 353-page report calling on "medical schools, hospitals, and physicians' groups to publicly report money they receive from drug companies, to not accept free gifts or meals from the industry, and to ban physicians who have financial conflicts of interest from testing new therapies on people."¹¹² These responses, however, fall well short of the more comprehensive policy proposal developed by the American Medical Association, discussed below.

VIII. SOLUTIONS PROPOSED TO COMBAT MEDICAL INDUSTRY CONFLICTS OF INTEREST

Three major solutions have been proposed to combat the medical industry conflicts of interest detailed above in this case. The first solution is embodied in the Physician Payments Sunshine Act, which requires companies manufacturing drugs, medical devices or medical supplies to make quarterly reports to the Secretary of Health and Human Services detailing payments made to physicians or their employers, and prohibits tax deductions for advertising, promotion or marketing expenses for any payments not disclosed.¹¹³ The reported information, in turn, will be published in the federal register permitting patients and consumers the

Clinic Discloses Doctors' Industry Ties, N.Y. TIMES (Dec. 2, 2008), <http://www.nytimes.com/2008/12/03/business/03clinic.html?fta=y>.

¹¹⁰ Josh Goldstein, *Penn Medicine to disclose doctors' drug ties*, PHILADELPHIA INQUIRER (Dec. 5, 2008),

http://www.philly.com/philly/hp/news_update/20081205_Penn_Medicine_to_disclose_doctors_drug_ties.html.

¹¹¹ Josh Fischman, *Psychiatrists Say No to Drug Company Events at Their Annual Meeting*, CHRON. OF HIGHER EDUC. (Mar. 26, 2009), <http://chronicle.com/article/Psychiatrists-Say-No-to-Dru/42636/> ("The American Psychiatric Association said yesterday that it would no longer allow education seminars and meals sponsored by pharmaceutical companies at its annual meeting").

¹¹² Katherine Mangan, *Institute of Medicine Calls for Ban on Drug-Company gifts to Professors and Others*, CHRON. OF HIGHER EDUC. (Apr. 28, 2009), <http://chronicle.com/article/Institute-of-Medicine-Calls/42815/>.

¹¹³ The Physician Payments Sunshine Act of 2008, H.R. 5605, 110th Cong. (2008), <http://www.govtrack.us/congress/bill.xpd?bill=h110-5605>. A more comprehensive version of the Physician Payments Sunshine Act was introduced on January 20, 2009. See Press Release, Grassley Works to Disclose Financial Ties Between Drug Companies and Doctors (Jan. 22, 2009) (http://grassley.senate.gov/news/Article.cfm?customer_dataPageID_1502=18901#). The Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009), <http://www.govtrack.us/congress/bill.xpd?bill=s111-301>.

opportunity to learn about medical industry conflicts of interest, and thereby augmenting transparency and accountability for the various payments made to physicians.¹¹⁴ Notably, a significant number of medical companies and organizations have endorsed the Physician Payments Sunshine Act.¹¹⁵ Moreover, perhaps realizing the inevitability of public disclosure, Eli Lilly, GlaxoSmithKline, Merck, and Pfizer have agreed to publicly disclose payments they make to doctors.¹¹⁶

The public disclosure approach contained in the Physician Payments Sunshine Act and conceded by several major pharmaceutical firms, however, is only one-half of the normal legal resolution recommended for conflicts of interest within corporate governance. More particularly, when directors or officers find themselves in a conflict of interest, they must make full disclosure of the conflict and refrain from any participation in the transaction approval process. The latter requirement – not participating in the transaction

¹¹⁴ See *More disclosure needed on drug company payouts*, DENVER POST (Aug. 10, 2007), http://www.denverpost.com/search/ci_6586804.

¹¹⁵ The following organizations have endorsed the Physician Payments Sunshine Act: American Medical Association, Association of American Medical Colleges, Advamed, Pharma, Abbott and Abbott Lab, Amgen, Astra Zeneca, Baxter, Boston Scientific, Bristol Myers Squibb, Eli Lilly, Johnson and Johnson, Medtronic, Inc., Merck, Pfizer, St. Jude Medical, Stryker, Wyeth, and Zimmer Holdings. Press Release, Support for S. 2029, the Grassley-Kohl Physicians Payments Sunshine Act (July 20, 2010) (<http://finance.senate.gov/newsroom/ranking/release/?id=e869c734-de40-4b4f-9b7e-fd9d5d742c87>). The following companies support the disclosure of financial contributions to continuing medical education: Baxter, Medtronic, Boston Scientific, Merck, Pfizer, St. Jude Medical, Abbott Lab, Amgen, AstraZeneca, Bristol Myers Squibb, Johnson & Johnson, Schering-Plough, Stryker, Wyeth, and Zimmer Holdings. Press Release, Responses From Pharmaceutical Drug and Device Makers to Grassley Request for Disclosure of Support for Continuing Medical Education (Apr. 11, 2008) (<http://finance.senate.gov/newsroom/ranking/release/?id=637bd77c-508f-489d-84fd-133c94e6ea3b>).

¹¹⁶ In September 2008, Eli Lilly began disclosing on its website payments to doctors who serve as consultants. Shirley S. Wang, *Eli Lilly's Payments to Doctors Revealed*, WALL ST. J. (July 31, 2009), <http://blogs.wsj.com/health/2009/07/31/eli-lillys-payments-to-doctors-revealed/tab/print/>. Pfizer, GlaxoSmithKline, and Merck have also agreed to disclose payments made to doctors. See Linda A. Johnson, *Pfizer to disclose payments to doctors next year*, COURIER POST (Feb. 10, 2009), http://seattletimes.nwsourc.com/html/health/2008726701_pfizer10.html (“Pfizer Inc., the world’s biggest drugmaker, said Monday it will begin disclosing all sizable payments it makes to doctors, including those who test experimental drugs in people, a first for the industry. The disclosures would begin early next year and are planned to include all payments to medical personnel who prescribe drugs -- doctors, physician’s assistants and nurse-practitioners -- exceeding \$500 in a year, the New York-based company told The Associated Press.”); Maria Panaritis, *Glaxo to change training-payment practices*, PHILADELPHIA INQUIRER (Sept. 22, 2009), <http://www.allbusiness.com/education-training/curricula-medical-education/13010850-1.html> (“By year’s end, Glaxo said, it also would begin publicly disclosing all payments it makes to doctors. . . . In September 2008, drugmakers Merck & Co., and Eli Lilly & Co., said they would begin publicly disclosing payments to physicians”).

approval process – is not explicitly included in the Physician Payments Sunshine Act. Significantly, in at least one instance, public disclosure of conflicts of interest resulted in the removal of members of the FDA advisory committee charged with determining whether an extended-release version of pharmaceutical company AstraZeneca’s Seroquel XR, a powerful antipsychotic used to treat depression and anxiety, should be approved. Jorge Armenteros, the chair and a voting member of the committee, who was paid by AstraZeneca to promote the drug in talks to other doctors, and four other committee members, were removed from the committee because of conflicts of interest made public by attorneys representing patients who are suing AstraZeneca and other makers of antipsychotics and claim the drugs triggered their diabetes.¹¹⁷ The FDA panel, meeting without the five removed members, approved a limited use for Seroquel XR as an additional therapy for patients suffering from depression who do not respond to their current medications, and declined to approve the broader use requested by AstraZeneca to treat depression and anxiety as a single therapy. Approval of the broader use of Seroquel XR would have “dramatically expanded the market for Seroquel,” which currently generates \$4.7 billion in annual sales.¹¹⁸

The second proposed solution is the creation of a National Institute of Drug Testing (NIDT). The principal justifications advanced for this proposal are threefold: (1) “endemic” conflicts of interest in the system of drug evaluation have “been exacerbated by the rise in for-profit clinical trials, fast-tracking of drug approvals, government-industry partnerships, direct consumer advertising, and industry-funded salaries for FDA regulators;” (2) “those who manufacture and market products should not have undue influence and control over how the product is evaluated;” and (3) the concept of “independent science” should be reintroduced in drug testing to “prevent even the appearance of conflict of interest.”¹¹⁹ Under this proposal, the NIDT will be added to NIH and charged with the responsibility of independently testing the efficacy and safety of drugs and medical devices.¹²⁰ While medical companies can continue to pre-test drugs and medical devices using their own scientists or contracted researchers, the medical companies must submit the drug or device to NIDT for testing, thereby creating a “buffer” or “firewall” between drug companies and researchers who test drugs in animals or in human subjects.¹²¹ NIDT will be financed by fees paid

¹¹⁷ Miriam Hill, *Conflict for FDA panel on Seroquel*, PHILADELPHIA INQUIRER (Apr. 4, 2009), <http://bipolarsoupkitchen-stephany.blogspot.com/2009/04/conflict-of-interest-fda.html>.

¹¹⁸ Miriam Hill, *A minor victory in Seroquel battle*, PHILADELPHIA INQUIRER (Apr. 8, 2009), <http://www.philly.com/philly/business/42724807.html>.

¹¹⁹ Krimsky, *supra* note 37.

¹²⁰ *Id.*

¹²¹ *Id.*

by the drug companies based on accepted research costs set by the institute; the NIDT will solicit qualified scientists to conduct the tests subject to protocols designed to protect the confidentiality of business information; and data from test results will be made fully accessible to the drug companies, health care providers and the general public.¹²²

The third proposal is the far more comprehensive policy developed by the American Medical Association and aimed at academic medical centers. In issuing its proposed policy, the AMA noted that the “standing of the profession, as much as the integrity of the pharmaceutical and medical device industries, is jeopardized by allowing obvious conflicts to continue,” and that academic medical centers “must more strongly regulate, and some cases prohibit, many common practices that constitute conflicts of interest with drug and medical device companies.”¹²³ The AMA preliminarily emphasized that a wide range of psychological, sociological, and economic research demonstrates that even small gifts significantly influence physicians’ behavior and that public disclosure of conflicts of interest alone is insufficient to satisfy the need to protect the interests of patients.¹²⁴ The

AMA policy recommends:

- All gifts (zero dollar limit), free meals, payment for time for travel to or time at meetings, and payment for participating in online [continuing medical education] from drug and medical device companies to physicians should be prohibited.
- The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low income patients or other arrangements that distance the company and its products from the physician.
- Hospital and medical group formulary committees and committees overseeing purchases of medical devices should exclude physicians (and all health care professionals) with financial relationships with drug manufacturers, including those who receive any gift, inducement, grant or contract.
- [Drug manufacturers] should not be permitted to provide support directly or indirectly through a subsidiary agency to any [academic center continuing medical education]-accredited program. Manufacturers wishing to support education for

¹²² *Id.*

¹²³ Brennan, *supra* note 7, at 429-33.

¹²⁴ *Id.* at 430.

medical students, residents, and/or practicing physicians should contribute to a central repository . . . which, in turn, would disburse the funds to ACCME-approved programs.

- Pharmaceutical and device manufacturers interested in having faculty or fellows attend meetings should provide grants to a central office at the AMC. That office could then disburse funds to faculty and training program directors.
- Faculty at AMCs should not serve as members of speakers bureaus for pharmaceutical or device manufacturers. Speakers bureaus are an extension of manufacturers marketing apparatus. Because AMC faculty have a central role in training of new physicians and represent their own institution, they should not function as paid marketers or spokespersons for medicine-related industries.
- [C]onsulting with or accepting research support from industry should not be prohibited. However, to ensure scientific integrity, far greater transparency and more open communication are necessary. Accordingly, consulting or honoraria for speaking should always take place with an explicit contract with specific deliverables, and the deliverables should be restricted to scientific issues, not marketing efforts. So-called 'no strings attached' grants or gifts to individual researchers should be prohibited.
- AMCs should be able to accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies provided that the grants are not designated for use by specific individuals.
- [C]onsulting agreements and unconditional grants should be posted on a publicly available internet site, ideally at the academic institution.¹²⁵

¹²⁵ *Id.* at 431-32.

IX. POTENTIAL DISCUSSION QUESTIONS

A. Do payments by medical industry companies to practicing physicians and medical school department heads create conflicts of interest?

The payments by medical industry companies to practicing physicians and medical school department heads in the form of free meals and drug samples, travel expenses to attend professional meetings or continuing education programs, payments for consulting, lectures, and enrolling patients in clinical trials, donated research equipment, financial support for residency and fellowship training, and service on advisory boards, do create conflicts of interest. Having accepted those financial benefits, the practicing physicians and academic department heads cannot be said to be acting solely for the benefits of their patients or their academic employers. Whenever a reasonable observer cannot ascertain with certainty what motivated the physician to recommend a medical treatment (best interest of the patient or gratitude to a medical company) or the academic department head to undertake medical research (best scientific answer or best outcome for the medical company), a material conflict of interest exists, and the public interest in guaranteeing the safety and effectiveness of medical treatments and devices is threatened.

B. Do the failures of Drs. Schatzberg, Wang, Biederman, and Nemeroff to disclose fully their financial interests and ties to medical industry companies violate their fiduciary obligations as employees respectively of Stanford, UCLA, Harvard and Emory Universities?

As employees of Stanford, Harvard, Emory, and UCLA, Drs. Schatzberg, Biederman, Nemeroff and Wang owe multiple fiduciary duties to their employers: (a) to use reasonable diligence and skill in performing their duties, (b) to notify their employers of all information that comes to their attention and is relevant to the employment relationship, (c) to act solely for the benefit of their employers, (d) to follow all lawful and clearly stated instructions given to them by their employers, and (e) to account for all property and funds received and expended on behalf of the employer.¹²⁶ Their failure to disclose fully their financial ties to medical industry companies violates three of those duties. First, they failed to notify their employer of the true extent of their financial links to the medical industry companies, and that failure not only prevents the four physicians from fulfilling their employment obligations but also causes their employers to

¹²⁶ Cross, *supra* note 1, at 485-86; Restatement (Third) of Agency §§ 8.01, 8.02, 8.07, 8.08, 8.09(2), 8.10, and 8.11.

suffer significant damages in the form of lost external research funding and future research funding opportunities, doubts about the reliability of research undertaken by the University's medical scientists, and significant distractions as the universities respond to inquiries of the U.S. Senate Finance Committee and various news organizations. Second, Drs. Schatzberg, Wang, Biederman, and Nemeroff breached their fiduciary obligation to act solely for the benefit of their employer by accepting financial contributions and holding financial interests in medical industry companies and failing to disclose same. From that moment on, Drs. Schatzberg, Wang, Biederman, and Nemeroff placed their own financial interests and the interest of the medical industry companies above the interest of their employers. Third, Drs. Schatzberg, Biederman, Nemeroff and Wang failed to follow the clear instructions of their employers to disclose financial conflicts as part of their duties as principal investigators on externally funded research grants and thereby placed their Universities at risk of losing research funding in the future and thwarted the efforts of NIH and FDA to uncover pervasive conflicts of interest.

C. Three inherent forces are identified in this case for fomenting conflicts of interest: the vertical integration of the pharmaceutical industry, the 1980 Bayh-Dole Act, and the accelerating need of the medical industry to conduct human experiments. Which of the three suggested solutions for eliminating conflicts of interest in the medical industry best addresses these inherent forces?

The proposed Physicians Payments in Sunshine Act requires medical industry companies to file quarterly reports with the Secretary of Health and Human Services detailing payments made to physicians or their employers, denies tax deductions for advertising, promotion or marketing expenses for any payments not disclosed, and mandates publication of those quarterly reports in the Federal Register to notify the public of the existence and extent of financial interest conflicts. Hence, to the extent payments to physicians are brought to the attention of the public, that aspect of the vertical integration of the pharmaceutical industry is addressed. The proposed Physicians Payments in Sunshine Act, however, does not address the removal of physicians and medical scientists from participation in the transaction approval process, the financial incentives provided to physicians and medical scientists by the Bayh-Dole Act to commercialize medical drugs and devices, or the accelerating need of the medical industry to conduct human experiments.

Requiring independent testing of the efficacy and safety of drugs and medical devices by a newly created federal agency removes the physician and medical scientist with financial links to the medical industry from the

ultimate approval process for the drug or medical device, and thereby does address the impact of the financial contributions made by pharmaceutical industries on the approval process. Independent testing, however, does not mandate public disclosure of the financial conflicts of interest, does not address the financial incentives provided by the Bayh-Dole Act, and will likely exacerbate the need of the medical industry to conduct human experiments.

The American Medical Association proposal provides the most comprehensive means of disclosing financial conflicts of interest and eliminating the benefits flowing to medical industry companies from its direct financial support of medical conferences and continuing education programs. All gifts, meals, travel expense reimbursement, and payments for participating in medical company programs are prohibited. Free drug samples are replaced by vouchers for low income patients. Decisions on medical institution purchases of medical devices and equipment are made only by those without financial conflicts of interests. Financial support for continuing education programs and meetings are funneled through and disbursed by a central depository thereby eliminating the identification of the medical company with the financial support for those programs. Medical school faculty members are prohibited from participating in speaker bureaus and accepting fees for marketing and promoting medical products. And significant transparency is provided for accepting consulting fees and research support. While these proposals provide far greater disclosure of financial conflicts of interest and eliminate many practices creating such conflicts, they do not address the financial incentives provided to physicians and medical scientists by the Bayh-Dole Act to participate in the commercialization of medical products and the rapidly expanding need of the medical industry to conduct human experiments.

D. Discuss whether the drug company practice of "medical ghostwriting," in which medical companies prepare drafts of articles, editorials and research papers, invite prominent doctors and scientists to add their names as coauthors, and publish the work in prominent medical journals read by practitioners who believe the publications contain independent research, is ethical.

The drug industry practice of medical ghostwriting is likely unethical. To begin with, the practice of medical ghostwriting permits drug approval processes to proceed based on scientific evidence selected by the drug company to support the conclusion that the medical companies prefer, rather than the conclusion based on the best scientific evidence. This may lead to the approval of drugs in new markets that improve the profitability of the

drug companies, but may cause harm to patients in that market, as apparently happened in the case of the "fen-phen" drug combination and the prescribed use of antidepressants in adolescents. Likewise, practicing physicians who read and rely on these articles and papers may prescribe drugs that may harm their patients. From the utilitarian point of view, the practice of medical ghostwriting may cause more negative consequences than beneficial consequences, particularly if it triggers a loss of public confidence in the integrity of drug companies and the drug approval process and legislative action to reform the regulatory oversight over the drug industry.¹²⁷

Likewise, the practice of medical ghostwriting likely misleads the readers of the journals in which the ghostwritten papers and studies appear about the extent to which the co-authors, generally perceived to be the leading doctors and scientists in their fields, actually conducted the research and formulated the scientific conclusions. From a Kantian point of view, such deception is unethical, because it uses the readers of the ghostwritten works as a means only to advance the interest of the pharmaceutical companies. Further, it is unlikely that medical ghostwriting is an acceptable universal practice that all participants in drug formulation, production, testing, approval, and consumption would be willing to accept.¹²⁸

Finally, viewed from the perspective of the Rawls' Original Position/Veil of Ignorance Theory, it is unlikely that parties, who do not know what position they will occupy in society or what advantages or disadvantages they will possess, would be willing to permit society to employ rules or practices that permit drug companies to engage in medical ghostwriting. Likewise, employing Rawls' Principle of Equal Liberty, the deceptive nature of medical ghostwriting appears to deny equal and universal enjoyment of the most extensive basic liberties.¹²⁹

E. Discuss whether the employment of the "celebrity medical expert" to provide testimonials about the effectiveness of food products or medicines is ethical.

The practice of food and drug manufacturers employing celebrity medical experts to tout the health benefits of their products is unethical in the absence of a disclosure that the celebrity medical expert has a conflict of interest in promoting the products. Lisa Hark's promotions of orange juice and Tyson Foods chicken products are misleading, if the target audience of her message is not told she was paid as a consultant to promote those products. Frederick Goodwin's recommendations that bipolar children could

¹²⁷ Velasquez, *supra* note 3, at 70-72.

¹²⁸ *Id.* at 94-97.

¹²⁹ *Id.* at 114-16.

be treated safely with mood stabilizers are misleading, if the significant consulting fees he earned to promote those drugs are not fully disclosed. As noted above, the use of deception does not normally produce the greatest net amount of good for those affected by the deception; deception uses the victim of the deception as a means only, and does not constitute an acceptable universal practice; and deception violates Rawls' theory of justice.

F. Should the policy of the Bayh-Dole Act to fund academic research, give academic researchers and their institutions the right to products developed with government money, and to permit physicians and medical scientists to commercialize drugs and medical devices be modified or abandoned?

The Bayh-Dole Act encourages scientific research and the commercialization of drugs and medical devices by permitting academic researchers to license their intellectual property and develop financial ties with the biotechnology or pharmaceutical industries. The Bayh-Dole Act has significantly increased the participation of academic institutions in technology transfer, enhanced their income streams, spawned new businesses, and facilitated the movement of discoveries from the university laboratory to the marketplace quickly and efficiently. It also enhances employment opportunities and federal and state tax revenues, thereby returning the benefits of scientific research full circle. Recent results of a survey conducted by the Association of University Technology Managers, for example, reported significant economic development was spurred in 2008 by University research and inventions: 543 new university spinoff companies; \$2.3 billion in licensing revenue for 154 institutions and their inventors; and 4,350 licenses of inventions for new products.¹³⁰ Hence, given the benefits generated by the Bayh-Dole act, it is doubtful whether the incentives it provides should be modified or abandoned.

One recent example of the impact of Bayh-Dole is the disclosure by the University of Wisconsin that Thomas A. Zdeblick, a renowned surgeon and chairman of the department of orthopedics, earned royalty income in the amount \$19.4 million between 2003 and 2007 from Medtronic, which sells spinal implants developed by Dr. Zdeblick. Dr. Zdeblick was the inventor of 25 U.S. patents, 7 pending U.S. patent applications, 41 foreign patents, and 20 pending foreign patent applications developed with Medtronic. In accordance with University of Wisconsin policy, Dr. Zdeblick fully disclosed

¹³⁰ Goldie Blumenstyk, *University Inventions Sparked Record Number of Companies in 2008*, CHRON. OF HIGHER EDUC. (Feb. 15, 2010), http://chronicle.com/article/University-Inventions-Sparked/64204/?sid=pm&utm_source=pm&utm_medium=en.

his income from outside sources. Dr. Zdeblick also insists that he does not receive any royalties on devices implanted into his patients.¹³¹

As Dr. Zdeblick's experience demonstrates, it is possible to neutralize the potential impact of conflicts of interest resulting from outside income from medical companies by fully complying with disclosure requirements, declining royalties on products selected for the physician's patients, and refraining from any decision making process in which the outside income creates a conflict of interest. In short, the significant benefits of the Bayh-Dole Act in encouraging the development and commercialization of drugs and medical devices by supporting scientific research and ceding ownership of the intellectual property to the academic researchers and institutions can be maintained without triggering injurious conflicts of interest.

¹³¹ See Paul Basken, *Surgeon's Royalties Bring Heat to a Medical School with Strict Ethics Policy*, CHRON. OF HIGHER EDUC. (Feb. 27, 2009), http://chronicle.com/daily/2009/02/12570n.htm?utm_source=at&utm_medium=en. Dr. Zdeblick was not the only physician receiving payments from drug and medical devices companies. "Paul A. Anderson, a professor of orthopedic surgery . . . was paid \$150,000 by Medtronic for eight days of work as a consultant; Ben K. Graf, an associate professor of orthopedic surgery . . . collected \$770,000 in royalties from the medical-device manufacturer Smith & Nephew; and Clifford B. Tribus, an associate professor of orthopedic surgery . . . was paid \$310,000 for royalties and 15 days of work as a speaker and consultant for Stryker Spine, another device company." Paul Basken, *Several U. of Wisconsin Medical-School Professors Accepted Large Corporate Payments*, CHRON. OF HIGHER EDUC. (June 22, 2009), <http://chronicle.com/article/Several-U-of-Wisconsin-Med/47784/>.

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