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Confronting Conflict: Addressing Institutional Conflicts of Interest in Academic Medical Centers

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ABSTRACT

Individual conflicts of interest are rife in healthcare, and substantial attention has been given to address them. Yet a more substantive concern—institutional conflicts of interest ("ICOIs") in academic medical centers ("AMCs") engaged in research and clinical care—have yet to garner sufficient attention, despite their higher stakes for patient safety and welfare. ICOIs are standard in AMCs, are virtually unregulated, and have led to patient deaths. Upon review of ICOIs, we find a clear absence of substantive efforts to confront these conflicts. We also assess the Jesse Gelsinger case, which resulted in the death of a study participant exemplifying a deep-seated culture of institutional indifference and complicity in unmanaged conflicts. Federal policy, particularly the Bayh-Dole Act, also creates and promotes ICOIs. Efforts to address ICOIs are narrow or abstract, and do not provide for a systemic infrastructure with effective enforcement mechanisms. Hence, in this paper, we provide a comprehensive proposal to address ICOIs utilizing a "Centralized System" model that would proactively review, manage, approve, and conduct assessments of conflicts, and would have independent power to evaluate and enforce any violations via sanctions. It would also manage any industry funds and pharmaceutical samples and be a condition of participation in public healthcare reimbursement and federal grant funding.

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The ICOI policy itself would provide for disclosure requirements, separate management of commercial enterprise units from academic units, voluntary remediation of conflicts, and education on ICOIs. Finally, we propose a new model of medical education—academic detailing—in place of current marketing-focused "education." Using such a system, AMCs can wean themselves from industry reliance and promote a culture of accountability and independence from industry influence. By doing so, clinical research and treatment can return to a focus on patient care, not profits.

I. INTRODUCTION

Academic Medical Centers ("AMCs") have become the front line for the conflict between scientific integrity in medicine and corporate interests. Conflicts of interest occur on a daily basis in the practice decisions made by individual physicians, which have been well recognized in a variety of settings.[1] However, importantly, they also occur at the institutional, AMC level. These conflicts have created significant concerns regarding what approaches should be adopted to ensure that clinical and research decisions are made with social concerns foremost, rather than institutional self-interest.[2]

Conflicts frequently arise when pharmaceutical companies and AMCs wish to share in lucrative business arrangements originating from research underwritten by corporate funds performed at the AMC and the products arising therefrom.[3] The issues implicated by this conflict encompass patients and their safety, trust in physicians and medical institutions, the overall

[1] Individual conflicts of interest in the health care setting are rife, where "physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain." Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers,* 295 JAMA 429, 430 (2006); *see also* Niteesha K. Choudhry et al., *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612, 615 (2002) (up to 59% of physician authors of clinical practice guidelines had financial relationships with drug companies).

[2] Note that pharmaceutical companies have a completely different, and legitimate, focus. Pharmaceutical manufacturers engage in research and development of drugs that can benefit patients and at the same time attempt to make products that are economically viable for the purposes of profit. *See* Brennan, *supra* note 1, at 429. While there are clearly patient benefits that result from industry efforts, their ultimate fiduciary duty is to bring value to their shareholders through profit-maximizing behavior. This distinction often directly conflicts with the needs and welfare of the patient. *See id.* This reifies the need for AMCs to manage conflicts of interest.

[3] These conflicts pose significant challenges to patient care by imposing competing, nonmedical interests in clinical decision making. The root cause of the majority of conflicts of interest is the direct relationships between physicians and the pharmaceutical industry. *See id.*

economic cost through increased health care expenditures, and academic and scientific integrity.[4]

Industry involvement and support of AMCs may nevertheless be acceptable if conducted in an appropriate manner. However, industry relationships with AMCs that give rise to conflicts of interest pose a significant concern and challenge to AMCs. Those relationships have the potential to compromise the integrity of an institution and undermine the public's trust in the medical and research community. Further, these conflicts can endanger patient lives with little or no benefit to the individual patient or society. These problems are analogous to similar concerns regarding individual and institutional conflicts of interest by lenders and universities which participate in federal government student loan programs.[5]

Unfortunately, AMCs have not substantively addressed institutional conflicts of interests ("ICOIs"), nor do they see it as a major concern. The limitations of the current framework have been illustrated by an analysis that found substantial variation in policies adopted by AMCs governing conflicts of interest, one-fourth of investigators had industry affiliations, two-thirds of academic institutions had equity holdings representing the presence of an ICOI, and management of conflicts of interest and enforcement or sanctions for failure to disclose were almost universally discretionary.[6] More recent studies show that though AMC conflict of interest policies are improving, 34% of AMCs continue to receive failing grades.[7] In addition, the methodology of

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[4] With a recent survey showing that 94% of physicians reported some type of relationship with the pharmaceutical industry, it is clear that industry interactions are commonplace with physicians. Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships,* 356 New Eng. J. Med. 1742, 1746 (2007); *see also* Kamran Abbasi & Richard Smith, *No More Free Lunches: Patients Will Benefit From Doctors and Drug Companies Disentangling*, 326 Brit. Med. J. 1155 (2003) (reporting similar data). The primary public policy issue that emerges from this data is whether the marketing and promotional efforts that create these conflicts of interest lead to negative outcomes in provider prescribing habits and in decisions regarding patient care. This is not a new question. As early as the late 1950s, when the late Senator Estes Kefauver expressed concerns regarding predatory pricing, excessive markups in costs and pricing due to large expenditures in marketing, and questionable effectiveness of new drugs compared to more established drugs, today's echoing of these identical issues has resulted in growing scrutiny of the practice of pharmaceutical marketing to physicians. *See* Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotional Expenditures in the United States*, 5 PLoS Med. 29, 29 (2008).

[5] *See* Bryan A. Liang, *Crisis on Campus: Student Access to Health Care*, 43(3) U. Mich. J.L. Reform (forthcoming 2010); U.S. Government Accountability Office, Federal Family Education Loan Program: Increased Department of Education Oversight of Lender and School Activities Needed to Help Ensure Program Compliance (2001), *available at* http://www.gao.gov/new.items/d07750.pdf; Associated Press, *College Loan Scandal 'Like Peeling an Onion,',* MSNBC, April 10, 2007, http://www.msnbc.msn.com/id/18040824.

[6] *See* Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review,* 289 JAMA 454, 463 (2003).

[7] According to the American Medical Student Association ("AMSA") PharmFree Scorecard which grades schools on their policies regulating interactions between the industry and students and faculty using a methodology evaluating conflict of interest policies in 11 areas, over 1/5th of U.S. medical schools improved their conflict-of-interest rules in a one year period. However, in the second year of the project 17 institutions (11%) received "D" grades and 35 (13%) received "F" grades. *See* Press Release, Pew Prescription Project, Med. Students, Pew Prescription Project Find Improvements in Med. School Pharmaceutical Conflict-of-Interest Policies, but Many Lag (June 16, 2009) *available at* http://www.prescriptionproject.org/news/pressreleases?id=0023.

these assessments continues to focus on individual conflicts of interest, and not on policies related to ICOIs.[8]

As centers for advancement in biomedical research and standards of excellence in clinical care, AMCs should set the example in dealing with these issues and mitigating ICOIs. Hence, this paper discusses approaches to ensure AMCs are effectively managing these conflicts.

In Part II, this paper examines the Jesse Gelsinger case, which resulted in his death after participating in a clinical study at the University of Pennsylvania. Upon assessment, this case illustrates the negative results of unmanaged ICOIs at AMCs and how they impact the lives of patients and the conduct of scientific research in a very real and tragic way.

In Part III, this paper examines ICOIs in more detail. Through this examination, it becomes apparent that these types of conflicts of interest are much more difficult to define and detect, and have not been adequately addressed by any of the relevant stakeholders, including AMCs themselves. The root cause of these forms of conflict arises from the commercialization of research through federal legislation, and the need for subsidization of scientific progress by the pharmaceutical industry. The interdependence between academia and commercial interests in these practices leads to a dangerous partnership that gives rise to questionable financial relationships, and has not spurred appropriate self-regulation to mitigate ICOI effects.

In Part IV, attempts by the federal government to respond to the challenges posed by ICOIs at AMCs are also discussed. This assessment reveals high-level principles and concepts for addressing ICOIs, but finds they fall short in providing an effective organizational framework that identifies, addresses, and proactively manages these conflicts.

In Part V, this paper analyzes and discusses the limitations of current responses and proposed solutions to ICOIs. This includes a discussion of the limitations of disclosure laws and legislation, academic policies on conflicts of interest, current regulations governing ICOIs, and the inherent challenges of relying on self-policing by AMCs and industry.

In Part VI, to address this issue, a set of policy proposals is presented. These proposals include the development of independent oversight mechanisms to ensure compliance of ICOI policies, mandatory adoption and standardization of policies and procedures to address ICOIs, and the development of alternative forms of scientifically-sound methods to limit the need of institutional-industry interactions, focusing particularly on medical education so as to promote a culture of institutional independence. The proposed solutions include the establishment of a centralized system to manage and administer conflicts of interests from an organizational standpoint, mandatory adoption by AMCs of a comprehensive policy on institutionally-based conflicts of interest, and adoption of academic-detailing

[8] AMSA PharmFree Scorecard methodology includes a rating system on policy domains focusing on individual conflicts of interest. The scorecard does not assess AMC policies on equity arrangements, intellectual property transfer programs, or board participation in lieu of potential conflicts of interest. *See* AMSA, AMSA PharmFree Scorecard 2009: Methodology, http://www.amsascorecard.org/methodology (last visited December 24, 2009).

programs. The integration of these policies addresses deficiencies in current self-regulation of ICOIs by AMCs.

II. THE JESSE GELSINGER CASE

It is important to realize that the negative implications of ICOIs are not merely theoretical constructs. These conflicts have resulted in serious negative outcomes for patients and research.[9]

A. The Death of Jesse Gelsinger

A prime example of the consequences of failing to manage ICOIs at AMCs is the death of Jessse Gelsinger, an 18-year-old study participant, in a gene therapy clinical trial conducted at the University of Pennsylvania.[10] Gelsinger suffered from a rare genetic disorder known as ornithine transcarbamylase deficiency, which affects the body's ability to eliminate ammonia.[11] Though potentially life threatening, Geslinger had effectively managed his condition with a low-protein diet and medication, and otherwise enjoyed a productive and normal life.[12] Though Gelsinger allegedly understood that he would not

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[9] On the individual level, hidden effects include negative results from the interactions between physicians and the pharmaceutical industry. *See infra* text accompanying note 40. Studies show that physicians requesting additions to drug formularies are more likely to have accepted free meals and travel, and that the rate of specific drug prescribing increases after detailing (i.e., sales visits and promotional activities conducted by pharmaceutical sales representatives directly to physicians, acceptance of samples, and attendance at industry sponsored symposia). *See* Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review,* 5 Yale J. Health Pol'y, Law & Ethics 785, 786-87 (2005). The pharmaceutical industry is heavily invested in pharmaceutical detailing, with the majority of its vast marketing expenditures going towards these activities through legions of sales representatives. *See* Brennan, *supra* note 1, at 431; *see also* Michael A. Steinman et al., *Characteristics and Impact of Drug Detailing for Gabapentin,* 4 PLoS Med. 743, 747 (2007) (pharmaceutical industry also utilizes sophisticated marketing techniques that allow for tracking of prescribing habits, delivery of tailored marketing messages, and customization of content when visiting with a physician to achieve maximum influence). Unfortunately, physicians have come to rely on the association of gifts with medical education. While the pharmaceutical industry may argue that these forms of promotion help educate physicians and allow them to make better and more informed decisions for their patients, studies show that attendance at educational events would decline if it were not for gifts and meals. *See* Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 375 (2000). Studies have also shown that physicians remain skeptical of the motives of pharmaceutical companies in these interactions, yet changes in prescribing habits and professional behavior can still be correlated with these kinds of promotion. *See id.* at 378. However, physicians show little concern about the influence of marketing activities on their own practice of medicine in comparison to the practice of other physicians, creating a dangerous combination of ambivalence. *See id.* A common misguided assumption is that gifts of small value do not influence physician behavior. *See* Brennan, *supra* note 1, at 430. However, social science research has assessed these corporate strategies and come to the conclusion that even gifts of small value can affect physician prescribing habits. *See id.* These beliefs may manifest themselves in inappropriate management of ICOIs for the decision maker's own institution.

[10] *See* David J. Rothman, *Academic Medical Centers and Financial Conflicts of Interest,* 299 JAMA 695, 696 (2008).

[11] *See* Leslie E. Wolf & Bernard Lo, *Ethical Issues in Clinical Research: An Issue for All Internists*, 109 Am. J. Med. 82, 82 (2000).

[12] *See* Sheryl G. Stolberg, *The Biotech Death of Jesse Gelsinger,* N.Y. Times (Magazine), Nov. 28, 1999, § 6, at 137.

benefit from his participation in the Phase I study of the gene therapy, his decision to participate was motivated by his hope that results from the study would free him from his restrictive diet routine in the future.[13]

Gelsinger began the study, but soon problems emerged. The night of his injection with the gene therapy, he experienced a high fever and abdominal pain, and by the next morning, he experienced severe hepatic failure and blood clotting, then lapsed into a coma.[14] From this point his condition rapidly deteriorated, and over the next few days, Geslinger suffered multi-organ failure and, subsequently, brain death.[15] Only four days after receiving the gene therapy treatment, he was removed from life support and died.[16] Jesse Gelsinger's death was then reported to government officials.[17]

B. Investigations

Initial investigations into Gelsinger's death suggested the gene therapy vector administered to him caused systemic inflammatory response syndrome, which led to acute respiratory distress syndrome.[18] This clinical status eventually led to his death from multiple organ failure due to anoxia.[19]

These initial investigations focused on the safety of the vector used in the gene therapy treatment, known as an adenovirus,[20] and possible human error.[21] However, during these assessments, highly troubling revelations of both individual conflicts of interests and ICOIs existing with the investigators and the university began to emerge, leading to more detailed scrutiny of the motivations and judgment exercised by those involved in the trial.[22]

A few months later, officials from the FDA announced that Gelsinger, due to the condition of his liver, should never have been a participant in the study.[23] Further, the University of Pennsylvania clinical investigators had violated FDA requirements by failing to immediately report information about participants who had experienced serious side effects prior to the Gelsinger study.[24] In addition, informed consent forms provided to participants were altered from that approved by the FDA through omission of important information regarding the death of animal subjects that had undergone similar treatment.[25]

Yet these FDA announcements were just the beginning. Gelsinger's death eventually led to worldwide negative publicity on gene therapy, an independent investigation, FDA suspension of clinical trials at University of

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[13] *See* Wolf, *supra* note 11, at 82.
[14] *See* Stolberg, *supra* note 12, at 137.
[15] *See id.*
[16] *See id.*
[17] *See id.*
[18] *See* Tom Hollon, *Researchers and Regulators Reflect on First Gene Therapy Death,* 6 Nature Med. 6, 6 (2000).
[19] *Id.*
[20] *See* Sheryl Stolberg, *A Death Puts Gene Therapy Under Increasing Scrutiny,* N.Y. Times, Nov. 4, 1999, at A24.
[21] *See* Stolberg, *supra* note 12, at 137.
[22] *See* Wolf & Lo, *supra* note 11, at 83.
[23] *See* Sheryl Stolberg, *F.D.A. Officials Fault Penn Team in Gene Therapy Death,* N.Y. Times, Dec. 9, 1999, at A22.
[24] *Id.*
[25] *Id.*

Pennsylvania's Institute for Gene Therapy, FDA and Senate subcommittee investigations and hearings,[26] enforcement action by the U.S. Department of Justice, and a wrongful death lawsuit that was settled for an undisclosed sum.[27]

C. Institutional Conflicts of Interest

Importantly, this case was rife with substantive institutional wrongdoing spurred by unmanaged financial conflicts. First, reports submitted to the FDA, NIH, and IRBs misrepresented the actual clinical findings, and proper disclosures to participants did not occur in the informed consent process.[28]

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[26] *See* Julian Savulescu, Editorial, *Harm, Ethics Committees and the Gene Therapy Death*, 27 J. Med. Ethics 148, 148 (2001).

[27] *See Penn Settles Suit on Genetic Test,* N.Y. Times, Nov. 4, 2000, at A18.

[28] *See* Press Release, Department of Justice, U.S. Settles Case of Gene Therapy Study that Ended with Teen's Death, at 1-2 (Feb. 9, 2005), *available at* http://www.durrelllaw.com/UofPSettlementReleaseFinal.pdf. Note that the National Institutes of Health ("NIH") has had its own challenges in addressing ICOIs. NIH acts as the steward of billions of dollars of federal grants for funding of research in the US. *See* National Institutes of Health Website, About NIH, http://www.nih.gov/about/#mission (last visited July 11, 2009) (reporting $30.6 billion in grant monies in FY 2009 Budget). This responsibility requires that NIH employees and its policies be held to the highest standards to ensure that relationships with industry do not unduly influence NIH decisions and that these decisions are not based on financial incentives. Further, all grantee institutions that receive NIH funding must provide evidence that they have established a written policy for identifying financial conflicts of interest and any existing or subsequent conflicts will be reported, managed, reduced or eliminated pursuant to federal regulations. *See* Daniel R. Levinson, Office of Inspector General, National Institutes of Health: Conflicts of Interest in Extramural Research (2008), *available at* http://www.oig.hhs.gov/oei/reports/oei-03-06-00460.pdf. Although the NIH requires that its grantees adhere to certain federal regulations regarding conflicts of interest, NIH itself has been challenged in the area of ensuring that its own employees and the institution are free of these influences. Primarily, questions regarding the financial ties of high-ranking NIH officials with the pharmaceutical industry have been reported in the media. *See* Robert Steinbrook, *Conflicts of Interest at the NIH – Resolving the Problem,* 351 New Eng. J. Med. 955, 955 (2004). In December 2003, the *Los Angeles Times* broke a story exposing serious financial conflicts of interest between senior NIH officials, including directors of the NIH, and industry, immediately bringing into question the integrity of NIH. *See* Jennifer L. Gold, *Conflict over Conflicts of Interest: An Analysis of the New NIH Rules,* 34 J. Law, Med. & Ethics 105, 105 (2006). These reports brought to light potential conflicts involving NIH employees who were engaged in outside consulting arrangements or had other financial ties to the industry as well as instances where employees did not disclose or receive approvals for their outside consulting agreements appropriately. *See* Steinbrook, *supra*, at 955.

The repercussions of the NIH's limited policy on this issue further emerged in 2006 when an NIH researcher was charged with and plead guilty to a misdemeanor criminal offense stemming from a conflict of interest for earning private consulting fees from Pfizer. *See* Alex Dominguez, *NIH Scientist Pleads Guilty in Ethics Case,* Deseret News, Dec. 10, 2006, at A22. In these examples, ICOIs within the NIH existed when senior officials made decisions as part of their representation and employment by this important government institution. Even though policies at mitigating conflicts of interest existed, they were not adequately managed either for individual conflicts and, importantly, for the institution itself.

This result is another in a long line of problems with NIH efforts to address conflicts of interest generally. Prior to 1995, NIH rules governing employees' involvement with the industry were severely restrictive. *See* Gold, *supra*, at 105-06. In an effort to strengthen recruitment of top talent in researchers, the NIH's outside activity policies were loosened by removing restrictions on dollar caps and outside hours for consulting payments and ownership of stock options in 1995. *See id.* at 106. This change in policy opened the floodgates for industry involvement with NIH employees, and as a result of this change and subsequent

Further, upon additional investigation, it was found that both the director of the institute leading the research, and the institution itself had significant financial interests in the biotechnology company that would bring the therapy to market.[29] Indeed, both the former dean of the University of Pennsylvania Medical School and James Wilson, the lead investigator of the study, stood to benefit financially from the commercialization of the therapy through their

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media reports, congressional investigations into the NIH were initiated. *See id.* These revelations led to comprehensive reform and the tightening of conflict of interest policies and guidelines by the NIH in August of 2005 in an effort to shore up public perception and trust in the agency. *See* Press Release, National Institutes of Health, NIH Announces Final Ethics Rules (Aug. 25, 2005), *available at* http://www.nih.gov/news/pr/aug2005/od-25.htm. The changes in conflict of interest rules included restrictions on: stock holdings (including divestiture); receiving gifts or anything of monetary value from the industry; and on outside employment and consulting activities. *See id.* Many NIH employees reacted to these changes negatively based on the belief that they were overly restrictive, would be detrimental to the NIH talent pool, and that the vast majority of NIH employees were doing nothing wrong. *See* Gold, *supra*, at 106-07. Yet another report by the Government Accountability Office in 2007 reported that recusal policies for senior employees of the NIH were unclear and could exacerbate situations in which conflicts of interest could potentially be avoided. *See* U.S. Gov't Accountability Office, NIH Conflict of Interest: Recusal Policies for Senior Employees Need Clarification 17-24 (2007), *available at* http://www.gao.gov/new.items/d07319.pdf. More problems have arisen with respect to NIH efforts. In June 2008, US Senator Chuck Grassley expressed his concerns that the NIH was not meeting its obligations of effectively monitoring financial conflict of interests of individuals. *See* Sen. Chuck Grassley, Press Release, U.S. Senate, Committee on Finance, Grassley Calls on Congress and NIH Leaders to Identify Conflicts of Interest in Taxpayer Sponsored Medical Research (June 25, 2008), *available at* http://finance.senate.gov/press/Gpress/2008/prg062508CEG%20urges%20NIH.pdf. An article in the *New York Times* highlighted the passiveness of the NIH in verifying the accuracy of voluntary disclosures when it was discovered that physicians receiving NIH grants were receiving exorbitant sums of money from pharmaceutical companies and did not disclose those relationships as required. *See* Gardiner Harris & Benedict Carey, *Researchers Fail to Reveal Full Drug Pay,* N.Y. Times, June 8, 2008, at A1.

Unfortunately, despite challenges to managing conflict of interest issues on the institutional level, NIH has focused instead on monitoring conflicts of interest of external researchers and grantees. *See* Steinbrook, *supra*, at 955. However, OIG investigation in concert with this effort did provide important findings with respect to ICOIs. In 2008, OIG issued findings that the NIH was not maintaining accurate conflict of interest reports from institutions receiving grants, that such reports did not provide relevant information on the nature of reported conflict or how they are managed, that NIH's primary method of oversight was based on assurances by grantees that they were following conflict of interest regulations, and that NIH did not appropriately follow up on reported conflicts. *See* Levinson, *supra*, at 9-13. OIG subsequently recommended that NIH: (1) increase its oversight of grantee institutions to ensure compliance; (2) require grantee institutions to provide more details regarding the nature of conflicts of interest and how they deal with them; and (3) ensure that all reports are accurately contained in a centralized database. *See id.* at 16-18. In a recent November 2009 report by the GAO it was further reported that the most common type of financial conflict of interest was equity ownership, that grantee institutions rarely reduce or eliminate these financial conflicts, and that vulnerabilities continue to remain in detection, reporting, and management of conflicts of interests of grantee institutions and researchers. *See* U.S. General Accounting Office., How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health (2009), *available at* http://www.oig.hhs.gov/oei/reports/oei-03-07-00700.pdf. Given the continued difficulty of NIH regulating conflict of interest within and outside itself, relying upon it to ensure effective oversight of ICOIs is likely misplaced.

[29] *See* Rothman, *supra* note 10, at 696.

ownership of patents.[30] In addition, the AMC itself also had an equity stake in Genovo, the biotechnology company collaborator, which would have profited from commercialization of the gene therapy treatment.[31]

Further revelations showed even deeper problems. The university culture was passive, and resulted in nothing being done to address these conflicts. Although a university committee expressly recognized and noted that there were one or more conflicts of interest between Genovo and university employees, it nevertheless approved their presence and continued to allow these individuals to plan and conduct the clinical experiments.[32]

The presence of these ICOIs in the Gelsinger case brought into question the clinical decisions that were made during the course of the study.[33] Specifically, concerns were raised regarding whether investigators proceeded forward with the study despite their knowledge of negative data, such as the risks the adenovirus vector posed to study participants, whether investigators were incorrectly motivated by financial incentives to develop a marketable product that may have influenced their clinical decisions, whether investigators were misleading in setting expectations of therapeutic benefit and the risks of participation in the study, and the decision of whether Gelsinger was eligible for the study given his impaired liver function.[34]

These types of issues are pervasive when conflicts of interest exist in clinical research, and pose the danger of real harm to participants, and serve to undermine the legitimacy of scientific research. This incident also catapulted the issue of ICOIs into the national media, while at the same time dealing a major setback to the progress of gene therapy.[35] In February, 2005, the Department of Justice issued a release detailing the enforcement actions taken against both the University of Pennsylvania and the three investigators involved in the research.[36] These included over one million dollars in punitive fines for false claims allegations, and placement of restrictive controls on the clinical research activities of the named investigators.[37] Gelsinger's death also led to the adoption of more stringent policies related to conflicts of interest in clinical research by the Association of American Medical Colleges, Association of American Universities, and the U.S. Department of Health and Human Services, and led to the formation of the Association for Accreditation of Human Research Protection Programs, which provides voluntary accreditation for organizations which conduct human subject research.[38]

The Gelsinger case epitomizes the inherent risks associated with ICOIs as they exist in scientific research and serves as an important case study for identifying deficiencies in monitoring and managing ICOIs at AMCs. It also

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[30] *See* Jeffrey Fox, *Gene-Therapy Death Prompts Broad Civil Lawsuit*, 18 NATURE BIOTECH. 1136, 1136 (2000).

[31] *See id.* at 1136.

[32] *See id.*

[33] This factor resulted in the FDA suspending genetic research at the institute. Rothman, *supra* note 10, at 696.

[34] Wolf & Lo, *supra* note 11, at 83.

[35] *See* Sheryl Stolberg, *Teenager's Death is Shaking Up New Field of Human Gene-Therapy Experiments,* N.Y. TIMES, Jan. 27, 2000, at A20.

[36] *See* Press Release, U.S. Dept. of Justice, *supra* note 28, at 1-5.

[37] *See id.*

[38] *See* David Blumenthal, *Academic-Industrial Relationships in the Life Sciences,* 349 NEW ENG. J. MED. 2452, 2456 (2003).

acted as a catalyst for current calls for additional oversight of ICOIs in clinical research, but has yet to lead to comprehensive reform. This case is not isolated, with other examples of patient death resulting from financial interests of investigators in clinical research also reported.[39]

[39] A Boston Globe article describes several cases in which investigators in clinical trials for antipsychotic drugs disregarded exclusion criteria, used questionable recruitment methods and incentives for participants, and engaged in fraudulent activity for the purpose of maximizing revenue derived from conducting clinical trials. In some of these cases, participants died as a result of their participation in a study from which they should have been excluded. *See* Robert Whitaker, *Doing Harm: Research on the Mentally Ill,* BOSTON GLOBE, Nov. 17, 1998, at A1.

In addition, fraud on the taxpayer has occurred even with government participation in oversight. For example, allegations of individual conflicts of interest at the University of Southern California ("USC") in a federally funded HIV/AIDS educator training program led to the issuance of an OIG audit report in 2004 which recommended that the university repay over $1 million dollars in federal funds that may have been misappropriated on the basis of fraud. *See* OFFICE OF INSPECTOR GENERAL, AUDIT OF HEALTH RESOURCES AND SERVICES ADMINISTRATION COOPERATIVE AGREEMENT NUMBER U69-HA-00040, UNIVERSITY OF SOUTHERN CALIFORNIA, LOS ANGELES, CALIFORNIA iii (2004), *available at* http://oig.hhs.gov/oas/reports/region9/90201004.pdf. In September 1999 the Health Resources and Services Administration ("HRSA") awarded $2.5 million dollars in federal funds to USC for the development of a HIV/AIDS peer treatment educator program to provide counseling and treatment education in certain communities. *Id.* at i, 1. As part of this award, USC entered into a cooperative agreement that established the objectives of the program and also outlined the role the HRSA would play in assessing the program and providing technical assistance. *See id.* at 1. In performance of the cooperative agreement, USC utilized several organizational components to administer the program, including a grants office with responsibility to ensure that the university was in compliance with applicable requirements of the award and which prepared and administered subcontracts for the program, and an IRB that ensured the safety of human subjects and reviewed research proposals. *Id.* at 1-2. USC also utilized program positions such as a principal investigator ("PI"), director or co-PI, project manager, and other administrative positions. In addition, a portion of the work to be performed for the program, including providing office and training space, equipment, and salary support, was subcontracted to a nonprofit corporation whose founder was also the program's co-PI, a clear violation of federal conflict of interest regulations. *Id.* at 3.

In July of 2001, HRSA conducted an audit of USC in response to concerns regarding adherence to IRB conditions, misuse of federal funds, failure to deliver program objectives, and concerns relating to conflicts of interest. *Id.* At this point, the majority of funds incurred by USC for the program had already been reimbursed by the federal government, close to half of which were paid to the aforementioned subcontractor and were unverifiable. *See id.* at 4. After the audit, the OIG concluded, among other deficiencies, that USC failed to adequately address the conflict of interest held by the co-PI who also was the chief executive officer, president, and executive director of the subcontractor, constituting a violation of federal regulations. *Id.* at 11. After HRSA expressed concerns about this conflict of interest, the co-PI resigned his managerial positions but continued to serve as chairman of the board of the subcontractor thus retaining his managerial authority. *Id.* at 11-12. In sum, HRSA concluded that USC failed to properly manage the situation and in doing so, failed to comply with federal regulations. *Id.* at 4-5. This led to continuing violations and mismanagement of federal funds that may have been spent by the subcontractor on activities not connected with the program. *See id.* at ii. Further, of the program costs incurred, 85% were deemed as inappropriate and thus recommended to be disallowed. *Id.* at 13. In addition, these conflicts led to research involving human subjects without the approval of the monitoring IRB, also in violation of federal regulations. *Id.* at 8-9.

III. INSTITUTIONAL CONFLICTS OF INTEREST

A. Overview

Individual conflicts of interests between physicians and the industry are well documented and have undergone detailed scrutiny from the public, media, and the government.[40] However, ICOIs have yet to be given the same

[40] Strategies include various gifts, free lunches/dinners, and other payments to physicians. *See* Catherine D. DeAngelis, *Conflict of Interest and the Public Trust*, 284 JAMA 2237, 2237 (2000). Other strategies include no-fee continuing medical education ("CME"), payment for travel, grants for research projects, payment for consulting services, and payment of honorarium. Brennan, *supra* note 1, at 430. Studies have shown that such interactions between physicians and the pharmaceutical industry can lead to negative results for patients including: (a) inability to identify wrong claims about medications; (b) making formulary requests for medications with no apparent significant advantage over existing medication; (c) non-rational prescribing behavior; and (d) prescribing fewer generics in favor of newer medications with no demonstrated advantage. Wazana, *supra* note 9, at 378. Pharmaceutical companies start their marketing efforts early, beginning their courtship of medical professionals as early as medical school and continue to meet with them in varying frequency through residency by providing industry-sponsored meals and samples. *See id.* at 375. As physicians enter practice, marketing from pharmaceutical companies is more targeted towards the payment of honoraria, conference travel, and research funding. *Id.*

In addition, media outlets have uncovered such activities. A 2007 *New York Times* investigative article interviewed several former pharmaceutical sales representatives. Each agreed that the marketing practices that they employed were used for the purposes of influencing physicians' prescribing habits and manipulating physicians into favorable opinions about their products. *See* Gardiner Harris & Janet Roberts, *A State's Files Put Doctor's Ties to Drug Makerson Close View,* N.Y. Times, Mar. 21, 2007, at A1. They also explained that financial incentives easily seduced physicians, and that there are many ways to provide for mutual financial benefit for both the physician and the pharmaceutical company. *See id.* In another *New York Times* article, the perspective of a physician who was paid by the pharmaceutical industry for detailing drugs was outlined. It revealed a glamorous, high-paying, benefit-filled lifestyle in which the physician provided "education" to other physicians, in the form of lunches. The purpose of these events was to change prescribing habits and for the detailing physician to advocate questionable positive clinical conclusions about the company's products. *See* Daniel Carlat, *Dr. Drug Rep,* N.Y. Times (Magazine), Nov. 25, 2007, at 64. He eventually ended his detailing career based on his own admissions that gifts and payments may have clouded his own clinical judgment. *See id.* In another *New York Times* article the Senate's Special Committee on Aging made public a marketing document used by Forest Laboratories for its expensive antidepressant drug Lexapro which details a $34.7 million dollar marketing campaign that included dinners, lunches and questionable funding of CME in order to influence physician prescribing habits. *See* Gardiner Harris, *Document Details Plan to Promote Costly Drug,* N.Y. Times, September 2, 2009, at B1.

Other even more questionable strategies have been employed. A recent *New York Times* article discussed a particularly novel method by which pharmaceutical companies attempt to influence physicians. This article outlined company active recruitment of cheerleaders for pharmaceutical sales representative positions. *See* Stephanie Saul, *Gimme an Rx! Cheerleaders Pep Up Drug Sales,* N.Y. Times, Nov. 28, 2008, at A1. Good looking and highly energetic, these individuals may represent a "variation" on traditional forms of industry marketing and promotion, but nevertheless represent a potential to lead to conflict of interest situations. The demand is so great for cheerleaders that specialized recruiting firms have been established to meet needs of prospective pharmaceutical employers. *See id.* Often times a cheerleader's educational background is of no consequence. *See id.* Reports of sexual harassment and allegations that pharmaceutical companies have encouraged the use of sex to promote drug

level of attention, even though they pose an equal or even greater risk to the integrity of academic research and to patient safety as made evident in the Gelsinger case.[41] Currently, no laws or regulations[42] directly regulate ICOIs or the representatives of institutions that make decisions on behalf of the institutions as a whole.[43]

In a broad sense, ICOIs are defined as "when the institution, any of its senior management or trustees," a department or other sub-unit, or any "affiliated foundation or organization, has an external relationship or financial interest" with the industry that also has a financial interest in research being conducted at or by the institution.[44] These types of conflicts encompass decisions made by institutional units and departments. The most common forms of ICOIs that currently exist in AMCs are: (a) equity holdings or royalty arrangements; (b) intellectual property transfer arrangements in research programs; (c) decisions by university officials unduly influenced by conflicts of

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sales and have their female employees exploit their personal relationships with physicians have also served to scrutinize these practices of hiring and marketing. *See id.*

Other well known examples include a *Business Week* investigation of the world's best selling drug, Lipitor. Questions regarding the efficacy of Lipitor in patients without heart disease, and the inherent risk in taking the drug if there is no apparent health benefit, have brought industry influence through pharmaceutical promotion to the forefront of our public debate. *See* John Carey, *Do Cholesterol Drugs Do Any Good?,* 4068 BUS. WK., JAN. 28, 2008, at 52.

In a recent fraud and abuse settlement, Pfizer agreed to pay a record $2.3 *billion* dollars and pleaded guilty to a single felony charge for its marketing of its anti-inflammatory drug Bextra. *See* Carrie Johnson, *In Settlement, A Warning to Drugmakers,* WASH. POST, Sept. 3, 2009, at A1. Pfizer allegedly influenced doctors by providing expensive vacations, sending unsolicited advertising materials to physicians, and drafting of articles promoting their product without disclosing its role in funding the articles. *Id.*

Certain physician groups have also been supportive of physician-industry financial relationships, with the recently formed group, Association of Clinical Researchers and Educators, advocating benefits of industry interaction and condemning recent reforms and policy proposals to regulate these activities. Association of Clinical Researchers and Educators, Who We Are, http://www.acreonline.org/eng/pages/who-we-are (last visited July 28, 2009).

[41] *See* Ezekiel J. Emanuel & Daniel Steiner, *Institutional Conflicts of Interest*, 332 NEW ENG. J. MED. 262, 262 (1995).

[42] Note, however, that there have been federal prosecutions against pharmaceutical companies for inappropriate marketing and promotion to physicians. *See* David Studdert et al., *Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry – Self-Regulation in the Shadow of Federal Prosecution,* 351 NEW ENG. J. MED.1891, 1893 (2004) (discussing TAP Pharmaceuticals case, which resulted in a settlement with government prosecutors of $290 million in criminal fines and $585 million in civil penalties and numerous private class action lawsuits; $355 million criminal fraud fine against AstraZeneca; and $350 million fine against Schering-Plough). A $499 million civil fine has also been administered against Bristol Meyers Squibb. *See* Press Release, Office of Inspector General, OIG Reports More Than $2 Billion in Recoveries From Fighting Fraud, Waste, and Abuse for First-Half FY 2008 (June 12, 2008), *available at* http://www.oig.hhs.gov/publications/docs/press/2008/semiannual_press_spring2008.pdf. Yet appropriately transparent marketing may be beneficial for patient access particularly for rare disease treatment if regulatory structures are put into place, again emphasizing the need for sound infrastructures and policies that integrate government and industry. *See, e.g.,* Bryan A. Liang & Tim Mackey, *Reforming Off-Label Promotion to Promote Orphan Disease Access,* 327 SCIENCE 273 (2010).

[43] *See* Michael M. E. Johns et al., *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Conflicts of Interest,* 289 JAMA 741, 742 (2003).

[44] *See* AAU TASK FORCE ON RESEARCH ACCOUNTABILITY, ASS'N OF AM. UNIVS., REPORT ON INDIVIDUAL AND INSTITUTIONAL FINANCIAL CONFLICT OF INTEREST 10 (2001).

interests ("COIs") that have institution-wide implications; and (d) university officials participating as members of the board of a corporation with a potential COI.[45]

ICOIs also arise from institutional representatives that have individual COIs that are then transferred to decisions made by the institution as a whole due to the authority and influence over research that these individuals exercise.[46] ICOIs in this context include situations where an institution has equity in a company funding the institution's research; investigators who are employed by the institution and "conduct research that could affect the value of the equity interest;" or when an institution has intellectual property which it then licenses to companies and investigators employed by the institution to conduct research.[47]

ICOIs can also arise from more complex arrangements such as when AMCs engage in incorporation of start-up companies where the institution and its faculty act as major shareholders, secure cash payments for right of first refusal options on discoveries, market or exploit branding of commercialized products,[48] and maintain and profit from corporate equity positions in university endowments or gift funds.[49] However, a chief characteristic underlying all ICOIs is that arrangements are made at an institutional level, often at a department or unit of an AMC, or when AMC representatives make decisions with broad, institutional impact. These are often the product of AMC dependence on the industry for research funding or AMC-industry commercialization of advances in life sciences through licensing and technology transfer.

B. Limited Attention to ICOI

Based on concerns arising from highly publicized ICOI incidents, the Association of American Universities ("AAU"), Association of American Medical Colleges ("AAMC"), and the Department of Health and Human Services ("DHHS"), through their recommendations and guidance, have urged institutions to recognize and address ICOIs as a separate area of concern,[50] and mitigate these issues through disclosure, managing conflicts, and prohibiting these kinds of activities.[51] However, recent studies show that

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[45] *See id.* at 11-12. Note that ICOIs can extend to any situation in which a financial relationship with the industry affects an institutional process or decision making or when the institution has a direct financial interest. This can include more common forms of individual financial conflicts of interest such as funding of CME, research and development, and scholarship or training grants that have an institutional impact. *See* Brennan, *supra* note 1, at 430; DeAngelis, *supra* note 40, at 2237.

[46] *See* Johns et al., *supra* note 43, at 742.

[47] *See* Emanuel & Steiger, *supra* note 41, at 263.

[48] *See* Johns et. al., *supra* note 43, at 741.

[49] *See* AUU Task Force on Research Accountability, Ass'n of Am. Univs., *supra* note 44, at 11.

[50] *See* Susan H. Ehringhaus et al., *Responses of Medical Schools to Institutional Conflicts of Interest,* 299 JAMA 665, 665 (2008).

[51] *See* AUU Task Force on Research Accountability, Ass'n of Am. Univs., *supra* note 44, at 12. Note that individual conflicts of interest have been extensively assessed, and management strategies proposed and employed. These strategies include state law as in California, Minnesota, Maine, Massachusetts, West Virginia, Vermont, and the District of Columbia. *See* Troyen A. Brennan & Michelle M. Mello, *Sunshine Laws and the*

Pharmaceutical Industry, 297 JAMA 1255, 1255-56 (2007); Joseph S. Ross et al., *Pharmaceutical Company Payments to Physicians,* 279 JAMA 1216, 1216-17 (2007); Press Release, Mass. Office of Health and Human Servs., Patrick Admin. Passes Tough New Rules Governing Pharm. and Med. Device Indus. (March 11, 2009), http://www.mass.gov/?pageID=eohhs2pressrelease&L=1&L0=Home&sid=Eeohhs2&b=pressrelease&f=090311_tough_new_rules&csid=Eeohhs2. New Jersey has recommended a ban on gifts and imposing disclosure requirements directly on physicians licensed in the state. *See* N.J. OFFICE OF THE ATTORNEY GEN., REPORT ON PHYSICIAN COMPENSATION ARRANGEMENTS 2, 3, 6-8, *available at* http://www.nj.gov/oag/newsreleases09/pr20091203b-ReportOnPhysicianCompensationArrangements.pdf. In addition, proposed federal legislation has sought to address individual conflicts of interest through increased transparency. *See, e.g.*, Affordable Health Care for America Act of 2009 ("Physician Payment Sunshine Provision"), H.R. 3962 111th Cong. § 1451 (2009), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3962pcs.txt.pdf; Patient Protection and Affordable Care Act, H.R. 3590 111th Cong. (2009), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590eas.txt.pdf; Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s301is.txt.pdf; Drug and Medical Device Company Gift Disclosure Act, H.R. 3023, 110th Cong. (2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h3023ih.txt.pdf; Physician Payments Sunshine Act of 2007, S. 2029, 110th Cong. (2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s2029is.txt.pdf.

Guidelines for individual conflicts of interest have emanated as well from stakeholder groups, e.g., the American Medical Association, *see* AM. MED. ASS'N, CODE OF MEDICAL ETHICS, OPINION E-8.061 - GIFTS TO PHYSICIANS FROM THE INDUSTRY (1992), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml (last visited July 10, 2009), the Pharmaceutical Research and Manufacturers of American ("PhRMA"), *see* PHRMA, CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2008), *available at* http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf (last visited July 10, 2009), as well as individual drug and device companies in anticipation of Congressional action. In the latter case, Medtronic will report consulting fees, royalties or honoraria to physicians of $5,000 or more. Sarah Rubenstein, *Medtronic to Report Pay to Doctors Who Get $5,000 Annually,* WALL ST. J. HEALTH BLOG, http://blogs.wsj.com/health/2009/02/24/medtronic-to-report-pay-to-doctors-who-get-5000-annually (Feb. 24, 2009, 16:32 EST). Pfizer and Eli Lilly have announced that they will report payments that total more than $500 annually. Jacob Goldstein, *How Pfizer's Doctor-Payment Disclosure Compares to Grassley Plan*, WALL ST. J. HEALTH BLOG, http://blogs.wsj.com/health/2009/02/10/how-pfizers-doctor-payment-disclosure-compares-to-grassley-plan/ (Feb. 10, 2009, 09:20 EST); Jacob Goldstein, *Eli Lilly to Disclose Payments to Doctors*, WALL ST. J. HEALTH BLOG, http://blogs.wsj.com/health/2008/09/24/eli-lilly-to-disclose-payments-to-doctors/ (Sept. 24, 2008, 09:06 EST). Merck has stated that it will report payments made to doctors for speaking arrangements. Jacob Goldstein, *Merck to Report (Some) Payments to Doctors, Medical Education Groups*, WALL ST. J. HEALTH BLOG, http://blogs.wsj.com/health/2008/09/25/merck-to-report-some-payments-to-doctors-medical-education-groups/ (Sept. 25, 2008, 17:23 EST). GlaxoSmithKline has announced that it will publicly report payments to physicians and cap payments at $150,000 per year. Jacob Goldstein, *Another Drug Maker to Report Payments to Doctors*, WALL ST. J. HEALTH BLOG, http://blogs.wsj.com/health/2008/10/23/another-drug-maker-to-report-payments-to-doctors/ (Oct. 23, 2008, 09:07 EST). And Johnson & Johnson announced that it would support the proposed Physician Payments Sunshine Act and begin disclosing payments made to physicians by its pharmaceutical, medical device, and diagnostic companies. Press Release, Reuters, Johnson & Johnson Announces Support for Kohl-Grassley Physician Payment Sunshine Act of 2009 (May 7, 2009), http://www.reuters.com/article/pressRelease/idUS203817+07-May-2009+PRN20090507.

among AMC respondents, less than 38% have adopted ICOI policies, 37% have begun to work on them, and one quarter of respondents were not working on a policy or "did not know."[52]

This low compliance rate is in stark contrast to much higher affirmative responses in addressing individual financial COIs in these same institutions.[53] Hence, it appears that in the four years since the issuance of guidance from the AAMC,[54] only approximately one-third of AMCs have actually adopted such policies even though these relationships continue to be commonplace and pose a potential threat.[55] These results also imply that monitoring of ICOIs is simply not a priority for AMCs.

C. Driving ICOIs: Bayh-Dole Act

Possibly the most highly debated issue regarding managing ICOIs in AMCs is the situation where an institution holds an equity position or has royalty agreements with a company that will utilize the AMC's developed technology. These forms of AMC-industry collaboration were encouraged

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In addition, the Office of Inspector General of the Department of Health and Human Services has entered the discussion for individual conflicts of interest. OIG has taken a much more comprehensive approach in its guidance statements on conflict of interest. Its approach is detailing to both physicians and manufacturers the types of industry practices that will most likely give rise to federal prosecution under fraud and abuse laws and encourages structuring of physician-industry relationships within certain statutory "safe harbors," i.e. business arrangements which will not be subject to enforcement. *See* Studdert et al., *supra* note 42, at 1898-99. In instances that are not covered by safe harbors, the government uses four factors in determining whether a payment to a physician constitutes a kickback, including, (a) the likelihood of the arrangement interfering with clinical decisions or objective professional judgment; (b) the likelihood of increasing prescribing of product; (c) the potential to lead to increased expenditures for federal health care programs; and (d) whether the arrangement compromises patient safety or quality of care. *See id.* at 1899. The OIG also provides guidance in relation to conflicts of interest in medical education by advising that physicians and researchers face potential liability when manufacturers have influence over the content of education programs and when education is used as a method of remuneration for physicians. *See id.* The guidance further provides that research support from manufacturers should not be directed or funded by sales and marketing departments and that gifts and entertainment to physicians are potentially in violation of anti-kickback regulations. *See id.* Comments by Tony Maida, deputy chief of the OIG's administrative and civil remedies branch, have reinforced the agency's position that pursuing anti-kickback violations against both physicians and the industry and further scrutinizing physician financial relationships will be a priority of federal enforcement. *See* Bureau of Nat'l Affairs, *HHS Official Says Physician Relationships with Device Makers are Enforcement Priority,* 12 Health Care Fraud Rep. 927 (Nov. 19, 2008). Note, however, that none of these efforts extend to institutional conflicts of interest.

[52] Ehringhaus et al., *supra* note 50, at 668. This national survey of all 125 accredited U.S. allopathic medical schools in 2006 revealed that policies regarding institutional forms of conflicts of interests are not being adequately addressed by AMCs. *See id.* This study provides strong evidence that even though the AAMC has provided specific recommendation to deal with ICOIs, many institutions have failed to do so. *See id.*

[53] AMCs have adopted individual conflict of interest policies for between 60% and 81% of individuals at these institutions. *Id.*

[54] *See* Ass'n of Am. Med. Colls., Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subject Research (2002), http://www.aamc.org/research/coi/2002coireport.pdf.

[55] *See* Ehringhaus et al., *supra* note 50, at 668.

through the passage of the Bayh-Dole Act in 1980.[56] Under this law, the U.S. government sought to facilitate cooperation between private industry and research institutions by allowing them to enter into technology transfer arrangements to better utilize developed innovations and accelerate their use for products brought to market.[57] Specifically, the Bayh-Dole Act allows for the grant of patent rights for innovator inventions conceived and funded in government-sponsored research and development programs, and allows grantees to profit from its commercialization.[58] The law provides for the ownership of patents by universities, nonprofit corporations, and small businesses, as well as permitting licensing arrangements.[59]

As a result of the passage of this Act, relationships between AMCs and the industry have rapidly accelerated, with industry investment in biomedical research increasing from 32% in 1980, to 62% in 2000.[60] Concomitant financial benefits from licensing arrangements with industry are estimated to generate close to $2 billion dollars annually for AMCs.[61]

While the Act may have resulted in the development of cooperation between AMCs and industry,[62] these relationships have promoted a framework of ICOIs that have the potential to compromise research integrity and patient safety in favor of institutional financial interests.[63] Fundamental to this problem is the fact that the Act allows AMCs to make patenting and licensing decisions on behalf of taxpayer-funded public agencies based on the AMC's own motivations, which usually includes a profit motive, at the expense of facilitating future research and maximizing social benefit.[64] In addition, it is difficult to effectively monitor these decisions by AMCs given their complexity and the subject matter expertise necessary to evaluate the technology and its potential commercial use.[65] Indeed, questions have been raised regarding whether there have been any actual social benefits for technology licensing under the Bayh-Dole Act.[66]

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[56] University and Small Business Patent Procedures Act, 35 U.S.C. § 200 (2000); 37 C.F.R. § 401 (2000).

[57] *See* U.S. General Accounting Office, Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest 6 (2001), *available at* http://www.gao.gov/new.items/d0289.pdf.

[58] *See* U.S. General Accounting Office, Technology Transfer, Agencies' Rights to Federally Sponsored Biomedical Inventions 1 (2003), *available at* http://www.gao.gov/new.items/d03536.pdf.

[59] *See* U.S. General Accounting Office, *supra* note 57, at 6.

[60] *See* Bekelman et al., *supra* note 6, at 454.

[61] *See* Rothman, *supra* note 10, at 696.

[62] *See* Wendy H. Schacht, The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology, CRS Report for Congress 8 (2006), *available at* http://ncseonline.org/NLE/CRSreports/07Jan/RL32076.pdf.

[63] *See* U.S. General Accounting Office, *supra* note 57, at 1.

[64] *See* Bhaven N. Sampat, *Patenting and U.S. Academic Research in the 20th Century: The World Before and After Bayh-Dole,* 35 Res. Pol'y 772, 786 (2006).

[65] *See id.* at 786-87.

[66] Studies have questioned the actual benefits of the Bayh-Dole Act on technology licensing, indicating that there is little empirical evidence to show that the Act was the primary moving force that led to increased patent activities and licensing in universities over the past almost 30 years. *See* David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980,* 30 Res. Pol'y 99, 100-01 (2001). These studies also indicate that even without the passage of the Act,

Importantly, the cultures of these institutions are focused upon financial benefits, and its representatives act accordingly. A survey in 2001 revealed that administrators and faculty researchers at AMCs believed that the most important outcome of technology transfer activity was the generation of revenue, not scientific progress.[67] Another survey reported that 68% of AMCs held equity positions in companies who sponsored their research.[68] These skewed motivations and the close financial ties between industry and academia that are encouraged and even mandated by the Act result in a plethora of ICOI situations, and have also resulted in negative consequences for human participants in research.[69]

Beyond the doubts raised regarding the effectiveness of the Act in promoting patent and licensing activities at AMCs, questions related to increased costs to the healthcare system have led to greater scrutiny of the Act.[70] For example, Emtriva, a drug developed by researchers at Emory University for the treatment of HIV, embodies the complexities surrounding AMC-industry collaboration in patenting and licensing, where scientific discovery is mired in patent litigation, delays in drug approval, and disputes regarding inventorship.[71] In this case, researchers were in parallel development of very similar compound which led to multiple lawsuits over rights and licensing of the compound.[72] This included four challenges at the U.S. Patent & Trademark Office and several more in other foreign regulatory bodies, millions of dollars in legal expenditures, and a decade and a half of continuing disputes in court.[73] However, this case represented only one of 494 patent suits filed by pharmaceutical companies from 1992 to September 2003 and represents a significant cost and burden to both taxpayers and consumers of pharmaceutical products.[74] Cases such as Emtriva lead to an increase in the

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universities would have nonetheless continued their corporate relationships and expansion of licensing and patenting activities due to other factors, such as the growth in biomedical research and technology. *See id.* Other factors such as U.S. Supreme Court rulings allowing patenting of novel organisms, increased government funding, and the increase of research companies in information technology that utilize university research are also cited as reasons for the upswing in university patenting and licensing. *See id.* at 101-03. Given this possibility, the Bayh-Dole Act may be counterproductive to the overall progress of technology transfer and bringing such technology to market as the exclusivity of patents acts to restrict the use of scientific research. Indeed, without the passage of the Act, the public good may have been better served through the dissemination of such discoveries in the public domain. *See id.* at 103.

[67] *See* Clifton Leaf, *The Law of Unintended Consequences,* 152 FORTUNE MAG., September 19, 2005, at 250-68.

[68] *See* Josephine Johnston, *Conflict of Interest in Biomedical Research,* THE HASTINGS CENTER 32 (2008), *available at* http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/conflict%20of%20interest%20chapter.pdf.

[69] *See supra* Part II (discussing the Jesse Gelsinger case).

[70] *See* Leaf, *supra* note 67, at 250-68.

[71] *See id.* Emory later sold its rights to Emtriva for a lump sum of $525 million, at that time the largest university-related IP transaction. *See* Dave Chokshi, *Improving Access to Medicines in Poor Countries: The Role of Universities,* 3, PLOS MED. 723, 724 (2006). However, questions have been raised regarding accessibility of Emtriva for poorer countries and the need to establish favorable licensing provisions for humanitarian access in future IP transactions by universities. *Id.*

[72] *See* Leaf, *supra* note 67, at 250-68.

[73] *See id.*

[74] *See id.*

ultimate cost of pharmaceuticals to consumers, barriers to access, questionable return on investment for taxpayer-funded research, and retardation of the dissemination and sharing of scientific discoveries.[75] These costs, coupled with stagnation in the development of more novel and innovative drugs,[76] the government's failure to exercise "march-in rights,"[77] and questions regarding whether universities as a whole actually profit from patenting and licensing activities,[78] bring the merits of the Act into serious question.

Despite the debates on the extent of the law's influence on AMC commercialization incentives, the Bayh-Dole Act has certainly created an environment in which individual researchers and institutions can derive direct financial reward through industry collaboration.[79] This general fact presents serious challenges in self-policing of ICOI situations in AMCs, given that researchers and institutions share a collective interest in profiting from commercialization of scientific discoveries.[80] In this respect, the Act continues to encourage and facilitate ICOI situations that flourish in an environment free from external oversight.[81]

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[75] *See id.*

[76] *See id.* New Molecular Entities ("NMEs") are active ingredients that the FDA considers to have never been marketed in the United States in any form. *See* U.S. Food and Drug Administration, Drugs@FDA Glossary of Terms, http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#NewMolecularEntity (last visited July 11, 2009). During the period from 2000-2003 the average number of priority NMEs was half as much as the previous 4 years. *See* Leaf, *supra* note 67, at 250-68. This indicates the possibility that increasing patenting and commercialization of pharmaceuticals may be attributed to reformulations, old compounds with new indications for use, or "me too" drugs, and that discovery of innovative drugs may be limited. *See id.*

[77] "March-in rights" are statutory rights exercised by the government to compel licensing of university government-funded patents if the university or its licensee has not taken, or is not expected to take effective steps in achieving practical application of the patent, or if licensing is necessary to alleviate public health or safety needs or requirements for public use as specified by federal regulations. 35 U.S.C. § 203 (2006). However, historically the NIH has declined to utilize the march-in rights statutorily afforded to the agency. Examples such as the CellPro petition in which CellPro, Inc. requested that the NIH investigate Baxter Healthcare Corporation's alleged failure to successfully commercialize government-funded stem cell isolation technology, resulted in a denial of that petition by the NIH. *See* Amy Schofield, *The Demise of Bayh-Dole Protections Against Pharmaceutical Industry's Abuses of Government-Funded Inventions,* 32 J. L. MED. & ETHICS 777, 778 (2004). Similarly, the NORVIR petition in which it was alleged that Abbott Laboratories' 400% price increase of its HIV/AIDS drug NORVIR in 2003 constituted a failure to reasonable satisfy the needs and safety of public health, resulted in a denial by the NIH as well. *See id.* at 778-79.

[78] *See* Richard Nelson, *Observations on the Post-Bayh-Dole Rise of Patenting at American Universities,* 26 J. TECH. TRANSFER 13, 17 (2001).

[79] *See* JENNIFER HENDERSON & JOHN SMITH, CENTER FOR INTEGRATION OF MEDICINE AND INNOVATIVE TECHNOLOGY, ACADEMIA, INDUSTRY, AND THE BAYH-DOLE ACT: AN IMPLIED DUTY TO COMMERCIALIZE 6 (2002), *available at* http://www.cimit.com/news/regulatory/coi_part3.pdf.

[80] *See* Hamilton Moses III & Joseph Martin, *Academic Relationships With Industry: A New Model for Biomedical Research,* 258 JAMA 933, 933 (2001).

[81] Senator Chuck Grassley has continually voiced his concerns over the lack of oversight in conflict of interest monitoring which has resulted from the Bayh-Dole Act. He has targeted individual physicians, universities and government funded researchers in an attempt to address concerns regarding biased decisions in research. *See* Jocelyn Kaiser, *Ethics: Private Money, Public Disclosure,* 325 SCIENCE 28, 29-30 (2009).

D. Driving ICOIs: Research Oversight

The closely linked practices of biomedical and scientific research and commercialization of advances from that research have created economic partnerships between AMCs and industry with questionable benefits to society. The conflicts of interest that arise from these partnerships have become imbedded into the organizational operations of AMCs.[82]

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[82] This is particularly true in research. Conflicts of interest that occur in research settings can lead to adverse effects on collection, analysis and interpretation of results, hiring decisions, procurement activities, study design, information dissemination, and participation of human subjects. *See* AUU Task Force on Research Accountability, Ass'n of Am. Univs., *supra* note 44, at 2. Physicians and researchers participating in a study often receive direct financial benefit, such as patient recruitment incentives, which complicates their relationship with the industry, commercializes the practice of medical research, and can lead to compromised research data. *See* Trudo Lemmens & Paul Miller, *Regulating the Market in Human Research Participants,* 3 PLoS Med. 1237, 1237 (2006). Even scientific journals have participated in incentivizing physicians for the purpose of profit, with a recent report revealing that publishing company Elsevier offered gift cards to academics in exchange for favorable reviews of publications. *See* Helen Mooney, *Elsevier Says Offering $25 Gift Cards for Positive Reviews of Psychology Textbook was a Mistake,* 339 Brit. Med. J. 125, 131 (2009). Further, more institutionalized forms of financial conflicts of interest include equity ownership in companies that sponsor research and commercialize such discoveries, research support and funding through grants and contracts, consultancy arrangements, and other forms of research-related remuneration and gifts from the industry, which are particularly problematic and difficult to manage. *See* Michael M. E. Johns et al., *Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest,* 280 JAMA 741, 741-42 (2003). In these cases, researchers as well as other staff and faculty, may be heavily invested in the outcome and success of research they are conducting, and thus act upon these influences that may compromise study participant safety. Further, success in the academic enterprise focuses upon research publications, and hence corporate strategies have exploited this as well. Recent studies and news reports have shed light on a troubling practice that is commonly known and practiced in the scientific community known as "ghost writing" or "ghost authorship," where pharmaceutical companies or their agents write academic articles for publication and pay researchers to place their names on the pieces. *See, e.g.,* Barton Moffatt & Carl Elliot, *Ghost Writing: Pharmaceutical Companies and Ghostwritten Journal Articles,* 50 Perspectives in Biology & Med. 18, 19-20 (2007). Variation include co-writing an article or collaborating with a ghost writer by reviewing, revising, or, in some cases, simply signing their name to a manuscript. *See id.* at 20-22. For the pharmaceutical company, these hired experts lend credibility and legitimacy to the paper; yet these relationships clearly create questions regarding the accuracy of findings and issues regarding accountability and responsibility of its content. *See* Stephanie Ngai et al., *Haunted Manuscripts: Ghost Authorship in the Medical Literature,* 12 Accountability Res. 103, 104-05 (2005). These papers, which health professionals rely upon heavily, may be the product of marketing campaigns coordinated by pharmaceutical companies or their agents rather than the result of scientifically sound research. They may unduly influence and mislead physicians about the benefits and risks involved with specific pharmaceuticals and endanger the public's health. *See, e.g.,* Moffatt & Elliot, *supra,* at 19-20 (discussing pharmaceutical publication strategy linked to product marketing). Unfortunately, the literature is now rife with examples of this practice. *See, e.g., id.* at 22-23 (study conducted on articles published on Pfizer's antidepressant Zoloft during a 3 year period showed that 57% of articles potentially involved ghost writing, including articles in prestigious journals such as *Annals of Internal Medicine and the Journal of the American Medical Association*); *see also* Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation,* 299 JAMA 1800, 1802-03 (2008) (Vioxx papers ghost written). Recently, a federal judge ordered the unsealing of documents regarding ghostwriting practices by Wyeth for its drugs Prempro and Premarin, which are the subject of litigation alleging that these hormone-replacement drugs caused breast cancer in more than 10,000 women. *See* Jeff Feeley & Sonny Rhodes, *Wyeth Ordered to Unseal Prempro Ghostwriting Files (Update 2),* Bloomberg, July 24, 2009, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a0QT8.Bt2Ud4.

AMCs clearly have a vested interest in the performance, success, and marketability of research that allows a transfer of technology, given that the more successful the results, the more potential revenue it provides to the AMC.[83] These ICOIs in the research arena may serve to negatively affect an institution's ability to make neutral, independent decisions, may incorrectly incentivize individuals to make decisions based on their own financial interest that then implicates institutional actions, and may make it difficult for institutions to produce unbiased and scientifically-sound data in research.[84] Further, the mere presence of these ICOIs brings into question the motives and decisions made by AMCs and their representatives, and compromises public trust in research regardless of whether a COI has been acted upon or not.

Distrust in institutions because of ICOIs in research appears well-founded. The prevalence of institutional academic-industry relationships is alarming. A recent study reported that an astounding 67% of departments

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This follows both a federal study which found that the drug increased the risk of breast cancer and requests made by US Senator Chuck Grassley for Wyeth to disclose documentation of payments, articles and activities associated with possible ghost writing with a medical communication and education company and physicians. *See* Duff Wilson, *Investigation Links Wyeth to Articles on its Drugs,* N.Y. TIMES, Dec 13, 2008, at B1. Senator Grassley has recently expanded this request by asking eight leading medical journals to describe their policies and practices regarding ghostwriting, disclosure policies, and enforcement mechanisms. *See* Sen. Chuck Grassley, Press Release, US Senate, Committee on Finance, Grassley Asks Top Medical Journals About Ghostwriting (July 2, 2009), *available at* http://finance.senate.gov/press/Gpress/2009/prg070209.pdf. Grassley, in a recent letter, has also requested that the top ten medical schools explain what steps they are taking with professors whose names are included in ghostwritten articles in medical journals. *See* Duff Wilson, *Medical Schools Quizzed on Ghostwriting,* N.Y. TIMES, November 18, 2009, at B2. Unfortunately, it appears that journals themselves condemn conflict of interest non-disclosure yet engage in the practice themselves if it furthers their own agenda. *See, e.g.,* Bryan A. Liang, *Commentary: Accuracy of Conflict-of-Interest Disclosures by Physicians*, SURVEY OF ANESTHESIOLOGY (2010), forthcoming (describing New England Journal of Medicine non-disclosure of generic industry author bias despite "requiring" full conflict of interest disclosure stated in the journal only a week before).

[83] Potential revenue includes, for example, increased dividend payments of equity ownership or revenue derived from royalty/licensing fees. Licensing revenues derived from technology transfer, such as university originated patents and licensing revenues, are significant revenue and profit streams for universities with a recent survey reporting $1.5 *billion* dollars in research-related income. Maureen Farrell, *Universities That Turn Research into Revenue,* FORBES.COM, Sept. 12, 2008, http://www.forbes.com/2008/09/12/google-general-electric-ent-tech-cx_mf_0912universitypatent.html. Another study has shown that equity positions in start-up companies by universities can lead to increased revenues over traditional licensing arrangements further emphasizing the need for oversight of ICOIs. *See* Michael J. Bray & James N. Lee, *University Revenues from Technology Transfer: Licensing Fees vs. Equity Positions*, 15 J. BUS. VENTURING. 385, 391 (2000).

[84] The potential adverse results of these forms of individual financial conflicts of interest in research can also extend to include the manipulation of study design to produce favorable results, inappropriate encouragement for human subject participation, changes of inclusion/exclusion criteria to affect participation*, see* Emanuel & Steiner, *supra* note 41, at 264, failure to disclose conflicts of interest, *see* AAU TASKFORCE ON RESEARCH ACCOUNTABILITY, ASS'N OF AM. UNIVS., *supra* note 44, at i, and inadequate or incomplete informed consent, *see* ASS'N OF AM. MED. COLLEGES, PROTECTING PATIENTS, PRESERVING INTEGRITY, ADVANCING HEALTH: ACCELERATING THE IMPLEMENTATION OF COI POLICIES IN HUMAN SUBJECTS RESEARCH 15 (2008), *available at.* https://services.aamc.org/publications/showfile.cfm?file=version107.pdf.

and 60% of department chairs have relationships with the industry.[85] This data is alarming not simply due to extensive presence of ICOIs among institutional representatives who make decisions on behalf of AMCs, but also due to the fact that most AMCs do not have systematic processes to address these forms of ICOIs.

These partnerships have produced a lucrative revenue stream for AMCs, but at the same time have created an environment where institutional medical entrepreneurism has become the norm in academic operations.[86] Some have argued that the consequences of these incentives have led AMCs to shift away from their primary goal of unfettered scientific research, to focus on industry-oriented research and technology transfer incentives, which has transformed them into corporate research laboratories, dampening the progression of discovery.[87] Hence, the AMC can be seen as an actor interested in research that can result in patent exclusivity, which in the drug development context results in higher costs of pharmaceuticals, with a focus on prioritizing projects with immediate marketability.[88] AMCs are consequently similar to corporate actors that focus on commercialization for their (or individuals who act in their name) financial benefit. This undermines the basic tenet of the AMC, and the physicians and researchers who work within it, to benefit the public good first.

In addition, the primary system used for review of clinical research fosters a number of ICOI issues due to the nature and relationship between Institutional Review Boards ("IRBs"), research sponsors, and researchers.[89] While IRBs are meant to serve the important role of independent and formally designated review and monitoring of biomedical research to ensure the rights and welfare of human participants are protected,[90] oftentimes funding sources for an IRB may be identical to the institution conducting the research; further, preexisting relationships may exist between IRB members and research faculty who will perform the work.[91] This results in a lack of IRB functional autonomy, and the overshadowing presence of financial ties in monitoring places serious constraints on the IRB's ability to make decisions in the best interests of the study participant.

The heavy financial burden of financial costs for providing the infrastructure of research facilities and IRBs to monitor clinical research creates the need for corporate sponsorship, which again may give rise to ICOIs. Indeed, clinical studies may even include direct involvement of a sponsor in the trial, which can result in selectively publishing research data, issues of scientific quality in journal articles, and failure to report adverse

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[85] Eric G. Campbell et al., *Institutional Academic-Industry Relationships*, 298 JAMA 1799, 1783 (2007).

[86] *See* Bekelman et al., *supra* note 6, at 463.

[87] *See* Leaf, *supra* note 63, at 250.

[88] *See* Janet Rae-Dupree, *When Academia Puts Profit Ahead of Wonder,* N.Y. TIMES, Sept. 7, 2008, at BU4.

[89] *See* Ezekiel J. Emanuel et al., *Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals,* 141 ANNALS INTERNAL MED. 282, 283 (2004).

[90] *See* Food and Drug Admin., Running Clinical Trials: Frequently Asked Questions (Aug. 21, 2009), http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm115632.htm.

[91] *See* Emanuel et al., *supra* note 89, at 283.

events.[92] The Office of Inspector General ("OIG") has voiced significant concerns as early as 1998, and more recently in 2007, regarding the inadequacy of the current regulatory framework of clinical trials, specifically in FDA participation.[93] This lack of adequate federal oversight, and lack of AMC interest, policies, or methods of managing the ICOIs that arise from industry funding and support of research may compromise the safety of participants and the data collected.

Due to this high prevalence of industry-related funding in almost all facets of academic research, encouragement of technology transfer by the federal government, and continued depletion of government funding, AMCs have become increasingly dependent upon industry support for their activities.[94] The result is a system rife for exploitation by institutions, industry, and individual representatives therein for the purpose of maximizing financial gain.

IV. RESPONSES AND PROPOSED SOLUTIONS

A. Federal Guidelines

1. NIH Guidelines

The concerns regarding ICOIs in biomedical research and clinical practice are not novel or new. As early as 1989, NIH proposed guidelines that prohibited relationships that might present a conflict through requiring full disclosure by researchers.[95] However, the 1989 guidelines were withdrawn due to criticisms that they were too restrictive, and were subsequently replaced in 1995 by revised guidelines issued by the Public Health Service ("PHS") and the National Science Foundation ("NSF"). These guidelines were much more lenient on AMCs, and gave research institutions discretion in how they managed conflicts of interest, and required only minimal disclosure as a condition for government funding.[96] These guidelines set a management threshold of $10,000 in annual income, or 5% ownership interest, but did not specify how AMCs should manage conflicts that arise.[97]

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[92] *See supra* text accompanying note 82 (discussing industry practices of selective publishing, manipulation of data and ghost writing in clinical trials); Emanuel et al., *supra* note 89, at 283 (discussing funding of IRBs by institution conducting research IRB reviews); Michael A. Morse et al., *Monitoring and Ensuring Safety During Clinical Research*, 285 JAMA 1201, 1202-03 (2001) (discussing challenges faced by IRBs in evaluating adverse event reports).

[93] Daniel R. Levinson, Office of Inspector General, The Food and Drug Administration's Oversight of Clinical Trials 8 (2007), *available at* http://www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf.

[94] *See* Bekelman et al., *supra* note 6, at 464. A recent informal survey of medical schools found that up to sixteen percent of some medical schools' annual budgets originate from the pharmaceutical industry. Joe Neel, *Medical Schools and Drug Firm Dollars* (Nat'l Pub. Radio broadcast June 9, 2005), http://www.npr.org/templates/story/story.php?storyId=4696316.

[95] S. Van McCrary et al., *A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research*, 343 New Eng. J. Med. 1621, 1621 (2000).

[96] *See id.*

[97] *See id.*

This hands-off approach has created what is now the current state of AMC self-policing of ICOIs, and the absence of a comprehensive regulatory framework in managing conflicts of interest. The resulting weaknesses include inconsistencies in disclosure of conflicts of interest, lack of external disclosure, inability to capture all forms of financial conflicts, and confusion regarding disclosure requirements and definition of terms.[98] The outcome is consistent with other circumstances that show a failure to adequately manage these conflicts.[99] In addition, this reality has been affirmed by a recent study examining the accuracy of disclosure of conflicts of interest by physicians, with rates of nondisclosure ranging from 20-50%.[100] This study brings into question the potential effectiveness of disclosure-only policies of addressing ICOIs.

In 2009, NIH released a proposed rule on managing institutional grantees' financial conflicts of interest.[101] This proposal includes discussion regarding expanding the scope of current regulations so that they address both individual conflicts of interest and ICOIs more effectively.[102] In specifically addressing ICOIs, the proposed rules include disclosure requirements for investigators to report financial conflicts of interest related to their institutional responsibilities, possible enhanced enforcement options for conflicts of interest violations, mandated conflicts of interest training of investigators on a routine basis, possible accreditation compliance of ICOI programs through independent auditing, additional information reporting regarding identified conflicts, and amendments of current regulations to

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[98] *See id.* at 1624-25.

[99] Evidence of the failure to self-police conflicts of interests in the public sector of U.S. government agencies provide some interesting parallels to this discussion. Recent controversies regarding financial ties to the industry between government agency officials such as the NIH, *see* Steinbrook, *supra* note 28, at 955-57, and the FDA, *see* Robert Steinbrook, *Financial Conflicts of Interest and the Food and Drug Administration's Advisory Committees*, 353 New Eng. J. Med. 116, 118 (2005), have resulted in congressional inquiry, demands for agency reform, and criminal convictions, *see* Janice Hopkins Tanne, *Former FDA Commissioner Pleads Guilty to Two Charges,* 333 Brit. Med. J. 874, 874 (2006). Even more recently, conflict of interest allegations of top level FDA employees, including current FDA Commissioner Margaret Hamburg, have emerged. *See* Ellen Brown, *The Mercury Mischief: As Obama Warns of Hazards, The FDA Approves Mercury Dental Fillings*, The Huffington Post, Aug. 28, 2009, http://www.huffingtonpost.com/ellen-brown/the-mercury-mischief-as-o_b_271520.html, and Alicia Mundy, *Drug Chief at the FDA Is Accused of Conflict,* Wall St. J., August 12, 2009, at B1.

[100] *See* Kanu Okike et al., *Accuracy of Conflict-of-Interest Disclosures Reported by Physicians*, 361 New Eng. J. Med. 1466, 1471 (2009).

[101] On May 8, 2009 the NIH issued an Advanced Notice of Proposed Rulemaking in the federal register to solicit public comment on whether changes to the agency's conflict of interest policies regarding federally funded research should be adopted. *See* DHHS, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Request for Comments, 74 Fed. Reg. 21610 (proposed May 8, 2009), *available at* http://edocket.access.gpo.gov/2009/pdf/E9-10666.pdf.

[102] The NIH proposal includes discussion regarding requiring institutions who are recipient of federal funds for research to implement additional controls to identify and manage financial conflicts of interests such as an independent committee to review conflicts of interests, development and disclosure of a conflict management plan when a conflict arises, additional limitations for participation by investigators who have a potential conflict of interest, and imposing maximum thresholds for financial contributions from certain organizations. *See id.* at 21612.

specifically address ICOIs.[103] Members of the U.S. Senate have also taken notice of these reform efforts, and have recommended, in a letter to the NIH, increased transparency through added disclosure requirements for researchers who receive NIH funding, requiring institutions to complete a plan to manage researcher conflicts of interest, and public disclosure via the NIH's website of such requirements.[104] These recommendations are a follow-up to unsuccessful efforts to amend the American Reinvestment and Recovery Act of 2009 to include additional enforcement of the conflicts of interest requirement by the NIH.[105] These potential changes significantly expand the scope of NIH monitoring over conflicts of interest, which previously were only enforced against intramural scientists working for NIH, and may reflect a commitment to re-establishing the integrity of scientific research on the institutional level.[106] Importantly, they represent recognition by government research agencies of the importance in specifically dealing with ICOIs as a separate concern, although relying on this mechanism and NIH enforcement may not result in substantive change if history is any guide.[107]

2. IOM Guidelines

Most recently, the Institute of Medicine ("IOM") released a report recommending that medical institutions, including AMCs, establish conflict of interest policies that include implementing ways to manage ICOIs. In 2007, the IOM formed a Committee on Conflict of Interest in Medical Research, Education, and Practice to examine and report recommendations on how to identify, limit, and manage conflicts of interest while maintaining positive interactions between industry and academia.[108] This report is primarily in response to recent steps taken by AMCs and other groups to prevent detrimental conflicts of interests between industry and physicians, researchers, and medical institutions, which had received notoriety in the

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[103] *See id.*

[104] *See Press Release*, Senator Chuck Grassley of Iowa, Grassley, Kohl Work to Bring Transparency to Biomedical Research Funding (July 9, 2009), *available at* http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=21709.

[105] The amendment would have required the NIH to actively enforce conflict of interest policies and respond in a timely manner to any violations by grant fund recipients. 155 CONG. REC. S1709 (daily ed. Feb. 5, 2009), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2009_record&page=S1709&position=all. It would have also required additional disclosures by recipients regarding the degree and amount of financial conflicts of interest as well as a report detailing how conflicts of interest would be managed by the recipient. *Id.*

[106] *See* DHHS, *supra* note 101, at 21612.

[107] *See* Steinbrook, *supra* note 28, at 955 (noting the failure of NIH to address internal and external ICOIs).

[108] *See* INSTITUTE OF MEDICINE, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 1 (2009). The IOM also suggested methods by which individual conflicts of interest be addressed. These included:

establishment of federal regulations requiring disclosure of physician payments by the industry; removal of individual conflicts of interest from research; prohibition of gifts, meals and entertainment as well as forms of physician remuneration by the industry;

restrict access to AMCs by pharmaceutical representatives; and establishment of system of accredited CME providers free of industry influence.

See id. at 18-22.

media, such as those linked to the death of Jesse Gelsinger.[109] Specifically, the IOM suggested the following actions be taken: establish conflict of interest committees; standardize conflict of interest disclosure procedures by AMCs; prohibit industry funding of professional societies which develop clinical practice guidelines; develop incentives for adoption of conflict of interest policies by health insurers, accrediting bodies, and government agencies; and perform further DHHS research on the issue of conflict of interest policies.[110]

In general, the IOM report supports certain forms of prohibitions and restrictions on industry interactions and further disclosure and oversight of permitted relationships.[111] Also, it promotes the development of a national standardized content, format, and procedure for disclosure of payments due to current variation in adopted policies.[112] The express notion that ICOIs must be addressed builds upon NIH proposals, and signals the importance of managing ICOIs. However, an organizational framework and systemic infrastructure to both address ICOIs as well as proactively manage them were not provided in the IOM report.

V. REFORM CONSIDERATIONS

A. Limitations of Current Responses and Proposed Solutions

Beyond suggested, high-level efforts noted above,[113] a wide spectrum of stakeholders have attempted to take more detailed steps in dealing with ICOIs through a variety of laws, guidelines, and policy proposals, all with questionable efficacy. The solutions proposed have primarily been in the form of disclosure of physician payments and financial interests with the industry, banning of certain forms of marketing and promotion to physicians,[114] and prohibition of certain industry interactions with physicians and institutions. Although these solutions provide some short-term responses to this issue, they also face significant limitations, as described below.

1. Disclosure Laws

Federal and state disclosure laws have been proposed and enacted in response to the need for increased transparency and access to data that will

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[109] *See id.* at 217.

[110] *See id.* at 18-22.

[111] *See* Robert Steinbrook, *Controlling Conflict of Interest – Proposals from the Institute of Medicine,* 360 New Eng. J. Med. 2160, 2160 (2009).

[112] *See id.* at 2162.

[113] *See supra* Part IV.

[114] There is little question that the practice of pharmaceutical industry marketing, estimated to be valued between some $27.7 billion and $57.5 billion in 2004, is a key strategy to attempt to secure physician prescriptions. Gagnon, *supra* note 4, at 30. The pharmaceutical industry spent some $9.2 billion dollars in 1996 for marketing and promotion that tripled to $27.7 billion in 2004, according to IMS Health and Competitive Media Reporting, a firm specializing in pharmaceutical marketing intelligence. *See* Gagnon, *supra* note 4, at 30; *see also* The Nat'l Inst. for Health Care Mgmt. Research and Educ. Found., Prescription Drugs and Mass Media Advertising 11 (2001), *available at* http://www.nihcm.org/~nihcmor/pdf/DTCbrief2001.pdf. The pharmaceutical industry has also enjoyed increased profits during this time, indicative of the fact that such marketing and promotion may have a positive effect on sales of product. *See id.*

allow both the public and policymakers to address industry influence on individual physicians. Some states, such as Vermont, have also taken more proactive measures in ensuring that ICOIs are adequately addressed in regulating physician-industry relationships.[115] However, more importantly, federal legislative efforts do not specifically address forms of payments made directly to certain institutions,[116] significantly limiting the effectiveness in identifying forms of ICOIs, which are already difficult to detect.[117] The exclusion of such a reporting requirement limits the scope of data which will be provided and disclosed and could also lead to a shift in directing payments away from physicians and redirected to institutions, further complicating detection and monitoring of ICOIs. In response to this limitation, both IOM and the Medicare Payment Advisory Commission[118] have proposed that Congress enact broader legislation that requires disclosure of industry payment data made to physicians, researchers, healthcare institutions, professional societies, patient advocacy groups, and providers of CME.[119] By advocating a more comprehensive reporting requirement, the public and government will have access to more accurate and reliable payment data relating to ICOIs. This will also allow researchers and policymakers the opportunity to identify and analyze the scope and prevalence of forms of conflicts of interest in scientific research and clinical practice at both an individual and institutional level. In addition, Senator Chuck Grassley, the key sponsor of a proposed federal disclosure bill, recently requested that certain AMCs disclose their policies on conflicts of interest and requirements for disclosure of financial relationships between faculty and industry, apparently recognizing the importance of disclosure at the institutional level.[120]

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[115] Vermont's law on pharmaceutical marketing has expanded to include disclosures of payments made to institutions such as medical schools. *See* Robert Steinbrook, *A Higher Bar – Vermont's New Law on Marketing Prescribed Products,* 361 NEW ENG. J. MED. 8, 8 (2009).

[116] Proposed federal legislation in the Senate only requires the disclosure of payments made to receiving physicians and teaching hospitals of certain information regarding forms of transfer or payment and ownership or investment interests held by physicians. Patient Protection and Affordable Care Act, H.R.3590, 111th Cong. § 1128G (1st Sess. 2009). Disclosure requirements do not include payments made to other institutions or their non-physician representatives. It should be noted that the Physician Payment Sunshine provisions contained in the House of Representative's version of the Affordable Health Care for America Act of 2009 includes many forms of institutions, including medical schools, as "covered recipients" subject to reporting requirements. *Id.* at § 1128G(e)(6). This would enhance federal disclosure legislation to include reporting of payments made to institutions. However, it is questionable whether these disclosure requirements will make it into the final reconciled bill. Additionally certain sections specifically limit the effectiveness of the proposed bill by excluding reporting of discounts and rebates, delaying certain reporting requirements related to product development and clinical investigation, and classifying same data as confidential and thus not accessible to the public. *See* Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 1451 (1st Sess. 2009).

[117] *See supra* text accompanying notes 99-102 (describing complexity and limited mechanisms to detect ICOIs).

[118] The Medicare Payment Advisory Commission, or MedPAC, is an independent congressional agency that advises the U.S. Congress on issues affecting the Medicare program. MedPAC, About MedPAC,, http://www.medpac.gov/about.cfm (last visited July 24, 2009).

[119] *See* Steinbrook, *supra* note 111, at 2162.

[120] Julie Steenhuysen, *US Senator Seeks Med Schools' Disclosure Policies*, REUTERS, June 24, 2009, http://www.reuters.com/article/idUSN2419553620090624. In addition, Senator Grassley has recently sent letters to the American Medical Association and thirty-two other disease and medical advocacy groups. He requested the groups provide details regarding

Although promising, these current efforts still fall short of substantively addressing these conflicts. Payment shifting, a focus on individuals rather than institutions, and the lack of internal AMC infrastructural components to address ICOIs indicate the need for a more comprehensive solution.

2. Academic Policies

Academia itself has attempted to address conflicts of interest that arise from industry relationships and financial arrangements through guidance, voluntary adoption of policies of interaction, and disclosure. However, currently there is no standardized, binding system that requires AMCs to adequately address ICOIs. While a number of institutions have implemented policies in dealing with individual conflicts of interest,[121] variation in adopted policies,[122] lack of formal administrative processes in managing conflicts of interest, inadequacy in addressing ICOIs, and slow adoption rates have lead to a fragmented system in institutions that self-regulate these relationships at varying degrees.[123]

While professional trade associations have provided a framework for developing voluntary conflict of interest policies, the proper regulatory incentives for implementing such policies to ensure quality clinical care and

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funding that they and their directors received from both the pharmaceutical and medical device industry given the strong influence of these groups over public policy. Gardiner Harris, *Senator Grassley Seeks Financial Details From Medical Groups,* N.Y. TIMES (Online), Dec. 7, 2009, http://www.nytimes.com/2009/12/07/health/policy/07grassley.html.

[121] *See supra* text accompanying notes 7, 8 (discussing results of AMSA PharmFree Scorecard). UC Davis Health System is an example of one such school which received an "A" grade (the highest grade possible) on the AMSA scorecard with a policy enacted in July 2007 that includes a ban on gifts and samples, limitations on industry funding of on-campus and off-campus education, controls on consulting compensation, limited disclosure, mandatory training and other controls designed to limit potential financial conflicts of interest. UC Davis Health System, *Medical School Receives "A" Grade for Conflict-of-Interest Policies,* http://www.ucdmc.ucdavis.edu/welcome/features/20080716_no_conflict/ (last visited July 11, 2009).

[122] A survey of the top US institutions receiving funding from the NIH in 1998 were analyzed for their policies of conflicts of interest including an examination of their processes for disclosure, review and management. This study showed a high variation in policies in regards to requiring disclosure of financial relationships and sanctions for violations of rules. *See* Mildred Cho et al., *Policies on Faculty Conflicts of Interest at U.S. Universities*, 284 JAMA 2203, 2207-08 (2000); *see also* Van McCrary et al., *supra* note 95, at 1622-23 (discussing substantial differences in conflict of interest policies at AMCs including the percentage having conflict of interest policies, variation on the definition and management of conflicts, percentage of policies which exceed current federal guidelines, and policies on disclosure of conflicts of interest).

[123] The results of the AMSA PharmFree Scorecare reported in June 2008 revealed that only 21 of 150 medical schools had strong policies (scored A or B) governing conflicts of interest. Only 7 schools received "A" scores, with 9% receiving "B" scores, 3% receiving "C" scores, 13% receiving "D" scores, and 40% receiving "F", or failing scores, which included schools which failed to submit their policies after repeated requests. Press Release, The Pew Charitable Trusts, PharmFree Scorecard Grades U.S. Medical Schools on Conflict-of-Interest Policies (June 3, 2008), *available at* http://www.pewtrusts.org/news_room_detail.aspx?id=39910. Twenty-eight respondents also received "In Progress" scores as their policies were then currently under review or revision. *Id.* The results of the AMSA's survey reveal a high level of variation in how AMCs regulate conflict of interest situations in the absence of a standardized and mandatory policy and when left to self-regulation. *Id.*

research are absent.[124] Indeed, although the AAMC has advocated stronger conflict of interest policies,[125] federal agencies themselves only require the disclosure of conflicts of interest from investigators on a periodic basis, and rely on AMCs to internally develop policies and manage these conflicts with little oversight.[126] This lack of substantive mandates has failed to incentivize AMCs to enact effective policies even in the wake of scandals such as Jesse Gelsinger's gene therapy death.

For example, as early as November, 2000, some members of the Harvard Medical School faculty called for a forum of medical schools to develop a national policy to effectively govern conflicts of interest at AMCs.[127] However, some nine years later, Harvard has not enacted policies to effectively limit the perception that conflicts of interest with the industry significantly influence medical education and scientific research performed there.[128]

3. Current Regulation of ICOIs

Examples of ICOIs in AMCs provide real and sobering illustrations of the potential tragic consequences of the inability to detect and the inadequacy of institutions in self-regulating ICOIs. In the Gelsinger case, these ICOIs may have resulted in the unnecessary death of an individual who could have effectively managed his disease, was in no immediate danger of mortality, and who could have potentially lived a long and productive life. Decisions

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[124] Note that relying upon voluntary industry efforts will likely be ineffective if individual conflicts of interest experience is any guide. For example, concerns regarding the voluntary nature of the revised PhRMA code have been expressed by the Prescription Project, a project aimed at promoting evidence-based medicine and research, which has concluded that enforcement through self-policing of PhRMA members is not effective. Press Release, The Pew Charitable Trusts, Prescription Project Statement on PhRMA's Revised Code on Marketing (July 10, 2008) *available at* http://www.pewtrusts.org/news_room_detail.aspx?id=41964. Since the enactment of the 2002 code, promotional spending has increased not decreased, state disclosure data shows that promotional activities have not adhered to the 2002 code, and PhRMA members have not been investigated or sanctioned for violations. *Id.* In addition, the revisions to certain sections of the Code still allow the industry to provide meals to healthcare professionals provided they are accompanied by educational presentations and pay physicians "fair market value" for consultancy relationships, further limiting the effectiveness of such restrictions. Natasha Singer, *No Lipitor Mug? Drug Makers Cut Out Goodies for Doctors*, N.Y. TIMES, Dec. 31, 2008, at A1. Code of Conduct revisions enacted by the pharmaceutical industry provide for questionable self-regulation and compliance with federal regulations on individual conflicts of interest and fraud and abuse violations, which further emphasizes the need for independent, mandatory intervention for ICOIs.

[125] *See* Ehringhaus et al., *supra* note 50, at 665.

[126] *See* Van McCrary et al., *supra* note 95, at 1623-24 (discussing survey results of federal agency policies on conflicts of interest in extramural research).

[127] Joseph B. Martin & Dennis L. Kasper, *In Whose Best Interest? Breaching the Academic-Industrial Wall,* 343 NEW ENG. J. MED. 1646, 1651 (2000).

[128] *See* Duff Wilson, *Patching a Wound,* N.Y. TIMES, Mar. 3, 2009, at B1. In addition, in January 2009 Harvard Medical School re-convened a conflict of interest review committee which at the time did not include notable critics of AMC-industry relationships such as Jerry Avorn, a proponent of "academic detailing" and also a past member of the Prescription Project's advisory group. *See* Harvard Medical School, HMS Review Committee, January 2009, *available at* http://hms.harvard.edu/public/coi/review/index.html#members (last visited Dec. 24, 2009); Press Release, The Pew Charitable Trusts, New Campaign Champions Changes in Medical Prescribing to End Conflicts of Interest (Feb. 12, 2007), *available at* http://www.pewtrusts.org/news_room_detail.aspx?id=30377.

regarding the eligibility of his participation and his own expectations of benefit from participation in a Phase I trial have raised serious questions about the motivations of investigators and institutions who have conflicts of interest in clinical research. Decisions by researchers and the institution in both the research design and clinical decisions made during the trial may have been motivated by the expectation of financial gain, placing the trial's research subjects in harms way.

Further, the Gelsinger case shows the limitations of current AMC policies regarding ICOIs and self-policing of industry interactions by AMCs. It is a striking and dramatic example of poor institutional culture that a university committee was fully aware of the conflicts of interest between investigators, administrators, and commercial interests, but took no action to address them. Indeed, the committee did not even review or comment on ICOIs that existed between the institution and industry and the results of the research. The end result was an innocent person's death, civil litigation, government enforcement action, reversal in the progress of gene therapy research, and the loss of public trust in human subject research at academic medical institutions. Though professional trade groups and the government have proposed stronger stances in attempting to regulate conflicts of interests in biomedical research through recommendations and reports, Gelsinger's death makes it abundantly clear that policymakers need to address AMCs activities to effectively deal with conflicts of interest at an institutional level in order to uphold scientific integrity and patient safety.[129] This need for reform is ever more important due to the failure of even joint university-government oversight in preventing negative results associated with ICOIs.[130]

Federal laws which encourage industry investment and participation in scientific research at AMCs also need to be taken into account when

[129] As the rate of clinical research trials continues to increase while the availability of federal funding in research continues to lessen, issues regarding these conflicts as well as dependency and pressure from commercial sponsors for faster and more favorable results creates concerns regarding the erosion of patient safety and public trust in the integrity of scientific research. *See* Lemmens, *supra* note 82, at 1238. As seen by the Gelsinger case, financial incentives and conflicts of interest can place personal financial gain over objective judgment. This can lead to tragic results in which patients are harmed or even die as a result of the unethical actions of investigators under such influences. *Id.* (discussing alteration of patient medical records to influence enrollment eligibility as well as the act of convincing potentially high risk patients to participate in research).

[130] The USC example, *supra* note 39, illustrates a failure at both an educational and government institutional level of effectively dealing with ICOIs. In this case, the university and federal government had shared responsibilities of oversight, and had many of the traditional tools and organizational components necessary for the monitoring and policing of conflicts of interest. Yet in this case, even though an ICOI situation was identified, both the university and government failed to take the steps necessary to mitigate an ICOI situation and prevent the subcontractor from continuing to misuse federal funds. From the AMC standpoint, though USC had conflict of interest policies in place, and institutional units that could manage these conflicts, they were not sufficient in ensuring that federal funds were used responsibly, or that once an ICOI was detected, it was dealt with in a manner consistent with the requirements of federal regulations. This case is a clear example of the ineffectiveness of self-policing and limited oversight of AMC policies on both individual conflicts of interest and ICOIs and how government involvement does not guarantee effective management of these conflicts.

managing ICOIs.[131] This is particularly needed because of the Bayh-Dole incentive structure creating, and indeed, promoting ICOIs.[132]

While OIG has recommended that DHHS develop specific guidance to address ICOIs,[133] it is clear that recommendations and self-policing alone will not be adequate in addressing compliance, as illustrated by the Gelsinger case study.[134] This lack of action seems to reflect the deep-rooted interdependent and codependent relationship academia shares with the pharmaceutical industry. From a pragmatic standpoint, industry involvement in academic research is both necessary and closely tied to government action or inaction in funding of research. Given the fundamentals by which the federal government encourages AMC-industry partnerships through licensing agreements, the lack of alternative expertise to conduct biomedical research for the industry, and increasing financial constraints on academic and healthcare institutions, it is highly unlikely that comprehensive reform of the current system, which fails to address ICOIs, is forthcoming.[135] It is equally less probable that AMCs will be effective in self-policing against these forms of ICOIs given the fact that they are difficult to detect and often are part of a fundamental construct of the way AMCs do business. For this reason, policymakers must take a critical look at what solutions and safeguards can practically be implemented to wean academia's dependence on commercial funding, while at the same time not endangering their ability to conduct research. By continuing to allow the existence of ICOIs, the current system risks compromising academic and scientific integrity and places both AMC employees and institutional processes in circumstances that can result in patient harm.[136]

VI. A POLICY PROPOSAL

A. Key Aspects of the Problem

It is apparent that previous efforts to address AMC ICOIs have been of limited effectiveness. A focus on individual conflicts of interest and high-level guidelines with limited infrastructural components do not address the issue.

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[131] The regulation of financial incentives and managing these forms of individual conflicts of interest in scientific research is yet to be adequately addressed. Much of this regulation falls to IRBs, which simply lack the required federal regulation oversight and needed independence from investigators and sponsors required to protect patient safety. Lemmens, *supra* note 82, at 1239; *see also supra* text accompanying notes 89, 90 (discussing IRB issues and ICOI).

[132] Other policy reasons also exist that support reform in this area. Concerns regarding the need for exemptions to use technology for noncommercial research, providing access to technology for upstream inventions and research tools, preventing fragmented ownership of inventions, and allowing access of technology for humanitarian purposes all are important policy goals that may be blocked without attention to ICOIs. *See* Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 Nature Biotech. 320, 321 (2006). Without these reforms, other universities and non-profit organizations cannot take advantage of technological innovations that may be completely or partially funded by the taxpayer. This lack of access prevents the overall progress of noncommercial research by restricting use of research tools while at the same time creating financial interdependent relationships that blur the lines between public and private interests. *Id.* at 321-22.

[133] *See* U.S. General Accounting Office, *supra* note 57, at 5.

[134] *See* Rothman, *supra* note 10, at 696.

[135] *See* Emanuel & Steiner, *supra* note 41, at 265.

[136] *See* Ehringhaus et al., *supra* note 50, at 665.

AMCs themselves have specifically failed in their ability to detect and manage ICOIs, and voluntary adoption of policies by the few that recognize the issue[137] has not been sufficient to create a comprehensive, uniform, and effective framework to regulate these conflicts. Though it may be argued that market-based disincentives such as litigation, enforcement actions of federal and state authorities, and loss of reputation, funding or licensure may be sufficient in deterring situations which give rise to ICOIs, problems with establishing an effective system of detection and the need to ensure patient safety require proactive external regulation over the current system of self-policing. Without the ability to consistently detect and manage ICOIs as they arise, AMCs will not be in a position to appropriately mitigate the detrimental effects of these conflicts. Further, industry actors need to understand what is deemed appropriate behavior when interacting with physicians and AMCs. Hence, what is needed is a mandatory, harmonized, clear, and comprehensive model policy for AMCs. Primarily, this policy must address three key areas to effectively manage and regulate AMC ICOIs, including:

Development of independent oversight mechanisms to adequately enforce and ensure compliance to AMC policies on ICOIs, diminishing the need of AMCs and the industry to self-regulate; Mandatory adoption and standardization of institutional policies and procedures which explicitly recognize and manage ICOIs separate from individual financial conflicts of interest; and Development of alternative forms of disseminating important information in order to mitigate the need for institutional-industry interactions and promote a culture of independence from industry presence and influence.

An integrated approach is thus necessary to address ICOIs. Three strategic components can substantively address many of these issues:

Establishment of "centralized systems" at AMCs to manage conflicts of interest from an organizational standpoint; Mandatory adoption of comprehensive policy on industry interactions and conflicts of interest by AMCs; and Adoption of "academic detailing programs" by AMCs.
These concepts are explored below.

B. A Policy Proposal

1. "Centralized System" Model

In order to establish an effective internal administrative process to ensure proper detection and management of ICOIs and effectively implement ICOI policies, a fully independent body within the institution must be created with oversight and enforcement capacity. We propose an independent "Centralized System" through which a compliance office would monitor, manage, audit, and enforce ICOI policy set forth by AMCs and most importantly, act independently of any internal or external industry influence. This conflict of interest compliance office could fall under the purview of an AMC's central compliance office as a subdivision focusing exclusively on both individual and institutional forms of conflicts of interest or act as a completely separate

[137] *See supra* text accompanying notes 52, 53 (discussing how few AMCs are concerned with or recognize ICOIs).

academic division. The use of such a system would be similar to having an "independent watchdog" within the institution and also allow AMCs to centralize and streamline reporting, disclosure, data gathering, and compliance with respect to ICOIs in a single, responsible department.[138]

Several benefits would attend such a Centralized System. The compliance office would act as the single authority in reviewing, managing, approving, and conducting enforcement actions for conflict of interest situations, as well as housing information relating to such activities. This would provide efficiency in addressing ICOIs, as well as provide an institutional memory with regard to these conflicts, and how they were detected and addressed.

As a proactive matter, the compliance office could effectively coordinate with scientific research, technology transfer, as well as AMC departments, to ensure the proper screening and removal of adverse forms of conflicts of interest before they arise and research has started. Further, because of the developing nature of ICOIs, this office would have the ability to modify policies in order to meet changing demands of the regulatory environment. This role would ensure that the AMC was meeting future regulatory requirements regarding managing conflicts of interest. A Centralized System could also act as a single repository of financial interest data at an institutional level, allowing for comprehensive disclosure reporting and cross-checking for conflicts that might arise. The system could more effectively detect and manage ICOIs through its broad understanding and data gathering of all the conflicts that occur throughout the institution.

A Centralized System could also act as a central administrator of unrestricted funds donated by the industry, which would then be redistributed anonymously to different departments and physicians for funding of education and research upon separate approval by the AMCs' fiscal offices for an added layer of checks and balances. In a similar fashion, the compliance office could effectively partner with accredited evidence-based medicine medical education providers and provide an "approved" list of providers to staff, faculty, and students, while using industry funds that are not tied to its marketing presence at these educational venues. This will promote a culture of independent activities and education, particularly for those who will be future AMC leaders and researchers. Similarly, the system could also act as a central repository of pharmaceutical samples, which would be redistributed directly to patients and physicians outside the presence of

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[138] Compliance Officers at AMCs may report to a variety of top level management including Directors, Deans, Vice provosts, Vice chancellors, Chief Financial Officers, and other research-related offices or departments. *See* Geoffrey Grant et al., *Creating Effective Research Compliance Programs in Academic Institutions,* 74 ACAD. MED. 951, 958 (1999). This structure has the potential to influence decision making. Hence, there are arguments in favor of both a centralized approach and independent approach of establishing a compliance program. *See id.* at 957. However, ownership of the compliance program by senior-level management, appointment of a "high level" individual to oversee the program, appointment of a compliance officer, committee and liaisons, reporting responsibility to the board of an AMC, and independent authority of a compliance officer are essential in the success of any compliance structure that is implemented. *See id.* at 957-63.

industry representatives and on the basis of accepted neutral comparative assessments.[139]

In addition, again to promote a culture of appropriate ICOI management, the compliance office could be the central point for training associated with industry interactions and ICOIs that may arise for AMC employees, policies that address them, and strategies to mitigate their presence and impact. This process could be standardized and harmonized for the entire AMC.

Hence, the Centralized System and its compliance office would effectively act as a filter between the industry and AMC employees and institutional units and divisions for the purpose of maintaining scientific integrity. Through centralization of policymaking, disclosure, reporting, data gathering, and enforcement, this system would ensure that policies were upheld, violations met with proper sanctions, and ICOIs were dealt with effectively through the establishment of dedicated administrative processes to specifically deal with these complex institutional-industry relationships. The system could also proactively engage in culture change for present and future researchers and clinicians by promoting independent activities at the AMC that are free of industry influence.

a. Structure

The structure and organization of the compliance office is important to ensure that the responsibilities described in the ICOI policy are adequately upheld and performed by the AMC. The basic structure of the compliance office could be comprised of 3 core components as described below:

Compliance Department: This department would be the umbrella unit that acts as the administrative body to ensure that policies on industry interactions and conflicts of interest are maintained. This entity has power to monitor and enforce existing policies and guidelines, and is responsible for ensuring the day-to-day compliance of the AMC.

Compliance Officer: This individual is the officer who oversees the operations of the compliance department and provides ultimate certification and attestation that the AMC is adhering to the conflict of interest policy and any applicable federal and state laws and regulations. In conjunction with senior management of the board of the AMC, the Compliance Officer can enact new policies, procedures, and guidelines with respect to industry interactions and conflicts of interest. The Compliance Officer may also act as the liaison with government officials and institutions.

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[139] Several AMCs, such as the University of Pittsburgh, have already taken steps to ensure that pharmaceutical samples are not distributed directly to physicians, establishing methods to assess and approve use of samples, and implementing centralized systems for disbursement of samples to eliminate industry-physician interaction. *See, e.g.,* AMSA, AMSA PharmFree Scorecard 2009, University of Pittsburgh Medical Center (June 16, 2009), http://www.amsascorecard.org/institutions/37. Efforts to promote access via public-private partnerships for pharmaceutical samples at AMCs could also be modeled after patient assistance programs enacted by state legislation establishing "central fill" pharmacies such as West Virginia's Pharmaceutical Discount Program. *See* Nat'l Conf. of State Legislatures, State Pharm. Assistance Programs (June 30, 2009), *available at* http://www.ncsl.org/IssuesResearch/Health/StatePharmaceuticalAssistanceProgramsNCSL200/tabid/14334/Default.aspx.

Conflicts Committee: This specifically designated advisory committee acts as a subject matter expert and independent reviewer of conflicts of interest that cannot be adequately assessed using the current policy. The committee is made up of a diversity of medical professionals, ethicists, researchers, and administrators on a rotating appointment basis. In addition, the Conflicts Committee reviews and renders binding decisions on appeals of determinations of enforcement actions and sanctions taken by the Compliance Department.

Other organizational units may need to be created under the Centralized System to assist in administering the ICOI policy. These may include an advisory panel to review and approve medical literature and pharmaceutical samples provided by the industry using evidence-based medicine criteria, and a pharmaceutical sample distribution division to effectively manage, inventory, and distribute pharmaceutical samples to AMC divisions and subsections, and subsequently to patients. All individuals who participate in the Compliance Office should go through a comprehensive vetting and review process to ensure that they do not have conflicts of interest with the industry.

2. Development of Incentives for Participation

Central to the success in dealing with ICOIs at AMCs is the need to develop regulatory incentives to promote universal adoption of conflicts of interest policies. This could be accomplished through the development of federal regulations that would require periodic conflict of interest auditing reports by AMCs. Such a system could be coupled with conditions of participation associated with Medicare program inclusion, or as a condition to receiving any public research funds.[140]

This system of compliance could be overseen by a government agency, such as the DHHS OIG, which could implement random conflict of interest testing and auditing to ensure compliance with federal regulations for all institutions that receive government grants or funding of scientific research and reimbursement by federal programs for the provision of medical services.[141] This solution would address conflicts of interest that occur at both

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[140] A mandatory system of auditing for conflict of interest policies by the Centers for Medicare & Medicaid Services ("CMS") could be incorporated into federal regulations for conditions for coverage & conditions of participation for the administration of hospitals. *See* 42 C.F.R. § 482(B) (2009). In addition, the requirements of the National Institutes of Health, Office of Extramural Research, terms and conditions for grants award could be expanded to include the proposed conflict of interest auditing system as part of requirement for all participants to maintain a written and enforced policy on conflict of interest. *See* 42 C.F.R. § 50.604 (2009).

[141] These audits could also be accomplished by the implementation of third party accreditation or independent review boards that would also manage mandatory event reporting and disclosure by AMCs, such as the American Association for the Accreditation of Human Protection Programs ("AAHRPP"). AAHRP already provides accreditation for research institutions, and its mission in this area would provide important experience and applicability for ICOI assessment. *See* AAHRPP, About AAHRPP: Indications of Quality in Human Research Protection, http://www.aahrpp.org/www.aspx?PageID=284 (last visited June 29, 2009). Another potential auditor could be the AAMC, whose activities and work focuses on AMCs. These organizations would provide independent accreditation of institutions and also could provide guidance on how AMCs should implement such policies. Accreditation would require policies managing institutional forms of conflicts of interest and would be contingent upon successful implementation of such policies as prescribed by the

medical facilities and research institutions by subjecting them to consistent oversight while penalizing organizations that did not meet specific criteria in managing and enforcing conflict of interest policies. Auditing and periodic unannounced inspection of institutions to assess adherence to these conflict of interest criteria would force AMCs to develop systems and organizational structures to deal with conflicts of interest, as repercussions for failing to act would have serious ramifications for the institution.

Beyond periodic auditing, assessment could be conducted at the government's discretion or for cause, such as after a reportable event or alleged complaint that could lead to the rescission of their compliance status pending investigation and/or remedy of an alleged violation. Failure to adhere to the federal mandates, or a failed conflict of interest test/audit that was not remedied within a prescribed period of time, could result in possible entry into an agreement to remedy (such as a corporate integrity agreement), potential sanctions and penalties, including, for the most egregious offenses, exclusion from federal reimbursement programs as well as from NIH grants for institutional research or medical departments as well as for individual employees, staff or faculty.[142] A similar system of compliance with federal mandates and exclusion has been associated with other programs, and has been proposed as well in other federally regulated areas.[143]

Auditing and enforcement activity could also be publicized with results from AMC audits and AMC status on exclusion lists made available for public viewing, further allowing for full transparency and limiting an AMC's ability to conduct business with other healthcare organizations if it had derogatory information on its record. These institutions would still be allowed to pursue private contracts with the industry to conduct biomedical research, but would not be eligible for important forms of government funding. In addition, publication in journals would be severely restricted, and organizations such as the International Committee of Medical Journal Editors ("ICMJE")[144] could bar these institutions from publishing results of their studies in its

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government. State governments could also adopt conflict of interest regulations equal in scope or more restrictive than federal regulations in an attempt to address regional differences of industry interactions and influence.

[142] NIH or CMS exclusion would be severely detrimental to both research and medical institutions which would become ineligible for federal reimbursement and/or NIH grants and funding and significantly restrict their ability to operate. Changes to include conflict of interest violations as a basis for exclusion could be made by the OIG through an amendment of the Social Security Act, *see* 42 U.S.C. § 1320a-7 (2007), and such excluded entities/individuals could be added to the online exclusion list database, *see* OIG, List of Excluded Individuals/Entities Search, http://exclusions.oig.hhs.gov/ (last visited July 11, 2009). Exclusion from federal programs may also make institutions ineligible for NIH grants. *See* 45 C.F.R. § 76 (2009).

[143] For example, ICOI in the student loan programs, where universities were profiting off specific vendors to which they pushed their students to use resulted in state prosecutions and settlements as well as federal law that created a system of compliance with federally-based ICOI policies. *See* Liang, *supra* note 5, at 19. Using a similar approach, ensuring appropriate ICOI with respect to health insurance has been proposed through amendment of the Higher Education Act. *See id.* at 42-44.

[144] ICMJE represents the editors of some of the most prestigious academic journals in the world, *see* ICMJE, Journals that have Requested Inclusion on the List of Publications that follow the ICMJE's Uniform Requirements For Manuscripts Submitted to Biomedical Journals (2009), http://www.icmje.org/journals.html (last visited July 9, 2009), and hence would have tremendous sway if excluded AMCs would not be able to publish in these forums.

membership journals due to the potential of biased or compromised scientific data of excluded AMCs.

By implementing an independent and government-audited program with random conflict of interest auditing, inspection, and accreditation with the adequate teeth of enforcement, AMCs would be subject to an ICOI system that has substantive power to promote attention to the issue as well as compliance with acceptable ICOI policies. Most importantly, the problems regarding the adequacy of self-policing by AMCs and the industry would be resolved through proper oversight and enforcement. The public at large could then be assured that the quality and integrity of scientific research and patient care at AMCs are adequate and provided with independence from at least the most egregious forms of industry influence.

3. Mandatory Adoption of Comprehensive Policy

In response to the need for a uniform and comprehensive system to manage conflicts of interest, a comprehensive policy addressing industry interactions with AMCs should be created and adopted. The comprehensive policy should employ the Centralized System, identify common institution-industry interactions, and provide strategies to manage ICOIs, as well as create penalties for non-compliance. We provide a model policy for consideration below.

First, it is important to indicate clearly in the preamble the purpose of the policy and important definitions going forth within it.

POLICIES AND PROCEDURES FOR CONFLICTS OF INTEREST AND INTERACTIONS BETWEEN UNIVERSITY REPRESENTATITVES, INSTITUTIONAL UNITS, AND INDUSTRY REPRESENTATIVES

PURPOSE OF POLICY

The purpose of this policy ("Policy") is to establish binding procedures and guidelines for [AMC Name] ("University") representatives as well as University institutional units in addressing conflicts of interest and interactions with industry representatives. These policies are necessary in order to ensure that the University and its representatives make choices in line with the mission statement of the University to promote patient welfare and safety, integrity in education and research, and benefit to the community. Several forms of interaction between industry representatives and the University have become commonplace including marketing and promotion of industry products, support of medical education and research, and certain forms of remuneration. While some forms of interactions may be beneficial to the University, care must be taken to effectively identify, monitor, manage, disclose, and take enforcement action against interactions that create conflicts of interest and are not appropriate.

SCOPE OF POLICY

This policy governs all interactions between University staff, faculty, medical staff, students, researchers, consultants, sub-contractors, and trainees

as well as University departments, divisions and other institutional units and industry representatives. It includes all facilities owned or controlled by the University and may supplement or supersede existing policies that are less restrictive regarding industry interactions or conflicts of interest. The Compliance Department, which is made part of a University Centralized System described in this Policy, will be responsible for administering, managing and enforcing this Policy.

Important Definitions:

"Centralized System": Organizational Structure by which a dedicated, independent department of the University will administer, manage and enforce this Policy.

"Compliance Department": Department within the Centralized System which is implementing this Policy.

"Industry": Includes all pharmaceutical manufacturers, biotechnology companies, medical device companies, medical equipment supply companies, medical marketing companies, and their representatives or agents.

"University Institutional Unit" or "Institutional Unit": Includes all University departments, divisions, administrative units, and University Representatives who represent or make decisions on behalf of the University as an Institution.

"University Representative": Includes all University staff, faculty, medical staff, students, researchers, consultants, sub-contractors, and trainees.

University Representatives also represent the University and its principles of excellence during their personal time outside of their employment. Care must be taken to ensure that interactions outside of the scope of employment with the University do not influence decisions and actions taken on behalf of the University.

The Policy's preamble, scope, and definitions of terminology would specifically include the mention of interactions involving Institutional Units and University Representatives in effectively dealing with conflicts of interest with the pharmaceutical and other industries, reiterating the importance and making the policy inclusive of institutional forms of conflicts of interest. It also provides for an expanded, defined term identifying University Institutional Units that are subject to the policy, which includes University Representatives who make decisions on behalf of the institution, and provides guidance that University Representatives represent the institution through their employment, and must take care to ensure that interactions outside of their employment do not influence their decision-making regarding issues involving or affecting the institution.

The overall substance of the Policy structure, prescriptions, and proscriptions should then be defined. This is accomplished through the Statement of Policy.

STATEMENT OF POLICY

This Policy is designed to ensure that decisions made regarding clinical treatment, education, and scientific research are free from inappropriate industry influence and that conflicts of interest between University Representatives and University Institutional Units are managed and enforced as appropriate. The Policy is also essential in promoting relationships and behaviors with the Industry that are appropriate and ensuring that both the quality and cost of healthcare are optimized.

This Policy begins with the establishment of the Centralized System. This system will be the implementing unit for the institutional conflict of interest policy.

CENTRALIZED SYSTEM

I. Establishment of University Centralized System to Manage Industry Interactions and Conflicts of Interest

A. Establishment of a Centralized System

B. Structure of Centralized System

This Policy includes the following industry interactions and relationships:

INDUSTRY INTERACTIONS POLICY

Gifts and Entertainment
Pharmaceutical Samples
Medical Education Support and University Events Support and Funding
Scientific Research Support and Funding
University Purchasing Departments/Committees

This Policy also includes the following procedures for managing industry interactions and administering this Policy by the University:

UNIVERSITY POLICIES AND PROCEDURES FOR MANAGING AND ADMINISTERING POLICY

Disclosure Requirements for University Representatives and University Institutional Units

Separation of Management of Funds from Commercial Enterprise Divisions

Voluntary Remediation of Conflicts

Enforcement Actions for Violation of Policy

Training of University Representatives Regarding Policy

The Statement of Policy begins by identifying the Centralized System that will implement the ICOI Policy. The Policy specifically includes decisions made at an institutional level and also outlines types of institutional conflicts of interest, such as distribution of pharmaceutical samples, support and

funding of medical education and scientific research, industry sponsorship of AMC events and associations, separation of management of funds from commercial enterprise divisions, and disclosure, training, and establishment of a Centralized System to better detect and manage ICOIs. This statement foreshadows the comprehensive nature of the Policy in dealing with situations that impact the institution as a whole, including sanctions for non-compliance.

The Centralized System is first described to provide the infrastructural foundation on which the ICOI policy will rest.

CENTRALIZED SYSTEM

I. Establishment of University Centralized System to Manage Industry Interactions and Conflicts of Interest

Establishment of Centralized System: In order to effectively implement the Policy, the University requires an organizational structure to administer the Policy to prevent adverse Industry interactions and the conflicts of interest that arise from these interactions. The adoption of such a system is instrumental in addressing institutional forms of conflicts of interest. The organization of such a system will use the concept of a "Centralized System" by which the Compliance Department as the central piece of the Centralized System will administer, monitor, manage, audit and enforce the Policy and, most importantly, act independently of any internal or external influence. Through centralization of policymaking, disclosure, reporting and enforcement, this system would ensure that the Policy is upheld, violations met with proper sanctions, and that University Representatives, patients of the University and the public at large are shielded from unnecessary and potentially adverse forms of Industry interactions.

Structure of Centralized System: The Centralized System will be comprised of the following administrative units:

Compliance Department: This department acts as the administrative body to ensure that the Policy on industry interactions and conflicts of interest are maintained and implemented. This entity has power to monitor and enforce the existing Policy and is responsible for the day-to-day compliance of University Representatives and University Institutional Units.

Compliance Officer: This individual is the officer who oversees the operations of the Compliance Department and provides ultimate certification and attestation that the University is adhering to the Policy and applicable federal and state laws and regulations. In conjunction with senior management and the Board of the University, the Compliance Officer can enact new policies, procedures and guidelines with respect to Industry interactions and conflicts of interest. The Compliance Officer also acts as the liaison with government officials and institutions.

Conflicts Committee: This specifically designated advisory committee acts as a subject matter expert and independent reviewer of conflicts of interest that cannot be adequately assessed using the existing Policy. The committee is made up of a diversity of medical professionals, ethicists,

researchers, and administrators on a rotating appointment basis. In addition, the Conflicts Committee will review and render binding decisions on appeals of determinations of enforcement actions and sanctions taken by the Compliance Department.

Here, the key components of the Centralized System are described, including the core compliance department, compliance officer, and conflicts committee. Details regarding specific AMC-industry interactions must then be provided.

INDUSTRY INTERACTIONS POLICY

Gifts and Entertainment

No Acceptance or Use. University Representatives and University Institutional Units will not accept or use gifts or entertainment from the Industry regardless of form or value of the gift or entertainment. All gifts and entertainment, even of nominal value, have the potential to adversely influence decisions regarding clinical treatment, education, and scientific research and also add unnecessary costs to the healthcare system. These inducements also create an inappropriate culture of dependence that may serve to affect, or have the appearance of affecting, independent judgment of University Representatives.

Inclusiveness. This prohibition specifically includes all promotional items (e.g. pens, notepads, other items with Industry branding), meals either on or off-site that are funded by the Industry, and entertainment (e.g. tickets to sporting events, cultural events) provided to both University Representatives and University Institutional Units by the Industry.

The prohibitions in this section would include forms of marketing and promotion provided to Institutional Units to ensure a comprehensive ban on gifts, entertainment, and funds associated with these practices. Under this clear and focused policy, both physicians and other AMC faculty and staff will be insulated from all forms of this kind of promotion, regardless of value. This promotes a culture of independence from industry influence and actual or perceived impropriety.

Pharmaceutical samples are a common source of ICOIs. Managing their receipt, use, and distribution is critical, since they represent opportunities for industry influence through direct provider contact.

Pharmaceutical Samples

Policy Basis. The provision of free prescription drug or device samples has been associated with marketing and promotion by the Industry, designed to influence prescribing and clinical treatment behavior and drive sales. At the same time, pharmaceutical samples are essential in providing patients access to new forms of treatment and choice of treatment. However, the benefits of pharmaceutical samples must be weighed with respect to their safety, efficacy in comparison to existing treatments, and overall cost to the delivery of healthcare.

Pharmaceutical Sample Evaluation and Distribution System. In consideration of these challenges, the University will establish through the Centralized System within the Compliance Department a Pharmaceutical Sample Evaluation and Distribution System, using the following organizational structures to receive, manage, inventory, and distribute pharmaceutical samples appropriately:

Centralized Inventory and Distribution Department: This department will act to log in electronically (including lot number and expiration date) all approved pharmaceutical samples. This department will also distribute pharmaceutical samples to AMC departments on a recurring basis and as requested. Use of a centralized distribution method will eliminate the need for direct industry-physician interaction, including physicians in training.

Pharmaceutical Sample Advisory Panel: This advisory panel will review and approve inclusion and exclusion of pharmaceutical samples for use and distribution using evidence-based medicine criteria to determine if the pharmaceutical product offers a beneficial therapeutic option in comparison to existing treatments.

Assessment. The Pharmaceutical Sample Evaluation and Distribution System will be continuously assessed by the Centralized System to improve efficiencies in use, management and distribution of pharmaceutical samples and may explore using external service providers in meeting the requirements contained in this Section.

These Policy provisions specifically address the provision of pharmaceutical samples by the industry to alleviate the potential influence of this form of marketing while maintaining the ability for patients and physicians to access and make assessments about effective treatment options. This is accomplished at an institutional level by establishing a Pharmaceutical Evaluation and Distribution System with a centralized inventory and distribution department to manage and distribute pharmaceutical samples accordingly only after they have passed through independent review by an advisory panel based on evidence-based criteria.

The prevalence of industry support for medical education creates significant opportunities for conflicts of interest, and fosters a culture of accepted industry presence and influence at the very earliest stages of physician education. To promote culture change, the institution must be seen as operating and acting independently of industry presence and influence. Through the general prohibition of restricted grants to both individuals and Institutional Units for medical education, AMCs can be seen by internal and external stakeholders to make clinical and institutional decisions that are motivated by public benefit and scientific progress, instead of a “quid pro quo” for education in exchange for industry access to health care providers. Ensuring no “rewards” for industry or academic units for allowing such activities would provide another systemic means to limit industry influence on Institutional Units while promoting a culture of separation of learning,

clinical, and research activities from industrial presence and attempted influence.

III. Medical Education and University Events Support and Funding

Medical Education: Financial support of medical education can be beneficial for patients by providing physicians with the most current information about available clinical treatments. However, maintaining academic and scientific independence in medical education and clinical decision-making is of the utmost importance and industry involvement must be minimized. For this reason, Industry sponsors who wish to support any educational events conducted at the University must submit unrestricted grants through the Centralized System that will distribute such funds anonymously. The Industry will have no input into the content, organization, or preparation of the educational event but may request that funds be directed towards certain clinical departments. Such request will be considered and made at the sole discretion of the Compliance Department. University facilities may not be rented by or used for Industry-sponsored programs unless approved by the Compliance Department. No Industry Representatives shall be permitted to have representation, marketing, or other presence at any medical education activity or event.

B. University Events. Industry sponsorship of University Events may in some isolated cases, represent a form of remuneration to University Representatives and University Institutional Units and may pose an issue of conflict of interest. For this reason, all forms of industry sponsorship of University events, symposiums, meetings, and affiliated associations must be reviewed and approved by the Compliance Department in the event the amount of such sponsorship exceeds $1,000.

Industry support for medical education is addressed in this section by requiring the donation by industry of only "unrestricted" forms of grants. This section also explicitly states that the industry will not have any involvement or input in the content, organization or preparation of education events, effectively limiting the introduction of potentially biased information in the provision of medical education to institution employees. In addition, any marketing presence is prohibited to further distance inappropriate efforts to influence providers, or reward academic units for permitting such activities and access. In addition, the *de minimus* requirements for review of forms of industry sponsorship of events place further scrutiny on marketing and promotional expenditures directed towards Institutional Units and departments, or the institution as a whole, and further de-links the association of the institution with the interests of the industry.

Funding and research support is, of course, a key area, and is considered next.

Scientific Research Support and Funding

Funding of University Research: Industry involvement in clinical and biomedical research is important as the expertise of University Representatives is required for the advancement of clinical research and treatment and Industry support is necessary to supplement existing

government funding. However, Industry funding must be appropriate and must not in any way influence the conduct or results of research conducted. Funding of scientific research should be unrestricted and minimize Industry involvement in research activities. All Industry-sponsored research must be conducted using University-approved research contracts, and the University reserves the right to request changes or mandate termination of any research arrangement if terms are not in compliance with this Policy. The University Office of Research and Contracts will work in conjunction with the Compliance Department to ensure that Industry interactions and conflicts of interest are managed effectively and ethical mandates are strictly followed.

Review of Conflicts of Interest for University Representatives and University Institutional Units: Managing institutional conflicts of interest as they arise in scientific research is essential to ensure safety of participants and integrity of scientific data produced by such studies. For this reason, the Compliance Department will review all University Representatives and University Institutional Units for potential conflicts of interest and manage them as appropriate. Management of conflict of interest is described in the "University Policies and Procedures for Managing and Administering Policy" section of this Policy.

Review of Conflicts of Interest for Institutional Review Boards: Independent management of conflicts of interest in IRBs is equally essential in ensuring safety of participants and integrity of scientific data produced by scientific research. IRB members, as members of the University, play an essential role in institutional decision making, and thus will be screened for conflicts of interest by the University, and potential conflicts will be managed as appropriate by the Compliance Department. For this reason, the Compliance Department will review all University Representatives for potential conflicts of interest. IRBs should not be sponsored by the Industry and IRB members should not have any financial ties to Industry that is sponsoring scientific research at the University. Any research performed at the University shall be subject to IRB conflict of interest assessment under this Policy, and no commercial IRBs shall be permitted to review or approve any research performed at the University.

Publication Criteria: Industry sponsors of scientific research conducted by the University are prohibited from having any input or decision-making on the content, timing, or decision to publish results of research.

Prohibition of Direct Financial Benefit by University Representatives: Forms of direct financial benefit provided to University Representatives (e.g., recruitment incentives) by the Industry to influence the success of clinical research endanger subject safety and scientific integrity. For this reason, any form of direct financial benefit tied to performance in clinical research conducted by a University Representative is strictly prohibited.

Auditing of Research Contracts: The Compliance Department in conjunction with the University Office of Research and Office of Contracts

will conduct periodic audits of research contracts and work conducted at the University.

This section establishes strict controls, procedural policies, disclosures, and checks and balances to address ICOIs in the funding and support of scientific research by industry. A zero tolerance approach prohibiting all individuals, Institutional Units, and IRB members who have potential conflicts of interest from participation in associated research is adopted in order to ensure that decisions made by these stakeholders do not have negative repercussions that affect the institution as a whole. A process and strategy in the Policy is available to remove these conflicts for those individuals or Institutional Units who wish to continue participating in research and to focus on scientific endeavors. The terms of this section also state that funding of research by industry should be unrestricted, that research contracts must be in compliance with agreements in a form approved by the Institution (which may include industry input regarding prohibitions on publication, timing of publications, right of first refusal clauses, etc.), establish a system of internal auditing of research contracts, specifically a system of management and review of conflicts of interest in IRBs, and mandate review of financial conflicts of interest among University Representatives and University Institutional Units. These steps at mitigating ICOIs, which often result in either AMC officers or departments making decisions based on financial interests tied to the outcome of research, serve to separate sponsorship of research from clinical decision-making to ensure participant protection and safety.

Additional ICOIs arise in other capacities. Purchasing panels and committees can be influenced by industry inducements and must be addressed for institutional purposes.

University Purchasing Departments/Committees

A. Prohibition of Financial Relationships. University supply management and pharmaceutical purchasing panels and committees can significantly influence which pharmaceutical products are purchased and utilized on University formularies. For this reason, all University Representatives participating in such departments are prohibited from having financial relationships with Industry that represent conflicts of interest as indicated in this Policy.

Purchasing and requisition departments are covered in this section. For departments and committees who make purchasing decisions on behalf of an institution, a zero tolerance approach is also adopted here, prohibiting all individuals who have potential conflicts of interest from participating in these departments or committees. This strategy attempts to ensure that decisions made by these individuals do not affect the institution as a whole. This provision addresses the potential use of purchasing and requisition to circumvent institutional systems for acceptance and distribution of samples in or for a particular Institutional Unit or department.

Methods to collect, maintain, and use information on ICOIs must be practical. Annual reporting by academic units, as well as individual reporting systems, should be put into place to provide situational awareness as to the

scope of potential ICOIs, as well as provide rapid identification of issues by the Centralized System as they arise. Further, transparency mandates will also promote knowledge of the extent to which ICOIs exist and are managed for the benefit of the general public as well as interested policymakers.

UNIVERSITY POLICIES AND PROCEDURES FOR MANAGING AND ADMINISTERING POLICY

I. Disclosure Requirements for University Representatives and University Institutional Units

A. Institutional Level Disclosure: University Representatives and Institutional Units will disclose financial interests and revenue derived from commercial relationships with the Industry and how they are managed to the Compliance Department on no less than an annual basis. New or previously unreported conflicts of interest shall be immediately reported to the Compliance Department as they arise. University Representatives and Institutional Units will submit such disclosures on the Compliance Department's website. In addition, the University will voluntarily report material violations of the Policy to federal funding agencies and IRBs. The Compliance Department will also make this data accessible to the public through the Internet.

B. University Conflicts of Interest Reporting: University employees and the public may report any violations of this Policy via a conflicts of interest hotline maintained by the Compliance Department, to the Compliance Department's website, or directly to the Compliance Officer.

This section specifically addresses disclosure of ICOIs by University Representatives and Institutional Units and departments on no less than an annual basis, and new or previously unreported ones immediately as they arise. This places the responsibility on University Representatives, Institutional departments, and their administrators and staff to identify and disclose forms of ICOIs to an independent reviewing body allowing for management of ICOIs more effectively through the enforcement actions described in the Policy. In addition, the Policy mandates that the institution will make information regarding ICOI disclosures available to the public. This provides for a comprehensive policy of disclosure and promotes needed transparency of industry-institutional relationships for development of future public policies and accountability.

The important issue of managing ICOI and managing financial benefits to the institution must be addressed. Total separation of the two functions must be put into place.

II. Separation of Management of Funds from Commercial Enterprise Divisions

A. "Firewalling." In response to concerns regarding institutional forms of conflicts of interest and decisions made by University Representatives or University Institutional Units at the Institutional level, the University will implement mandatory "firewall" arrangements separating the management of Industry funds from the University's commercial and research enterprise departments (including its Technology Transfer Offices). Firewall design and

implementation will be conducted by the Compliance Department in the Centralized System.

The importance of separating management of funds in research and commercialization of discoveries cannot be understated. This section addresses the potential for ICOIs in the commercialization and funding of research by establishing mandatory "firewalling" arrangements between institution departments and affiliated entities and providing oversight of these arrangements by an independent oversight body. Effectively managing forms of ICOIs resulting from technology transfer and industry partnerships encouraged by government policy, such as the Bayh-Dole Act, necessitates these forms of internal separation.

A process that allows voluntary submission of academic unit or individual reporting of conflict of interest to the Centralized System for remediation would promote their discussion and resolution. An opportunity to participate in such a process will create important means of fulfilling the duty to manage these conflicts while also providing information for Institutional learning.

III. Voluntary Remediation of Conflicts

A. Means to Remedy Conflicts. When the Compliance Department identifies a conflict of interest that must be addressed, or when an individual self-reports a conflict of interest that implicates University Policy that must be addressed, University Representatives and University Institutional Units will have the following options to voluntarily remedy identified conflicts:

i. Divestiture of financial interest: University Representatives and University Representatives making decisions on an Institutional level may elect to voluntarily divest the financial interest that gives rise to a conflict of interest. Ownership of equity in technology transfer arrangements is not required to be mitigated. Conflicts of interest for such arrangements is mitigated through the firewall organizational structure described in this Policy or a written conflict management plan submitted and approved by the Compliance Department.

ii. Restriction on role of involvement/interaction: University Representatives and University Institutional Units may be restricted in their involvement, participation, or interaction with a situation, project, or related research activities that gives rise to a conflict of interest.

iii. Voluntary removal or resignation: In some cases University Representatives may elect to remove themselves or resign from a particular position with the University in order to resolve a conflict of interest situation.

iv. Other means: Because of the variety of conflicts that may arise in the University setting and with a wide array of persons, other means of managing the conflict will be considered.

B. Compliance Department Discretion. The Compliance Department reserves the right, at its sole discretion, to determine if voluntary remediation

efforts taken are sufficient in resolving the conflict of interest situation. If the Compliance Department deems that voluntary remediation efforts are not adequate, it may require additional actions or alternatives to those noted above. If such actions are not taken by the Institutional Units or reporting individual, the Institutional Units or reporting individual shall be deemed in non-compliance and subject to enforcement action.

This section covers voluntary remediation procedures that University Representatives who make institution-wide decisions can take in order to mitigate conflicts of interest, thus enabling them to continue participation in research-related activities. Possible remediation includes restriction of the Representative's involvement or interaction in the related research, divestiture of financial interest giving rise to the conflict of interest, or voluntary removal or resignation from the position that gives rise to the conflict of interest. Two of these options provide Institutional Representatives the freedom of choice in deciding whether to pursue academic and scientific interests in research free from potential industry influences. This clause also specifically exempts financial interests held by Institutional Units, and attempts to mitigate these forms of ICOIs through firewalling. However, the Policy also provides for other solutions to mitigate conflicts to address new forms of ICOIs. Ultimately, voluntary remediation efforts are to be reviewed and their adequacy determined at the Compliance Department's sole discretion. Critically, beyond standard conflict mitigation efforts, if it does not believe such efforts are in fact adequate, it may require more. Non-compliant Units and individuals are then expressly subject to enforcement actions for Policy violations, which we consider next.

IV. Enforcement Actions for Violations of Policy

A. Enforcement and Sanctions: The Compliance Department set specific guidelines for enforcement actions in the event of a violation of the Policy and will determine appropriate sanctions against University Representatives and University Institutional Units accordingly. The guidelines for enforcement actions and possible sanctions will be made available on the Compliance Department's website. Possible sanctions may include: termination, suspension, removal of privileges/access, and specific forms of restriction to mitigate forms of conflict of interest. Violations of the conflict of interest policy may also be considered unprofessional conduct, and hence subject this violation to reporting to the relevant professional society or group.

B. Appeals: University Representatives and University Institutional Units may appeal enforcement and sanction determinations made by the Compliance Office through a formalized appeal process through review by the independent Conflicts Committee. In submitting appeals, University Representatives and University Institutional Units should detail steps they have taken to mitigate such conflicts of interest and provide evidence of such mitigation efforts.

In order to maintain an effective policy and ensure compliance, clear and consistent enforcement of the Policy must be carried out in the event of a discovery of non-compliance or violation. In this section, the Policy sets forth

that enforcement actions and sanctions will be made accessible to University Representatives and University Institutional Units and will be carried out in a fair and consistent manner. It should be noted that enforcement may be taken against both University Representatives as well as individual University Institutional Units, allowing for effective enforcement against individuals as well as the Institutional Units. An appeals process using the advisory Conflicts Committee is also described to provide an avenue through which to seek potential remedy or reconsideration of an enforcement decision.

Education is a key area to ensure that members of the University community understand ICOIs and their roles to mitigate its presence.

V. Training of University Representatives and University Institutional Units Regarding Policy

A. Training and Education. The Compliance Department will develop a comprehensive training and education program for recognizing and effectively dealing with industry interactions and conflicts of interests at the University. University Representatives and University Institutional Units must complete the conflicts of interest training on no less than semi-annual basis. University employment of University Representatives shall be conditioned upon agreement to abide by the Policy, including training and education under this Policy.

This section establishes training programs for both University Representatives as well as entire University Institutional Units, similar to proposals from NIH requiring such efforts for individual conflicts of interest.[145] Further, these activities would be required on a recurrent basis and made a condition of employment, signaling their importance.

B. Adoption of "Academic" Detailing Programs

In order to effectively limit the necessity of industry interaction at both an individual and institutional level, AMCs will need to develop alternative sources of information-sharing and clinical education free from industry support and influence.[146] This is an important area where conflicts can easily arise and that directly implicate patient safety.[147]

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[145] On May 8, 2009, the NIH published proposed amendments to its regulations in relation to financial conflicts of interest and requested comments from interested parties. *See* DHHS, *supra* note 101, at 21610. These amendments include expanded requirements to ensure institutional compliance including requirements for submission or ability for NIH to audit records. *Id.* at 21612. Included in the request for comment is the question of whether extramural investigators should be required to complete routine financial conflict of interest training. *Id.*

[146] CME is a multi-billion dollar industry estimated at $2.38 billion dollars in 2006. *See* Robert Steinbrook, *Financial Support of Continuing Medical Education,* 299 JAMA 1060, 1060 (2008). This medical education is heavily subsidized and sponsored by the pharmaceutical industry and thus has become synonymous with pharmaceutical marketing and promotion, which allows AMCs and other institutions to pass off educational responsibilities (and cost) to industry. *See id.* The reliance upon and significant involvement of commercial support in medical education gives rise to several concerns regarding individual financial conflicts of interest and the integrity of the content of educational programs. Through its sponsorship, the pharmaceutical industry may be involved and have control over several facets of CME events, including assistance in organizing and advertising events, preparation of educational material (presentations and curriculum), subsidization of fees and expenses for attendance by medical professionals, providing attendees with gifts and incentives to participate, and coordination of speakers and payment of their honoraria. *See*

The Policy addresses issues of industry underwriting to minimize industry influence on materials and messages provided in academic, educational, and other activities. However, a need arises for impartial information to be provided. One strategy is the use of an educational method known as "academic detailing" in which a healthcare professional, using specialized training and interactive techniques, approaches a physician in a face-to-face encounter with evidence-based medical information to promote optimal clinical approaches.[148] This method endeavors to provide neutral, independent

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Arnold Relman, *Separating Continuing Medical Education From Pharmaceutical Marketing,* 285 JAMA 2009, 2009-10 (2001). Indeed, the risks of this approach to funding provider CME are apparent. The industry can create a customizable experience for physicians aimed at influencing their prescribing habits through the use of targeted marketing, potentially biased or misleading information, and the giving of gifts and entertainment all under the label of "education." *Id.* This has spurred the development of an industry to work in influencing continuing education. For-profit, Medical Education and Communication Companies ("MECCs") work directly with pharmaceutical manufacturers to provide organization of meetings, develop educational materials, provide public relations services, and organize and prepare marketing campaigns. *See* Steinbrook, *supra,* at 1060-61. These MECCs, which rely heavily on commercial support, may act as proxies for the industry in developing and arranging CME events that solely exist to promote specific pharmaceutical products. *See* Relman, *supra*, at 2009-10. However, as support for CME generally originates from the marketing budgets of pharmaceutical manufacturers, the industry's support and funding of medical education simply represents another form of pharmaceutical detailing. *See id.* at 2009. In fact, a recent report by the Senate Finance Committee has confirmed these concerns by concluding that some CME providers may still allow industry sponsors to exert improper influence on the content of educational activities despite the guise of independence. *See* U.S. Senate Comm. on Fin., Comm. Staff Report to the Chairman and Ranking Member, Use of Educational Grants by Pharmaceutical Manufacturers (2007), *available at* http://www.acme-assn.org/home/prb042507a.pdf. Recent Senate hearings on conflicts of interest in medical education have re-emphasized these concerns in light of growing industry funding, and have led to calls for increased transparency and better control mechanisms. *See* Press Release, U.S. Senate Special Committee on Aging, Kohl Hearing Considers Effects of Billions in Drug, Device Funding on Medical Education in America (July 29, 2009), *available at* http://aging.senate.gov/hearing_detail.cfm?id=316395&. Testimony included in this hearing discussed accreditation standards and oversight of CME, off-label promotion in CME, and federal enforcement of industry-sponsored CME practices. *See Commercial Sponsorship of Continuing Medical Education: Hearing Before Senate Special Comm. on Aging,* 111th Cong. (2009) (statement of Lewis Morris, Chief Counsel of the OIG DHHS), *available at* http://oig.hhs.gov/testimony/docs/2009/07292009_oig_testimony.pdf. Reform considerations included establishing appropriate safeguards to prevent undue industry influence in commercial sponsorship of CME including, separating grant making functions from sales and marketing, establishing criteria or creation of independent CME grant organizations for grants to CME providers, and eliminating control over speakers or content of CME, as well as shifting the cost of CME to physicians similar to other professions. *Id.* at 6-7. Analogous to these proposals is a recent special communication in the Journal of the American Medical Association, which called for professional medical associations to adopt policies that significantly minimize or eliminate industry involvement including working towards a complete ban on industry funding with the exception of journal advertising and exhibit hall fees, instituting interim policies in order to achieve a complete ban such as establishing central pools for CME funds, seeking alternative funding, and implementing prohibitions on certain industry marketing and sponsorship activities. *See* David J. Rothman et al., *Professional Medical Associations and Their Relationships With Industry: A Proposal for Controlling Conflict of Interest,* 301 JAMA 1367, 1367-72 (2009).

[147] *See, e.g., supra* text accompanying notes 9 and 82 (discussing off-label promotion and detailing).

[148] *See* Stephen Graham et al., *Effect of an Academic Detailing Intervention on the Utilization Rate of Cyclooxygenase-2 Inhibitors in the Elderly,* 42 Ann. Pharmacotherapy 749, 749 (2008).

information with no commercial interest, which physicians can use to evaluate specific drugs and technology to determine their optimal use.[149]

Multiple studies have attributed positive results associated with academic detailing, including changes in drug utilization resulting in clinical benefits to patients,[150] improvements in physician performance, and a high perception of educational value by physicians.[151] In Canada and Australia, public sector initiatives such as Canada's Canadian Optimal Medication Prescribing and Utilization Service, and the Australian National Prescribing Service, have the goals of promoting optimal prescribing behavior, educating both physicians and policymakers on the efficacy of drugs and drug classes, as well as promoting "critical thinking" regarding the accuracy of data that is provided by the pharmaceutical industry.[152] These academic detailing sessions can also double as CME, relieving some of the subsidization by the pharmaceutical industry of medical education by providing a non-biased alternative.[153]

U.S.-based programs advocating the use of academic detailing have also begun to materialize at government agencies and AMCs such as the University of Vermont,[154] the State of Pennsylvania in partnership with Harvard Medical School,[155] and the South Carolina Department of Health and Human Services in conjunction with the University of South Carolina College of Pharmacy.[156] All of these programs advocate academic detailing as a practice by which physicians can receive free, evidence-based, commercially-unbiased, and patient-centered information compiled and summarized by health professionals, to make both clinical and cost-effective decisions about drug therapy that would otherwise not be available to them.[157]

The merits of academic detailing have also recently come to the attention of the U.S. Senate, which held a special hearing considering the implementation of a federal academic detailing program to fund the creation of educational academic material and employ medical professionals to present such information to physicians at their place of practice.[158] This has led to the proposed Independent Drug Education and Outreach Act of 2009 bill (IDEA) (S.767 and H.R. 1859) pending in the House and Senate, which would establish academic detailing programs run by AMCs and other non-profit

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[149] *See* Wayne Kondro, *Academic Drug Detailing: An Evidence-Based Alternative,* 176 CAN. MED. ASSN. J. 429, 429 (2007).

[150] *See* Graham et al., *supra* note 148, at 749.

[151] *See* Michael Allen et al., *Family Physicians' Perception of Academic Detailing: A Quantitative and Qualitative Study,* 7(36) BMC MED. EDUC. 1, 2 (2007).

[152] *See* Kondro, *supra* note 149, at 429-30.

[153] *See id.*

[154] *See* The University of Vermont College of Medicine, Vermont Academic Detailing Program*,* http://www.med.uvm.edu/ahec/TB1+BL.asp?SiteAreaID=290 (last visited July 11, 2009).

[155] *See* Independent Drug Information Service (iDiS), About Academic Detailing: PACE Program of Pennsylvania Dept. of Aging, http://www.rxfacts.org/detailing.php (last visited July 11, 2009).

[156] *See* South Carolina College of Pharmacy, What is SCORxE?, http://www.sccp.sc.edu/SCORxE/index.aspx (last visited July 11, 2009).

[157] *See* Fred Gebhart, *Academic Detailing Gathers Momentum,* 152(6) DRUG TOPICS 1, 1 (2008).

[158] Press Release, U.S. Senate Special Committee on Aging, Kohl Hearing Seeks Alternative to Drug Industry's Controversial Practice of Educating Doctors About New Drugs (Mar. 12, 2008), *available at* http://aging.senate.gov/record.cfm?id=294740.

organizations, and has also resulted in States such as Maine, Massachusetts, New York, as well as Washington, D.C. implementing academic detailing programs.[159]

This alternative form of medical education and information dissemination about clinical efficacy data has the potential to lessen the need for industry interaction with AMCs and their employees. Further, it offers an attractive, low-cost alternative to the current subsidization by the clinical education industry, and allows physicians and patients to make decisions based on unbiased, scientifically-sound data. AMCs can take a pivotal step in utilizing this alternative form of education while at the same time limiting the occurrence of conflicts of interest situations by only allowing academic detailing to occur at their sites and denying site access to all traditional industry detailing. By adopting "academic only" forms of detailing, in combination with a comprehensive ICOI system and Policy, AMCs can manage industry influence over health care providers, reduce costs associated with more expensive treatments, eliminate dependency of industry involvement in medical education, promote safe and effective research and treatment, and further manage ICOIs in a productive manner.

VII. CONCLUSION

With ever-increasing costs associated with the research and development for drugs and biologics[160] and a decreasing number of new drugs in drug discovery pipelines,[161] pharmaceutical companies will continue to rely upon forms of influence through individual and institutional financial incentives to promote and market their products. These efforts appear to be effective, reflected by rising prescription drug expenditures and pharmaceutical industry profits. The importance of regulating the ICOIs that arise from these questionable practices and the financial relationships that currently exist between academia and the industry is essential to protect patient safety and public health, as well as maintaining the public's trust in physicians and institutions and slowing the rising cost of healthcare.

Yet although highly publicized case studies, such as Jessie Gelsinger's tragic death and other reports detailing the close financial ties between

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[159] *See* The Prescription Project, Academic Detailing: Evidence –Based Prescribing Information 3 (2009), http://www.prescriptionproject.org/tools/fact_sheets/files/0007.pdf. States such as Maine and Vermont assess fees on manufacturers to fund academic detailing programs. *See* Prescription Policy Choices, Prescriber Education Programs (2009), http://www.policychoices.org/documents/StatePrescriberEducationPrograms0909.pdf. D.C.'s SafeRx Act which requires licensure and fees for pharmaceutical detailing includes provisions for establishing and funding academic detailing programs. *See* SafeRx Amendment Act, D.C. Law 17-131, 55 D.C. Reg. 1659 (2008). Note that the Massachusetts Academic Detailing Program had a $250,000 reduction in the FY2009 budget. *See* Mass.gov, Fy2009 Budget Summary, 45100716 Academic Detailing Program, June 22, 2009, *available at* http://www.mass.gov/bb/gaa/fy2009/app_09/act_09/h45100716.htm.

[160] *See* PhRMA, Profile 2008 Pharmaceutical Industry 2 (2008), *available at* http://www.phrma.org/files/2008%20Profile.pdf.

[161] *See* Andrew Pollack, *Despite Billions for Discoveries, Pipeline of Drugs Is Far From Full,* N.Y. Times, Apr. 19, 2002, at C1; *see also* Bryan A. Liang, *Regulating Follow-On Biologics*, 44 Harv. J. Legis. 363, 384-92 (2007) (arguing that the extensive regulatory approval system exacerbates the problem of decreasing new drug discovery).

physicians, government representatives, and institutions and the private sector, have recently brought awareness to this important issue, they have yet to lead to meaningful reform. Indeed, the operations of AMCs and their current cultures have resulted in lackluster attention or even total ignorance of ICOI issues.

The complex nature and entrenched position of ICOIs in AMCs pose serious challenges in crafting policy proposals to limit their influences and harm. While state and federal government agencies, professional associations, and the pharmaceutical industry have all made limited forays in addressing this issue, historical perspectives and analyses of their attempts indicate their effectiveness is doubtful.

Hence, a comprehensive policy must be put into place that provides for both proactive and reactive means to identify, manage, and address ICOIs. An internal system with enforcement means backed by government authority and audit can accomplish the goals that previous, more limited proposals have not been able to reach.

The consequences of failing to deal with the systemic problems of commercial subsidization and dependence of academia on industry are apparent: deeper questioning of scientific integrity, higher healthcare costs, mistrust of healthcare providers, and transformation of academia into corporate agents focused on financial benefits, not the acquisition, exploration, and application of knowledge for the benefit of humankind. But the key consequences are the resultant, real, human harms. We should never forget the sacrifice of Jesse Gelsinger when considering institutional conflicts of interest. For ultimately, if ICOIs are not managed for the benefit of the public, we and our loved ones may be the next victims of an institutional culture that values profits over patients.