2024

Ethics of Innovation: A Framework for Responsible Innovation Governance

Nicole Morris  
Emory University School of Law

Recommended Citation

This Symposium Article is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in SMU Science and Technology Law Review by an authorized administrator of SMU Scholar. For more information, please visit http://digitalrepository.smu.edu.
ETHICS OF INNOVATION: A FRAMEWORK FOR RESPONSIBLE INNOVATION GOVERNANCE

Nicole N. Morris*

ABSTRACT

Over the past several years, startups that once seemed destined for greatness have failed or collapsed because of fraud committed by the founders. Most notable are the Theranos and FTX business collapses, which culminated in the convictions of two infamous entrepreneurs, Elizabeth Holmes and Sam Bankman-Fried, respectively. Startup innovators are not alone when it comes to morally dubious behavior. According to Retraction Watch, nearly 5000 papers published in science & engineering journals were retracted in 2022.1 Research misconduct allegations eventually led to the resignation of Stanford University President Marc Tessier-Lavigne in July 2023.2 The research scandal at Stanford received lots of public attention. Absent such public scrutiny, however, organizations are slow to act on allegations of research falsification. This raises several important questions: are these occurrences becoming more frequent? What governance frameworks are available to effectively detect and prevent such misconduct and fraudulent behavior?

This Essay examines the current business ethics and corporate governance framework applicable to innovation, argues that it lacks sufficient safeguards to prevent misconduct and promote responsible practices. This Essay offers a two-pronged approach to address the ethical void in innovation. First, the implementation of stricter oversight by federal agencies (such as NSF or NIH), including penalties for non-compliance. Second, the legal profession must play a more active role in shaping and advising on ethical frameworks for responsible innovation. Lawyers can play a crucial role in evaluating both

https://doi.org/10.25172/smustlr.27.1.4

* Professor of Practice, Director of Innovation & Legal Tech, TI:GER® Program Director, Emory University School of Law. This work was presented as part of the SMU Science & Technology Law Review 2024 Symposium. I am tremendously grateful for the feedback and guidance received from Dorothy Brown, Martin Sybillis, Wendy Muchman, Myles Lynk, Keith Swisher, Edward Queen III and others; Excellent research assistance was provided by Anshu Garg and Sang Park and the library staff of the MacMillan Law Library at Emory University.


the risks and benefits of innovation, while also utilizing innovative tools to improve legal service delivery. By combining enhanced oversight with deeper legal involvement, we can create a more robust and comprehensive framework that fosters responsible innovation governance.

INTRODUCTION

In a competitive market, speed and product-market fit are crucial for success. However, achieving this success should not come through innovation fraud. Throughout this Essay, I use the story of Theranos to illustrate how a promising innovation failed to become a successful product. Theranos serves as a cautionary tale of how a seemingly well-intentioned company, plagued by unethical leadership and weak corporate oversight, can devolve into a fraudulent enterprise. Elizabeth Holmes, the now disgraced founder of Theranos, proposed a game-changing concept: one vial of blood, hundreds of diagnostic tests. However, the technology’s viability and business practices later came under scrutiny.³

Let’s review what happened in the Theranos scandal. Like many entrepreneurs, Elizabeth Holmes was inspired to satisfy an unmet need—provide consumers with a simple method to draw blood. In 2003, she dropped out of her engineering program at Stanford and founded Theranos, on the premise it would disrupt the business of blood testing, replacing the services provided by giants like Laboratory Corp. of America and Quest Diagnostics.⁴ Holmes wanted to build a device that would make blood testing easier and less painful.⁵ Users would prick their fingers and submit a small vial of blood—about 1.3cm—that could run hundreds of tests.⁶ There was just one problem: Theranos did not have a working prototype device.⁷ Nonetheless, Holmes continued to woo and mislead investors, hiding the fact that the technology was flawed and had serious limitations.⁸

---


⁵ See Parloff, supra note 3.

⁶ Id.


⁸ Id.
Public scandals involving fraud and misconduct are not limited to the private sector. A high-profile case of academic misconduct occurred in 2023 with the resignation of Stanford University President Marc Tessier-Lavigne.\(^9\) The resignation came after a months-long investigation into allegations of scientific misconduct.\(^10\) The university investigation found that as a neuroscientist and biotechnology executive, Dr. Tessier-Lavigne had fostered an environment that led to “unusual frequency of manipulation of research data and/or sub-standard scientific practices” across labs at multiple institutions.\(^11\) Against all odds, a freshman student reporter at the Stanford Daily brought this major story to light.\(^12\)

Does every research lab have someone like Elizabeth Holmes or Dr. Tessier-Lavigne? Some researchers speculate that the answer might be yes.\(^13\)

The absence of a comprehensive ethical framework for innovation presents challenges. First, it undermines research integrity by leaving researchers to navigate complex ethical dilemmas without clear guidelines. This can lead to inadvertent misconduct or a chilling effect on research exploration. Second, a lack of robust ethical standards erodes investor confidence. Imagine a world where venture capitalists, wary of unforeseen harms, shy away from promising early-stage companies, demanding mountains of data and proof of concept before taking a chance. This hesitancy would hinder the very breakthroughs that could benefit society. Moreover, the most significant problem (or true cost) with innovation fraud extends beyond lost opportunities. Resources—time, money, and grant funding—are squandered on fraudulent research and technology, diverting them from credible innovation initiatives.

Exploring the ethical complexities of innovation fraud through a novel lens, this Essay argues for a paradigm shift towards a more accountable governance framework. This Essay proceeds in three parts. Part I provides a primer on the product innovation process. Product development and technology commercialization efforts are critical components in any innovation endeavor. Part I spotlights specific product development failures to showcase the key differences between such challenges and outright fraudulent intent. Part II critically examines the frameworks that govern the innovation process. On the academic side, there are few guardrails to monitor innovators and deter misconduct. On the private sector side, innovators are governed by company norms and their own moral code. The line between product development failure and innovation fraud is thin. The current approaches to address innovation fraud do not provide adequate measures to deter deceptive practices. Part III provides a normative approach for decreasing the number of fraudulent occurrences. Specifically, the Essay proposes two novel mitigation strategies for addressing innovation fraud. 14 One approach involves greater support for whistleblowers and a permissive framework that allows attorneys to disclose confidential information. The second mitigation strategy involves greater oversight and action by the federal agencies that fund research. The grant recipients who commit innovation fraud should be required to pay restitution to the federal agencies. This approach creates an incentive structure that will reduce the number of research misconduct incidents. By implementing these measures, we can strive to mitigate the occurrence of innovation fraud, ensuring that the pursuit of progress remains grounded in ethical principles.

I. FAILURE OR DECEPTION: NUANCES OF PRODUCT DEVELOPMENT OUTCOMES

A. Beyond Features: Unveiling the Good, Bad, & Ugly of Product Development

Product development is the process of transforming ideas into commercially viable products. It bridges the gap between technological innovation and market adoption. Bringing a new product from concept to market is an iterative journey. It is a constant dance between business needs, market trends, user

---

14. This Essay will explore instances of scientific misconduct and fraud specifically within the realm of technological innovation in both the private sector and academic institutions. The Essay will not delve into purely financial fraud schemes. Moreover, this Essay is not the first to recognize the harm caused by scientific misconduct. See, e.g., Dan L. Burk, Research Misconduct: Deviance, Due Process and the Disestablishment of Science, 3 GEO. MASON IND. L. REV. 305 (1995) (detailing the role that scientific misconduct is playing in shaping the future of science); Patrick O’Leary, Policing Research Misconduct, 25 ALB. L.J. SCI. & TECH. 39 (2000) (considers a variety of regulatory changes aimed at generating more reliable data to measure the scope of the misconduct problem and improving enforcement when misconduct occurs).
feedback (through prototype testing MVP), pricing considerations, and artistic vision, all within the constraints of resources and technology. An initial idea can morph significantly through this process, with the final product often bearing only a distant resemblance to its earliest iteration. This is best illustrated by the product development funnel:

![Product Development Funnel Diagram]

Some examples of companies with successful product development strategies include Apple (iPhone), Byte Dance (Tik Tok), and Microsoft (Office software). “Why do some companies move quickly and efficiently to bring to market outstanding new products, while others expend tremendous resources to develop products that are late and poorly designed?” This question is a frequently discussed topic in business schools across the country. The answer varies but usually includes the ability to produce a meaningful and superior product that delivers value to the customer and effective project management strategies. As one study notes, “product meaningfulness concerns the benefits users receive from buying and using the product whereas product superiority captures the extent to which a new product outperforms competing products.”


16. Id.


Bringing technology to market exposes it to real-world user experiences and challenges. What happens when the product development process is unsuccessful or when there is a failed product launch? Well, here are three high-profile examples: Samsung Note 7, Google Glass, and New Coke.

1. The Samsung Galaxy Note S7, a tablet phone that launched in August 2016, was initially well received. However, it had a serious flaw. A problem with the battery software resulted in the phones catching fire on several occasions, including once on a Southwest Airlines flight, which had to be evacuated. Soon, the Department of Transportation made it illegal to bring a Note 7 on a commercial flight.20 By October 2016, after an extremely expensive recall21, Samsung permanently ended production of the Note 7 worldwide.22

2. When Google Glass, wearable smart glasses, debuted in 2013, it was touted as the future of augmented reality.23 It was publicly available for purchase in 2014 but was withdrawn from the market in 2015.24 The camera feature allowed users to take photos or record videos using the glasses which raised serious privacy concerns. Google Glass was marketed as a luxury item with a high price, but the company failed to gain traction outside of its niche customer base.

3. In April 1985, The Coca-Cola Company took arguably the biggest risk in consumer goods history, announcing that it was changing the formula for the world’s most popular soft drink, and spawning consumer angst the likes of which no business has ever seen.25 “The Coca-Cola Company introduced reformulated Coca-Cola, often referred to as

---


‘new Coke,’ marking the first formula change in 99 years.”

“The company didn’t set out to create the firestorm of consumer protest that ensued; instead, the company intended to re-energize its Coca-Cola brand and the cola category in its largest market, the United States.”

To say that this new product launch failed miserably is an understatement. The company reintroduced the original formula, now called Coca-Cola classic, in July 1985. The return of the original formula Coca-Cola put the cap on 79 days that revolutionized the soft-drink industry, transformed The Coca-Cola Company and stands today as testimony to the power of taking intelligent risks, even when they don’t quite work as intended.

In each of these product fails, the product was launched with much fanfare and promise. However, each product failed to reach success in the market for various reasons: product safety concerns (Samsung Galaxy Note 7), privacy concerns (Google Glass) and lack of consumer demand (New Coke). The important lesson in each of these cases is how the company leadership team handled the product failure. In each case, the company withdrew the product and shared information about the product safety issues. In the case of New Coke, The Coca-Cola Company used it as a teachable moment and created a website devoted to memorializing the story. Now let’s revisit the Theranos product failure. The company hid the truth from the public and purposely misled its investors and consumers into believing that the blood testing device was functional. This kind of purposeful deceit designed to provide a perpetrator with unlawful gains is called fraud.

B. Fraud

Fraud is costly. American consumers lost $8.8 billion dollars to fraud in 2022—up 44% from 2021, according to the latest data from the Federal Trade Commission. Moreover, fraud not only harms its immediate victim, but it also generates negative externalities by reducing people’s incentives to engage in welfare-enhancing interactions with one another. Professor Jonathan Macey writes in his recent paper (Fraud in the Land of Plenty) that it does not appear to be the case that societies which experience high levels of fraud suffer.

26. Id.
27. Id.
28. Id.
from low levels of interpersonal interactions. In fact, the opposite seems to be true: wealthy societies thrive despite what appears to be widespread, even ubiquitous fraud.

Product development and scientific research are not perfect processes. As we noted in section IA, sometimes the best ideas do not translate into successful products. Similarly, there are often mistakes or errors made in the pursuit of scientific research. The problem is not the error. The problem is the deliberate effort to hide the error or mischaracterize the data as being “error-free.”

A quick note on terminology: I am using the term “innovation fraud” to broadly define fraud to include research misconduct like falsifying research data or deliberately presenting misleading data. Under this inclusive definition of fraud, I describe conduct to be fraudulent when others might characterize it as “academic misconduct or breach of research integrity.” As one author stated, scholars and members of the media, are overly cautious about the language of investigations and usage of such explicit legal terms as “corruption,” “bribery,” and “fraud,” instead choosing to replace them with such terms and euphemisms such as “academic misconduct” and “breach of integrity.” Thus, the term “innovation fraud” is intended to capture intentional acts of research misconduct that occurs in research institutions and product development fraud in the private sector.

Many employees left Theranos because they had concerns about the company’s insistence on commercializing technology that was not a finished

31. Id.
32. Id.
33. See 42 C.F.R. § 93.103 (2023).
35. Note, transgressions that stem from incompetence rather than deviance are not intentional acts for innovation fraud. This includes errors of judgment; errors in recording, selection or analysis of data; and differences of opinion involving the interpretation of data.
36. This is consistent with the requirements for findings of research misconduct stated in 42 C.F.R. §93.104 (“A finding of research misconduct made under this part requires that – (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly’ and (c) The allegation be proven by a preponderance of the evidence.”). See also Burk, supra note 14 at 311-12 (“Scientific fraud may also be more subtle than the outright fabrication of data. Data may actually be generated, but then deliberately manipulated or falsified so as to support conclusions that are incorrect.”).
product. Holmes had successfully recruited several product designers and engineers from Apple to help build the Theranos Edison device. But one by one, these former Apple employees resigned from Theranos, raising concerns about Elizabeth Holmes’s lack of transparency regarding the technology’s shortcomings. Things eventually began to unravel once WSJ reporter John Carreyrou got a tip about flaws with the device and falsified test demos; he began investigating the company and talking to current employees who later became whistleblowers. In 2015, the WSJ began reporting on questions about Theranos, revealing that only a few tests could be performed on its proprietary technology and that most tests were run on commercially available machines. The technology that propelled Theranos into stardom did not work, and the company dissolved in 2018 after facing several civil and criminal probes.

Holmes was convicted of four out of eleven counts of fraud in January 2022 for misleading investors that her innovative idea (running hundreds of tests) from a tiny sample of blood actually worked. Perhaps the most intriguing aspect of the Theranos hoax was the company’s use of intellectual property rights, both real and suspected, to establish a facade of innovation. They falsely claimed that their innovation was a trade secret to avoid having to disclose any details of what we all learned to be an inoperable medical device. The deception was fairly easy to pull off because most people know that you must keep trade secrets a “secret” to ensure protection (to have a valid trade secret). So, what initially appeared to be a groundbreaking innovation devolved into a fraudulent scheme.

38. Id.
39. Id.
41. Id.
43. Id.
44. See generally Carreyrou, supra note 36.
45. See generally id.
46. See generally id.
47. See generally id.
The rise and fall of Theranos has been documented in the book by John Carreyrou and other investigative journalists, dramatized in the Hulu series “The Dropout,” and explored in podcasts like “Bad Blood: The Final Chapter.” The story is also referenced in numerous law review articles. Theranos is the poster child for what is wrong in startup culture. For many investors, when confronted with an investment decision that is “innovation-related,” people appear to become far more tolerant of risks than they are in other, economically equivalent settings. Then there is FOMO, or Fear of Missing Out, where investors bypass a robust due diligence process for fear of missing out on the next big thing.

Unfortunately, the Theranos hoax is not the only example of what goes wrong when there is a lack of oversight of the startup founders’ authority. Meet Charlie Javice. Javice is the founder and former CEO of Frank, a student financial aid application assistance company. Javice founded Frank in 2016 as a company that assists student borrowers in obtaining loans and financial aid. Javice told her alma mater that she founded the company to make higher education more affordable after her own struggles re-negotiating financial aid at Penn. There were a series of missteps soon after the company began. Then in April 2023, the Wall Street Journal reported that the financial giant JP

48. See Carreyrou, supra note 36.
53. Id.
Morgan Chase, which acquired Frank in 2021, was suing Javice for inventing millions of fake customers to justify the bank’s $175 million acquisition of the startup. The Department of Justice charged Javice with fraud in connection with the company’s sale to JP Morgan. Like Elizabeth Holmes, she was arrested, and her trial date is set for October 2024.

The final example of a startup with a very public scandal is FTX and its founder Sam Bankman-Fried or the commonly used abbreviation, SBF. Bankman-Fried rose quickly from relative obscurity to fame thanks to his early success in bitcoin. In late 2017, only three years after graduating from MIT, SBF founded Alameda Research. Prior to starting Alameda Research, SBF was an international ETF trader at a proprietary trading firm. SBF’s investment strategy with Alameda Research was a huge success catapulting him into billionaire status and prompting the launch of a Hong Kong based cryptocurrency futures exchange FTX in 2019. By August 2021, FTX was valued at $18 billion and had just completed an industry-record $900 million


57. Id.


60. See id.


fundraising round.\textsuperscript{64} As part of an industry effort, he testified before the House Committee on Financial Services in December 2021, joining other executives to advocate for regulations on the cryptocurrency industry.\textsuperscript{65} FTX and SBF’s success was short-lived. In November 2022, CoinDesk issued a report about the Alameda Research balance sheet and its large dependence on FTT (FTT is the crypto token behind FTX).\textsuperscript{66} Then Binance CEO Changpeng Zhao decided to sell off his FTT holdings (worth about $584 million).\textsuperscript{67} Within two weeks, FTX filed for bankruptcy.\textsuperscript{68} A significant factor in the FTX collapse was the use of customer funds to support Alameda Research. The bankruptcy filing revealed that FTX loaned customer funds to Alameda, and Alameda was unable to repay the loans when it incurred significant losses in its trading operations.\textsuperscript{69} The collapse of FTX is yet another example of what goes wrong when a startup grows quickly and the founder is allowed to operate without any oversight.

Fraudulent behavior exists in academic and/or research institutions and in the private sector. Scholars have known about innovation fraud in the halls of the academy for decades. “Fraud has always existed in some form throughout the history of science among important and relevant scientists, including

\textsuperscript{64} See id.


Ptolemy, Copernicus, Galileo, Newton, Dalton, Kepler, Mendel, Freud, and Pasteur have been accused of, and arguably may have actually committed, some fraudulent research over the course of their scientific careers. Authors William Broad and Nicholas Wade disclosed this fraud in their groundbreaking book, Betrayers of the Truth: Fraud and Deceit in the Halls of Science. The authors present case studies observing fraudulent conduct that occurs during scientific research, from the manipulation of results to the total fabrication of whole experiments. Unethical research practices, like manipulating participant data or falsifying data, can erode public trust in science and lead to harmful policies based on flawed findings, ultimately jeopardizing public health and safety. The negative effects of research misconduct may not be apparent until the research is applied in practice or leads to a product’s development. Such is the case, for example, where drug therapies and other medical technologies are based on fabricated data. Misconduct often has little adverse impact, other than the waste of funds, until the scientist publishes fraudulent or misleading


72. See, e.g., Kreutzberg, supra note 70, at 330.

73. William J. Broad, After 400 Years, a Challenge to Kepler: He Fabricated His Data, Scholar Says, N.Y. Times, Jan. 23, 1990, at C1.

74. See, e.g., David Goodstein, What Do We Mean When We Use the Term ‘Science Fraud’?, TheScientist, Mar. 1, 1992, at 11 [https://perma.cc/N62W-RSWA].


76. Broad & Wade, supra note 73; see, e.g., Martina Franzen et al, Fraud: Causes and Culprits as Perceived by Science and the Media, 8 EMBO Reps. 3, 4 (2007); see also Kreutzberg, supra note 70, at 331 (noting that an overlooked reason for the growth in fraud is that fraud tends to beget more fraud; once you have gotten away from it, you do it again, each time more audaciously).

77. Broad & Wade, supra note 73.

78. Id. at 8–9.

research results in scholarly journals.\textsuperscript{80} Once published, the information pollutes the stream of knowledge, perverts the scientific process, and sends researchers on false lines of inquiry.\textsuperscript{81} Researchers apply for grants based on this fraudulent data, continuing the cycle of wasted funds.\textsuperscript{82}

Recently scientists at the Dana-Farber Cancer Institute, one of the nation’s leading cancer research and treatment centers, announced that they intend to retract one paper and correct others amid an expanding investigation of data manipulation, officials told STAT.\textsuperscript{83} The investigation includes scores of papers authored by four top scientists and institute leaders, including chief executive Laurie Glimcher and chief operating officer William Hahn.\textsuperscript{84} Dana-Farber officials disclosed that the review process began for some studies more than a year ago.\textsuperscript{85} The institute’s research integrity officer, Barrett Rollins, told STAT that while Dana-Farber has not completed reviewing all of the claims, several are serious enough that researchers are talking with journals about retracting one paper and correcting others.\textsuperscript{86}

As noted in the Stanford misconduct investigation, the student journalist’s tenacity was critical for the University to take the allegations seriously. In November 2022, the Stanford Daily published a story unveiling seven years of scientific misconduct allegations involving four papers published by Dr. Tessier-Lavigne, prompting the University to launch an investigation that uncovered a fifth paper with serious errors.\textsuperscript{87} The student journalist, Theo Baker,
received a message from a Stanford graduate about chatter on PubPeer—a website where scientists raise questions about published research that pointed out aberrations in reports from Tessier-Lavigne’s research team.88 In early October 2022, Baker engaged scientific experts89 to review the papers co-authored by Tessier-Lavigne that contained images alleged by experts to be manipulated.90 Baker’s reporting enlisted multiple scientific experts to examine, corroborate and ultimately expand upon the concerns raised on PubPeer.91 The University investigators concluded that Dr. Tessier-Lavigne had failed to correct errors in years-old scientific papers and had overseen labs with an “unusual frequency” of data manipulations. In July 2023, Dr. Tessier-Lavigne announced his resignation as President of Stanford effective August 31, 2023.92

In the Dana-Farber investigation, the institute’s review was expanded and gained fresh urgency after a scientific sleuth, Sholto David, began pouring through papers co-authored by Dana-Farber researchers in December 2023.93 He claims to have spotted problems with figures in fifty-seven papers, many of them widely cited, whose authors include four of the Harvard-affiliated institute’s top scientists, including Glimcher, Hahn, Irene Ghobrial, and Kenneth Anderson.94 Some of these alleged issues were first described by David himself, while others had been flagged online years ago.95 In many cases, David believes that images were clearly and deliberately manipulated to deceive the reader, alleging scientific misconduct.96


89. Id.; see e.g., Elisabeth Bik, Science Has a Nasty Photoshopping Problem, N.Y. TIMES (Oct. 29, 2022), https://www.nytimes.com/interactive/2022/10/29/opinion/science-fraud-image-manipulation-photoshop.html [https://perma.cc/NTM6-Q79N] (Dr. Bik is a former Stanford microbiologist who now works full-time finding and reporting cases of scientific fraud).

90. Bonos, supra note 88.

91. Id.


93. See Wosen & Chen, supra note 83.

94. Id.

95. Id.

96. Id.
The Dana-Farber incident underscores the need for an adequate governance framework. But for the watchdog activities of Sholto David and others, it is not clear whether the Institution would have taken the same swift actions. Scientists, unlike their professional counterparts in medicine and law, do not answer to any regulatory body for violations of ethical and moral professional standards. This absence of effective accountability measures creates a system vulnerable to unethical practices, such as data manipulation, fabrication, and plagiarism. As we see in Part II, the existing governance models, designed for a pre-AI world, are woefully inadequate for addressing the ethical, legal, and social challenges posed by AI.

II. FALLING SHORT: WHY CURRENT MEASURES ARE FAILING

The prevention of innovation fraud currently relies on a combination of organizational values, established social norms, and professional codes of ethics set by specific organizations. Private and public companies face little scrutiny about their decision-making processes. Most organizations’ company culture and norms provide the governance framework for innovation teams. This raises crucial questions: what safeguards exist to prevent “innovation fraud,” and how do they differ between research institutions and the private sector? Recognizing that a single solution may not suffice, Part II critically examines the existing frameworks that govern the innovation process.

A. The Peer Review Process Is Broken

Published research is subject to substantial critique. Scientific and medical journals use the peer review process to decide which studies are worthy of publication. When a manuscript is submitted to a journal, it is assessed by researchers to see if it meets their criteria for submission. If it does, the editorial team selects potential peer reviewers within the field of

97. See id.
98. See id.
100. Such as IEEE, BIO, and Committee on Publication Ethics (“COPE”).
102. Note, this analysis excludes the peer review in the promotion and tenure process.
103. See Peer Review Process, supra note 101.
104. See id.
research to peer-review the manuscript and make recommendations. Peer reviewers also act as gatekeepers in these fields, wielding vast influence through their evaluations of research for publication, funding, conference slots, and recognition in the discipline. Often, this is a superficial popularity contest with underrepresented and marginalized authors left out of the process or subjected to unwarranted criticism. A major criticism of peer review is that there is little evidence that the process actually works, that it is actually an effective screen for quality scientific work, and that it actually improves the quality of scientific literature.

The number of retractions in scientific research publications has been rising for years. Retraction Watch is a database that catalogs and compiles retractions from existing databases like PubMed. It has curated a searchable database of over 46,000 retractions. The website cataloged more than 5,400 retractions in 2022, up from about 120 in 2002. More than 10,000 papers were retracted by journals in 2023, according to Nature. Following the resignation of Stanford University President Dr. Tessier-Lavigne and the Retraction Watch co-founders (Ivan Oransky and Adam Marcus) coauthored op-eds in the Guardian and Scientific American noting that scientific misconduct was more common than is reported.

Oransky and Marcus cite two main reasons for sharp rise in retractions: (1) sleuthing largely by volunteers who comb academic literature for anomalies; and (2) major publishers’ (belated) recognition that their business models

105. See id.


109. See Richard Van Noorden, More Than 10,000 Research Papers were Retracted in 2023 – A New Record, Nature (Dec. 12, 2023) https://www.nature.com/articles/d41586-023-03974-8. (The bulk of 2023’s retractions were from journals owned by Hindawi, a London-based subsidiary of the publisher Wiley. At last count in December 2023, Hindawi journals pulled more than 8,000 articles, citing factors such as “concerns that the peer review process has been compromised” and “systematic manipulation of the publication and peer-review process”, after investigations prompted by internal editors and by research-integrity sleuths who raised questions about incoherent text and irrelevant references in thousands of papers). On December 6, 2023, Wiley announced on an earnings call that it would stop using the Hindawi brand name altogether, having previously shuttered four Hindawi titles and, towards the end of 2022, temporarily paused special-issue publication. Wiley will fold existing titles back into its own brand.
have made them susceptible to paper mills (scientific chop shops that sell everything from authorships to entire manuscripts to researchers who need to publish lest they perish).\footnote{110}{See Ivan Oransky & Adam Marcus, There’s Far More Scientific Fraud Than Anyone Wants to Admit,\textit{ The Guardian} (August 9, 2023), https://www.theguardian.com/commentisfree/2023/aug/09/scientific-misconduct-retraction-watch [https://perma.cc/7QXJ-U2GP].}

As the number of retracted articles continues to rise, it is clear that the peer review process is no longer the most effective way to prevent innovation fraud. Journal editors acknowledge that errors or fraud can escape notice because reviewers don’t audit underlying data sets.\footnote{111}{See Subbaraman,\textit{ supra} note 108.} Typically, reviewers are working scientists. Journal editors ask them to critique submissions and recommend whether they should appear in print.\footnote{112}{Id.} Bad data goes undetected in academic journals largely because the publications rely on volunteer experts to ensure the quality of published work, not to detect fraud.\footnote{113}{See infra note 152.} Despite assurances from journals that peer review ensures quality control, publishers have increasingly outsourced this task to volunteer sleuths outside the peer review process. However, these volunteer investigators often report that their well-founded critiques are ignored or downplayed by editors.\footnote{114}{See Ivan Oransky & Adam Marcus, Science Corrects Itself, Right? A Scandal at Stanford Says It Doesn’t, Sci. Am. (August 1, 2023), https://www.scientificamerican.com/article/science-corrects-itself-right-a-scandal-at-stanford-says-it-doesnt/ [https://perma.cc/24SR-4P5U].} As uncovered in the Stanford investigation, Dr. Tessier-Lavigne did an able job of initially pursuing corrective efforts with the journals Cell and Science between 2015-16. But Cell determined a correction wasn’t necessary, and Science said it would publish Tessier-Lavigne’s corrections—and then didn’t.\footnote{115}{Id.} Lax gatekeeping by journals is compromising the scientific integrity of published research. A stricter approach is necessary to uphold trust in scientific findings.

\textbf{B. Government Oversight is Inadequate}

The federal government needs to play a greater role in regulating innovation fraud. The Office of Research Integrity (ORI)\footnote{116}{See About ORI, U.S. Dep’t of Health and Human Services (2024), https://ori.hhs.gov/about-ori (“ORI oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services.”) (PHS includes the NIH, CDC and FDA among several other offices and agencies).} provides investigative...
oversight for agencies under Secretary of Health and Human Services HHS including the National Institute of Health (NIH), the primary federal agency for biomedical and public health research.\textsuperscript{117} The ORI was established to remove the responsibility of research misconduct investigations from the funding agencies.\textsuperscript{118} Unfortunately, ORI is not well respected within the scientific community due to several controversial scientific misconduct investigations.\textsuperscript{119} In 1999, ORI was stripped of its policing aspects and was reassigned to teach. As a result, in 2022, ORI received 269 allegations of research misconduct.\textsuperscript{120}

The funding agencies such as the NIH and the National Science Foundation (NSF) typically require the institution that receives funds from the agency to investigate and report allegations of research misconduct.\textsuperscript{121} Although the NSF regulations allow the agency to investigate a research institution if it obtains any evidence that a high-level administrative official of the awardee institution is involved in misconduct or in a cover up of misconduct, NSF frequently continues its past practice of allowing the awardee institution to perform its own investigation.\textsuperscript{122}

First, let’s look at the advantages of requiring the awardee institution to perform the investigation. Research grants from these agencies are made to the institution, rather than to the individual researcher whose work is to be funded, thus making the institution accountable for the use of the funds.\textsuperscript{123} The employing institution, not the federal government, is capable of imposing a full range of sanctions, including dismissal, if misconduct is proven.\textsuperscript{124} Institutions are generally responsible for faculty and employee disciplinary actions and must synchronize scientific misconduct proceedings with their

\textsuperscript{117} Id.

\textsuperscript{118} See \textit{Historical Background}, U.S. Dep’t of Health and Human Services (2024), https://ori.hhs.gov/historical-background (The NIH Revitalization Act of 1993 established the ORI as an independent entity and removed the responsibility for handling allegations of research misconduct from the funding agencies.).


\textsuperscript{120} See FY2022 ORI Annual Report, U.S. Dep’t of Health and Human Services (2024), https://ori.hhs.gov/ori-annual-reports.

\textsuperscript{121} See 42 C.F.R § 93.300-19.

\textsuperscript{122} See Andersen, \textit{supra} note 79, at 133.

\textsuperscript{123} \textit{Id.} at 132.

\textsuperscript{124} \textit{Id.} at 134.
own disciplinary codes and applicable state employment laws.\textsuperscript{125} Investigations must be tailored to meet these requirements, which may not permit an institution to rely solely upon a federal investigation or hearing to support a disciplinary action. Furthermore, the employing institution, not the federal government, is often the first to learn of allegations of misconduct and can move quickly and efficiently to handle local matters that are actually only misunderstandings between individuals or relatively minor matters.\textsuperscript{126} The institution usually has more direct and unfettered access to labs, witnesses, primary data, and other evidence.\textsuperscript{127} Full-scale misconduct investigations are expensive no matter who conducts them.\textsuperscript{128} However, the local institution is probably the most cost-effective choice to undertake most investigations.\textsuperscript{129}

The NIH is also involved in policing research misconduct.\textsuperscript{130} If an individual involved in NIH funded research is found to have committed research misconduct, the administrative actions that may be taken against this person may include, but are not limited to:\textsuperscript{131}

- debarment from eligibility to receive Federal funds for grants and contracts
- prohibition from service on Public Health Service (PHS) advisory committees, peer review committees, or as consultants
- certification of information sources by the respondent that is forwarded by the institution
- certification of data by the institution
- imposition of supervision on the respondent by the institution
- submission of a correction of published articles by the respondent
- submission of a retraction of published articles by the respondent

The default governance framework of self-policing policy is failing because research misconduct is not caught until after the data is published.\textsuperscript{132} There needs to be a governance framework that catches falsified data before

\begin{itemize}
\item Id.
\item Id. at 135.
\item Id.
\item Andersen, supra note 79, at 135.
\item Id.
\item Id. at 132.
\item See What Happens if there is a Finding of Research Misconduct?, NIH CENT. RES. FOR GRANTS AND FUNDING INFO., https://grants.nih.gov/policy/research_integrity/finding.htm (last visited March 5, 2024) [https://perma.cc/YPK3-RGCP].
\item See generally Justin M. Ganderson, GAO Recommends Improvements to DOE’s Fraud Risk Management Controls; DOE Fires Back, 3 Pratt’s Gov’t Contracting L. REP. §29.03 (2024) (discussing proposals for a new governance framework that can detect falsified data before publication).
\end{itemize}
publication. In addition, there needs to be greater accountability for institutions with a high rate of retractions for research papers or individual researchers who commit innovation fraud.

C. Corporate Board of Directors: Failure of Oversight

It is axiomatic that all private and public securities transactions, no matter the sophistication of the parties, must be free from fraud.” These words are taken from a speech given by the former SEC Chairwoman Mary Jo White in March 2016. White also discussed one of the chief concerns with startups, insufficient internal controls, and lack of oversight by the Board. “The risk of distortion and inaccuracy is amplified because start-up companies, even quite mature ones, often have far less robust internal controls and governance procedures that most public companies.” Although innovation fraud can occur in both public and private companies, this concern is amplified with private startup companies because they often have inadequate internal controls and governance frameworks. Startup founders often justify wrongdoing through anticipation of the ultimate benefits. Thus, the Board of Directors plays an important governance role for startups. Arguably the most critical function of the Board of Directors is to oversee the CEO and senior management, holding the C-suite accountable for the company’s performance.

It is impossible for the board to know everything or every decision by management, thus the oversight function of the board is essential for a well-positioned board. Moreover, corporate directors have strong incentives to remain ignorant about decisions that prioritize profits over safety or skirt regulatory requirements more generally. Prioritizing profits is good for directors

133. Id.


136. Id.


138. See generally 1 CORP. GOVERNANCE: L. AND PRAC. NOMINATING/CORPORATE GOVERNANCE COMMITTEE DUTIES AND RESPONSIBILITIES § 8.03 (2023).

who receive substantial stock-based compensation.\textsuperscript{140} And remaining ignorant about how profits were obtained is good for directors’ ability to maintain plausible deniability and escape accountability.\textsuperscript{141} However, directors can be liable for failing to provide oversight.\textsuperscript{142} In other words, oversight liability holds directors liable for their failure to act under circumstances where it can be proven that directors should have acted and their actions could have prevented corporate harm. This director oversight duty applies to public and private companies alike.\textsuperscript{143}

D. AI Will Exacerbate This Problem

As the use of artificial intelligence (AI) becomes more widespread, it presents ethical, privacy, and data governance risks which is creating more regulatory oversight.\textsuperscript{144} There is a great potential for AI to be used to facilitate fraudulent activities such as generating fake or misleading information.\textsuperscript{145} Researchers at the University of Sydney noted that “the rapid development of artificial intelligence technology has brought to us promising image-generation models that can produce realistic fake images.”\textsuperscript{146} The researchers noted that these image-generation models can synthesize fake images, plagiarize existing images, and deliberately modify images. Thus, it will be very difficult to identify images generated by these models by visual inspection, image-forensic tools, and detection tools due to the unique paradigm of the generative models for processing images.

Recently, President Biden issued an executive order that is part of the Administration comprehensive strategy for responsible innovation.\textsuperscript{147} This landmark Executive Order aims to establish a comprehensive government-wide approach to ensure the responsible development and use of AI in the

\textsuperscript{140} Id.

\textsuperscript{141} Id.

\textsuperscript{142} Id. at 126.

\textsuperscript{143} See generally I Texas Torts and Remedies § 4.05 Vicarious Liability of Particular Entities (2024) (discussing director liability).

\textsuperscript{144} See generally 15 U.S.C.S. § 9451 (emphasizing the potential ethical, social, and security risks involved).

\textsuperscript{145} Id.

\textsuperscript{146} See Jinjin Gu et al., AI-Enabled Fraud in Scientific Publications, PATTERNS (July 8, 2022), https://www.cell.com/patterns/pdf/S2666-3899(22)00103-9.pdf (This paper includes examples of AI-generated images to show how these advanced generative models might be abused for scientific image fraud. “Our examples and identification results show troubling signs that this type of image fraud is efficient and covert and is expected to pose a threat to academic publishing.”).

\textsuperscript{147} Id.
The Executive Order establishes new standards and best practices for clearly labeling AI-generated content, which can easily be used to spread false information. Other key areas of focus include prohibiting discriminatory uses of AI in areas like employment, housing, and credit, promoting development of fair and unbiased AI system and improving access to AI technologies for underserved communities. Finally, the Executive Order directs over 50 federal agencies to take specific actions across the various areas.

Notably, FTC announced in November 2023 that it will begin to take action on companies making and selling AI-related products and services. Specifically, the Agency authorized the use of “compulsory process” in nonpublic investigations which allows the FTC to request the production of information, documents, or testimony relevant to an investigation. The recent Executive Order and FTC actions mark the start of the U.S. AI regulatory framework.

As AI scholar Ryan Calo notes, “Perhaps the most visible and developed area of AI policy to date involves the capacity of algorithms or trained systems to reflect human values such as fairness, accountability, and transparency.” These values are reflected in President Biden’s Executive Order and also within the responsible AI principles espoused by Microsoft, Google and others. As AI continues to reshape the productivity tools we use in our professional and personal lives, data governance issues such as data bias, data privacy and data security will remain top of mind for regulators. While AI’s sophisticated


149. Id.

150. See generally biometric data priv. compliance and best prac. § 8.03 Federal Trade Commission (2024) (discussing “reasonably foreseeable” harmful and fraudulent use cases for which AI tools could be applied prior to release).


152. Id.

153. Id.


capabilities may make some fraudulent activities more challenging to identify, its ability to analyze vast amounts of data and identify patterns can be used to effectively detect fraud. As the use of generative artificial intelligence continues to proliferate in a variety of innovation platforms, the need for an ethical governance framework becomes paramount.

III. THIS IS WHAT WE NEED: STRATEGIES TO MITIGATE INNOVATION FRAUD

This Essay argues for two novel mitigation strategies for addressing innovation fraud. One approach involves greater support for whistleblowers and a permissive framework that allows attorneys to disclose confidential information. The approach creates an incentive structure that will reduce the number of research misconduct incidents. The second mitigation strategy involves the federal government and requires greater action by the federal agencies that fund research. The grant recipients who commit innovation fraud should be required to pay restitution to the federal agencies. Recognizing that a single solution may not suffice, this proposed framework aims to incentivize ethical behavior, empower whistleblowers, and foster a culture of integrity within the innovation ecosystem.

A. Greater Protections for Whistleblowers

Being a whistleblower is hard. When an employee decides to speak out about transgressions in the workplace, they are taking a huge risk. Instead of being praised and rewarded, they are often ostracized and criticized. Research shows that frauds are discovered most often by whistleblowers – those people who see something and say something. Whistleblowers are an important resource for detecting fraud. In addition, whistleblowers are one of the key enforcement mechanisms that the SEC has to discover fraud and protect investors. This Essay focuses on three distinct roles where an insider can become a whistleblower: (1) corporate employee as a whistleblower; (2) scientist in a research institution as a whistleblower; and (3) lawyer as a whistleblower. Currently, there are several federal laws designed to encourage whistleblowers


158. To distinguish a scientist employed at a research institution and not at a publicly traded company.
to come forward.\textsuperscript{159} Although most whistleblower laws include anti-retaliation provisions, a detailed 2010 econometric study revealed that in 82\% of the whistleblower cases, the employee was fired, quit under the duress or had their responsibilities significantly altered.\textsuperscript{160} This discourages others from coming forward, silencing vital voices and hindering efforts to detect innovation fraud. However, a recent Supreme Court ruling is a legal victory for whistleblowers. The Court ruled that Sarbanes-Oxley Act whistleblower protections do not require an employee to demonstrate that the employer acted with “retaliatory intent.”\textsuperscript{161} This ruling resolved a split among the federal appeals courts and sets a consistent standard of proof in Sarbanes-Oxley cases.

1. \textbf{Corporate Whistleblowers}

Employees of publicly traded companies are protected under Sarbanes-Oxley when they report criminal fraud or securities law violations.\textsuperscript{162} Publicly traded companies may not “discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment” when they assert their rights under the Act.\textsuperscript{163} Under Dodd-Frank, however, whistleblowers not only receive protection from termination or adverse employment action but can also lay claim to financial rewards for bringing information to the SEC that leads to successful securities enforcement actions.\textsuperscript{164}

\begin{itemize}
  \item \textsuperscript{160} Alexander Dyck et al., \textit{Who Blows the Whistle on Corporate Fraud?}, 65 J. Fin. 2213, 2216 (2010).
  \item \textsuperscript{161} See Murray \textit{v. UBS Sec., LLC}, 144 S. Ct. 445, 446 (2024) (reversed the Second Circuit ruling and unanimously held that a whistleblower only needs to show that the whistleblower’s protected activity, such as reporting or disclosing violations of SEC rules and regulations, was a contributing factor in the adverse employment decision.).
  \item \textsuperscript{162} See 18 U.S.C. §1514A(a).
  \item \textsuperscript{163} Id.
  \item \textsuperscript{164} See Geoffrey Christopher Rapp, \textit{Mutiny by the Bounties? The Attempt to Reform Wall Street by the New Whistleblower Provisions of the Dodd-Frank Act}, B.Y.U.L. Rev. 73, 74-75 (2012); see also Jennifer M. Pacella, \textit{Silencing Whistleblowers by Contract}, 55 Am. Bus. L.J. 261, 262 (2018) (The financial reward to whistleblowers under Dodd-Frank is intended to offset the negative the common
Although statutory protections exist, whistleblowers often face retaliation and career setbacks\textsuperscript{165} for reporting wrongdoing. For instance, although Dodd-Frank provides antiretaliation protection from one’s current employer, no federal anti-fraud statutes provide legal recourse for retaliation carried out by future employers.\textsuperscript{166} According to the 2021 report by the Ethics & Compliance Initiative (ECI), retaliation against whistleblowers is on the rise.\textsuperscript{167} ECI has been tracking employee perceptions of retaliation for reporting misconduct since 2007.\textsuperscript{168} Since that time, retaliation has been increasing, with a jump from 22\% in 2013 to 44\% in 2017.\textsuperscript{169} In 2020, the rate of retaliation against employees for reporting wrongdoing in the U.S. was 79\%.\textsuperscript{170} If left unaddressed, high rates of retaliation can erode ethical culture and undermine efforts to encourage employees to speak up and raise concerns.\textsuperscript{171}

Without whistleblowers like Tyler Shultz and Erika Cheung from Theranos,\textsuperscript{172} the device failure could have gone undetected for months, potentially leading to misdiagnoses and serious harm to patients. Cheung worked for Theranos for six months before she discovered that the faulty test results were being erased.\textsuperscript{173} Shultz shared his concerns about the Edison test results in an email to Elizabeth Holmes and he received a threatening response from her partner Sunny Balwani.\textsuperscript{174} In 2015, Cheung wrote a letter to the regulatory agency Centers for Medicare & Medicaid Services (CMS), exposing the negative consequences of blowing the whistle, including the risk of reprisal and retaliation).


\textsuperscript{166} See Justin W. Evans et al., \textit{Reforming Dodd-Frank from the Whistleblower’s Vantage}, 58 Am. Bus. L.J. 453, 462 (2021) (citing Eisenstadt et al.).


\textsuperscript{168} Id. at 22.

\textsuperscript{169} Id.

\textsuperscript{170} Id.

\textsuperscript{171} Id.

\textsuperscript{172} See \textit{Bad Blood} at 185-99; 231-32 (Ericka Cheung worked on the immunoassay team along with Tyler Shultz and their job was to help run experiments to verify the accuracy of blood tests on the Theranos Edison devices before they were deployed for use on patients).

\textsuperscript{173} Id.

\textsuperscript{174} Id. at 192-96.
problems with the Theranos Edison device and lab procedures.\textsuperscript{175} The agency then undertook a surprise inspection of the start-up’s labs which uncovered numerous violations.\textsuperscript{176} Shultz spoke to the Wall Street Journal reporter John Carreyrou and with the help of Shultz’s information and his own research, Carreyrou published an article in October 2015 revealing that Theranos was not using its own machines for the blood tests and that the “Edison” device provided unreliable results.\textsuperscript{177} Cheung and Schultz reported the misconduct to the authorities and the WSJ once they resigned from the company, so they did not face any adverse employment action.\textsuperscript{178} However, counsel for Theranos threatened both with litigation for breach of their NDAs.\textsuperscript{179}

Numerous scholars have written about the protections for corporate whistleblowers and the effectiveness of the legislative framework.\textsuperscript{180} This Essay contributes to that body of literature by advocating for greater protections for whistleblowers. This trend of rising retaliation highlights the need for stronger protections for whistleblowers. By fostering a culture of open communication and ensuring safe reporting mechanisms, organizations can empower employees to make ethical choices. Although there are many factors that influence ethical behavior, the interplay of four major ethics outcomes is tied to the daily micro decisions employees make with respect to how they behave in the workplace. These are: pressure in the workplace to compromise ethical standards; observations of misconduct; reporting misconduct; and ultimately, the

\textsuperscript{175} Id. at 280-83.

\textsuperscript{176} Id.

\textsuperscript{177} Id. at 286.

\textsuperscript{178} Id. at 197-99.

\textsuperscript{179} Id. at 255-56 (Cheung received a letter from the Boies Schiller law firm accusing her of revealing Theranos trade secrets and demanded that she submit to an interview with the law firm).

retaliation perceived by employees after they reported misconduct. When employees feel supported in reporting misconduct, it disrupts the cycle of pressure, observation, and silence, ultimately leading to a more ethical and trustworthy workplace.

2. Scientists as Whistleblowers

What happens when your department head or the person leading the lab is the one suspected of innovation fraud? It is very difficult for graduate students to contradict the findings from his or her PhD advisor. Challenging an advisor’s findings can jeopardize a student’s progress and funding. Similarly, junior faculty members who report misconduct risk damaging relationships with tenured colleagues who hold sway over career advancement and grant opportunities. These valid concerns about negative career consequences often prevent scientists from reporting misconduct. Fortunately, many courageous scientists and other data detectives come forward to uncover innovation fraud. Only scientist whistleblowers, with their deep understanding of the field, can effectively expose fraudulent data, protecting the public from being misled.

Researchers in an academic institution or a private research institution do not benefit from the same whistleblower protections afforded to corporate whistleblowers. However, under the False Claims Act (FCA), whistleblowers can be rewarded for confidentially disclosing fraud that results in a financial loss to the federal government. Scientists who receive federal funds for research and falsify data to receive additional grant funding can be reported under the FCA. In order to access the FCA’s protections, the whistleblower must show that they were engaged in FCA-protected activity and that the

181. ECI REPORT, supra note 167, at 4.


184. The False Claims Act allows private parties to file qui tam actions alleging that defendants defrauded the federal government. See 18 U.S.C. § 286, 18 U.S.C. § 287, 31 U.S.C. § 3729 et seq. In these suits, the government is the real party in interest, and thus is considered the plaintiff. The private party who initiates the suit is called a relator.

185. See United States ex rel. Hill v. Univ. of Med. & Dentistry, 2010 U.S. Dist. LEXIS 111012 (D.N.J., Oct. 18, 2010) (court dismissed FCA whistleblower complaint where the relator argued that that data used to support a NIH grant was fabricated finding that plaintiff failed to establish defendants satisfied the scienter and materiality elements under the FCA and failed to establish that she suffered any adverse employment action.).
employer knew their activity was protected under the FCA. Since 2009, the FCA has also entitled *qui tam* whistleblowers to “all relief necessary to make [the whistleblower] whole,” if the whistleblower is discharged, demoted, suspended, harassed, or otherwise discriminated against due to their (1) lawful acts done in furtherance of a *qui tam* action or (2) other efforts to stop violations of the FCA.

The Public Health Service (PHS) Policy on Research Misconduct, outlined in 42 CFR Part 93, is the primary federal regulation that dictates how institutions receiving federal funding must address allegations of research misconduct. This regulation became effective on June 16, 2005 and replaced the old regulation, 42 CFR Part 50, Subpart A. To constitute research misconduct, three elements must be met: (1) a significant departure from accepted practices in the relevant research field, (2) intentional, knowing, or reckless behavior on the part of the researcher(s), and (3) evidence of the misconduct proven by a preponderance of the evidence. When an allegation of research misconduct is made, the grantee is responsible for establishing and maintaining the necessary process to monitor its compliance and that of its employees, consortium participants and contractors with the requirements of the grant.

The grantee is responsible for compliance with its research misconduct assurance for all awarded funds, including those made available to sub-awardees and contractors.

Scientist whistleblowers can be internal or external to the institution. When an internal whistleblower reports scientific misconduct, the institution must follow the process outlined in 42 CFR Part 93 and report the institutional findings to ORI. Investigations within the institution can be lengthy and can have a detrimental impact on the whistleblower (similar to that of the corporate whistleblower reporting “up-the-ladder.”). The scientist is often ostracized in the lab and occasionally demoted. In one recent example, a former Johns

---


188. 42 CFR § 93.104.

189. *Id*.

190. *Id*.


192. *Id*.

193. 42 CFR § 93.104.

194. *See* William E. Matthews et al., *Conflicting Loyalties Facing In-House Counsel: Ethical Care and Feeding of the Ravenous Multi-Headed Client*, 37 St. Mary’s L.J. 901, 921 (2006); *see also* The Evolving Legal and Ethical Role of
Hopkins scientist alleged he was terminated for reporting research misconduct and filed a wrongful termination suit against the University. The relevant facts of the case are as follows: The scientist, Dr. Yuan believed that the data in the SLAM project reported by his colleagues in the lab contained errors and led to false positive results. For about five years (2005-2011), he repeatedly reported this research misconduct concerning the SLAM project data claiming that his research colleagues were falsifying the results. The results from the alleged falsified data from the SLAM project were used to renew grant funding by the NIH and published in two papers. The two years following the grant renewal, Dr. Yuan was excluded from this research work. Also, during this time (between 2006 and 2008), the research in the lab was unsuccessful and the lab did not have any significant results to report to NIH. Dr. Boeke, the lead researcher asked other researchers to review the SLAM project data, excluding Dr. Yuan. The researchers corroborated Dr. Yuan’s findings and found that the data had an extraordinarily high “False Discovery Rate.” The University conducted a research misconduct investigation and concluded that there was no research misconduct despite the fact that the Dr. Boeke and his co-author retracted one of the published papers and issued a correction for the other – these published papers were the basis for the research misconduct allegations. Ultimately, Dr. Yuan did not prevail in his wrongful termination suit. His at-will employment contract expired and was not renewed, thus he was not terminated. The Court noted that “the scientific institution, not this Court, is in the best position and has the expertise to determine whether the


195. Id. at 441–42.

196. Id. at 458 (He directed his complaints about the SLAM data and experiments to other researchers in the lab in which he and Dr. Boeke worked. He did not report it to the director of the department or division affected as required by the University policy).

197. Id. at 442.

198. Id.

199. Id.

200. See William E. Matthews et al., supra note 194.

201. Id.

202. Id. at 445–46.

203. Id. at 458–62.

204. Id. at 444 (Here, Dr. Yuan’s employment contract simply expired; he was not wrongfully terminated in violation of a clear and specific public policy.).
research results of its employees amounted to impermissible research misconduct or permissible error or differences of opinion.\textsuperscript{205}

The case illustrates how acrimonious the workplace can become for an internal whistleblower. The case also highlights the vulnerability of scientist whistleblowers, who often struggle to find a clear legal basis to sue for wrongful termination after reporting misconduct.\textsuperscript{206}

External whistleblowing plays a significant role in uncovering scientific misconduct. Sites like PubPeer\textsuperscript{207} allows users to discuss and review scientific research after publication, i.e. post-publication peer review.\textsuperscript{208} The site has served as a whistleblowing platform, in that it highlighted shortcomings in several high-profile papers, in some cases leading to retractions that is often reported on Retraction Watch.\textsuperscript{209}

As reported by Dr. Elisabeth Bik, many external whistleblowers choose to remain anonymous because criticizing other scientists’ work is often not well received and concerns about negative career consequences can prevent scientists from speaking out.\textsuperscript{210}

With limited legal protections, being a scientist whistleblower can be a difficult decision. It can also have catastrophic consequences for researchers working with one accused of misconduct. If the principal investigator on the grant is responsible for research misconduct, the lab may be shut down putting students and others who work in the lab in jeopardy.\textsuperscript{211}

3. Lawyers as Whistleblowers

Traditionally viewed as client advocates, lawyers acting as whistleblowers can challenge professional conduct norms and threaten the attorney-client relationship. However, attorneys are sometimes the best insiders to report misconduct. Several scholars have written about how the SOX and Dodd-Frank reporting requirements could conflict with a lawyer’s obligations under Model

\textsuperscript{205} Id. at 440.

\textsuperscript{206} See William E. Matthews et al., supra note 194, at 440 (Dr. Yuan acknowledged in his brief that the regulations did not provide him with legal redress in the form of damages).

\textsuperscript{207} See PubPeer, https://pubpeer.com/.

\textsuperscript{208} Id. (PubPeer enables scientists to search for their publications or their peers’ publications and provide feedback and/or start a conversation anonymously).

\textsuperscript{209} Ivan Oransky, Weekend reads: ‘Objectionable conditions’ at psychiatry institute; impact factor obsession; Nobel winner acknowledges more errors, Retraction Watch (Apr. 6, 2024), https://retractionwatch.com/.

\textsuperscript{210} See Bik, supra note 89.

Rule 1.6. Nonetheless, lawyers have always had the discretion to disclose confidential information to prevent a client from committing certain crimes or frauds.

Under Rule 1.6(a) of the Model Rules of Professional Conduct, a lawyer cannot “reveal information relating to the representation of a client unless the client gives informed consent, the disclosure is impliedly authorized in order to carry out the representation or the disclosure is permitted” by one of the exceptions listed in Rule 1.6(b).

Model Rule 1.6(b)(2) permits a lawyer to disclose a client’s information “to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer’s services.” Model Rule 1.6(b)(3) permits a lawyer to reveal a client’s information “to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client’s commission of a crime or fraud in furtherance of which the client has used the lawyer’s services.”

In both circumstances, the disclosure of information related to the client’s representation must be limited to “the extent the lawyer reasonably believes necessary” to accomplish the rule’s purpose. This limitation on the information that a lawyer may reveal respects the general principle that exceptions to the duty of confidentiality should be narrowly construed.


213. See Dennis J. Ventry, Stitches for Snitches: Lawyers as Whistleblowers, 50 U.C. DAVIS L. REV. 1455, 1456 (2017); see also, Model Rule 1.2(d) (general prohibition on assisting clients in committing crimes or frauds).

214. MODEL RULES OF PRO. CONDUCT r. 1.6(a)-(b) (AM. BAR ASS’N 2021). The rule defines confidential information as “information gained during or relating to the representation of a client, whatever its source, that is (a) protected by the attorney-client privilege, (b) likely to be embarrassing or detrimental to the client if disclosed, or (c) information that the client has requested be kept confidential.”

215. Id. r. 1.6(b)(2).

216. Id. r. 1.6(b)(3).

217. Id. r. 1.6(b)(2)-(3).

The SEC rules require lawyers to “(1) report evidence of a material violation of securities law or breach of fiduciary duty or similar violation by the company or any agent thereof, to the chief legal counsel or the chief executive officer of the company (or the equivalent thereof); and (2) if the counsel or officer does not appropriately respond to the evidence . . . requiring the attorney to report the evidence to the audit committee of the board of directors of the issuer or to another committee of the board of directors comprised solely of directors not employed . . . by the issuer, or to the board of directors.” As noted by some scholars, the SEC rules ‘has made lawyers into “gatekeepers,” the permissive disclosure rules which act as a “whistleblower license for attorneys to use.”’ However, these rules put lawyers who disclose the wrongdoing in a worse position because they often must rely on confidential client information to fully inform the wrongdoing.

Lawyers who act as whistleblowers are often terminated after reporting the misconduct or sometimes, they must resign (arguably a constructive discharge) in order to report the misconduct.

Courts have issued inconsistent rulings on lawyer claims of retaliatory discharge. Some courts allowed lawyers to bring these claims, while “making every effort possible to avoid unnecessary disclosure” of client confidences, and encouraging the trial courts to issue orders that minimize “unnecessary disclosures.” Unfortunately, a majority of the jurisdictions deny retaliatory


220. See William E. Matthews et al., *supra* note 194.

221. See H. Lowell Brown, *The Dilemma of Corporate Counsel Faced with Client Misconduct: Disclosure of Client Confidences or Constructive Discharge*, 44 Buffalo L. Rev. 777, 788-89 (Counsel may well find that because continued representation of the corporation creates an irreconcilable conflict with counsel’s ethical responsibilities, there is no alternative but to resign from further representation of the corporation, thus setting the stage for a wrongful termination/constructive discharge claim.).


223. See, e.g., *Crews v. Buckman Labs*, 78 S.W.3d 852 (Tenn. 2002); *Spratley v. State Farm*, 78 P.3d 603 (Utah 2003); *Seidle v. Putnam Invest.*, 147 F.3d 7 (1st Cir. 1998); *Kachman v. Sunguard Data Sys.*, 109 F.3d 173 (3d Cir. 1997).
discharge claims by lawyers. In *United States v. Quest Diagnostics*, the court found that a lawyer whistleblower violated his ethical duties to his former employer, by disclosing confidential information that was “greater than reasonably necessary to prevent any alleged ongoing fraudulent scheme.” The court considered the “tension” between a lawyer’s duty of confidentiality and the government’s interest—as expressed through the federal False Claims Act—in encouraging whistleblowers to reveal legal violations that harm the government. After weighing the competing interests, the Court of Appeals agreed with the District Court that the federal FCA “did not preempt applicable state ethical rules.” To the contrary, it found that “nothing in the False Claims Act evinces a clear legislative intent to preempt state statutes and rules that regulate an attorney’s disclosure of client confidences.” The Second Circuit ruling in the *Quest Diagnostics* case illustrates that it is very difficult for lawyer whistleblowers to prevail when their reporting of wrongdoing involves breaching his duty of confidentiality and a financial reward.

Attorneys can play a role in eradicating corporate fraud and modeling good governance but cannot be the only party within a company working in the best long-term interests of investors and the market. However, the ethical rules governing attorneys do not protect lawyers from discipline if they take affirmative actions to prevent client misconduct. Moreover, the whistleblower protections do little to assuage the fear of professional ostracizing that will likely result from the attorneys’ actions.

224. See William E. Matthews et al., *supra* note 194.


226. *Id.* at 165 (former general counsel brought *qui tam* action against Quest Diagnostics for alleged violations of the federal Anti-Kickback Statute).

227. *Id.* at 157.

228. *Id.* at 162.

229. *Id.* at 163.

230. *Id.* at 165 (The Court questioned the attorney’s motive for participating in the *qui tam* action where he would receive a financial reward; he could have decided not to participate in the *qui tam* action and allowed the other two members of the FLPA to initiate the case on their own).


232. See *id.* at 700.

233. See *id.* at 702–07.
By the very nature of attorney representation, when fraud happens, the lawyers often know something. An attorney may have suspicions and may be counseling clients to avoid activities constituting crime or a fraud, but unless the client uses the attorney’s services to engage in crime or fraud, the attorney is prohibited from disclosing the information.\footnote{234} Under the preexisting standards, when communications between attorney and client are used to further a crime, fraud, or tort, the crime-fraud exception renders the privilege moot, but only if the action is carried out.\footnote{235} Mere speculation does not allow disclosure; instead, an attorney must have a reasonable belief.\footnote{236} An attorney is not permitted to report externally because they simply disagree with governance; an attorney needs evidence, gained from representation, or at least related to representation, that wrongdoing will result in substantial harm to the company, its shareholders, or the market.\footnote{237}

\section*{B. Role of Federal Government}

The role of the federal government is simple: to deter innovation fraud, federal research agencies should hold institutions and researchers accountable by seeking repayment of misused funds. The federal government has the authority to “seek to recover PHS funds spent in support of the activities that involved research misconduct.”\footnote{238} Federal research funding agencies should implement a tiered system for categorizing the research misconduct, with repayment penalties proportional to the severity of the misconduct and its potential negative impact on downstream research or clinical applications. The specific details on how to implement this could be addressed in a Notice of Proposed Rule Making (NPRM).\footnote{239}

Since the federal government is a major funding source for research and development conducted by universities,\footnote{240} private companies, and other non-governmental institutions, demanding restitution for fraudulent research represents a powerful tool to combat innovation fraud.

\begin{footnotes}
\footnote{234}{See id. at 683.}
\footnote{235}{See id.}
\footnote{236}{See id.}
\footnote{237}{Chatman, supra note 231.}
\footnote{238}{42 C.F.R. 93.407(11)(b).}
\footnote{239}{NPRM is a public notice that is issued by law when a U.S. federal agency wishes to add, remove, or change a rule or regulation as part of the rulemaking process.}
\footnote{240}{See Preface: The State of U.S. Science and Engineering 2022, NCSES (2022), https://ncses.nsf.gov/pubs/nsb20221/ (The federal government is the main funder of U.S. academic R&D spending, financing 50% of academic R&D expenditures in FY 2022).}
\end{footnotes}
CONCLUSION

Addressing innovation fraud will require many different interventions. The “fake it till you make it” mentality has gone too far and fostered an environment ripe for innovation fraud. While criminal prosecution for innovation fraud is a deterrent in the private sector, consequences for academic misconduct often fall short. This disparity exists despite the potentially significant and far-reaching impacts of scientific misconduct. Whistleblowers have played a significant role in detecting innovation fraud. When organizations support employees who report wrongdoing, it fosters a culture of trust, leading to better outcomes.

While AI may present risks of facilitating innovation fraud, its potential for detection should be actively explored and responsibly implemented. Finally, this Essay proposes a novel approach to strengthen the federal government’s role in managing research misconduct: actively seeking repayment of misused funds. This strategy would deter future fraud, recover taxpayer dollars for legitimate research, and ultimately promote greater scientific integrity.