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Nonfinancial Conflict of Interest in Medical Research: Is Regulation the Right Answer

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NONFINANCIAL CONFLICT OF INTEREST IN MEDICAL RESEARCH: IS REGULATION THE RIGHT ANSWER?

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ABSTRACT. Medical research plays a vital role in advancing human knowledge, developing new therapies and procedures, and reducing human suffering. Following the atrocities committed in the name of medical research by German physicians during the Nazi era, the Nuremberg trials were held, and an ethical code was created to establish the limits within which medical research can operate. Consequently, legal regimes built upon this ethical foundation to develop laws that ensure the integrity of medical research and the safety of human subjects. These laws sought to protect human subjects by minimizing conflicts of interest that may arise during the process. Furthermore, conflicts of interest may be financial such as monetary gain, or nonfinancial such as promotion and career advancement. However, with a $1.1 billion median cost of developing a new drug, the focus of these laws was directed towards financial conflicts of interest. But should we expand these laws to include nonfinancial conflicts of interest? This Article highlights prominent arguments in favor of and against the regulation of nonfinancial conflicts of interest in medical research. It further concludes that adequate institutional policies—not additional regulations—strike the right balance between the need to safeguard against the harmful effects of nonfinancial conflicts of interest on the one hand and avoiding the drawbacks of overregulation on the other.

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I. INTRODUCTION

Should we regulate nonfinancial conflicts of interest in medical research? Some scholars argue that we should because nonfinancial conflicts of interest pose a credible risk to the integrity of medical research as well as the safety of human subjects.[1] Additionally, the similarities between financial and nonfinancial conflicts of interest warrant similar regulation.[2] Others disagree because regulation will divert our attention from the more problematic financial conflicts of interest,[3] conflates bias with conflict of interest,[4] and undermines diversity in medical research.[5] Moreover, regulation is impractical, unnecessary, and would cause confusion.[6] This Article highlights prominent arguments on both sides and concludes that adequate institutional policies—not additional regulations—strike the right balance between the need to safeguard against the harmful effects of nonfinancial conflicts of interest on the one hand and avoiding the drawbacks of overregulation on the other.

Medical research plays a vital role in advancing human knowledge, developing new medications and procedures, and reducing human suffering. Furthermore, academic and commercial institutions have invested heavily in medical research. For example, between 2009 and 2018, the median cost of developing a new drug was $1.1 billion with recent estimates ranging from $314 million to $2.8 billion.[7] With such a huge financial interest at stake, conflicts of interest may arise in medical research.

Conflicts of interest may be financial or nonfinancial.[8] Financial conflicts of interest involve a financial gain or its equivalents such as in-kind goods, employment, or appointment to a position of authority.[9] Nonfinancial conflicts of interest include everything else such as an individual's interest in career advancement, tenure and promotion, enhanced reputation, and access to power.[10] Financial conflict of interest, however, has been the focus of governmental regulations.[11] Several commentators have argued for either (1) the extension of some of these regulations to cover nonfinancial conflicts of interest[12] or (2) the expansion of the traditional definition of conflicts of interest

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[1] Richard S. Saver, *Is It Really All About the Money? Reconsidering Non-Financial Interests in Medical Research*, 40 J.L. MED. & ETHICS 467, 469 (2012).
[2] *See id.* at 474-75.
[3] Lisa A. Bero & Quinn Grundy, *Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest*, 14 PLOS BIOL., no. 12, Dec. 21, 2016, at e2001221.
[4] Marc A. Rodwin, *Conflicts of Interest in Medicine: Should We Contract, Conserve, or Expand the Traditional Definition and Scope of Regulation?*, 21 J. HEALTH CARE L. & POL'Y 157, 177 (2018).
[5] Quinn Grundy, et al., *Conflict of interest as ethical shorthand: understanding the range and nature of "non-financial conflict of interest" in biomedicine*, 120 Journal of clinical epidemiology 1, 6 (2020).
[6] *See* Rodwin, *supra* note 4, at 158.
[7] Olivier J. Wouters, et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA, no. 9, Mar. 3, 2020, at 844.
[8] Marc A. Rodwin, *Conflicts of Interest in Human Subject Research: The Insufficiency of U.S. and International Standards*, 45 AM. J.L. & MED. 303, 305 (2019).
[9] *Id*.
[10] *See* Rodwin, *supra* note 4, at 174.
[11] *See* Saver, *supra* note 1, at 467.
[12] *Id*.

to include both nonfinancial and financial interests.[13] For example, after the National Institutes of Health introduced new rules in 2011, many argued that they should apply to both types of interests.[14] However, the Department of Health and Human Services has declined to expand the new rules to nonfinancial conflicts of interest.[15] This paper examines whether we should expand governmental regulation to include nonfinancial conflicts of interest.

Part II of this paper provides background information on nonfinancial conflict of interest, its importance, and current ethical and legal practices. Part III highlights prominent arguments in favor of regulation. Part IV highlights prominent arguments against regulation. Part V provides a discussion analyzing both positions. Finally, part VI concludes that clear well developed institutional policy provides an adequate solution.

II. BACKGROUND INFORMATION

A. What Is a Conflict of Interest?

Scholars have defined the concept of conflict of interest differently depending on the context. For example, a conflict of interest that may arise in a business setting is different from that which may arise in a public employment setting.[16] Two definitions, however, are relevant to medical research: (1) the definition adopted by the Institute of Medicine (now the National Academy of Medicine) that is often referenced in academic journal articles addressing medical research, and (2) the definition used by the legal profession to identify and manage conflicts of interest in the context of client representation. The distinction between the two definitions is important because writers who support regulation, such as Professor Richard S. Saver,[17] tend to rely on the Institute of Medicine (IOM) definition, whereas writers who oppose regulation, such as Professor Marc A. Rodwin,[18] tend to rely on the legal definition.

The Institute of Medicine (IOM) defined a conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[19] In this context, a primary interest may include promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education.[20] A secondary interest may include (1) financial interests such as economic gain or (2) nonfinancial interests such as professional advancement and recognition for personal achievements.[21] Secondary interests are

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[13] *See* Rodwin, *supra* note 4, at 158.
[14] *See* Saver, *supra* note 1, at 467.
[15] *Id*.
[16] *See* Rodwin, *supra* note 4, at 167-68.
[17] Richard S. Saver is a Professor of Law at the University of North Carolina School of Law, *see* UNC School of Law, *Richard S. Saver*, https://law.unc.edu/people/richard-s-saver/.
[18] Marc A. Rodwin is a Professor of Law at Suffolk University Law School, *see* Suffolk University, *Marc A. Rodwin*, https://www.suffolk.edu/academics/faculty/m/o/mrodwin.
[19] Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice, *Conflict of Interest in Medical Research, Education, and Practice*, Washington (DC): NATIONAL ACADEMIES PRESS (US) (Bernard Lo & Marilyn J. Field eds., 2009). https://www.ncbi.nlm.nih.gov/books/NBK22937/.
[20] *Id*.
[21] *Id*.

legitimate legal interests that may become problematic in some cases. For example, financial gain is not per se objectionable but requires disclosure and sometimes recusal. Additionally, financial gain is even sometimes desirable and endorsed by Congress. For example, the Bayh-Dole Act of 1980 allowed federal grant recipients to patent and license new products developed by their faculty members and to share royalties with the researchers.[22] Moreover, nonfinancial interests such as career advancement is a legitimate interest that incentivizes researchers to excel at their job.

On the other hand, the legal concept of conflict of interest has its origins in fiduciary law which requires fiduciaries to be loyal to the party they serve.[23] Additionally, the law provides remedies if a fiduciary breaches her duty.[24] Put differently, the legal concept of conflict of interest concerns conflicting loyalties or the breach of a duty or an obligation. The ABA Rules of Professional Conduct paid special attention to these two concerns. For example, rule 1.7 provides that a concurrent conflict of interest exists if:

> 1. The representation of one client will be directly adverse to another client, or
> 2. There is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client, a former client, or a third person or by a personal interest of the lawyer.[25]

Subsection 1 of rule 1.7 illustrates that a conflict of interest exists if conflicting loyalties exist, whereas subsection 2 illustrates that a conflict of interest exists if there is a significant risk that the lawyer may breach her duty during the representation.

In short, the IOM definition focuses on primary and secondary *interests* whereas the legal concept focuses on *duties* or *obligations.*[26] This distinction is important because the regulation of mere interests, which have not yet materialized into serious risks, requires more intrusive rules than the regulation of materialized risks such as a breach of duty.

B. What Is a Nonfinancial Conflict of Interest?

Nonfinancial conflicts of interest include motives and considerations other than direct economic gain that researchers still highly value such as career advancement.[27] Examples of nonfinancial conflicts of interest include the following:

> 1. Personal, religious, or political beliefs.
> 2. Personal experiences.

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[22] Jesse A. Goldner, *Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J.L. MED. & ETHICS 379, 384 (2000).
[23] *See* Rodwin, *supra* note 4, at 158-59.
[24] *Id*. at 159.
[25] Model Rules of Prof'l Conduct R. 1.7 (2021).
[26] Mark Rodwin, *Attempts to redefine conflicts of interest*, 25 ACCOUNTABILITY IN RESEARCH, no. 2, 2018 at 67.
[27] *See* Saver, *supra* note 1, at 468.

3. Advocacy or policy positions of the researcher or organization with which they are affiliated.
4. Intellectual, theoretical, or school of thought commitments.
5. Type of training; professional or academic education.
6. Profession or discipline.
7. Academic competition or rivalry.
8. Career advancement or promotion.
9. Glory seeking or desire for fame.
10. Dominant researcher in area of research.
11. Personal experience with subject of research.
12. Personal relationship with someone who has the disease or condition under study.
13. Role as investigator on study included in a systematic review.
14. Published opinion essay or commentary on topic of research.
15. Institutional affiliation or academic associations.[28]

C. Why is it Important to Manage Conflicts of Interest in Medical Research?

It is important to manage both financial and nonfinancial conflicts of interest in medical research to protect the integrity of research as well as the safety of human subjects. Unlike in the context of patient care, where a plaintiff may obtain a remedy through tort action such as medical malpractice, similar remedies may not be available to human subjects. While patient care and medical research share some similarities, their goals are different. The goal of patient care is to treat the patient receiving therapy whereas the goal of medical research is to inform the care of future patients about the benefits and risks of therapy.[29] Thus, medical research necessarily involves a risk of harm.[30]

Furthermore, psychological and sociological studies suggest that nonfinancial incentives influence human behavior similar to financial incentives.[31] Additionally, multiple reports indicated that clinical trials sponsored by pharmaceutical companies were more likely to show favorable results to those companies.[32] For example, one study compared the results of industry-sponsored drug studies to non-industry-sponsored studies and concluded that even well-designed studies are more likely to show better effectiveness and fewer harms of the studied drug if the study was industry-sponsored.[33] Both financial and nonfinancial interests may have influenced these results because the association with the pharmaceutical industry is not only a source of financial gain but also prestige and

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[28] *See* Bero, *supra* note 3.
[29] Paul G. Shekelle et al., *Maintaining Research Integrity: A Systematic Review of the Role of the Institutional Review Board in Managing Conflict of Interest [Internet]*, Washington (DC): DEPARTMENT OF VETERANS AFFAIRS (US), May 2012. https://www.ncbi.nlm.nih.gov/books/NBK98417/ (last visited Dec. 14, 2023).
[30] *Id*.
[31] Miriam Wiersma et al., *Dangers of neglecting non-financial conflicts of interest in health and medicine*, 44 JOURNAL OF MEDICAL ETHICS, no. 5, 2018, at 319.
[32] Paul L. Romain, *Conflicts of interest in research: looking out for number one means keeping the primary interest front and center*, 8 CURR REV MUSCULOSKELET MED 122 (2015).
[33] Andreas Lundh et al., *Industry sponsorship and research outcome*, COCHRANE DATABASE SYST REV., Dec. 12, 2012. doi:10.1002/14651858.MR000033.pub2 (last visited Dec. 14, 2023).

status.[34] This is evident in the case of "key opinion leaders" who usually receive consulting fees and enjoy a high social status associated with their roles.[35]

D. Legal Approaches

Before addressing the question of whether we should regulate nonfinancial conflicts of interest in medical research, it is helpful to highlight the current legal and ethical practices in medical research.

1. Ethics Codes

i. *The Nuremberg Code*

The tribunal that judged the Nazi physicians after the war created the Nuremberg Code to establish limits within which medical research can operate.[36] The Nuremberg Code continues to influence laws and regulations everywhere.[37] Although not binding, the Code provided a foundation upon which informed consent laws were based. It provided that voluntary consent of human subjects must include the following elements: (1) the human subject must have legal capacity to consent, (2) the human subject must have sufficient knowledge and comprehension of the research, and (3) the circumstances must allow for free power of choice—without the influence of force, duress, fraud, or coercion.[38] Additionally, the Code asserted that researchers are responsible for ensuring that human subjects voluntarily participate in their medical research.[39]

ii. *The Belmont Report*

The National Commission for the Protection of Human Subjects issued the Belmont Report in 1979.[40] The purpose of this report was to set boundaries between the practice of patient care and medical research.[41] It asserted that the purpose of patient care is to provide diagnosis, preventive treatment, or medical therapy to particular individuals—patients.[42] Conversely, medical research is designed to test a hypothesis, draw conclusions, and contribute to generalizable knowledge.[43] Furthermore, the Belmont Report outlined the three basic ethical principles of medical research—respect for persons, beneficence, and justice.[44]

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[34] Miriam Wiersma et al., *Status, Respect, and Stigma: A Qualitative Study of Non-financial Interests in Medicine*, 17 BIOETHICAL INQUIRY 203 (2020).
[35] *Id*.
[36] Janet L. Dolgin & Lois L. Shepherd, BIOETHICS AND THE LAW 740 (4th ed. 2019).
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.* at 741.
[41] *Id.*
[42] *Id.* at 742.
[43] *Id.*
[44] *Id.*

1. Respect for Persons

First, respect for persons entails that (1) individuals must be treated as autonomous agents, and (2) persons with diminished autonomy must be protected.[45] This principle requires that researchers acknowledge the autonomy of the research subjects and protect those with diminished autonomy. Autonomy is the capability of the individual to deliberate about personal goals and to act under the direction of such deliberation.[46] Thus, a researcher must give weight to the human subject's opinions and choices and refrain from obstructing their actions unless they are detrimental to others.[47] In short, respect for persons requires that human subjects participate in the research voluntarily and with adequate information.[48]

Furthermore, the respect for persons principle requires that researchers obtain informed consent from research subjects. Informed consent entails three elements: (1) information, (2) comprehension, and (3) voluntariness.[49] Researchers should inform research subjects about the research procedure and its purpose, anticipated benefits, and possible risks.[50] Additionally, they should allow subjects to withdraw at any time from the research and offer them an opportunity to ask questions.[51] Moreover, researchers should present the information in a manner and context that is easy to understand to ensure comprehension by research subjects. Finally, researchers must ensure that research subjects agree to participate in the research voluntarily without undue influence, coercion, or improper inducement.[52]

2. Beneficence

Second, beneficence includes the following two principles: (1) do not harm (nonmaleficence) and (2) maximize possible benefits and minimize possible harms.[53] This principle has been the cornerstone of patient care ethics.[54] Medical research, however, is different because it seeks to understand the risks and benefits of the therapy under investigation.[55] Thus, it necessarily involves risk and human subjects may be harmed in the process.[56] Therefore, researchers and members of their institutions must seek to maximize the benefits and reduce the risks of the research by engaging in a cost/benefit analysis of their research.[57]

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[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.* at 743.
[49] *Id.* at 745.
[50] *Id.*
[51] *Id.*
[52] *Id.* at 746.
[53] *Id.* at 743.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.* at 744.

3. Justice

Finally, the principle of justice is a question of fairness in distribution[58] and is often overlooked. It concerns who ought to receive the benefits of research and who bears its burden.[59] A person who is entitled to a benefit must receive it to prevent injustice.[60] Likewise, a person must not bear a burden unless she is reasonably required to.[61] Scholars use different formulations to ensure the just distribution of benefits and burdens: to each person (1) an equal share, (2) according to individual need, (3) according to individual effort, (4) according to societal contribution, and (5) according to merit.[62] These different formulations are helpful tools that are employed in different contexts. Finally, researchers must heed the principle of justice when selecting their research subjects to ensure that they do not systematically select subjects—for example, racial minorities or persons confined to institutions—because of their easy availability or disadvantaged position.[63]

2. Federal Regulations

In 1974, the Department of Health, Education, and Welfare (now the Department of Health and Human Services (DHHS)) started to adopt regulations regarding human subjects in medical research.[64] The DHHS continued to adopt various regulations until it adopted the Federal Policy for the Protection of Human Subjects in 1991.[65] These collective regulations are known as the Common Rule.[66] Several federal agencies have adopted the Common Rule to conduct, support, and regulate medical research.[67]

The Common Rule incorporates the basic ethical principles of the Belmont Report and offers additional protection for vulnerable populations such as mentally disabled persons, prisoners, and children.[68] Furthermore, the Common Rule requires (1) assurances, (2) institutional review boards, and (3) informed consent.[69] First, any institution that conducts federally funded human research must submit a written assurance that researchers will comply with the Common Rule.[70] Second, an Institutional Review Board (IRB) must oversee the research.[71] Finally, researchers must ensure that the research complies with the requirements of informed consent.[72]

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[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.* at 745.
[64] *Id.* at 749.
[65] *Id.* at 750.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*

3. Common Law

Perhaps the first and most famous case that concerned medical research was *Moore v. Regents of the University of California* where the Supreme Court of California ruled that a physician has a fiduciary duty to disclose all material personal interests that may influence her professional judgment.[73] However, its application is limited to situations where a physician is providing patient care as well as conducting medical research. Another case that may provide better guidance is *Grimes v. Kennedy Krieger Institute, Inc.* where the Court of Appeals of Maryland ruled that governmental regulations can create duties on the part of researchers towards human subjects. These duties may create "special relationships."[74] Additionally, the breach of these special relationships may give rise to negligence actions.[75] To be sure, this ruling is probably limited to non-therapeutic research on children.

With this background information in mind, we will examine some of the arguments that favor the regulation of nonfinancial conflicts of interest in medical research.

III. WHY SHOULD WE REGULATE NONFINANCIAL CONFLICTS OF INTEREST IN MEDICAL RESEARCH?

Several commentators argue that we should regulate nonfinancial conflicts of interest in medical research because it is (1) ethical and (2) more practical to regulate. Ethically, we need to safeguard against the dangers of nonfinancial conflicts of interest because they pose a great risk to the integrity of medical research[76] as well as the safety of research subjects.[77] Furthermore, both financial and nonfinancial interests share a common driving force[78] with a similar impact on medical research[79] and thus, require similar regulation. Additionally, the lack of a meaningful distinction between financial and nonfinancial interests calls into question the practicability of regulating one and not the other.[80]

A. Ethical Argument in Favor of Regulation

Society bears an ethical responsibility to protect the public against the risks of harm that nonfinancial conflicts of interest may create; such risks include (a) a risk to research integrity[81] and (b) a risk to the safety of human subjects.[82]

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[73] Moore v. Regents of Univ. of California, 51 Cal. 3d 120, 147 (1990).
[74] Grimes v. Kennedy Krieger Inst., Inc., 366 Md. 29, 113 (2001).
[75] *Id.*
[76] *See* Saver, *supra* note 1, at 469.
[77] *See* Rodwin, *supra* note 8, at 304.
[78] *See* Saver, *supra* note 1, at 473-74.
[79] *See* Wiersma *supra* note 31.
[80] *See* Saver, *supra* note 1, at 473-74.
[81] *See* Saver, *supra* note 1, at 469.
[82] *See* Rodwin, *supra* note 8, at 304.

1. Risk to Research Integrity

Commentators in favor of regulation argue that nonfinancial interests pose a great risk to the integrity of clinical research. In many instances, (1) a desire to publish,[83] (2) investigative zeal,[84] or (3) a researcher's commitment to her own hypotheses[85] have compromised the integrity of medical research and exposed research subjects to unnecessary risk.

For example, the Institute of Medicine (now the National Academy of Medicine) reported that the desire of some researchers to add publications to their curriculum vitaes has compromised the integrity of some medical research.[86] Such research exposed subjects to unnecessary risk to achieve very little for the medical community.[87] Furthermore, a *New England Journal of Medicine* study—examining treatment for mild gestational diabetes during pregnancy—exposed research subjects to unnecessary harm.[88] Critics of the study believe that the researchers prioritized the interests of the research over subject safety as a result of their investigative zeal.[89] Yet another example is Dr. Thomas Starzl who was a pioneer in transplantation research at the University of Pittsburgh. Dr. Starzl aggressively switched his patients to a new immunosuppressant drug even though he did not have any financial interest in the new drug.[90] Critics of Dr. Starzl allege that he unnecessarily exposed his patients to harm by switching them to the new therapy because of his passion for research.[91]

In addition, some researchers become so deeply invested in their hypothesis that they become no longer capable of objectively interpreting the evidence.[92] Many scientists have indeed reported difficulties being objective because of their intellectual commitment.[93] Ideally, scientific research should be a dispassionate pursuit of facts.[94] According to scientists, a researcher should be trained to test her hypothesis by trying to disprove it rather than prove it.[95] But in reality, researchers are human beings who have their own biases.[96] If unaware of one's own biases, a researcher becomes an advocate for a preferred hypothesis instead of an objective seeker of truth.[97] Consequently, biased researchers may produce biased results, thus limiting the usefulness of the research while exposing research subjects to unnecessary risks.

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[83] *See* Saver, *supra* note 1, at 469.
[84] *Id*.
[85] Eliot Marshall, *When Does Intellectual Passion Become Conflict of Interest?*, 257 SCIENCE 620, 620 (1992).
[86] *See* Saver, *supra* note 1, at 469.
[87] *Id*.
[88] *Id*.
[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] *See* Marshall, *supra* note 85, at 620.
[93] *See* Rodwin, *supra* note 4, at 174-75.
[94] *See* Marshall, *supra* note 85, at 620.
[95] *Id*. at 621.
[96] *Id*. at 620.
[97] *Id*.

2. Risk to Research Subjects

As mentioned above, medical research necessarily involves a risk to research subjects because its goal is to learn the benefits and risks of the therapy under study.[98] Researchers must manage this inherent risk to protect the safety of human subjects. Failure to do so may result in harm to research subjects, thus violating the nonmaleficence bioethical principle. History is replete with unethical experiments that caused harm to human subjects such as the medical experiments conducted by Nazi physicians during the war.[99]

In the United States, researchers have conducted similarly egregious experiments on human subjects. Perhaps the most obvious example is the Tuskegee Syphilis Study which did not involve financial interests.[100] The goal of the Tuskegee study was to "satisfy scientific curiosity" about the long-term health effects of untreated syphilis.[101] Unfortunately, the Tuskegee study was not an isolated incident. A nine-member committee, that was formed to investigate the circumstances surrounding the Tuskegee experiment, concluded that unethical conduct plagued medical research at the time.[102] For example, other unethical experiments included the injection of cancer cells into elderly patients at the Jewish Chronic Disease Hospital, deliberate infection of mentally disabled children with hepatitis, whole-body irradiation treatment of cancer patients at the University of Cincinnati, and drug research on prisoners.[103] These appalling examples targeted disadvantaged individuals and minorities such as African Americans, elderly patients, and mentally disabled children, thus violating the bioethical justice principle. In short, without proper regulation, causing harm to human subjects would violate many bioethical principles including nonmaleficence and justice.

B. Practicability Argument in Favor of Regulation

Many writers argue that the efforts to distinguish between financial and nonfinancial conflicts of interest have already failed.[104] This is because both types of interest (a) share a common driving force,[105] (b) have a similar impact on medical research,[106] and (c) are essentially indistinguishable.[107] Consequently, they are entwined and cannot be separated and thus, require similar regulation.

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[98] *See* Shekelle *supra* note 29.
[99] Jay Katz, *Human Experimentation and Human Rights*, 38 St. Louis U. L.J. 7, 8 (1993).
[100] *See* Saver, *supra* note 1, at 468.
[101] *See* Wiersma *supra* note 31.
[102] Jerry Menikoff, *Could Tuskegee Happen Today?*, 1 ST. LOUIS U.J. HEALTH L. & POL'Y 311, 314 (2008).
[103] *Id*. at 314-15.
[104] *See* Wiersma *supra* note 31.
[105] *See* Saver, *supra* note 1, at 473-74.
[106] *See* Wiersma *supra* note 31.
[107] *Id.*

1. Financial And Nonfinancial Conflicts of Interest Share a Common Driving Force

Professor Saver argues that financial and nonfinancial conflicts of interest share a common driving force.[108] For example, the psychological and social forces that drive a researcher's bias in financial interest situations are the same forces that drive her bias if the interest was nonfinancial.[109] These forces may include indebtedness and reciprocity.[110] For this reason, the law regulates even de minimis financial gains because these gains may psychologically influence the researcher.[111] Similarly, nonfinancial relationships—such as a researcher's feeling of indebtedness to her subjects—may produce bias.[112] Therefore, the law should regulate these nonfinancial conflicts of interest.

2. Financial And Nonfinancial Conflicts of Interest Have a Similar Impact on Medical Research

Furthermore, both types of conflicts of interest have a similar impact on medical research. In fact, the impact of nonfinancial interests may go beyond medical research.[113] It may influence policymaking and legislation which may, in turn, affect public health and medical research.[114] For example, the view of policymakers on the moral status of embryos has placed restrictions on stem cell research in the United States.[115] Therefore, the law should regulate nonfinancial conflicts of interest like financial conflicts of interest.

3. Financial And Nonfinancial Conflicts of Interest Are Indistinguishable

Finally, several commentators find no meaningful distinction between the two types of conflicts of interest.[116] Many argue that the pharmaceutical industry has exploited this fact to its advantage.[117] For example, pharmaceutical companies influence key opinion leaders by collaborating with them and offering financial and nonfinancial incentives.[118] In that context, financial incentives may include consultation fees and the like, whereas nonfinancial incentives may include recognition as an expert, increased status, and enhanced reputation.[119] This industry-physician relationship illustrates the entanglement of both types of interests.

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[108] *See* Saver, *supra* note 1, at 474.
[109] *Id*.
[110] *Id*.
[111] *Id*.
[112] *Id*. at 475.
[113] *See* Wiersma *supra* note 31.
[114] *Id*.
[115] *Id*.
[116] *Id*.
[117] *Id*.
[118] *Id*.
[119] *Id.*

Another example of this entanglement involved the death of Jesse Gelsinger who was a participant in a gene therapy study at the University of Pennsylvania.[120] The study aimed to evaluate risky procedures to treat a rare genetic liver disorder.[121] Researchers failed to follow the research protocol and Gelsinger died as a result. One of the researchers, James Wilson, had patents on some aspects of the procedure in addition to other financial interests.[122] Wilson, however, maintained that his interest in financial gain played little part in this tragedy.[123] It was rather investigative zeal, academic passion, and other nonfinancial pressures.[124] To him, it was about "leadership, notoriety, accomplishment, and publishing in first-rate journals."[125] Since the boundary between financial and nonfinancial interests is not always clear, nonfinancial conflicts of interest should also be regulated.[126]

To sum up, because nonfinancial conflicts of interest (1) may create a risk to research integrity, (2) may harm human subjects, (3) share a common origin with financial interests, (4) have a similar impact, and (5) essentially indistinguishable from financial interests, many scholars favor regulation.

IV. WHY SHOULD WE NOT REGULATE NONFINANCIAL CONFLICTS OF INTEREST IN MEDICAL RESEARCH?

On the other hand, several commentators disfavor the regulation of nonfinancial conflicts of interest in medical research for ethical and practical reasons. Ethically, they argue that focusing on nonfinancial conflicts of interest (1) diverts our attention from financial conflicts of interest which are more problematic,[127] (2) conflates bias with conflict of interest,[128] and (3) undermines the diversity of perspectives in medical research.[129] Furthermore, nonfinancial conflicts of interest are not easy to detect because they are everywhere, thus regulation will be difficult to implement[130] and will remove desirable incentives to do medical research.[131]

A. Ethical Argument Against Regulation

Shifting our focus to nonfinancial conflicts of interest (a) diverts attention from the more problematic financial conflicts of interest, (b) conflates bias with conflict of interest, and (c) undermines diversity in medical research.

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[120] *See* Saver, *supra* note 1, at 473.
[121] *Id*.
[122] *Id*.
[123] *Id*.
[124] *Id*.
[125] *Id*.
[126] *See* Saver, *supra* note 1, at 472.
[127] *See* Bero, *supra* note 3.
[128] *See* Rodwin, *supra* note 4, at 177.
[129] *See* Grundy, *supra* note 5, at 6.
[130] *See* Rodwin, *supra* note 4, at 180.
[131] *Id*. at 177.

1. Nonfinancial Interests Diverts Attention from The More Problematic Financial Interests

First, the focus on nonfinancial conflicts of interest may be problematic because it diverts our attention from financial conflicts of interest which—according to many studies—are more likely to influence the results of research.[132] This shift in focus will likely require a similar treatment of both types of conflicts of interest.[133] Consequently, we face two undesirable choices: (1) the deregulation of financial conflicts of interest or (2) the regulation of nonfinancial conflicts of interest. In fact, at least one commentator has called for the deregulation of financial conflicts of interest.[134] Conversely, others have called for the regulation of nonfinancial conflicts of interest.[135] Either path will probably have a negative effect on medical research.

If we regulate nonfinancial conflicts of interest, the government will probably fail to effectively enforce the new regulations due to limited resources. For example, the Office for Human Research Protections (OHRP), which is responsible for enforcing the Common Rule, will unlikely be able to efficiently allocate its resources because it has already been experiencing a significant decline in the number of investigations conducted in recent years.[136] Therefore, the OHRP will either shift its resources to enforce the new regulations on an already declining number of cases or will continue to focus on financial conflicts of interest leaving the new regulations unenforced.

Furthermore, if we choose to deregulate financial conflicts of interest, we will likely compromise research integrity and possibly harm human subjects. Such undesirable results are possible because several studies have indicated that financial conflicts of interest are more likely to influence research results.[137] This will cause a decline in research quality and may result in decreased confidence in the research industry. Additionally, the deregulation of financial conflicts of interest may cause public distrust in science allowing for the spread of misinformation.

2. Bias Is Not a Conflict of Interest

Professor Rodwin argues that although many nonfinancial interests may create bias, they do not necessarily constitute conflicts of interest that require regulation.[138] For example, many scientists reported that their commitment to certain ideas or schools of thought made it harder for them to be objective.[139] Yet the law does not and should not concern itself with personal biases such as a commitment to a certain idea, a desire to

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[132] *See* Bero, *supra* note 3.
[133] *See* Rodwin, *supra* note 26.
[134] *Id.*
[135] *See* Saver, *supra* note 1, at 467.
[136] *See* Dolgin & Shepherd, *supra* note 36, at 754.
[137] *See* Bero, *supra* note 3.
[138] *See* Rodwin, *supra* note 4, at 177.
[139] *Id*. at 174-75.

publish, or an interest in promotion and career advancement.[140] These interests do not interfere with the researcher's obligations to her human subjects.[141]

To illustrate, consider a researcher who represents a certain idea or a school of thought and who wants to publish a study to receive a promotion. First, the researcher's commitment to a certain idea or a school of thought is probably known to other scientists who will probably review her work and confirm its validity.[142] In fact, this is how scientific inquiry works—by debating, criticizing, and testing competing theories.[143] Furthermore, the researcher's desire to publish should not affect the results of her research because the ability to publish does not depend on what the study concludes.[144] Finally, the researcher's desire to receive a promotion is, in fact, an incentive for her to excel at her work.[145]

Conversely, the law regulates conflicts of interest in many other areas such as the legal profession because they can potentially compromise loyalty or limit a person's ability to perform an obligation.[146] Regulating bias in a similar fashion would conflate it with conflict of interest.[147] This will result in distorting the concept of a conflict of interest and will turn it into another synonym for bias. Therefore, it is important to keep these two concepts distinct because they do not refer to the same thing.

3. Diversity of Perspectives Is Necessary to Advance Scientific Knowledge

Scientists come from diverse backgrounds holding different beliefs whether it be personal, religious, social, or political. Moreover, they have different education, training, and unique experiences. Thus, they bring their own unique perspectives to the research environment which enrich the scientific discourse.[148] Similar to the marketplace of ideas concept that was introduced by Justice Oliver Wendell Holmes Jr. in First Amendment cases,[149] scientific theories compete, and the best ones prevail. Rigorous scientific inquiry entails that kind of competition to ensure that scientists have applied enough scrutiny to confirm their theories.

If we consider these personal perspectives to be undesirable conflicts of interest that require recusal, only individuals with certain personal attributes and beliefs—typically white, secular, and male—will claim objectivity.[150] Put differently, only *approved* ideas or schools of thought get to compete because other ideas are deemed biased and are excluded

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[140] *See Id*. at 177.
[141] *See Id*. at 179.
[142] *Id*. at 178-79.
[143] *Id*. at 179.
[144] *Id*. at 177.
[145] *Id*.
[146] *See* Model Rules of Pro. Conduct R. 1.7 (Am. Bar Ass'n 2021).
[147] *See Id*.
[148] *See* Bero, *supra* note 3.
[149] Abrams v. United States, 250 U.S. 616, 630 (1919).
[150] *See* Grundy, *supra* note 5, at 6.

from the debate.[151] As a result, we end up with a narrow and restricted scope of scientific inquiry that undermines our marketplace of ideas. A better solution would be to let good theories prevail through the free exchange of ideas.

B. Practicability Argument Against Regulation

Several commentators argue that it is not feasible to regulate nonfinancial conflicts of interest because such regulations (1) will be difficult to implement[152] and (2) will remove desirable incentives to do scientific research.[153]

1. Implementation Challenges

Several commentators find it difficult to implement nonfinancial conflicts of interest regulations because they (1) are hard to identify and control[154] and (2) would require an enormous scope of regulation.[155] First, nonfinancial interests include motives and considerations other than direct economic gain.[156] This broad definition captures many interests that are intangible and not easily detected.[157] Thus, even if a regulation is put in place to manage such interests, authorities may not effectively enforce it because these interests are subjective, not quantifiable, and hard to manage. In contrast, financial interests are tangible and easier to observe.[158] Thus, they are easier to manage because they are more objective and quantifiable.[159]

Furthermore, nonfinancial interests are ubiquitous.[160] Absolute objectivity is simply not possible.[161] For example, professionals everywhere have an interest in their good reputation, promotion, and career advancement.[162] Researchers may have additional interests concerning their personal beliefs—grounded in religious, philosophical, or political ideas—that may influence their conduct.[163] As mentioned earlier, the definition of nonfinancial conflicts of interest is broad enough to include these interests. Put differently, nonfinancial interests range from personal beliefs—even certain diets[164]—that have minimal effect on a researcher's conduct to researcher-industry relationships that may have a greater influence on conduct. As a result of this wide variation of these interests, they would require an enormous scope of regulations.[165] In addition, such regulations will

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[151] *See Id*.
[152] *See* Rodwin, *supra* note 4, at 180.
[153] *Id*. at 177.
[154] *See* Saver, *supra* note 1, at 469.
[155] *See* Rodwin, *supra* note 4, at 180.
[156] *See* Saver, *supra* note 1, at 468.
[157] *Id.* at 469.
[158] *Id*.
[159] *Id*.
[160] *See* Rodwin, *supra* note 4, at 180.
[161] *Id*. at 177.
[162] *Id*.
[163] *See Id*.
[164] *See* Grundy, *supra* note 5, at 6.
[165] *See* Rodwin, *supra* note 4, at 180.

probably face First Amendment constitutional challenges because they will implicate personal and religious beliefs.

2. Removal of a Legitimate and Desirable Incentive to Do Medical Research

Professor Rodwin argues that some nonfinancial conflicts of interest are, in fact, beneficial to medical research.[166] For example, a researcher who wants recognition would be more likely to perform her job very well and exceed the required standards to ensure earning that recognition.[167] Put differently, professional employees earn promotions by excelling at their jobs because they are incentivized to do so to advance in their careers. Consequently, their influential work will raise the standard pushing everybody else to compete by excelling at their work as well. This competition is ultimately beneficial for the advancement of science and human knowledge. Additionally, consider a researcher who represents an idea or a school of thought; she is more likely to examine her position with scrutiny because she knows that other scientists will put her theories to the test. As a result, adopting, defending, and criticizing different schools of thought enriches the process of scientific inquiry through the free exchange of ideas. These examples illustrate why some nonfinancial interests are beneficial to medical research.

Now imagine the state of medical research without these benefits. Consider, for example, a researcher who, because of new regulations, cannot earn a promotion after conducting her research; what motivates her to excel at her job? What motivates her to ensure the quality and accuracy of her work? What motivates her to even conduct medical research? Maybe altruism is part of her motivation but is probably not sufficient to motivate enough researchers to conduct medical research. Furthermore, absolute objectivity in medical research is an unattainable goal; perhaps even an undesirable one because it would require researchers to be totally disinterested parties without much at stake in their work. Fearful of being labeled biased, these disinterested researchers would not be motivated to debate different ideas. Ultimately, the research quality will probably deteriorate, and fewer people will pursue careers in medical research due to the lack of incentives. Thus, some nonfinancial interests are not only legitimate but also desirable.

To sum up, because the focus on nonfinancial conflicts of interest (1) may divert our attention from financial conflicts of interest, (2) conflates bias with conflict of interest, (3) undermines diversity in medical research, and (4) regulation will be difficult to implement and will remove desirable incentives to do scientific research, many scholars oppose regulation.

V. DISCUSSION

After highlighting prominent arguments on both sides, the question now is: should we regulate nonfinancial conflicts of interest in medical research? Perhaps this question is twofold: (1) Are nonfinancial conflicts of interest completely harmless? Or do we need to

[166] *Id.* at 177.
[167] *Id.*

safeguard against their potentially harmful effects? And if we need protection, (2) what kind of measures should we take? This paper concludes that nonfinancial conflicts of interest require the implementation of safeguards to protect against their potentially harmful effects and suggests that adopting clear institutional policies is an adequate solution.

A. Are Nonfinancial Conflicts of Interest Innocuous or Potentially Harmful?

Nonfinancial conflicts of interest can be potentially harmful and thus require the implementation of safeguards to protect against their potentially dangerous effects. There is no doubt that nonfinancial conflicts of interest deserve our attention, considering that the atrocities committed by the Nazi physicians and the Tuskegee researchers under the guise of medical research involved nonfinancial interests such as "scientific curiosity."[168] Indeed, we need to protect human subjects and research integrity, as well as maintain public trust in the research enterprise.

1. Protection of Human Subjects

As mentioned earlier, medical research involves risk to human subjects, thus we need to have measures in place to protect against nonfinancial interests that may exacerbate those risks. Additionally, nonfinancial conflicts of interest may undermine the four basic bioethical principles: (1) autonomy, (2) beneficence, (3) nonmaleficence, and (4) justice. The Tuskegee study, for example, violated all four principles. First, the researchers did not properly inform the subjects of the risks or purpose of the study, thus violating their autonomy by not obtaining their informed consent. Second, the risks of harming human subjects far outweighed the benefits of learning about the progress of syphilis, thus violating the beneficence principle. Third, the researchers directly harmed the human subjects by not providing available treatment leaving them to suffer for years, thus violating the principle of nonmaleficence. Finally, the study targeted impoverished African American individuals and promised them free medical care, thus violating the principle of justice. Therefore, we need to have measures in place to protect human subjects against the potentially harmful effects of nonfinancial conflicts of interest.

2. Protection of Research Integrity to Maintain Public Trust in The Research Enterprise

Furthermore, if left unaddressed, nonfinancial conflicts of interest can potentially compromise research integrity and undermine public trust in the research enterprise. If we allow another Tuskegee-like study to take place today, the public will lose trust in medical researchers and our institutions. Losing public trust in the research enterprise may have disastrous consequences. Specifically, it may open the door for anybody to discredit our institutions and spread misinformation. As a result, negative public health consequences will follow similar to the vaccine hesitancy effect during the COVID-19 pandemic.

[168] *See* Saver, *supra* note 1, at 468.

Therefore, not only do we need to safeguard against impropriety in medical research but also against the appearance of impropriety to maintain public trust in our institutions.

B. What Kind of Measures Should We Take?

Applying a Kantian approach, we would probably focus on the prevention of harm and would find that regulation is appropriate because it would prevent the harmful effects of nonfinancial conflicts of interest. A Kantian approach focuses on the act itself and does not consider the consequences of such regulations which may include intrusion of personal liberties. As mentioned earlier, the IOM definition of conflicts of interest is broad enough to include personal, political, and religious beliefs. Thus, a regulation that targets personal interests is likely more intrusive than a regulation that focuses on duties. Therefore, a less intrusive measure may be more desirable because excessive regulation may stifle medical research which is more harmful to our society.

A utilitarian approach, on the other hand, would consider the risks and benefits of regulation. Under a utilitarian approach, we would find that the risk of stifling medical research probably outweighs the benefits we will receive from regulation. Professor Heidi M. Hurd—a legal scholar and an ethicist—argues that when answers conflict, deontological approaches such as Kantianism should "patrol the borders of consequential justification."[169] Put differently, we should use a utilitarian approach in most cases, but in extreme cases, we should use Kantianism. Applying this principle, we would consider the costs and benefits of regulating nonfinancial conflicts of interest, but outlaw extreme cases such as when a researcher intentionally harms a human subject.

Thus, the implementation of clear institutional policies provides an adequate solution because it strikes the right balance between the benefits and risks of nonfinancial conflicts of interest. On the one hand, nonfinancial conflicts of interest may pose a risk but on the other, it provides an incentive for scientists to do research and advance our scientific knowledge. Therefore, regulation may excessively restrain researchers if they fear punishment for holding a personal view or a desire to earn a promotion. Such a research environment will probably stifle medical research. Therefore, unless a nonfinancial conflict of interest compromises the researcher's duty or obligation, it should not be regulated.[170]

Good institutional policies should include (a) individual-focused policies, (b) process-focused policies, and (c) outcome-focused policies.

1. Individual-Focused Policies

Individual-focused policies are policies that are directed toward the individual conduct of the researcher. They include (i) reflexivity, (ii) disclosure, and (iii) recusal.

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[169] Heidi M. Hurd, *The Deontology of Negligence*, 76 B.U. L. REV. 249, 254 (1996).
[170] *See* Rodwin, *supra* note 4, at 165.

i. Reflexivity

Reflexivity is the "examination of one's own beliefs, judgments, and practices during the research process and how these may have influenced the research."[171] Both the researcher and the institution may use reflexivity to examine their motives and potential biases.[172] Examples of key questions for reflexivity include the following:

- Who is the researcher?
- What are their *professional* identities? What is their discipline, educational background, or training? What is their career stage, and are they in a position of power or influence? What is their area of research or theoretical perspective? What are their advocacy positions?
- What are their relevant *personal* identities, including age, race/ethnicity, gender, religious or political affiliations, and life experience?
- How could they affect the design, conduct, or reporting of research?
- Who or what is the focus of the research? for whom does this have consequences? What are these consequences?
- Who or what is placed at risk by this research? How?
- Who or what is advantaged by this research? How?
- What are the ethical, social, political, or economic implications of this research?[173]
- Using reflexivity as a useful tool to examine one's own motives and biases is a good first step that should be followed by either disclosure or recusal.

ii. Disclosure

Disclosure is a simple and widely accepted solution, especially in the case of financial conflicts of interest.[174] Moreover, major guidelines have adopted it.[175] It includes the disclosure to one's own institution, peer reviewers, research subjects, and publishing journals.[176] Disclosure, however, has two main limitations that we should address to make it more effective. First, it is not clear how researchers, peer reviewers, or research subjects

[171] Michael Hammond, *Reflexivity*, EDUC. STUDIES, UNIV. OF WARWICK, COVENTRY, U. K. https://warwick.ac.uk/fac/soc/ces/research/current/socialtheory/maps/reflexivity/ (last visited Dec. 14, 2023).
[172] *See* Bero, *supra* note 3.
[173] *Id*.
[174] *See* Romain, *supra* note 32.
[175] *Id*.
[176] *Id*.

may interpret it.[177] For example, a research subject may believe that a study is going to be invalid because of the researcher's biases and may refuse to participate in it after learning about the researcher's conflicts of interest. We may address this issue by ensuring that researchers educate research subjects during the process of obtaining informed consent about the meaning and limitations of conflicts of interest disclosure.

Second, most academic journals do not have clear policies on the disclosure of nonfinancial conflicts of interest.[178] We may address this issue by encouraging academic journals to adopt clear policies to ensure that researchers understand what a nonfinancial conflict of interest is and why it is important to disclose it.

iii. Recusal

Recusal may have been more common in cases involving strong financial conflicts of interest such as holding significant equity interest that may be affected by the research results.[179] Similarly, strong nonfinancial conflicts of interest should require the recusal of the conflicted party. Again, this requires the adoption of clear policies on nonfinancial conflicts of interest and educating researchers and other stakeholders on the dangers of failure to disclose.

2. Process-Focused Policies

Process-focused policies are policies that focus on the methods of investigation, data analysis, and the presentation of the research.[180] Such policies may include educating researchers on the various elements of research design that may influence research outcomes.[181] For example, educating researchers on how to limit bias by ensuring adequate blinding, adequate control groups, and proper analytic techniques.[182] Additionally, these policies should guide Institutional Review Boards (IRBs) to not only ensure the absence of conflicts of interest in the study but also within the board itself.[183] Moreover, IRBs should have policies to ensure a thorough review of research protocols and supervision of the research process.[184]

Process-focused policies often have two major limitations that we need to address to make them more effective. First, many researchers find excessive policies that micromanage the research process intrusive and burdensome.[185] Moreover, these intrusive policies may have a negative impact on medical research. For example, they may unreasonably prolong the research process. Additionally, researchers—who want to ensure

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[177] *Id*.
[178] Khaled Shawwa et al., *Requirements of Clinical Journals for Authors' Disclosure of Financial and Non-Financial Conflicts of Interest: A Cross Sectional Study*, 11 PLoS ONE, no.3, 2016, at e0152301.
[179] *See* Romain, *supra* note 32.
[180] *Id*.
[181] *Id*.
[182] *Id*.
[183] *Id*.
[184] *Id*.
[185] *Id*.

compliance with such intrusive policies—may become overly cautious in interpreting the results of their research. Put differently, they may overcompensate in their attempt to ensure that the outcomes of their research are unbiased. Therefore, we must strike the right balance between the implementation of such policies and giving enough freedom to researchers to exercise their scientific judgment.

Secondly, IRBs are usually poorly equipped to identify nonfinancial conflicts of interest within themselves because their focus is usually on financial interests.[186] Therefore, they should expand their policies and guidelines to capture both financial and nonfinancial conflicts of interest.

3. Outcome-Focused Policies

Outcome-focused policies are policies that ensure that the editorial process involves the review of the research outcome by a skilled and non-conflicted scientist.[187] In other words, peer review ensures that the research outcomes have been confirmed by another scientist who does not share the same biases as the researcher who conducted the study. At least one expert suggested that peer review is a "great protection against conflicts of interest."[188]

VI. CONCLUSION

Because nonfinancial conflicts of interest (1) may create a risk to research integrity, (2) may harm human subjects, (3) share a common origin with financial interests, (4) have a similar impact, and (5) essentially indistinguishable from financial interests, we need to implement safeguards to protect against their harmful effects.

But because too much focus on nonfinancial conflicts of interest (1) may divert our attention from financial conflicts of interest, (2) may conflate bias with conflict of interest, (3) may undermine diversity in medical research, and (4) regulation will be difficult to implement and will remove desirable incentives to do scientific research, the implementation of good institutional policy should strike the right balance between the risk and benefits of nonfinancial interests in medical research.

Good institutional policies should include (1) individual-focused policies, (2) process-focused policies, and (3) outcome-focused policies. Individual-focused policies should include (a) reflexivity, (b) disclosure, and (c) recusal in some cases. Process-focused policies should focus on the methods of investigation such as adequate blinding and study design. Outcome-focused policies should focus on editorial processes such as peer review. Additionally, academic journals should have clear policies on the disclosure of nonfinancial conflicts of interest.

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[186] *Id.*
[187] *Id.*
[188] *Id.*