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MANAGING CONFLICTS OF INTEREST IN HEALTH CARE INNOVATION

Georgiana Avramidis*

I. Introduction: Information Exchange Through Industry-Provider Interactions

Close and ongoing collaboration between health care professionals and the pharmaceutical drug, device, and biotechnology industries is a fundamental and necessary aspect of medical innovation. Companies interact with health care providers in a variety of ways: through product training sessions or conferences, sales and promotional meetings, consulting or investment arrangements, research and trial arrangements, economic remuneration, grants, or charitable donations.¹ Industry-provider interactions aim to promote public health through sharing and exchanging information between health care professionals, who have clinical experience and expertise and the health care industry, which has the resources to expend on innovative and critical treatments and technologies. These collaborations between industry and health care professionals save and improve the lives of millions of patients through medical breakthroughs and daily patient treatment.



The vital role of information exchange in advancing medical technology cannot be downplayed.² The clinical experience and expertise of health care professionals provides invaluable insight into industry research and development and initiates progress and innovation. In a recent example of the essential

open flow of communication between clinicians and manufacturers, physicians relayed information to medical device companies about implanting metal plates into children's skulls.³ The feedback from physicians prompted manufacturers to fashion smaller sized plates customized for children, thereby improving the quality of health care for a specific population.

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Opponents of ongoing collaborations between industry and health care professionals express the belief that each health care player holds a conflicting and initially irreconcilable stake against the other's interests. Therefore, the mere appearance of such conflict draws suspicion of untoward behaviors and raises legitimate questions concerning the potential for prescriber bias. A close relationship between industry and health care professionals, however, does not necessarily indicate inappropriate relations or a relationship that will have a less beneficial effect on progress in health care. In fact, studies show that "fears that disclosed conflicts of interest are leading to tainted, unreliable recommendations are unfounded."⁴ This does not necessarily mean that improper behavior does not arise out of interactions in which there are conflicts of interest.⁵ The cases of *Moore v. Regents of California*⁶ and *Gelsinger v. Trustees of Univ. of Pennsylvania*⁷ drew a significant amount of public attention for the harm associated with research experiments in which physicians held a financial interest. In *Moore*, treating physicians influenced a patient's decision to undergo unnecessary tests, leading to an outcome that advanced their own gains rather than those of the patient.⁸ The California Supreme Court held that by failing to disclose their personal interests in the treatment the physicians did not satisfy the duty to give informed consent, thereby denying the patient the opportunity to properly balance the risks and the benefits of continued treatment.⁹

Also in the realm of clinical research, the *Gelsinger* case associated the death of a teenage participant in a University of Pennsylvania research study with the principal investigator's conflicting financial interest in the outcome of the study, which prompted attempts to regulate or otherwise monitor physicians with an interest in research.¹⁰ *Gelsinger* also presents a case where the industry-provider relationship was automatically viewed as unseemly because something went wrong.¹¹

The information exchange works both ways. Health care professionals often rely on industry input and training to properly and effectively dispense pharmaceutical drugs and devices. While promoting the free exchange of information between health care players, this approach tends to be controversial when it involves seemingly extravagant gifts or payments for meals, travel, and consulting. Physicians con-

tend, however, that “the best approach to optimize cost effectiveness of product prescribing is to promote more, not less, interaction among all stakeholders involved in healthcare delivery.”¹² Indeed, provided that the industry presents information to a physician without stipulation, the physician may decide freely which course of treatment to recommend.

The main purpose of industry-provider interactions is to promote an exchange of ideas and data regarding a product, an innovative idea, or a medical advancement.¹³ In a conflict of interest analysis, where the conflict of interest is reviewed for its anticipated impact, the promotion of medical technology and innovation is generally the primary interest. For the information exchange to be worth the valuable time of health care professionals, however, ties with the industry often involve monetary or non-monetary incentives. For instance, secondary interests in the interaction may be the fee provided in exchange for a physician’s consulting work. A secondary interest might also be a provider’s interest in a company or the gain in reputation from association with a groundbreaking treatment or technology. Both primary and secondary interests are desirable. Although one may have “a claim to priority” that undermines the integrity of the first interest, in order to make the interaction beneficial for all parties involved the challenge is to ensure that both interests are realized.¹⁴ Collaboration between these entities often gives rise to inherent conflicts of interest because incentives in industry-provider interactions are simultaneous and potentially incompatible.

II. Current Efforts in Managing Conflicts of Interest

In March and April of 2008, Congress responded to the growing mindfulness, if not wariness, of industry interaction with health care providers and its effects on the provision of health care by introducing legislation to regulate industry-provider interactions.¹⁵ Known as the Physician Payments Sunshine Act, the legislation aims to “shed light” on collaborations in health care by mandating quarterly disclosure of interactions resulting in monetary amounts over a certain threshold.¹⁶ By disclosing the existence of industry-provider interactions, the legislation empowers health care consumers with information about the development, the procurement, and the distribution of drugs and devices.

Disclosure legislation, such as the Physician Payments Sunshine Act and other state regulation, supplement efforts by industry trade associations to

create institutional codes of ethics. Media coverage characterizes these efforts as aimed towards “reining in doctors,” but the codes recognize the shared responsibility of the health care industry and providers in preserving public trust.¹⁷ These approaches are voluntary and set the standard within each industry for the management of interactions with health care providers while promoting the best interests of the health care consumer. For instance, the Pharmaceutical Research and Manufacturers of America’s (PhRMA) Code on Interactions with Health care Professionals provides guidance for interactions ranging from consulting arrangements to educational funding from pharmaceutical companies.¹⁸ The Advanced Medical Technology Association’s (AdvaMed) Code of Ethics on Interactions with Health Care Professionals provides guidance on the promotion of ethical industry-provider interactions in the device space.¹⁹

Legislative efforts, however, use disclosure as a means of regulating industry-provider interactions. While this is a reasonable and effective method of preventing abuse and negating the questionable impression that industry-provider ties often raise, it is important to recognize that conflicts of interest necessarily arise in all types of interactions where two or more intersecting interests exist. Moreover, in some cases, the outcome of an interaction that gives rise to an irresolvable conflict of interest is so desirable that it should nevertheless proceed. Where circumstances show that an interaction provides information so compelling and necessary, there is a rebuttable presumption that the interaction should continue despite a conflict of interest. This approach holds that industry influence negatively affects a physician’s decision-making process and makes the assumption that by virtue of this potentiality, the dual interests cannot co-exist unless they pass the high “compelling circumstances” bar.²⁰ This approach is problematic because interactions that are useful in providing meaningful outcomes, but not necessarily “compelling” ones, are unable to proceed. Indeed, conflicts of interest are so ubiquitous that the benefits that arise from industry-provider interactions stall under the high bar set by the rebuttable presumption approach.

The interests of science and research are better served when existing conflicts are managed, instead of disallowed, because it is often the case that two intersecting interests can co-exist in a manner that allows both to be fulfilled. Under the management perspective, an advisory board may require an individual to recuse him or herself from involvement in a particular project, place any equity interest in a trust for the duration of the project, or encourage disclosure of conflicts

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of interest to manage the conflict. The last requirement, disclosure, simultaneously satisfies the health care professionals' desire to continue with a project, the regulating body's interest in limiting untoward behavior, and the health care consumer's need for information with which he or she can make knowledgeable decisions about treatment options. Disclosure that includes details providing context for each interest is necessary to determine whether the conflict of interest is manageable in a way that renders its outcome desirable despite any initial reservations.²¹ This vital data aids health care consumers in understanding conflicts of interest in a way that does not preemptively find them unmanageable.

III. Value and Effects of Disclosures

Industry only gains when its products and technologies are implemented correctly and prescribed free of unseemly behavior. Technical procedures require that industry interact within health care professionals in operating rooms, private practices, and learning and training seminars without raising the specter of untoward influence.²³ Similarly, the financial support that health care professionals, and the health care system as a whole, acquire through industry is necessary to the promotion of research and development. This circular relationship establishes a conflict of interest.

A typical conflict of interest analysis calls for an inquiry into whether secondary interests can exist without jeopardizing the initial objectives of the industry-provider interaction. If the primary interest in an interaction between a pharmaceutical drug, device, or biotechnology company and a health care professional is collaboration towards an innovative medical product that promotes a better and more efficient health care system, then any secondary interests that directly interfere with that goal create a conflict of interest. A secondary interest may interfere either by compromising the original goal with tangible negative results (such as the *Gelsinger* case), or by affecting the mere appearance of impropriety. Generally, part of managing a conflict of interest includes acknowledging its existence through disclosures made to the public.²⁴ Industry benefits from full disclosure of its interactions with health care providers. Through disclosure, industry has an opportunity to cast its pursuits as driven not only by profit, but by the pioneering of new and important technologies in medicine for the betterment of health care. Moreover, industry has the opportunity to explain the important and justifiable reasons for its presence in a health care professional's practice. Disclosures detailing the circumstances of the industry-provider interactions help inform interested parties about the goals pursued by industry and the necessity for input from clinicians.

One of the benefits of disclosure legislation, which figuratively "shines light" on industry interactions, is the opportunity for industry to embrace disclosure as a means by which to shed the public perception of industry as a "dark force" and instead emerge as a vital means toward medical innovation and development. Industry's "bottom line" can, and does, co-exist with the promotion of public health.²⁵ Similarly, those goals can co-exist with the health care provider's interest in fees, investment, or other monetary or non-monetary gains.

As the largest health care insurer in the nation and a major purchaser of pharmaceutical drugs, devices, and biotechnology, the U.S. government has a financial interest in overseeing any conflict of interest that arises between the health care industry and health care professionals to ensure that health care choices are made in the patients' best interest.²² The government's attention to conflicts of interest in medicine is therefore aimed at controlling industry influence on prescribers' decision-making.

Interactions that promote innovation and information sharing, however, are in the best interest of the public. Any efforts to manage conflicts of interest through disclosure better serve health care consumers when tempered to encourage technological advancement. A thoughtful analysis of the value of managing conflicts of interest through disclosure includes an inquiry into the trade-offs of providing "light" on industry interactions. This article will suggest that disclosed information which is not properly managed through government or institutional regulation may hinder technological progress and information exchange between industry and health care providers. To ensure that the benefits of disclosure regulation outweigh its burdens, it is important to assess the information disclosed for its meaningfulness and for any unintended effects on the health care system. Finally, this article will suggest that disclosure of a conflict of interest is successful because it advances the fundamental value in health care of autonomy.

Through disclosure, industry has an opportunity to cast its pursuits as driven not only by profit, but by the pioneering of new and important technologies in medicine for the betterment of health care.

Information exchanged through industry-provider interactions is so vital and so meaningful to advances in health care that discouraging collaboration based on the existence of a conflict of interest would ultimately cause more harm than good to the greater health care system.²⁶ Recently proposed guidance from the Food and Drug Administration (FDA) provided clarity on its prohibition of “unlawful promotion” of a product in the dissemination of off-label information in the form of medical or scientific reference publications and medical journal articles.²⁷ In its draft guidance, the FDA recognized the “public health value to health care professionals of receiving truthful and non-misleading scientific and medical information” and that such uses may in cases “constitute a medically recognized standard of care.”²⁸ The Journal of the American Medical Association (JAMA) also recognizes the importance of impartiality and requires a neutral party to review industry-funded studies prior to publication. These efforts reflect recognition of the benefits arising from a health care professional in possession of clinical data that can improve a pharmaceutical drug or device, as well as assist a drug or device company by informing the company on how to best implement or use a product. In other words, the value placed on the exchange of information is often worth the risks that may arise from a conflict of interest. Disclosure of industry ties does not automatically negate the relationship. In more extreme instances, however, the specter of the disclosure itself is so detrimental that it threatens to negate those ties and the information attached to them.

IV. Unrestrained Disclosure May Harm, Rather than Promote, the Primary Interest of Improving Health Care by Obstructing the Information Shared

Although public disclosure of a conflict of interest in an industry-provider interaction is possible (or may be made possible through efforts of the parties involved), it is not necessarily information that *should* or *must be* shared if there are significant negative implications to its disclosure. Much of the regulation aimed at diminishing conflicts of interest actually regulates information exchange by setting standards for the types and the timing of disclosures. The level of required disclosure implicates the priorities that are placed on the information. To make informed value judgments an inquiry into the value of disclosures must incorporate questions around health care consumers’ need to know certain information, how the information is made known, whether the need to know outweighs the potential for unintended consequence of harming progress, and ultimately, harming the health care consumer.

A. Disclosures that Unintentionally Tarnish the Medical Profession

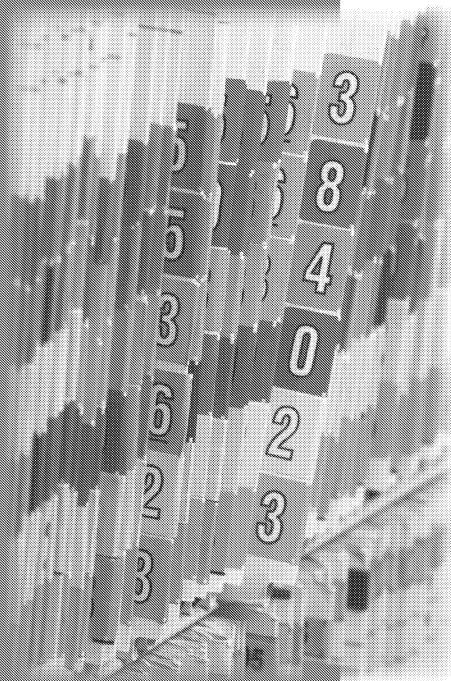
A primary consequence for a company accused of maintaining untoward ties with physicians is diminished reputation in the public eye.²⁹ “Critics aver, and politicians echo that the most grievous casualty of conflict of interest—indeed of even the appearance of it—is the public “Trust.”³⁰ Public trust in industry is not easily regained, although industry’s indiscretions are more forgivable than those of a health care practitioner who has a longer way to fall based on a long-standing public perception as a trustworthy and upstanding professional.³¹

Although it has been suggested that pressure related to a managed care system has the effect of “un-aligning” the interests of the health care provider and consumer, physicians abide by the Hippocratic Oath, which bestows the responsibility to do no harm and act in the best interest of the patient.³² This is not to suggest that industry-provider interactions go unchecked based on the assumed honesty of physicians, but rather highlights the sense of trust that embodies the profession.³³ As an illustration, physicians are held to a high legal standard of care that incorporates a sense of dependency on and regard for their knowledge and experience. Under the learned intermediary doctrine, for instance, physicians are charged with acting as the liaison between manufacturers and patients regarding the distribution and use of pharmaceutical products.³⁴ A recent case in Texas acknowledged that “[i]f the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided.”³⁵ As a result of this public trust in the profession, attempts to regulate conflicts of interest in health care arose significantly later than efforts in other fields.³⁶

As medicine becomes entangled in its function as a business, many questions that conflicts of interest raise relate directly to the seemingly contradictory role of the physician as a businessperson as well as a caretaker.³⁷ Indeed, it may be logical to suggest that collaboration in industry is another way that “doctors escaped becoming victims of capitalism and became small capitalists instead.”³⁸ The role of a physician somehow entangled in capitalistic pursuits tends not to sit well with the public. As a result, alarm bells go off when we observe a physician motivated by the bottom-line or an otherwise unseemly objective such as reputation of investment.

Disclosure allows affected parties to view industry-provider interactions with “additional skepticism.”³⁹ The first message that disclosure sends is that the health care provider holds an interest that conflicts with another goal in an industry-provider interaction. Insofar as the interests are managed or negated under the rebuttable presumption view, disclosure reveals that the physician has nothing to hide and as a result garners public trust through mere openness.⁴⁰ The second message that disclosure conveys, especially if it lacks specificity, is that industry ties may influence a physician’s decision-making in a way that makes the care received untrustworthy.⁴¹ Because disclosures incite suspicion of untoward behavior, they often lead to severe prophylactic measures to ensure that health care professionals behave in acceptable ways.⁴² These extreme measures may unintentionally quell the exchange of information and the innovation that stems from this exchange.

The Massachusetts legislature recently passed a bill that seeks to ban industry gifts to doctors under the reasoning that the mere appearance of impropriety is enough to warrant a severe restriction of an industry-provider interaction.⁴³ The curtailing of industry-provider interactions fails to take into account the curbing of information sharing and exchange. As a result of the distrust attached to their interactions with industry, health care providers willingly reject fees and remuneration for their time spent consulting with pharmaceutical drug or device companies in order to avoid suspicion that may threaten their reputation.⁴⁴ For example, a recent *New York Times* article presented the stories of physicians who, after “intense scrutiny” for accepting compensation for consulting or speaking with pharmaceutical drug or device companies, now decline to accept any remuneration from



industry. One physician continued to provide services free of charge to a company based on his belief that the work performed for the company was vital to progress in medicine.⁴⁵ Another felt less incentive to participate in these important interactions without compensation for his time and efforts.⁴⁶

B. Disclosures That Devalue the Information Exchanged

Insofar as a moral imperative to provide the best possible health care exists, it includes the duty to use the best possible information available. When a drug or device company possesses or learns of data with respect to its product, it bears a responsibility to share that information with health care consumers through physician intermediaries.⁴⁷ Likewise

from the provider's perspective, possessing clinical data creates a duty to share that information with manufacturers who are in the best position to use it in a way that benefits patients. Thus, the fact that physicians must balance losing fees or losing trust is not the sole issue in sanctioning industry-provider interactions. The health care system also risks losing opportunities to share valuable information that promotes safe and effective innovation in medicine and leads to more informed prescribing and other decision-making.

Mistrust regarding the veracity and value of information born out of interactions where a conflict of interest exists is not exclusive to medicine, even though it has a particularly detrimental effect in the field. Even the specter of a conflict of interest raises questions about the integrity of the information provided. Moreover, information disclosed as part of an institutional policy or under government regulation actually reveals relatively little: it reveals only that the information may be suspect.⁴⁸ For these reasons, all disclosures regarding conflicting interests should be accompanied by a detailed summary of the circumstances of the interaction.⁴⁹

Details in disclosure that qualify the physician's expertise and time spent are necessary to ensure that the data describes the interests of each party in a meaningful manner.⁵⁰ In this way, the circumstances under which gifts are received, consulting or speaking fees are paid, and other types of transfers are provided in context and tell a more complete story about the interests.⁵¹ The time frame during which the holder of the interest invested in the company, the circumstances and reasons surrounding this investment, and even a

pro-rated amount of the holding are all necessary to provide a more meaningful set of data with which one can make a more informed decision about the integrity of the information. As another example, payments made to health care providers for involvement in clinical research are often based on the intricacy or duration of the trial, providing a helpful context for payments that may otherwise seem exceedingly large or inappropriate. Further, the remuneration compensates for a physician's time spent away from his or her own practice, another detail that puts payment schemes into perspective. The key, therefore, is to ensure that the information provided is meaningful in the sense that it reveals the interest accurately. Providing context makes for a *truly full* disclosure and provides a complete set of data with which an affected party can more effectively analyze and manage the competing interests.

Despite proper disclosure, the Brennan study suggests an unconscious "impulse to reciprocate" for the donation of items and services renders interactions between industry and health care professionals by definition unmanageable.⁵² Its basis in "soft sciences," however, has made the Brennan study vulnerable to skepticism, especially amongst physicians. The theory can even be viewed as insulting: few physicians are willing to risk their professional reputation, let alone the health of a patient, on the influence of a logo pad or pen.⁵³ More importantly, physicians generally rely on their training and experience in their prescribing and decision-making and are thus unlikely to be persuaded otherwise in the absence of true scientific data. Unlike conflicts of interest in other fields, a conflict of interest that arises in health care is not merely an inquiry into whether "reasonable onlookers would find it plausible that the *average person* could be swayed by a temptation."⁵⁴ Physicians are held to a higher standard both legally and ethically;⁵⁵ demoting their clinical judgment to that of the reasonable person seems in and of itself unreasonable.⁵⁶

Information for the purposes of managing untoward interactions and disclosing conflicts of interests also has the unintended effect of revealing industry-provider interactions that lose their value when disclosed before a specific period of time. Device manufacturers in particular tend to be smaller start-up companies with little capital, but conduct research and development for intricate and sometimes unknown techniques or equipment. This type of innovation requires expert knowledge and clinical experience that at times only few possess: either the company's investors or specialists in a field. In addition, consulting or researching arrangements are sometimes made with physicians where the physician is so well known in

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his or her community that disclosure of the interaction will “tip off” competitors as to developing goals of a company. Under the rebuttable presumption approach, this situation makes the case for proceeding with an industry-provider interaction despite a conflict of interest. More importantly, it suggests that certain disclosures may cause more harm than good when they automatically de-value the purposes of an interaction by negating a competitive edge.

V. Autonomy: The Overarching Interest

Arguably, “[i]nappropriate industry influence may be dangerous because it threatens to compromise physicians’ judgment and prescribing patterns based on gifts or monetary incentives *about which patients are completely unaware*,”⁵⁷ highlighting the value of individual choice in the health care system.⁵⁸ When individuals are able to consider personally the implications that an interaction may have on treatment received or other health care choices, the principle of autonomy is maintained. Autonomy requires acquiring permission to perform medical procedures, providing ways to accommodate patient participation in treatment choices, and otherwise diminishing the chances that their person is abused.⁵⁹ These examples encompass a right that seems fundamental: the “right to know” as much information as is available. The value placed on the patients’ “right to know” in the context of conflicts of interest mirrors its significance in health care issues that are similarly value-based, namely, informed consent and confidentiality of health care information.

That the U.S. health care system is a communal system with a strong emphasis on individual rights justifies a recent court decision finding that the free flow of ideas is fundamental to research and science.⁶⁰ The holding that the patients had given up ownership rights to tissue used in university research studies by granting consent demonstrates how respect for autonomy sufficiently mitigates the taking of individual information in pursuit of greater knowledge.⁶¹ Indeed, the premium placed on providing informed consent is so high that any trade-offs associated with it, such as the physician’s time spent supplying the requisite information, are generally viewed as “de minimus or not worth analyzing.”⁶² Providing for autonomous choice in health care decision-making protects research and choices in care that would otherwise be viewed as unusable or compromised. Likewise, without the disclosure of conflicts of interest, a patient’s choice of treatment would not be truly informed and industry-provider interactions would not move forward in pursuit of improved health care.⁶³ Disclosure of pertinent information enables health care

consumers to make more informed choices.⁶⁴ Thus, disclosure adequately manages conflicts of interest because it provides for patient autonomy in health care decision-making.

There are few cases of documented harm as a result of conflicts of interest arising out of industry-provider interactions. Instances where an individual is physically or financially harmed when confidentiality of health care records is breached are similarly negligible.⁶⁵ Even the recent breaches in confidentiality of “celebrity” health records at the University of Los Angeles, California Medical Center, where it would be foreseeable that a person in the public eye could indeed be injured by the leaking of health care information, left only the snooping employees harmed through loss of employment or other retribution. The outcome indicates that the breach itself was the offense, not the loss of privacy or release of information.⁶⁶ Nonetheless, we continue to “mark” health care records as confidential and to have strong negative reactions when that interest is breached.⁶⁷

Likewise, protection against even the idea of unseemly behavior in industry-provider interactions is valuable in making informed choices, whether or not tangible “harm” is likely to occur. At the forefront of decisions regarding the uses and the disclosures of health care information is the sanctity of the individual’s ability to make his or her own decisions about those uses and disclosures. The balance is therefore based on needs: the patient’s need not to have his or her information disclosed takes priority over the need of an entity (other than a covered entity authorized under Health Insurance Portability and Accountability Act (HIPAA)) to use and disclose the information.⁶⁸ By protecting information about an individual’s state of health, diagnosis, and treatment, it seems that what we are actually protecting is the long-regarded principle of autonomy.⁶⁹

Health care records are confidential because they contain information that we have determined is the type of information that we must cover and conceal to the greatest extent possible. Similarly, we must balance whether the needs of industry or health care professionals to keep information undisclosed to prevent the unintended consequences described above trump the needs of health care consumers to know the information in those situations.⁷⁰ The trade-offs that occur when empowering health care consumers with information must be considered to the extent that they may harm the patient. Disclosures that lead to unintended consequences, such as physician recusal from interactions or other compromises that hinder innovation, should be better managed because the patient is at the receiving end of the information. In the end, the information that is disclosed contributes to the

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patient's ability to make autonomous choices. As the beneficiaries of new medical technology, especially when providers are fully informed on its appropriate dissemination, the welfare of patients seems to be one objective that can trump the idea of fully informed autonomy.

VI. Conclusion

Jerome P. Kassirer, former editor of the *New England Journal of Medicine* (NEJM), acknowledges that “[a]t present, the national mood favors individualism, profits, and entrepreneurship.”⁷¹ The three major stakeholders in industry-provider interactions, industry, health care professionals, and health care consumers, all hold basic interests: financial return, medical innovation, and autonomy in health care. While seemingly incompatible, these interests intersect in more ways than they diverge when all stakeholders gain from the promotion of these simultaneous objectives.⁷² When conflicts of interest threaten to deter a health care player from realizing its interest, disclosure of those interests maintains the “status quo.”⁷³ The key to enabling each player to assess the risks and the benefits associated with moving forward is finding a balance between any competing interests and the disclosure thereof.⁷⁴ To the extent that unintended consequences are mitigated, disclosure simultaneously promotes patient autonomy while allowing medical innovation to move forward through designated interactions aimed at sharing and exchanging information about health care products and ideas.

1 For the purposes of this article, these will be referred to collectively as “industry-provider interactions.”

2 See Ehud Arbit, Correspondence, *Academic-Industrial Relationships*, 353 *NEW ENG. J. MED.* 2720, 2720 (2005) (“Collaboration is the avenue to expediency and high quality from which we can all benefit.”)

3 See *Doctors Call For Kid-Sized Medical Devices*, MSNBC.com, April 23, 2008, <http://www.msnbc.com/id/24277116>.

4 See Food and Drug Administration (FDA) Comment on “Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings” (analyzing the data of a Public Citizen Health Research Group study concluding only a “weak relationship” between conflicts of interest and voting behavior of advisory board members and that the exclusion of members with conflicts would not change the vote outcome).

5 See Henry Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354 (1966) (presenting studies where providers made treatment choices that advanced their research interests and negatively affected the health of their patients).

6 51 Cal. 3d 120 (Cal. 1990), cert. denied 499 U.S. 936 (1991).

7 No. 001885, Pa. C.P., settled Nov. 2, 2000.

8 See *Moore*, 51 Cal. 3d at 126-27.

9 See *id.* at 131-32 (reasoning that informed consent includes the disclosure because an “interest extraneous to the patient’s health has affected the physician’s judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment”).

10 See Testimony of William F. Raub, Dep’t of Health & Human Services, before the National Institutes for Health, Conference on Human Subject Protection and Financial Conflicts of Interest, Aug. 15–16, 2000, available at <http://www.hhs.gov/ohrp/coi/8-15.htm> (noting that the events of the *Gelsinger* case instigated the efforts of the conference, including new requirements and guidelines regarding clinical investigators and review of investigations).

11 See Tammy Meyer, *The Role of Company Representatives in the Operating Room – Are They Exposed to Liability?*, IADC Newsletter, October 2005, at 1 (relaying that “the plaintiff’s attorney is sure to discover” the presence of a manufacturer representative in an operating room and may claim harm “as a result of” this practice”).

12 Harvard Docs: Bring on the Drug Reps, *The Wall Street Journal Health Blog*, <http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog> (April 17, 2008, 17:46 EST) (reporting on the comments made by Dr. Dennis Ausiello, chief of medicine at Massachusetts General Hospital and Dr. Thomas Stossel, Harvard Medical School in opposition to a proposed state ban of gifts to doctors from the pharmaceutical industry).

13 See Annetine C. Geljins & Samuel O. Their, *Medical Innovation and Institutional Interdependence*, 287 *JAMA* 72, 77 (2007) (describing the collaboration of health care scientists and industry as an “intellectual partnership” for working together to solve problems and promote new research).

14 See Dennis F. Thompson, *Understanding Conflicts of Interest* 329 *NEW ENG. J. MED.* 573, 573 (1993) (highlighting the “asymmetry between interests” in conflicts of interest in that “only one of the interests has a claim to priority, and the problem is to ensure that the other interests do not dominate”).

15 See, e.g., Barnaby J. Feder, *New Focus of Inquiry Into Bribes: Doctors*, *N.Y. TIMES*, March 22, 2008; Barry Meier, *Implant Program for Heart Device Was a Sales Spur*, *N.Y. TIMES*, Sept. 27, 2005; Reed Abelson, *Possible Conflicts for Doctors Are Seen on Medical Devices*, *N.Y. TIMES*, Sept. 22, 2005; *U.S. Picking Up Pace of Device Inquiries: Probe to Focus on Allegations of Fraud, Abuse*, *BOSTON GLOBE*, May 19, 2004. In addition to media attention, recent cases such as *Gelsinger* have brought considerable attention to the issue. See *supra* note 7.

16 See Physician Payments Sunshine Act of 2008, H.R.5605, S.2029, reintroduced in 2009, available at <http://aging.senate.gov/letters/ppsabill2009.pdf>.

17 See Arlene Weintraub & Amy Barrett, *Medicine in Conflict*, *BUSINESSWEEK*, Oct. 23, 2006, at 77.

18 Pharmaceutical Research and Manufacturers of America (PhRMA), Code on Interactions with Health Care Professionals (effective 2009), <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

19 Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals (Sept. 2003), <http://advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.

- 20 Association of an American Medical Colleges (AAMC) Task Force on Financial Conflicts of Interest in Clinical Research: *Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research* 7 (2001) (providing as an example of a compelling circumstance the situation in human subjects research where an individual is so “uniquely qualified” that the research cannot be conducted safely and effectiveness without his or her involvement).
- 21 *But see* Daylian M. Cain et al., *Coming Clean but Playing Dirtier: The Shortcomings of Disclosures as a Solution to Conflicts of Interest*, in *CONFLICTS OF INTEREST: CHALLENGES AND SOLUTIONS IN BUSINESS, LAW, MEDICINE AND PUBLIC POLICY* 108 (Don A. Moore et al., eds. 2005) (providing for the respective benefits to stakeholders, but proposing that disclosure’s effect may be “overestimated” because the information may not be meaningful to those it is intended to affect).
- 22 *See* Bernadette M. Broccoli & Jennifer S. Geetter, ‘Health’ and ‘Life Sciences’: *The Inevitable Merger of Distinct Industry Sectors*, 1 *BNA’S LIFE SCIENCES LAW & INDUSTRY* 2 (2007) (accounting for increased government interest in regulating the relationships forged between those life science companies and health care providers, as related to the changed role of government from a health care payor to an active health care purchaser).
- 23 *See* David A. Shaywitz & Dennis A. Ausiello, *Scientific Research With an Asterisk*, *BOSTON GLOBE*, April 29, 2008 (extolling on the importance of industry-provider interactions in providing new treatments).
- 24 *See, e.g.* Robert S. Schwartz, et al., Editorial, *Full Disclosure and the Funding of Biomedical Research*, 358 *JAMA* 1850, 1850 (2008) (emphasizing that disclosure reporting is necessary in biomedical research because “one cannot fully appreciate a study’s meaning without acknowledging the subtle biases and interpretation that may arise when a sponsor stands to gain from the report”).
- 25 *Cf.* Robert M. Tenery, Jr., *Interactions Between Physicians and the Health Care Technology Industry*, 283 *JAMA* 391, 393 (2000) (asserting the idea that industry goals compete with the best interests of health care consumers).
- 26 *See infra* Section II.
- 27 *See* Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publication on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, Feb. 2008, available at <http://www.fda.gov/oc/op/goodreprint.html>.
- 28 *Id.*
- 29 *See, e.g.*, Statement by David Dvorak, Zimmer Holdings President and Chief Executive Officer, Zimmer Announces New Compliance Model (Apr. 17, 2008) (announcing the company’s steps to change its methods of interacting with physicians to regain public trust after questions regarding its interactions with orthopedic surgeons arose through alleged anti-kickback violations, but maintaining that “[c]ollaboration with physicians will always be critical to advancing medical technology that improves patients’ lives”).
- 30 Thomas P. Stossel, *Regulating Financial Conflicts of Interest in Medicine: A Solution in Search of a Problem*, Presentation before the Hofstra University Conference on Biomedical Ethics and the Law (Oct. 4–5, 2006), in *Medical Progress Today*, Oct. 10, 2006, at Slide 2.
- 31 *See* Harris Poll, *Doctors and Teachers Most Trusted Among 22 Occupations and Professions: Fewer Adults Trust the President to Tell the Truth*, August 8, 2006, available at http://www.harrisinteractive.com/harris_poll/index.asp?PID=688 (ranking doctors as the most trusted profession with 85 percent of adults polled indicated they trust doctors to tell the truth).
- 32 *See* Kevin W. Williams, *Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting*, 59 *FOOD & DRUG L.J.* 45, 46 (2004) (asserting that the parallel pursuits of the physician and the patient have now been altered under the managed care setting that provides incentives for physicians based on the utilization and reporting of services).
- 33 *See* Jerome P. Kassirer, *Coming Clean but Playing Dirtier: The Shortcomings of Disclosures as a Solution to Conflicts of Interest*, in *CONFLICTS OF INTEREST: CHALLENGES AND SOLUTIONS IN BUSINESS, LAW, MEDICINE AND PUBLIC POLICY* 139 (Don A. Moore et al., eds. 2005) (“Unless medicine is willing to give up its long legacy of public trust that avers that doctors are performing in their patients’ best interests, the culture of ready acceptance of the industry’s largesse must change.”)
- 34 *See* PAUL STARR, *SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY* 26 (New York: Basic Books 1982) (highlighting the significant role of the “gatekeeping authority” because it gives physicians the “purchasing power” where “the authority to prescribe is the power to destroy”).
- 35 *Ackermann v. Wyeth*, No. 06-41774, slip op. (5th Cir. Apr. 24, 2008), at 6.
- 36 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific ‘Conflict of Interest,’* in *LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST, AND LIABILITY*, 63, 63-64 (Trudo Lemmens and Duff R. Waring, eds., 2006).
- 37 *See* PAUL STARR, *SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY* 424 (New York: Basic Books 1982) (foreseeing the practice of medicine a “zero-sum game” where competition drives physicians to make choices that may not benefit the patient population).
- 38 *See id.* at 25-27 (describing physician collaboration with, rather than against, insurance companies, hospitals, and other “bureaucratic organizations” that allows them to maintain their income and professional autonomy).
- 39 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific ‘Conflict of Interest,’* in *LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST, AND LIABILITY* 63, 69 (Trudo Lemmens and Duff R. Waring, eds., 2006).
- 40 *See* Dennis F. Thompson, *Understanding Conflicts of Interest* 329 *NEW ENG. J. MED.* 573, 573 (1993) (noting that the regulation of conflicts of interest upholds the integrity of and confidence in the profession).
- 41 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific ‘Conflict of Interest,’* in *LAW AND ETHICS IN BIOMEDICAL RESEARCH: REGULATION, CONFLICT OF INTEREST, AND LIABILITY* 63, 69 (Trudo Lemmens and Duff R. Waring, eds., 2006) (describing the effects of a conflict of interest revealed only after harm has occurred, thereby lessening public trust).
- 42 *See* Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships – Solving Problems or Stifling Progress?*, 353 *NEW ENG. J. MED.* 1060, 1063 (2005).
- 43 *See* Harvard Docs: Bring on the Drug Reps, *The Wall Street Journal Health Blog*, <http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog> (April 17, 2008, 17:46 EST) (reporting on the strong opposition taken by physicians who call the proposal “severe and vague, [and] inviting . . . personal grievances to harass physicians . . . [and] inevitably inhibit[ing] appropriate industry support”).
- 44 *See* Gina Kolata, *Citing Ethics, Some Doctors Are Rejecting Industry Pay*, *N.Y. TIMES*, April 15, 2008.
- 45 *See id.*
- 46 *See id.*
- 47 In the case of the medical device industry, manufacturers and providers often forge vital relationships in order to provide effective and efficient training for devices that would be useless or harmful in the hands of an untrained professional. *See* Paul A. LaViolette, *Medical Devices and Conflict of Interest: Unique Issues and An Industry Code to Address Them*, 74 *CLEVELAND CLINIC J. MED.* S26 (2007) (pointing to the interactive nature of devices as making “critical” physician interactions with medical device companies and calling for the implementation of the AdvaMed Code of Ethics to manage those interactions).
- 48 There is also an argument that “[i]f everyone is disclosing, it’s as if no one is disclosing.” In other words, the value of the information being disclosed becomes a “mere formality.” *See* Arlene Weintraub & Amy Barrett, *Medicine in Conflict*, *BUSINESSWEEK*, October 23, 2006, at 78 (quoting Dr. Ezekiel J. Emanuel, chair of the Department of Clinical Bioethics at the National Institutes of Health).
- 49 The Association of an American Medical Colleges and the Association of American Universities (AAMC-AAU) Advisory Committee suggestion that “[d]isclosure [of conflicts of interest] should be extended both in scope and in audience” does not go far enough in providing the vital context need to portray the conflict of interest as it truly exists. Its recommendation is limited to disclosure of the type of interaction between industry and the health care provider, but not specifics such as length or timing of remuneration or duration of the interaction. *See Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008, at 10.

- 50 See Testimony of Christopher L. White, Executive Vice President, General Counsel and Secretary, The Advanced Medical Technology Association (AdvaMed), before the Senate Special Committee on Aging, *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry*, February 27, 2008, <http://aging.senate.gov/events/hr188cw.pdf> (suggesting that disclosure legislation include the opportunity for information providing context of an industry-provider interaction because “[i]f sunshine is going to work, then patients need to understand what they are looking at and what it means”). Mr. White goes on to say that failing to provide context for an interaction could have the negative effect of discouraging physicians from collaborating with industry, which “would be a disservice to patients who are looking for the next breakthrough in medical technology that could improve their lives.” See *id.*
- 51 As part of its recent deferred prosecution agreement, Zimmer must list its interactions with physician consultants on its website. See *supra*, note 28. The information required, however, includes only the name, city of residence, amount and type of payment. See *Deferred Prosecution Agreement*, Zimmer website, para. 41, http://www.zimmer.com/web/enUS/pdf/Zimmer_DPA.pdf. No other contextual information that would create a more complete image of the interaction is required. See *Company Consultants – Identification and Payments*, Zimmer website, http://zimmer.com/web/enUS/pdf/Company_Consultants5.pdf.
- 52 See Troyen A. Brennan, et al., *Health Industry Practices That Create Conflicts of Interest*, 295 JAMA 429 (arguing that disclosure is ineffective in mediating the influence of gifts, meals, lectures and conferences, and samples because even the smallest influence is an absolute manipulation of decision-making).
- 53 See, e.g., Harvard Docs: Bring on the Drug Reps, Comments, The Wall Street Journal Health Blog, <http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog> (April 17, 2008, 17:46 EST) (postings of Keith Hartman MD in Wisconsin stating: “Frankly, I buy my own pens, but have learned a great deal from pharm-industry seminars and even some of the drug reps . . .” and Industry Must fight back!! stating: “. . . to say a pen or two from a pharma company influences how a doctor treats his/her patients is as ludicrous as it is demeaning and uninformed”).
- 54 Howard Brody, Correspondence, *Academic-Industrial Relationships*, 353 NEW ENG. J. MED. 2720, 2720 (2005) (emphasis added).
- 55 See *infra* Section IVa.
- 56 Moreover, “what reasonable onlookers find plausible on the basis of appearances is opinion, not fact.” Thomas P. Stossel, *Correspondence, Academic-Industrial Relationships*, 353 NEW ENG. J. MED. 2720, 2720 (2005) (responding to the points raised by Dr. Howard Brody, see *supra* note 54).
- 57 Robert M. Tenery, *Interactions Between Physicians and the Health Care Technology Industry*, 283 JAMA 390, 392 (2000) (emphasis added).
- 58 See BEAUFORT B. LONGEST, JR., HEALTH POLICYMAKING IN THE UNITED STATES 52-53 (AUPHA 1998) (explaining that respect for autonomy, which includes truthful information sharing, pervades health policymaking).
- 59 See *Cobbs v. Grant*, 8 Cal.3d 229, 243 (Cal. 1972) (holding that the physician has a duty of “reasonable disclosure” of available treatment choices to the patient).
- 60 See *Washington University v. Catalona*, 437 F.Supp. 2d 985 (E.D.Mo. 2006), *cert. denied* January 22, 2008.
- 61 But see Lori Andrews, *Who Owns Your Body? A Patient’s Perspective on Washington University v. Catalona*, 34 J. L., Med. & Ethics 398, 405 (2006) (forewarning a chilling effect on research when patient control over the use of donated information is not enforced).
- 62 See Peter Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 939 (1994) (reflecting that “courts tend to invoke the values of autonomy and decision-making and then analyze the implication of those values, while maintaining a silence on the issue of costs.”)
- 63 See *Cobbs v. Grant*, 8 Cal.3d 229, 240 (Cal. 1972) (quoting Prosser on Torts (4th ed. 1971) that consent is necessary to meet the professional standard of care).
- 64 “True consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.” *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. 1972).
- 65 See *Health Privacy Stories*, Health Privacy Project, March 5, 2007 (canvassing the “harms” befalling individuals subject to a breach of health care records. Very few of the harms include physical or proprietary assaults).
- 66 See *UCLA Hospital Employee Couldn’t Contain Celeb Curiosity*, The Wall Street Journal Health Blog, <http://blogs.wsj.com/health/2008/04/07/ucla-hospital-employee-couldnt-contain-celeb-curiosity/?mod=WSJBlog> (April 7, 2008, 9:25 EST).
- 67 See Thomas Claburn, *Government Report Finds Health Care Privacy Breaches Rampant*, INFORMATIONWEEK, September 5, 2006 (reporting that almost half of health insurance contractors and Medicaid agencies experienced a privacy breach in health care records, a statistic that Beth Givens, the director of Privacy Rights Clearinghouse finds “shocking” both because of the large number and the nature of the data).
- 68 See *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*.
- 69 See BEAUFORT B. LONGEST, JR., HEALTH POLICYMAKING IN THE UNITED STATES 52 (AUPHA 1998) (relating that the principle of autonomy as envisioned by the founders of the United States arises in health care in privacy rulemaking).
- 70 See *supra*, section IV.
- 71 Jerome P. Kassirer, *Coming Clean but Playing Dirty: The Shortcomings of Disclosures as a Solution to Conflicts of Interest*, in *CONFLICTS OF INTEREST: CHALLENGES AND SOLUTIONS IN BUSINESS, LAW, MEDICINE AND PUBLIC POLICY* 139 (Don A. Moore et al., eds. 2005).
- 72 See David A. Shaywitz & Dennis A. Ausiello, *Scientific Research With an Asterisk*, BOSTON GLOBE, April 29, 2008 (presenting the view of two physicians that the “battle is not drug companies v. academics, but rather between dreadful diseases and the medical researchers who are trying to subdue them”).
- 73 See Cain, *supra* note 21 and accompanying text.
- 74 See Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454, 464 (2003) (suggesting that conflicts of interest are here to stay and a “consensus around a system of checks and balances to promote medical innovation while improving oversight and transparency” is necessary).