COMMENTARY

Clinician Conflicts of Interest at the Cleveland Clinic: The Context and Functions of Disclosure Policy and What Remains Unknown

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Due to their financial incentive, clinicians who earn income from a firm that markets medical devices, pharmaceuticals, tests, etc. might inappropriately prescribe their products or services. The Cleveland Clinic's conflict of interest (CI) policy creates rules governing clinicians who accept compensation from outside firms that market products they prescribe or use in their practice (hereafter, covered financial relationships). The CI policy is implemented by the Innovation Management and Conflict of Interest Program (IM&COI) (hereafter the Committee).

The Committee reviews all covered relationships and clinicians "must receive approval" of any relationship yielding more than $20,000 annually or with an equity interest greater than five percent. Furthermore, the committee "may require ... disclosure to patients, limits on the relationship with the Non-Cleveland Clinic Entity or adoption of a Conflict Management Plan, to ensure ... that the clinical activity is free from bias...." At the same time, the Committee "strive[s] not to interfere with clinical practice" that clinicians "believe to be in the best interests of his/her patients."[1]

The Committee requires clinicians to report annually, and within 30 days of any material change, their financial relationships with entities that market products they use or prescribe.[2] Any covered financial relationship worth more than $5,000 a year is disclosed within the clinician's Cleveland Clinic online biography.[3] For any covered relationship yielding more than $20,000 income annually to a clinician or five percent equity interest in a privately held company, the Committee considers the size of the clinician's financial interest and the patient's medical risk from the treatment and decides whether the clinician should make additional, direct disclosures to the patient. The Committee distinguishes between three categories of financial interest: (1) low ($20,000 to $50,000 income); (2) moderate ($50,000 to $100,000 income); (3) high (either over $100,000 income or any equity interest). The committee distinguishes between five types of clinical treatment, and ranks these as involving low, medium or high medical risk.

For example, if a clinician earns $30,000 annually from a covered relationship and the Committee finds that a patient would bear a medium or high safety risk from the medical care, the Committee may require the clinician to disclose the relationship directly to the patient, either orally or in writing, whichever the clinician prefers, along with documentation in the patient's medical record that they made a disclosure. Similarly, if the patient will undergo a high-risk medical procedure and the clinician earns more than $20,000 annually from the covered relationship, the Committee may require disclosure when the clinician obtains the patient's informed consent and in the separate clinical consent form created in the Epic medical record.

In this issue of JLME, Derwin et al.[4] report data from 2016 to 2021 regarding the type and distribution of covered clinician financial relationships and patient medical risks, and types of disclosures required by the Cleveland Clinic. The authors describe the process that the Committee used to assess clini-

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cian financial interest and health risk, how the assessments of patient health risks changed over time, and the distribution of its ratings of financial interest and health risk. Approximately 2% of 7,500 individual clinicians (n= 157) revealed a covered financial relationship with an outside entity worth more than $20,000 annually or a greater than 5 percent equity interest. After assessing the risk of treatment in question, the Committee required 50% of those clinicians (n=78) to directly disclose the financial relationship to their patients.

reported and identified in ways that flag and explain the conflict of interest, the information is unlikely to caution patients.

The authors are correct that some relations pose greater risk than others. Some alternative forms of disclosure could have highlighted those risks and provided opportunities for public oversight. For example, the Cleveland Clinic web page could have made public the text of information disclosed directly to patients, and details of any management plan. It could also include a list of all clinicians with a covered relationship worth over $20,000 annually, and of clinicians who were required to make disclosures directly to

Each clinician biography includes a tab for "relations with industry," where the relationships are described as "collaborations" with industry "to help develop medical breakthroughs or provide medical expertise or education." The text portrays these relationships in a very positive light. It states the disclosures are made "to assure professional and commercial integrity…" as part of a policy that includes "measures … to minimize bias that may result from ties to industry." The page does not use the term "conflicts of interest," nor does it note the potential risk to patients from inappropriate prescribing or use of services. Unless financial ties are reported and identified in ways that flag and explain the conflict of interest, the information is unlikely to caution patients.

What Do Cleveland Clinic Disclosures Reveal?

Presumably, disclosures of covered financial relationships should illuminate the risk of a clinician's compromising financial ties to the patients at risk. But do they? It remains unclear how well the Cleveland Clinic disclosure policies advance that goal. One method used by the Cleveland Clinic to disclose covered financial relationships is through its online directory of clinician biographies. Each clinician biography includes a tab for "relations with industry," where the relationships are described as "collaborations" with industry "to help develop medical breakthroughs or provide medical expertise or education." The text portrays these relationships in a very positive light.[5] It states the disclosures are made "to assure professional and commercial integrity…" as part of a policy that includes "measures … to minimize bias that may result from ties to industry." The page does not use the term "conflicts of interest," nor does it note the potential risk to patients from inappropriate prescribing or use of services. Unless financial ties are patients. It already posts a similar list for all researchers funded by the Public Health Service as required by federal regulations.

Very little is known about the most important disclosures at the Cleveland Clinic, that is, those required to be made directly to the patient because of the clinician's level of financial interest and the risk of the treatment. What exactly were the patients of the 82 clinicians identified by Derwin et al. told? How was that different, if at all, from the information posted on the clinician's online biography?

Obviously, the information a clinician discloses directly to a patient via a conversation cannot be verified unless recorded. However, if we acknowledge that conflicts of interest can bias clinician decisions regarding use of a product or service, we should also recognize that it can bias how the clinician explains the financial relationship to patients. It is doubtful that a clinician believes that the financial relationship poses risk to the patient, and therefore is likely to downplay it when making an oral disclosure.[6] If our aim is to ensure that patients are fully informed, receive objec-

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tive advice, and understand the risks of their treatments, it would be better for someone other than the treating clinician to disclose any conflicts of interest. An independent third party would lack an incentive to downplay the risks and could also test for patient understanding.

As for written disclosures, the Committee suggests that the following language be inserted into the record.[7]

> Dr. [NAME] receives payments from [COMPANY] for [conduction educational activities and/or consulting]. A [COMPANY] product may be used in your care. Dr. [NAME] does not receive any money for products he/she or any other Cleveland Clinic physicians prescribe or use. Dr. [NAME]'s choice on which product to use in your case was not influenced by his/her relationship with [COMPANY]. Your physician selected the product that in his or her hands is believed to be the best option for your treatment.

The statement that the doctor "was not influenced by his/her relationship" begs the question. That is precisely the risk of a conflict of interest and the reason to restrict such relationships or warn patients about them. In fact, even though they do not contain any confidential patient information, the Cleveland Clinic does not make public the disclosures inserted into the medical record or informed consent forms. As such, it is impossible to assess whether the information provided to patients accurately describes the financial relationship between their clinician and outside firms and alerts them to risks arising from the financial relationship related to their medical treatments. The information could be vague, opaque, or delivered in a manner that deflects attention from the conflict of interest.

Finally, we lack information on the impact of disclosures on patients' understanding of the risks from conflicts of interest, their choice of clinicians, and their consent to treatment. Patients usually trust their doctors, view them as authority figures, and follow their advice, even when warned of conflicts of interest.[8] Studies find that although patients often understand that conflicts of interest can affect physicians' judgement and choices, most believe that they won't affect their own doctor's decision-making.[9] Research also shows that patients discount the risk of bias and have difficulty ignoring information that they know to be unreliable.[10] Furthermore, patients often receive consent forms disclosing risk shortly before surgery, after their decision to undergo the procedure has already been made, thereby reducing the potential effects of disclosures on patient decision-making.

The Context Around the Cleveland Clinic Policy

Derwin and colleagues explain that the Cleveland Clinic developed its 2013 policy following the publication of two independent and influential reports recommending disclosure of clinician financial interests. The Institute of Medicine (IOM) (2009) and American Association of Medical Colleges (AMC) (2010) both issued recommendations for institutions and clinicians to avert conflicts of interests when possible, and when unavoidable, disclose them.[11] The authors also note that the Cleveland Clinic disclosure policy "is rooted in our research demonstrating that more transparency appears to be better in terms of patient perspectives."[12] However, the institution's broader circumstances illuminate the disclosure policy's origins, functions, and limitations.

Between 2005 and 2008, the *New York Times*,[13] the *Wall Street Journal*,[14] *Forbes*,[15] and other press outlets published a series of articles critical of the Cleveland Clinic, reporting that a "web of relationships that … entangled many of its doctors and trustees" had created conflicts of interest.

Starting in 2005, the Cleveland Clinic engaged the law firm McDermott, Will & Emery to review its conflict of interest policies.[16] The result of the review was a policy, implemented by the Cleveland Clinic Board, "prevent[ing]doctors who have relationships to a particular drug or device companies [*sic*] from involvement in the clinic's purchasing decisions about those companies' products."[17] Among the Cleveland Clinic personnel that subsequently severed certain financial relationships with outside firms or changed their work responsibilities in accordance with the policy were Dr. Delos Cosgrove, CEO of the institution, and Dr. Erik Topal, a prominent cardiologist and inventor.

Nonetheless, the Cleveland Clinic "had no plans to abandon its entrepreneurial nature…"[18] Determined to continue its research and development partnerships with commercial interests, the Cleveland Clinic established the "Innovation Management and Conflict of Interest Committee" to oversee financial relationships and partnerships with industry.[19] Essentially, the disclosure policy was pursued in order to deflect criticisms without precluding activities that give rise to conflicts of interest. As one of the *New York Times* articles explained, most medical centers try to "avoid outright bans [on relationships that create conflicts of interest] by asking researchers to disclose their ties…"[20]

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In general, organizational policies requiring disclosure seek to advance institutional financial goals and avoid reputational damage as much as they seek to protect patients or accommodate their preferences.[21] Furthermore, many CI polices, including that of the Cleveland Clinic, include provisions safeguarding employee loyalty by prohibiting financial relationships with competitors. The objective of this type of CI policy is obviously quite different from that which is intended to protect patient interests.[22]

The Evolution of Policies on Conflicts of Interest in Medicine

Medical institutions and organizations have long debated the ethics of financial relationships that create conflicts of interest. In the early 20th century, as the practice of physician fee-splitting (a form of kickback) became popular, some physicians and professional associations argued that fee-splitting itself was unethical, while others maintained that the problem was merely the lack of its disclosure.[23] There are similar divisions in views today regarding whether disclosure requirements are sufficient or whether policies must go further and restrict certain financial relationships in order to protect patients.

Contemporary concerns regarding conflicts of interest among clinicians emerged in 1980 when *New England Journal of Medicine* editor Arnold Relman published a series of articles and editorials about investor-owned medical facilities, physician conflicts of interest, and related subjects.[24] Dr. Relman believed that conflicts of interest, particularly those arising from physician entrepreneurialism and investor-owned medical care, compromised clinician loyalty to patients and medical ethics. Some professional associations followed his lead and adopted ethical guidelines. However, after patients and research subjects began to sue doctors and medical organizations claiming that financial relationships, failure to disclose, and subsequent conduct violated their obligations, many more medical institutions moved to adopt CI policies, primarily to reduce their legal risk.[25]

By 1995, Congress had enacted legislation prohibiting physician self-referral in Medicare and Medicaid, that is, the practice of physician referral of patients to health related services in which they have financial interest.[26] Moreover, prosecutors began to more aggressively enforce the Medicare and Medicaid Anti-Kickback Act (AKA).[27] The AKA defines kickbacks very broadly and as such, the courts have interpreted the statute as a prohibition on financial payments if one of their purposes is to encourage referrals.[28] As a result, the AKA bars many transactions that constitute a conflict of interest but would not be considered kickbacks in other contexts. Even so, the Office of Inspector General's (OIG) compliance guidelines for the pharmaceutical industry stipulates that a rebuttable presumption of compliance with the AKA is established when physicians and medical organizations comply with the ethical guidelines of the American Medical Association (AMA),[29] the Pharmaceutical Research and Manufacturers Association (PhRMA),[30] and other professional organizations, which require disclosure.[31] Furthermore, the existence of an OIG-approved compliance program, which requires disclosure, reduces any penalties in the event of liability.[32]

Starting in the mid-1980s, but especially since the legal decision in *Moore v. Regents of the University of California* in 1990,[33] lawyers have advised physicians and medical centers that disclosure of financial ties reduces the risk of civil and criminal liability by establishing the defense that a patient consented and assumed any risk of harm. *Moore* held that "a physician who is seeking a patient's consent for a medical procedure must … disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."[34] In addition, since 1995, and with stricter rules since 2011, the US Health Service requires similar disclosures to research grant recipients. Today, disclosure of a clinician's financial relationships is considered a best practice within medical and research institutions. It is required for compliance and weakens or precludes legal claims based on lack of informed consent, deception, fraud, and the violation of the AKA. One article aptly characterizes current physician and professional organization policy on financial conflicts of interest as *self-regulation in the shadow of federal prosecution*.[35]

Can Disclosure Mitigate Conflicts of Interest?

How effective is disclosure in helping patients avoid the risk created by physicians' conflicts of interest, especially since these policies are overseen by medical centers which often have their own institutional conflicts of interest?[36] Conflicts of interest compromise the loyalty or independent judgement of medical professionals and thereby increase the risk that they will not act in the interest of patients they are supposed to serve.[37] Disclosure policies are a necessary condition to identify those conflicts of interests, but it does not eliminate the conflict.

Once a conflict of interest has been identified, one of two types of action can resolve the conflict. First, an organization can either require the clinician or institution to terminate the financial relationship that

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conflicts with clinical care or discontinue the medical work that conflicts with the financial relationship.[38] Alternatively, a medical institution can oversee the work of conflicted medical professionals to reduce the risk that they will abuse their patients' trust. The IOM and others anticipate such oversight as an appropriate management strategy for serious conflicts of interest when termination of the conflict of interest is not feasible. The Cleveland Clinic CI policy allows the committee to implement a CI management plan, yet the Cleveland Clinic's CI web page and article by Derwin et al. do not discuss these management plans, which are as important, if not more so, than informing patients of the existence of such relationships.

In certain situations, it might be reasonable for an organization to allow the conflicted relationship after its disclosure because patients might then be able to protect themselves by choosing to be treated by other clinicians or by seeking an alternative therapy or at least knowingly consent to the risk. However, in fact, patient risks often persist even after disclosure because patients either do not understand the implications of the conflict of interest or lack the time and resources to find an alternative unconflicted clinician.[39] In summary, there are many limitations to disclosure as a response to conflicts of interest, a theme I first explored over 35 years ago.[40] Recent publications have further analyzed the limitations.[41]

Considering its limited benefits to patients, why does disclosure remain the main response to conflicts of interest for so many organizations? It is likely because disclosure policies demand fewer restrictions and costs than the act of changing the actual relationships and practices that are creating the conflicts of interest. Consequently, we are now experiencing a shift from *managing conflicts of interest* through changing or overseeing clinical practice or ending compromising financial ties to *managing the disclosure of financial relationships*. The former is directed to protecting patients while the latter is aimed at protecting clinicians and institutions with some collateral benefit flowing to patients.

These shifts were exposed in a 2014 IOM workshop on conflicts of interest and medical innovation[42] in which Guy Chisholm, the director of the Cleveland Clinic IMCIP program, participated. The workshop participants' primary objective was to advance policies that foster partnerships with industry. Concerns with protecting patients from CI represented a secondary consideration. One participant commented, "once objectives for innovation are established, institutional conflicts of interest policies need to be aligned with these goals," suggesting very little interest in any actions that might compromise industry partnership.[43] Workshop participants preferred to speak of "disclosing relationships" rather than "conflicts of interest,"[44] and advocated for the development of voluntary standards before the establishment of "regulations issued by government agencies."[45]

There is a long history of organized medicine and institutions using ethical standards and organizational policies to deflect or preclude government regulation. From the 1970s to the 1990s, in hearings convened by Senator Edward Kennedy, the AMA testified that professional organizations and physicians could regulate themselves with respect to ethical standards and as such, any legislation regulating gifts from pharmaceutical firms to physicians or any other relationships or practices that created a conflict of interest was unnecessary. These assurances were made despite acknowledgement that enforcement of such standards was impossible. Shortly before providing their testimony, the AMA adopted guidelines which they presented as an alternative to regulation. Nevertheless, subsequent hearings revealed low compliance with the AMA organizational policies.[46]

Many of the IOM workshop participants portrayed conflict of interest disclosure as an impediment to good medical care that "chase[ed] away innovative people … [because] they do not have the time or energy for completing disclosure and do not want to create a poor impression." However, one participant reported that in his experience, patients typically did not respond negatively to disclosure of financial ties. Quite the contrary: "when a three-paragraph addition to a consent form was inserted to explain [the clinician's role] in the development of a treatment, patients interpreted it as meaning that their physician was an expert."[47] Disclosing financial relations in clinician biographies, the current Cleveland Clinic practice, might have a similar effect.

Disclosures intended to simultaneously warn patients and promote a clinician's expertise have antecedents. In the 1950s, pharmaceutical firms and the AMA sought tax exemptions for drug advertising in AMA medical journals on the grounds that the advertisements were informative and educational, rather than promotional.[48] This stance prompted Dr. Charles May, a dissenting member of the AMA Council on Drugs, to pen a critical article titled "Selling Drugs by 'Educating' Physicians." He criticized the idea that education and advertising were compatible as well as any attempt to blur the two.[49] The disclosure of financial relationships as a warning are similarly in tension with their use in an online biography that touts the physician's expertise and the value of the collaboration with industry.

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Future Research on Organizational Conflicts of Interest Policies

The study by Derwin et al. aptly describes the implementation of the disclosure component of the Cleveland Clinic's CI policy for clinicians. Yet other parts of the Cleveland Clinic's CI policy remain less well understood. We lack information on the kinds of relationships, if any, that the Committee has disallowed, or the management plans they have established to oversee a clinician's practice. Is that because few if any relationships are disallowed and there are few or no management plans? If the Cleveland Clinic restricts or manages financial relationships between outside entities and its clinicians, details about these activities should be made public. And if it prohibits or manages few or no relationships that also should be made clear.

In addition, while the study reports the broad categories of financial relationships that Cleveland Clinic clinicians are involved in, we know little about the specific nature of the relationships. The most frequent relationships were *speaker, trainer, educator* (58%) and *consultant* (69%). What work did these clinicians actually do? Were speakers engaged in activities that are, for all practical purposes, product promotion?[50] Information divulged through litigation reveal that the pharmaceutical and medical device industry sometimes engage doctors as speakers, educators and consultants as a means to disguise kickbacks for prescribing.[51] Were the Cleveland Clinic physicians selected as speakers, educators, and consultants in large part because of the prescriptions they could or did write at Cleveland Clinic?[52] How might these relationships affect their prescriptions?

Unaddressed aspects of CI policy that remain of interest to researchers, policymakers, and patients would be illuminated by answering these six questions:

1. When is a conflict of interest, created by a covered financial relationship, considered to be serious enough by the Cleveland Clinic as to require a termination or restriction of that relationship and how frequently have they restricted such relationships?
2. Under what circumstances is a conflict of interest, created by a covered financial relationship, considered to be serious enough by the Cleveland Clinic as to require a management plan to oversee the clinician's practice, how frequently has the Cleveland Clinic required management plans, and what plans are now in effect?
3. Aside from disclosure, how specifically has the Cleveland Clinic managed covered financial relationships or managed clinical care, in light of the relationships?
4. How are the covered financial relationships that the Cleveland Clinic has prohibited or restricted similar to or different from the covered financial relationships that it has allowed?
5. Is there any evidence that permitted and disclosed financial relationships produce equivalent or similar problems expected of the relationships that are disallowed or are overseen by a management plan?
6. What changes have occurred over time regarding the types and frequency of covered financial relationships restricted by or placed under a management plan by the Cleveland Clinic?

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