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Corporations, high-stakes biomedical research, and research misconduct: yes they can (and sometimes do)

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ABSTRACT

Science has long been vulnerable to research misconduct (RM). Biomedical sciences, with vast financial stakes, carry heightened temptations. However, RM is standardly seen as an undertaking of individual scientists, not as something that could be committed by an organization such as a corporation or university. Rather, organizations are generally regarded merely as supervisors to encourage scientific integrity and investigate suspected RM. Indeed, federal regulations expressly embrace this perspective, and the federal Office of Research Integrity has never deemed an organization guilty of committing RM. This article aims to rewrite this corner of research integrity: organizations can directly commit RM and should be held accountable as such. Although the conclusions apply to organizations such as universities and government agencies, the focus here is on corporations in the biomedical sciences. After defining 'research misconduct' in Part II, Part III describes corporate-level RM and distinguishes it from individuals' misconduct. Part IV provides five case studies exemplifying corporate RM, while Part V discusses implications, describes ways in which federal regulations could already encompass organization-level RM, and identifies some needed legal and regulatory adjustments.

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KEYWORDS: research misconduct, scientific integrity, scientific misconduct, corporation, federal

I. INTRODUCTION

History is replete with stories of research misconduct (RM) in science.[1] A 2005 study found that '[o]verall, 33% of the respondents said they had engaged in at least one of the top ten [potentially sanctionable offenses] during the previous three years. Among mid-career respondents, this proportion was 38%; in the early-career group, it was 28%.'[2]

In this setting it might seem obvious that organizations, qua organizations, could also commit research misconduct. After all, we know of pharmaceutical corporations' systematically hiding adverse drug effects or creating 'research' that was nothing more than marketing.[3] Recently articles were retracted by *The Lancet* and the *New England Journal of Medicine*[4] when their underlying database, provided by an obscure corporation, proved likely fictitious.[5] And surely now, amidst corporations' competition to

1 See William Broad & Nicholas Wade, Betrayers of the Truth: Fraud and Deceit in the Halls of Science (1982); Adil E. Shamoo & David B. Resnik, Responsible Conduct of Research 28 (3rd ed. 2015); M.C. LaFollette, *Pay Cheques on a Saturday Night: The Changing Politics and Bureaucracy of Research Integrity in the United States*, *in* 32 Biomed. Res. 32–47 (2001). In 1974, William Summerlin used a black magic marker on the backs of white lab mice to 'show' he had successfully transplanted skin from black mice onto the backs of white mice. John Darsee, beginning as a Harvard postdoctoral fellow in 1981, fabricated or falsified data on 17 papers and 53 abstracts. Although Nobel Prize winner David Baltimore was eventually cleared of misconduct, the ORI determined in 1994 that one of his leading postdoc fellows had manufactured data. In the early 2000s an investigatory committee found that Jan Hendrik Schön had faked data on 17 or more publications. South Korea's Woo Suk Hwang, in a particularly notorious scandal in 2005, was found to have faked copious data in his stem cell research.

2 B. Martison et al., *Scientists Behaving Badly*, 435 Nature 737, 738 (2005). The 10 worst offenses included falsifying or 'cooking' data, failing to disclose conflicts of interest, failing to present data that contradict one's own prior research, and overlooking others' use of flawed data. *Id.* at 738. See also Daniele Fanelli, *How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data*, PLOS ONE (May 29, 2009), https://journals. plos.org/plosone/article?id=10.1371/journal.pone.0005738 ('A pooled weighted average of 1.97 per cent . . . of scientists admitted to have fabricated, falsified, or modified data or results at least once—a serious form of misconduct by any standard—and up to 33.7 per cent admitted other questionable research practices. In surveys asking about the behavior of colleagues, admission rates were 14.12 per cent . . . for falsification, and up to 72 per cent for other questionable research practices.').

3 See *infra* Part IV (discussions of Merck's Vioxx and Parke–Davis's Neurontin).

4 M.R. et al., *Retraction: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, 2020 New. Eng. J. Med. (retracting original article); M.R. Mehra et al., *Retracted: Hydroxychloroquine or Chloroquine with or Without a Macrolide for Treatment of COVID-19: A Multinational Registry Analysis*, Lancet (May 22, 2020), https://doi.org/10.1016/S0140-6736(20)31180-6 (retracting original article).

5 M. Davey et al., *Surgisphere: Governments and WHO Changed Covid-19 Policy Based on Suspect Data from Tiny US Company*, The Guardian (June 30, 2020), https://www.theguardian.com/world/2020/jun/03/covid-19-surgisphere-who-world-health-organization-hydroxychloroquine. Surgisphere, whose employees appear to include a sci-fi writer and adult content model, provided database behind *The Lancet* and *New England Journal of Medicine* hydroxychloroquine studies. The episode:

> raise[d] troubling questions about the state of scientific research as the pandemic spreads. Thousands of papers are being rushed to online sites and journals with little or no peer review, and critics fear long-held standards of even the most discerning journals are eroding as they face pressure to rapidly vet and disseminate new scientific reports.

Id. See also Roni Caryn Rabin & Ellen Gabler, *Two Huge Covid-19 Studies are Retracted After Scientists Sound Alarms, New York Times*, N.Y. Times (June 4, 2020), https://www.nytimes.com/2020/06/04/health/coronavirus-hydroxychloroquine.html.; Ellen Gabler & Roni Caryn Rabin, *The Doctor Behind the Disputed*

produce tests, treatments, and vaccines to fight COVID-19, we might find corporate corner-cutting in pursuit of enormous profit.[6]

Where research misconduct occurs in the setting of corporate-sponsored research, an obvious potential perpetrator would be the corporation. It would seem implausible to suppose such a corporation's only failure would merely be poor supervision of way-

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Covid Data, N.Y. Times (July 27, 2020, https://www.nytimes.com/2020/07/27/science/coronavirus-retracted-studies-data.html.

6 Initially more than 30 vaccines were in clinical trials. See Sheila Kaplan, *Stephen Hahn, F.D.A. Chief, is Caught Between Scientists and the President*, N.Y. Times (Aug. 10, 2020), https://www.nytimes.com/2020/08/10/health/stephen-hahn-fda.html. Consider the following US government commitments:
∗Nearly $2 billion for pharmaceutical giant Pfizer if, but only if, it can produce an FDA-approved vaccine plus 100 million doses by December 2020. Noah Weiland et al., *Pfizer Gets $1.95 Billion to Produce Coronavirus Vaccine by Year's End*, N.Y. Times (July 22, 2020), https://www.nytimes.com/2020/07/22/us/politics/pfizer-coronavirus-vaccine.html; Hannah Denham & Carolyn Y. Johnson, *Pfizer, BioNTech Reach $1.95 Billion Covid-19 Vaccine Deal with U.S. Government*, Wash. Post (July 22, 2020), https://www.washingtonpost.com/business/2020/07/22/pfizer-biontech-vaccine-contract-coronavirus/.
∗Over $2 billion to Sanofi and GlaxoSmithKline to pay for clinical trials and 100 million doses. Katie Thomas, *Sanofi and GlaxoSmithKline Snag Biggest Coronavirus Vaccine Deal Yet*, N.Y. Times (July 31, 2020), https://www.nytimes.com/2020/07/31/health/covid-19-vaccine-sanofi-gsk.html.; *The Deal with Sanofi and GlaxoSmithKline is the Biggest so far with the U.S. Government*, N.Y. Times (July 31, 2020), https://www.nytimes.com/2020/07/31/world/coronavirus-covid-19.html; Carolyn Y. Johnson, *European Drugmakers Sanofi and GSK Strike $2.1 Billion Deal with U.S. for a Coronavirus Vaccine*, Wash. Post (July 31, 2020), https://www.washingtonpost.com/health/2020/07/31/coronavirus-vaccine-deal-sanofi-gsk/.
∗Up to $1.2 billion AstraZenica for a vaccine being developed at Oxford University; David D. Kirkpatrick, *$1.2 Billion from U.S. to Drugmaker to Pursue Coronavirus Vaccine*, N.Y. Times (May 21, 2020), https://www.nytimes.com/2020/05/21/health/coronavirus-vaccine-astrazeneca.html; William Booth & Carolyn Y. Johnson, *Oxford Coronavirus Vaccine Safe and Promising, According to Early Human Trial Results Published in the Lancet*, Wash. Post (July 20, 2020), https://www.washingtonpost.com/world/europe/oxford-coronavirus-vaccine-phase-1-lancet/2020/07/20/12fbbc92-c857-11ea-a825-8722004e4150_story.html.
∗Nearly half a billion to Moderna, a Massachusetts biotech company, to develop a vaccine using mRNA technology, with another $1.5 billion for 100 million doses of their vaccine. Carolyn Y. Johnson, *Moderna's Coronavirus Vaccine Shows Encouraging Early Results*, Wash. Post (May 19, 2020), https://www.washingtonpost.com/health/2020/05/18/coronavirus-vaccine-first-results/; H. Konnath, *Moderna Inks $1.5B Deal for COVID-19 Vaccine Candidate*, Law360 (Aug. 11, 2020), https://www.law360.com/health/articles/1300465/moderna-inks-1-5b-deal-for-covid-19-vaccine-candidate?nl_pk=20e5ff3e-d0e3-4336-a872-ce6f7747bcff&utm_source=newsletter&utm_medium=email&utm_campaign=health.
∗Contracts exceeding half a billion dollars for Johnson & Johnson to develop a vaccine and screen compounds for potential treatments and, more recently, $1 billion to produce 100 million doses of its vaccine. Christopher Rowland, *Trump Administration Makes it Easier for Drugmakers to Profit from Publicly Funded Coronavirus Drugs, Advocates Say*, Wash. Post (July 1, 2020), https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/; J. O'Sullivan, *J&J Strikes $1B COVID-19 Vaccine Agreement With the Feds*, Law360 (Aug. 5, 2020), https://www.law360.com/health/articles/1298664/j-j-strikes-1b-covid-19-vaccine-agreement-with-the-feds?nl_pk=20e5ff3e-d0e3-4336-a872-ce6f7747bcff&utm_source=newsletter&utm_medium=email&utm_campaign=health.
∗$1.6 billion for Maryland-based Novavax to expedite its vaccine development; Noah Weiland et al., *Pfizer Gets $1.95 Billion to Produce Coronavirus Vaccine by Year's End*, N.Y. Times (July 22, 2020), https://www.nytimes.com/2020/07/22/us/politics/pfizer-coronavirus-vaccine.html; Hannah Denham & Carolyn Y. Johnson, *Pfizer, BioNTech Reach $1.95 Billion Covid-19 Vaccine Deal with U.S. Government*, Wash. Post (July 22, 2020), https://www.washingtonpost.com/business/2020/07/22/pfizer-biontech-vaccine-contract-coronavirus/. Favorable headlines alone have made millions for investors. David Gelles & Jesse Drucker, *Corporate Insiders Pocket $1 Billion in Rush for Coronavirus Vaccine*, N.Y. Times (July 25, 2020), https://www.nytimes.com/2020/07/25/business/coronavirus-vaccine-profits-vaxart.html.

ward individual scientists . . . who somehow managed the considerable collaboration that would be needed to produce bogus research that is persuasive enough to gain regulatory approval and marketing panache.

And yet that argument has never been made. That is, it has never been argued that research misconduct—by the definition—has been or could be committed by an organization.[7] Historically, misconduct in science focuses exclusively on wayward individuals, from Galileo, to Newton, to Mendel, and beyond.[8] In the same vein, regulations governing RM for federally funded research expressly regard organizations just as supervisors whose job is to encourage scientific integrity and to investigate when RM is suspected.[9] Moreover, throughout its history the federal Office of Research Integrity (ORI), which addresses scientific integrity affecting a substantial portion of federally funded biomedical research,[10] has investigated hundreds of allegations of RM. All of them focus on individual persons, never on organizations.[11]

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7 See *infra* n. 167 for discussion of a somewhat parallel concept, 'institutional misconduct', and the limitations of that concept.

8 See sources cited *supra* note 1.

9 See *infra* Part II. In federally funded research, for instance, the PHS expects institutions receiving federal grants to supervise their scientists and to 'be fully accountable for the appropriate use of any funds awarded'. Grant-receiving organizations must 'take all reasonable and practical steps to foster research integrity', 'ensur[e] that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award,' and 'report promptly to ORI any decision to initiate an investigation of research misconduct. U.S. Dep't Health & Human Serv's, NIH Grants Policy Statement §4.1.27 (2019), https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf [hereinafter NIH Policy Statement].The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, ... [and] certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project. *Id.* at §2.3.6 (I-48 to I-49); see also *id.* at §2.3.10 (I-63). 42 CFR 93.412 provides:

> (a) Institutions must *foster a research environment that discourages misconduct* in all research and that deals forthrightly with possible misconduct associated with PHS-supported research.
> (b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance ....

(emphasis added); see also *Policies—Regulations Q&A: Question and Answers—42 CFR Part 93*, Off. Res. Integrity, https://ori.hhs.gov/QA-Reg-6-05 (last accessed Mar. 2, 2021) (extensively discussing institutions' responsibilities in the context of RM, following the DHHS final rule which became effective on June 16, 2005, 30 days after the date of its publication in the Federal Register at PHS Policies on Research Market, 70 Fed. Reg. 28370 (May 17, 2005).

10 See NIH Policy Statement, *supra* note 9, at § 4.1.27. The analogous investigative entity for research conducted under auspices of the National Science Foundation (NSF) is the NSF's Office of Inspector General. P. Kakuk, *The Legacy of the Hwang Case: research misconduct in Biosciences*, 15 Sci. Engineering Ethics 545, 557 n.22 (2009). For discussion of some differences between research funding rules within the PHS and the NSF, see Nat'l Acads. Sci., Engineering, & Med., Fostering Integrity in Research 48–53, 65–65 (2017).

11 For currently active cases see *Case Summaries*, Off. Res. Integrity, https://ori.hhs.gov/content/case_summary (last accessed Mar. 2, 2021). From 1992 to 2011, for instance, 208 of those investigations led to official findings of misconduct. See Shamoo, *supra* note 1, at 45. 'From 1994 to 2003, research institutions and the ORI conducted 259 formal investigations into allegations of RM in biomedical or behavioral research, research training or related research activities supported by the PHS.' Lawrence J. Rhoades, Off. Res. Integrity, ORI Closed Investigations into Misconduct Allegations Involving Research Supported by the Public Health Service 1994–2003 (2004), https://ori.hhs.gov/sites/default/files/Investigations1994-2003-2.pdf. 'In 2002, the ORI reported that 99 institutions had 83 cases of misconduct, with 71 institutions reporting a new allegation.' Kakuk, *supra* note 11 at 557 n.22; see also D.S. Kornfield, *Research Misconduct: The Search for a Remedy*, 87 Acad. Med. 1, 2 (2012), https://ombudsman-fuer-die-wissenschaft.de/wp-content/uploads/2019/01/Kornfeld_Research-Misconduct.pdf. Per Korn-

Organizations have of course been held accountable in the setting of RM, but never for directly committing RM. This was the case, e.g., when in 2019 Duke University agreed to pay the federal government $112.5 million to settle False Claims Act (FCA) charges in connection with RM. Duke was held responsible for its employee's actions, not because Duke was said to have committed misconduct, but because the university agreed to be financially responsible as a condition of receiving federal research money, and because the researcher was acting within the scope of her employment.[12]

Admittedly, detecting and proving RM by an organization, orchestrated within the highest levels of management, can be difficult without substantial legal action and prodigious discovery to unearth the in-house emails and other communications that would reveal organization-level RM. Yet, as discussed below,[13] this is precisely what becomes available where corporate misdeeds spark intensive litigation.

This article aims to rewrite this corner of research integrity, arguing that organizations can directly commit research misconduct—by the definition—and that organizations can and should be held accountable not just for failures of oversight, but also for their own direct actions to corrupt science. Although these conclusions apply broadly, including to universities and government agencies, this article focuses on corporations engaged in biomedical research.

After defining 'research misconduct' in Part II, we will consider in Part III what it would look like for a corporation to commit RM, and how we might distinguish between corporate versus individual actors. Part IV first reframes several historic lawsuits to show how corporate misdeeds almost certainly amounted to RM even though RM was never expressly alleged. Part IV then details a new instance, also exposed through litigation, in which arguably a corporation directly committed RM. Finally,

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feld, one retrospective review of ORI guilty verdicts opined that misconduct was largely attributable to 'individual psychological traits and the circumstances in which the researchers found themselves', whereas another review found that '[a]pproximately one-third of the respondents (the accused) were support staff, one-third were postdoctoral fellows and graduate students, and one-third were faculty. Accusations of fabrication represented 45 per cent of the offenses, falsification 66 per cent, and plagiarism 12 per cent. The first two offenses frequently occurred together. Approximately three-quarters of the respondents admitted their guilt or did not provide a defense'. *Id*. at 1–2.

12 Press Release, Dep't of Justice, Office of Public Affairs, Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct (March 25, 2019), https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related (referring to Thomas v. Duke Univ., No. 1:17-CV-276, 2018 WL 4211375 (M.D.N.C. Sep. 4, 2018)); Bill Chappell, *Duke Whistleblower Gets More Than $33 Million in Research Fraud Settlement*, NPR (Mar. 25, 2019), https://www.npr.org/2019/03/25/706604033/duke-whistleblower-gets-more-than-33-million-in-research-fraud-settlement; S. Kaplan, *Duke University to Pay $112.5 Million to Settle Claims of Research Misconduct*, N.Y. Times (Mar. 25, 2019), https://www.nytimes.com/2019/03/25/science/duke-settlement-research.html. Duke pulmonary researcher Erin Potts-Kant had fabricated or falsified data on some 30 federal grant applications and on reports as far back as 2006. Seventeen papers have now been retracted. ORI found Erin Potts-Kant guilty on November 7, 2019. See *Case Summary: Potts Kant, Erin N.*, Off. Res. Integrity, https://ori.hhs.gov/content/case-summary-potts-kant-erin-n (last accessed Mar. 2, 2021). Once whistle-blower Joseph Thomas and the federal government brought suit under the False Claims Act, Duke's oversight obligations and its agreement to federal grant conditions forced it to settle and pay. See Relator's Memorandum in Support of Motion for Partial Summary Judgment—Imputation of Potts-Kant's Knowledge to Duke, Thomas v. Duke Univ. No. 1-17-cv-00276-CCE-JLW, (M.D.N.C. Aug. 8, 2018), https://apps.npr.org/documents/document.html?id=5780563-Thomas-v-Duke-Whistleblower-Case.

13 See *infra* Part IV.

Part V explores some implications of this novel finding. Although this article does not purport to provide an exhaustive exploration, federal regulations illustrate the necessary adjustments in how to identify and sanction research misconduct.

II. DEFINING RESEARCH MISCONDUCT

To make the case that an organization can commit research misconduct—by the definition—we must first define 'research misconduct'. The concept is variably defined,[14] yet two elements are universally included—fabrication and falsification. Both are included in the federal definition, which serves as the template for definitions worldwide[15] and on which this article relies.

Per 42 CFR § 93.103:

> *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record . . . .
>
> (d) Research misconduct does not include honest error or differences of opinion.[16]

42 CFR § 93.104 continues:

> 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

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14 See, *e.g.*, K.J. Ryan et al., Comm'n on Research Integrity, Integrity and Misconduct in Research Report of the Commission on Research Integrity 6–18 (1995), https://ori.hhs.gov/sites/default/files/report_commission.pdf. The 'Ryan Commission', for instance, encompasses actions such as sabotage of research within its definition that emphasizes misappropriation, interference, and misrepresentation:

> Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in reviewing the proposals or research reports of others.

Id. at 15.

15 See, e.g., ALLEA, The European Code of Conduct for Research Integrity 8–9 (2017), https://allea.org/code-of-conduct/.While internationally virtually all definitions include fabrication, falsification and plagiarism, some add other offenses. See, e.g., D.B Resnik et al., *An International Study of Research Misconduct Policies*, 22 Accountability in Res. Pol'ys & Quality Assurance 249, https://www.researchgate.net/publication/275666303_An_International_Study_of_Research_Misconduct_Policies (last accessed March 5, 2021) (finding that "twenty-two of the top forty research and development funding countries (55 per cent) had a national misconduct policy. . . . All twenty-two countries (100 per cent) with national policies included fabrication, falsification, and plagiarism in the definition of misconduct, but beyond that there was considerable diversity," encompassing such matters as unethical authorship, unethical publication practices, human subjects mistreatment and the like). See also D. B. Resnik & Z. Master, *Policies and Initiatives Aimed at Addressing Research Misconduct in High-Income Countries*,10(3) PLOS Med. e1001406 (2013), https://doi.org/10.1371/journal.pmed.1001406; D.B. Resnik et al., *Research Misconduct Definitions Adopted by U.S. Research Institutions*, 22 Accountability in Res. Pol'ys & Quality Assurance 14, 14–21 (2015). We need not decide here which approach to embrace, because our conclusions will hold for any definition that includes fabrication and falsification, which all definitions do.

16 Virtually all definitions also include plagiarism. Per 42 C.F.R. § 93.103(c): "Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit." Plagiarism is not a prominent issue here, hence not part of our discussion.

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.[17]

Importantly, this definition emphasizes the research record. A solitary scientist inventing numbers in a lab is not a serious threat to science until she/he actually shares those fictitions with a claim that they represent proper science. Federal regulations governing research funded by the Public Health Service (PHS) are instructive:

> *Research record* means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to Department of Health and Human Services (HHS) or an institutional official by a respondent in the course of the research misconduct proceeding.[18]

In other words, the research record essentially is any assertion purporting to describe the underlying scientific work and its findings.

This article proposes distinguishing RM from a broader concept: scientific misconduct. *Research misconduct* focuses on individual research projects and violations of proper design, execution, analysis, and reporting, whereas *scientific misconduct* emphasizes damage to the broader scientific literature, where the problem may not specifically reside within any particular study/studies.

To illustrate the difference, suppose a pharmaceutical company seeking Food and Drug Administration (FDA) approval for a new drug provides just one study showing the drug to be safe and effective, while withholding nine studies concluding the contrary. This would not be *research misconduct* if all 10 studies feature high-quality methodology, data gathering, analysis, and reporting. It might, however, be *scientific misconduct* if the company purposely mischaracterizes the overall science as supporting the drug, when greater, but buried, evidence suggests otherwise.[19] Similarly, pharmaceutical firms' use of physician 'thought leaders' to promote off-label drug uses potentially promotes incorrect beliefs about what the underlying science actually

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17 In December 2000, the federal government updated its policies regarding RM, which would now apply to all research and all researchers, including such fields as anthropology, biology, economics, education, linguistics, medicine, psychology, social sciences, statistics mathematics etc. See Federal Policy on Research Misconduct, 65 Fed. Reg. 235, 76260–64 (Dec. 6 2000), https://www.govinfo.gov/content/pkg/FR-2000-12-06/pdf/00-30852.pdf. As a result of this rule expansion, virtually all universities and research institutions must adopt these rules, since virtually all receive federal funding of one sort or another. "Independent researchers and small research institutions are [also] covered by this policy" (Federal Policy on Research Misconduct at II[c]).

18 Research Record, 42 C.F.R § 93.224.

19 See B Holman & K.C. Elliott, *The Promise and Perils of Industry-Funded Science*, 2018 Phil. Compass. at 5:

> [R]esearchers used the Freedom of Information Act to retrieve every antidepressant study submitted to the FDA between 1987 and 2004. Of the results reported, 38 studies found the antidepressants to be effective, and 36 found them to be no better than a placebo. However, while nearly every positive study was published, only three of the 36 negative studies were published as such (although 11 of the negative studies were published as if they were positive).

Thus, whereas the FDA saw 38 positive studies and 36 negative studies, doctors and patients saw 48 positive studies and three negative studies in the published literature. Erick H. Turner et al., *Selective Publication of Antidepressant Trials and its Influence on Apparent Efficacy*, 17 New. Eng. J. Med 252 (2008).

supports–potentially scientific misconduct even if the relevant individual studies do not feature research misconduct.[20]

In contrast, if the company were "cooking" or selectively deleting data to produce desired conclusions in a given study, this would be direct, organization-level RM. Research misconduct is thus a subset of scientific misconduct.

Plagiarism, often listed as a core genre of RM,[21] exemplifies the distinction. Inasmuch as the plagiarist falsely states that she/he, rather than the true author, created the research concept, design, execution, etc., then she/he arguably commits RM, in essence falsifying the report of authorship.[22] It is akin to another well-recognized genre of falsification, namely, stating that a research project has secured institutional review board (IRB) approval when it has not. Ghostwriting, another form of authorship falsification, is discussed below.[23]

In contrast, plagiarism can also be a form of *scientific* misconduct, e.g., where it amounts to duplication. Duplicate publication damages the scientific literature as a whole by incorrectly augmenting the number of studies that reach a particular conclusion,[24] even where that study (and thereby its duplications) has internal scientific integrity.

The cornerstone of the distinction is that, for scientific misconduct: if the underlying individual research projects and reports are faithful to the truth, we can at least potentially wade through the mess and find our way to correct it. However, for research misconduct: if the design of a study is contoured to avoid truth, or if the data are falsified/fabricated or the report is otherwise untruthful, we have nowhere else to

20 Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Science*, 32 J.L., Med. & Ethics 641, 641–57 (2004).

21 42 C.F.R. § 93.103(c): "Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."

22 Similarly, falsifying one's credentials may also be a form of RM. See, e.g., D.M. Parrish, *Falsification of Credentials in the Research Setting: Scientific Misconduct?*, 24 J.L., Med. & Ethics 260, 260–66 (1996). Parrish does not distinguish between RM and scientific misconduct and, per the definitions presented in this article, actually conflates the two. His discussion, however, mainly falls within the bounds of RM.

23 Admittedly, team science and the large numbers of authors identified in much of contemporary biomedical research pose challenges. The challenges, however, concern not the basic concepts of RM versus SM, but rather the question of how to allocate responsibility where participation in the research is so diffuse. Some approaches to authorship expect that everyone claiming to be an author should be responsible where RM has occurred, whereas others propose that accountability should be more narrowly focused. See, e.g., K. Hussinger & M. Pellens, *Scientific Misconduct and Accountability in Teams*, 14 PLoS ONE e0215962 (2019), https://doi.org/10.1371/journal.pone.0215962.

24 "Duplicate publication is a serious issue that not only raises copyright concerns and undermines research integrity but also distorts evidence if duplicate publications were included in systematic reviews simultaneously. RCTs may be more likely to have duplicates, as the prevalence of duplicates for RCTs in this study was higher than that in other article types in another study (12 per cent in this study vs 5 per cent in all article types)." V. Zhang et al., *Avoidance of Duplicate Publications From Randomized Clinical Trials*, 3(12) JAMA Network Open e2027184 (2020), https://jamanetwork.com/article.aspx?doi=10.1001/jamanetworkopen.2020.27184&utm_campaign=articlePDFpercent26utm_medium=articlePDFlink%26utm_source=articlePDF-%26utm_content=jamanetworkopen.2020.27104; see also X Jia et al, *Assessment of Duplicate Publication of Chinese-Sponsored Randomized Clinical Trials*, 3(12) JAMA Network Open e2027104 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773491. Similarly, where corrupted research projects are incorporated into meta-analyses, RM becomes scientific misconduct, writ large. See C.A. Garamendia et al., *Research Misconduct in FDA-Regulated Clinical Trials: A Cross-sectional Analysis of Warning Letters and Disqualification Proceedings*, 52 Therapeutic Innovation & Reg. Sci. 592, 592–605 (2018), https://journals.sagepub.com/doi/abs/10.1177/2168479017749514.

turn. This article thus focuses on research misconduct because, as it violates science's integrity at the most basic level—the individual study—it is a particularly pernicious form of scientific misconduct.

We next consider the questions of what RM would look like when undertaken by an organization and, in any given instance, how one would determine whether the actor is the organization versus the individual scientist(s).

III. RESEARCH MISCONDUCT BY A CORPORATION

III.A. How Would an Organization Commit Research Misconduct

Organizations can commit fabrication or falsification via the same avenues as individuals: in design, execution, analysis, and reporting of the research. Although data manipulation comprises the great majority of instances in which, e.g., ORI has found RM,[25] myriad other avenues are available for producing a research record that does not accurately reflect underlying realities.

1. Design

To ensure a product will shine regardless of realities, potential avenues by which design could implicate RM include:

- selecting for research only those questions whose results will likely favor the corporation;[26]
- unrepresentative patient selection, e.g., formulating the study's inclusion/exclusion criteria to enroll only those individuals likely to benefit and unlikely to experience adverse effects;[27]
- selective use of surrogate endpoints;
- failure to define endpoints clearly;
- follow-up intervals that maximize the likelihood of favorable outcomes and minimize the tally of adverse events;
- trials that are too small to show differences from competitor drugs;
- multiple endpoints in the trial, selecting for publication only those with favorable results;
- testing a drug against competing treatment(s) known to be inferior;
- testing a drug against too low a dose of a competitor drug (making one's own drug appear more effective), or too high a dose (making one's drug appear less toxic).[28]

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25 See *Case Summaries*, *supra* notes 11–12.

26 "Large pharmaceutical companies have the financial means to conduct wide-ranging trials, but may be selective in the type of questions they want answered. Once a drug is approved, there is considerable commercial pressure not to inquire further into potential side-effects, and this absence of statistical evidence is then used as a shield against criticism." Lemmens, *supra* note 20, at 652.

27 Per a former Chief Executive of a CRO: 'Companies can now pick and choose populations . . . in order to get a most pronounced drug benefit signal as well as a "no-harm" signal.' S. Sismondo, Ghost Managed Medicine: Big Pharma's Invisible Hands 54 (2018), https://www.matteringpress.org/books/ghost-managed-medicine; see also D.W. Light et al., *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 41 J.L., Med. & Ethics 590, 594 (2013).

28 Holman & Elliott, *supra* note 19, at 4 (Design bias 'occurs when companies shape science by designing studies in ways that are most likely to generate results that are favorable to them . . . . Researchers can give a competitor's drug in an overly high dose to make their drug look safe by comparison or in a low dose to make theirs look more effective. They can also selectively report outcomes or positive subgroups, secondary

This is not to say that each of the foregoing is RM *per se*. Every research project must circumscribe its attention, and focusing on whatever is most likely to succeed could exhibit bias shy of misconduct. However, a line is crossed when research is consciously designed to produce a result that is, or likely is, contrary to underlying realities.

2. Execution

Once a clinical trial is designed, companies must select investigators to recruit human participants, provide research interventions according to protocol, gather data, and submit results. Ideally a company will select highly qualified investigators known for meticulous work. Instead, however, it might select and financially incentivize investigators known to recruit subjects and complete trials with lightning speed, potentially glossing over eligibility criteria, steering people selectively into trial groups rather than honoring randomization, or 'tuning' data to whatever is needed.[29]

Contract research organizations (CROs) often play a large role in conducting clinical trials, planning logistics and running trials. '[P]harma companies sponsor some 70% of all clinical trials, and 70–75% of these are run by CROs'[30] that typically recruit the physicians who then recruit the trial subjects and collect the data. Those physicians, in turn, may or may not adhere scrupulously to trial protocols.[31] Unlike academicians or private practice physicians, CROs generally 'have no interest in publishing the results under their own names—they produce data that is wholly owned by their sponsors. As a result, pharma companies have complete control over an enormous trove of clinical trial data'[32] they can then potentially use to their best advantage.[33]

Data manipulation can occur during data gathering or at the ensuing stage of data analysis (discussed just below). Investigators could, e.g., concoct, shade, delete, or

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analyses, or post hoc analyses as if they were always the intended focus of the paper.'). See M. Wynia & D. Boren, *Better Regulation of Industry-Sponsored Clinical Trials is Long Overdue*, 37 J.L., Med & Ethics 410, 410–19 (2009); M. Angell, *Industry-Sponsored Clinical Research: A Broken System*, 300 JAMA 1069, 1070 (2008); M. Gaudino et al, *Characteristics of Contemporary Randomized Clinical Trials and Their Association With the Trial Funding Source in Invasive Cardiovascular Interventions*, JAMA Internal Med. (June 1, 2020); R. Smith, *Medical Journals are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PLoS Med. 0364, 0365 (2005), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020138; see also M.A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J.L., Med. & Ethics 511, 513 (2012); Sismondo, *supra* note 27, at 60.

29 'The growing use of financial recruitment incentives, targeting both research subjects and the health care workers who recruit them, has been discussed in the literature. Commentators have also pointed out that financial interests may negatively impact researchers' dealings with research subjects during a trial. When huge profits lure, and pressure mounts to bring novel drugs or therapies quickly to the market, potential risks may be perceived somewhat more lightly, and inclusion or exclusion criteria may become more flexible.' Lemmens. *supra* note 20, at 645.

30 Sismondo, *supra* note 27, at 68.

31 '[P]erhaps the simplest way to boost recruitment is to establish good rapport with your patients. "I'd say that about 20 percent of the volunteers we recruit are our own patients, who enroll because they like the close attention they get when they are in a study" says Elinolf. Another 30 to 40 percent are also patients, who sign up on the strength of our relationship with them. They like us, trust us, and figure it's going to be okay for them if we suggest it.' D.A. Grandinetti, *Add Fun and Profits to Your Practice: Do Research*, 74 Med. Econ. 67, 79 (1997).

32 Sismondo, *supra* note 27, at 68.

33 *Id*. at 54.

simply not record unfavorable data.[34] Sometimes an investigator might be sloppy, failing to conform to protocol, yet the company may use the data anyway.[35] Overall, if an investigator or a company 'ma[kes] up data or results and record[s] or report[s] them,' that is fabrication.[36] If it 'manipulat[es] research materials, equipment, or processes, or chang[es] or omit[s] data or results such that the research is not accurately represented in the research record,'[37] then it commits falsification. Importantly, one act (e.g., fabricating a dataset) can corrupt multiple trials that rely on that dataset.[38] Finally, if all this is done with the intent, encouragement or tacit knowledge of the company, it could be corporate-level RM.

3. *Analysis*

Once data are gathered they must be analyzed. Data can 'cooked', a concept 'Charles Babbage in 1830 defined as "an art of various forms, the object of which is to give to ordinary observations the appearance and character of those of the highest degree of accuracy"; it can be "mined" to find a statistically significant relationship that is then presented as the original target of the study'.[39] Data points can be dropped to conform to expectations, or design or methodology descriptions can be changed, *post hoc*, to produce favorable results.[40] In one instance, a packaging problem permitted nine subjects to see which medication they were receiving—a violation of the trial's blinded protocol. Initially the pharmaceutical company 'ran the numbers without those nine, and the result fell just short of statistical significance, at which point eight of the subjects were added back into the analysis, improving the statistics enough to make the results significant—the problem was later hidden in the submission to the FDA . . . '[41].

In another genre of data manipulation, 'many published results of randomised trials are biased by selective reporting of trials with positive results, and by researchers . . . selectively reporting nominally statistically significant outcomes. This latter practice has been called P-hacking'.[42] It can involve 'monitoring data accrual and stopping a trial if an analysis yields a significant P-value or using different statistical analyses, data

34 See, e.g., P. Brock, *A Pharmaceutical Company's Approach to the Threat of Research Fraud*, in Fraud and Misconduct in Biomedical Research 89–104 (3rd ed., 2001), https://epdf.pub/fraud-and-misconduct-in-biomedical-research-3rd-edition.html; see also A. Horowitz, *Role of the FDA, NIH, and Other Bodies in the United States*, in Fraud and Misconduct in Biomedical Research 89–104 (3rd ed., 2001), https://epdf.pub/fraud-and-misconduct-in-biomedical-research-3rd-edition.html.

35 S.D. Krumholz et al., *Study of Neurontin: Titrate to Effect, Profile of Safety (STEPS) Trial – A Narrative Account of a Gabapentin Seeding Trial*, 171 Archive Internal Med. 1100, 1102 (2011). See also C.S. Landefeld & M.A. Steinman, *The neurontin legacy - marketing through misinformation and manipulation*. 360 New Engl. J. Med. 103 (2009).

36 42 C.F.R. § 93.103(a).

37 42 C.F.R. § 93.103(b). (emphasis added)

38 As discussed above, *supra* note 5, more than one article had to be retracted from major medical journals when it became apparent that the dataset on which those articles relied had been fabricated. See M. Davey et al., *supra* note 5.

39 Fanelli, *supra* note 2, at 1.

40 *Id*. at 8; see also Wynia & Boren D, *supra* note 28.

41 Sismondo, *supra* note 27, at 87.

42 M. Prior er al., *Inadvertent P-Hacking Among Trials and Systematic Reviews of the Effect of Progestogens in Pregnancy? A Systematic Review and Meta-Analysis*, 124 BJOG 1008, 1008 (2017), https://doi.org/10.1111/1471-0528.14506.

eligibility criteria, outcomes and treatment groups before deciding which to report post-analysis'.[43] Perhaps worse, in nonregistered clinical trials, postulated outcomes may be silently switched once analysis shows where statistical significance lies. [44]

In a particularly troubling development, drug makers or their CROs can commit covert data manipulation in bioequivalence trials.[45] Essentially, the practice involves 'manipulat[ing] bioequivalence trial data for non-approvable formulations by performing an interim analysis followed by re-analysis of pharmacokinetic [PK] profiles under new subject aliases, with a switch of Test and Reference and/or dilutions', 'performing an undocumented interim statistical analysis after a portion of the subject PK-data has become available'.[46]

Federal regulations identify myriad kinds of behavior that can trigger warnings or sanctions at the *execution* and *analysis* stages, including[47]: fabrication of data and their recording and reporting; manipulation of data so that data no longer accurately reflect what was observed; repeated and systematic deviation from the established protocol; deviation from investigational plan; failure to maintain adequate/accurate source documentation; failure to personally supervise the study; submission of false information to the FDA and sponsor. Organization-specific violations include[48]: '[f]ailure to select qualified clinical investigators'[49]; '[f]ailure to provide investigators with the information they need to conduct the investigation'[50]; '[f]ailure to adequately monitor the study'[51]; '[f]ailure to bring non-compliant investigators into compliance'.[52]

4. Reporting

Even if a trial is properly designed, its procedures followed, and data gathered and analyzed appropriately, RM can still occur if write-ups do not accurately reflect reality. As noted above, the research record is essentially any assertion that purports to describe the underlying scientific work and its findings.[53]

Reports can misrepresent the findings and, if underlying details of design, data, and analysis are not made available, misrepresentation can be difficult to detect.[54] In one example discussed below, Merck pharmaceutical corporation is said to have 'omitted

43 *Id*.

44 *Id*. at 1013.

45 First described in a Notice of Concern from the World Health Organization (2016) and an Untitled Letter and a form 483 from U.S. FDA (2015, 2016), the practice is exceedingly difficult to detect. A. Fuglsang, *Detection of Data Manipulation in Bioequivalence Trials*, 156 Eur. J. Pharmaceutical Sci. 105595 (2021).

46 *Id*. at 1–2.

47 See Garamendia et al., *supra* note 24.

48 U.S. Food & Drug Admin., *Part V—Regulatory/Administrative Strategy*, in Compliance Program 7348.810 Bioresearch Monitoring (2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/compliance-program-7348810-bioresearch-monitoring.

49 21 C.F.R. §§ 312.53(a), 312.53(c)(1)(iii), 312.53(c)(1)(iv), 812.43(a), 812.20(b)(7).

50 21 C.F.R. §§ 312.50, 312.55, 812.40, 812.45.

51 21 C.F.R. §§ 312.50, 312.53(d), 312.56(a), 511.1(b)(8)(ii)*, 812.40, 812.43(d), 812.46

52 21 C.F.R. §§ 312.56(b), 812.46(a).

53 Research Record, 42 C.F.R. §93.224.

54 See, e.g., *supra* note 5 and the retractions of two articles in major medical journals, necessitated because the papers' underlying database turned out to be likely fictitious.

key incidences of heart troubles, creating "misleading" conclusions about [the drug Vioxx's] safety.'[55]

Ghostwriting is a particularly insidious form of RM.[56] As early as 1994, editors of prominent medical journals lamented:

> There are ghosts as well as guests lurking in the bylines—shadowy figures who, increasingly, are in fact the actual writers .... These ghosts might be clinical research associates at pharmaceutical companies who are bound by employment contracts not to be listed as authors or public relations officers writing for government officials or organization executives ... and prominent physicians have then been hired to allow their names to be attached as 'authors' before the reviews were submitted to learned journals.[57]

Ghostwriting has been defined as 'the failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript'.[58] The treachery is then completed by inducing—usually paying—a well-known academic thought leader(s) to serve as the first author(s) of the article. This latter is a form of guest/honorary authorship, defined as 'the designation of an individual who does not meet authorship criteria as an author'.[59] In typical ghost-plus-guest authorship, 'the trial itself and the analyses [are] complete before the academically affiliated investigators [are] involved in the manuscript'.[60] Among major, peer-reviewed medical journals, ghostwriting and guest authorship are disturbingly frequent.[61]

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55 Before the drug was pulled from the market, according to a review by an FDA investigator, it caused an extra 27,000 heart attacks and cardiac-related deaths. P. Whoriskey, *As Drug Industry's Influence Over Research Grows, So Does the Potential for Bias*, Wash. Post (Nov. 24, 2012), http://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html?hpid=z1; K.B. O'Reilly, *Drugmakers Pledge Transparency to Tackle Credibility Problem in Journals*, AMA News (May 21, 2012), http://www.ama-assn.org/amednews/2012/05/21/prsb0521.htm.

56 'The growing phenomenon of ghost writing is clearly the most extreme challenge to the integrity of the medical literature." Lemmens. *supra* note 20, at 647.

57 D. Rennie & A. Flanagin, *Authorship! Authorship! Guests, Ghosts, Grafters, and the Two-Sided Coin*, 271 JAMA 469, 470 (1994).

58 J.S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 JAMA 1800, 1800 (2008); A. Flanagin et al., *Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals*, 2002 JAMA 280, 282–85, 1998 JAMA 222, 222.

59 See sources cited *supra* note 58. Admittedly, journals vary in their standards as to what will count as an author, versus a non-author contributor. See, e.g., Sismondo, *supra* note 27; L.R. Lacasse & J. Leo, *Ghostwriting at Elite Academic Medical Centers in the United States*, 7(2) PLoS Med e1000230 (2010), doi:10.1371/journal.pmed.1000230; Hussinger & Pellens, *supra* note 23; Flanagin et al., *supra* note 58. That said, however, someone who has contributed essentially nothing to the design, execution, or data analysis of a research project cannot be deemed an author.

60 J.S. Ross et al., *supra* note 58, at 1802.

61 Flanagin et al. studied six leading journals, finding that 11 per cent had evidence of ghost authors, 19 per cent had evidence of honorary authors, and 2 per cent had evidence of both. Flanagin et al., *supra* note 58. In other studies, ghost- and guest-authorship were seen in 13 per cent of research articles, 10 per cent of review articles, 6 per cent of editorials, and 11 per cent of Cochrane reviews. J.S. Ross et al., *supra* note 58 (citing Flanagin). A 2009 study examined six prominent medical journals, finding that for ghost-authorship, the worst was *New England Journal of Medicine* (11 per cent), whereas the worst for honorary authorship was *Nature Medicine*, at 39 per cent. J. Wislar et al., Abstract, *Prevalence of Honorary and Ghost Authorship in Six General Medical Journals*, Sixth Int'l Congress on Peer Review & Biomedical Pub. 10–12 (2009). See

It is clear, albeit under-recognized, that ghost and guest authorship are a form of research misconduct. Analogous to plagiarism,[62] they falsely state who bears responsibility (not just credit) for the work in question. Hence, the research record thus does not correctly reflect the underlying research realities. More importantly, they conceal what may be ulterior agendas embedded in the work, thereby rendering more difficult the task of discerning its credibility.

In biomedical science ghostwriting as RM is, by its very nature, almost uniquely attributable to organizations rather than to individual scientists. In the case of pharmaceutical studies, the corporation as an entity designs the research, hires the CRO or local investigators, analyzes the data and does the write-up. Only then does it hire the lead 'authors'. The correlative guest authorship RM, conversely, is attributable to the individuals who allow themselves to be listed as authors when they know they have done no real authoring.

5. Intentional/Knowing/Reckless

Where these research offenses are committed intentionally, knowingly, or recklessly, and constitute a significant departure from accepted research practices,[63] research misconduct has arguably occurred.[64] As explored in Part IV, discerning corporation-level intentionality can be difficult—until litigation reveals the in-house communications that evidence actors' underlying agendas. Several historic examples showing just such intent/knowledge will be explored, as well as a newer case of corporate RM.

III.B. Research Misconduct: by Organization versus by Individual

It is one thing to suggest that an organization can commit RM, but quite another to discern, in a given instance, whether the organization or individual actors are responsible. The answer begins by considering how and by whom the project was conceived, and under whose direction it was carried out. Concepts of agency and of authorship help us identify that 'moving force'.

1. Agency

US law has long recognized that a corporation is a 'person' capable of setting and accomplishing objectives, mainly by directing employees.[65] While organizations can be

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also Rennie & Flanagin, *supra* note 57; D.W. Shapiro et al., *The Contributions of Authors to Multiauthored Biomedical Research Papers*, 271 JAMA 438, 438–442 (1994).

62 Lacasse & Leo, *supra* note 59.

63 42 C.F.R. § 93.104.

64 A related but distinct issue concerns team science, in which large numbers of individual scientists collaborate in a research project. Where tasks and authorship are widely diffused, attributing responsibility and discerning each author's level of intention or knowledge regarding corruption within the project can be challenging. Nevertheless, the distinction between RM undertaken at the corporate level and steered by high-level management, versus RM at the level of individual scientists, remains valid even if in a given instance it may be difficult to determine which individuals knew what. See, e.g., Hussinger & Pellens, *supra* note 23.

65 Per *Citizens United v Fed. Election Comm'n*:

> The Court has recognized that First Amendment protection extends to corporations .... ('The identity of the speaker is not decisive in determining whether speech is protected. Corporations and other associations, like individuals, contribute to the "discussion, debate, and the dissemination of information and ideas" that the First Amendment seeks to foster' ...) The Court has thus rejected the argument that political speech of corporations or other associations should be treated differently under the First Amendment simply because such associations are not 'natural persons'.

vicariously liable for employees' conduct, they can also be directly liable for their own actions. Hence, whereas *respondeat superior* penalizes a company when its employee carelessly causes a car accident, that same company can be directly liable for negligent entrustment if it knew or should have known the employee was a chronic drunk with a lengthy crash record.[66]

Guidance regarding corporation-as-actor comes from the Restatement 3d of Agency: 'an employee is an agent whose principal controls or has the right to control the manner and means of the agent's performance of work . . . .'[67] Here, where the corporation acts as principal steering the employee's action, then we look to the corporation to assess potential RM. Thus, a pharmaceutical firm typically decides which areas of research will be pursued or abandoned, which employees will work on which projects, etc.

Corporate persons are also capable of acting knowingly, intentionally or recklessly. Since 1863, for instance, the FCA has been invoked to hold both corporations and individual persons responsible for defrauding the federal government.[68] A key criterion of that statute is that the false claim be 'knowing', defined to include deliberate ignorance and reckless disregard of the truth.[69]

Accordingly, so long as a research project is undertaken by an organization controlling its agents' performance and designed to serve the organization's purposes, RM can ordinarily be attributed to the organization. In contrast, research grants illustrate initiatives by individual scientists. The scientists conceive of an idea, write up a grant

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558 U.S. 310, 342–43 (2010) [citing First Nat. Bank v. Bellotti, 435 U.S. 765, 785 (1978)]; see also *Bellotti* 435 U.S. at 822 ('This Court decided at an early date, with neither argument nor discussion, that a business corporation is a "person" entitled to the protection of the Equal Protection Clause of the Fourteenth Amendment.') [citing Santa Clara City. v. Southern Pac. R.R. Co., 118 U.S. 394, 396 (1886)].

66 J.J. Burns, *Respondent Superior as an Affirmative Defense: How Employers Immunize Themselves from Direct Negligence Claims*, 109 Mich. L. R, 657, 657–82 (2011).

> An employer who is liable solely because of respondeat superior is not necessarily negligent; instead, it is liable because we have made a 'public policy determination that liability for acts committed within the scope of employment should be allocated to the employer as a cost of engaging in that business'. In situations of liability for negligent entrustment, on the other hand, the negligence of the employer is likely the focus of the claim. In other words, '[d]irect liability is liability for breach of one's own duty of care, while vicarious liability . . . is liability for breach of another's duty of care. A negligent entrustment claim is therefore an instance of direct liability', as one of the key components of the tort is that the employer breached its own duty of care.

Id. at 668–69. (citations omitted)

67 Restatement (Third) of Agency §7.07(3) (Am. Law Inst. 2006). Per §7.07(2):

> An employee acts within the scope of employment when performing work assigned by the employer or engaging in a course of conduct subject to the employer's control. An employee's act is not within the scope of employment when it occurs within an independent course of conduct not intended by the employee to serve any purpose of the employer.

68 Per 31 U.S.C. § 3729(a)(1):

> [A]ny person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

69 Per 31 U.S.C. § 3729(b)(1): 'For purposes of this section—(1) the terms "knowing" and "knowingly"—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information . . . .' See discussion of Duke University's March 2019 settlement, *supra* note 12.

proposal and seek funding. An organization such as a university might then, as envisioned in federal grant regulations,[70] manage the funds to ensure the work complies with funding rules. Here, the individual scientists would most likely be the perpetrators if RM occurs.

That said, although this article focuses on corporations and RM, we note here that a university could also be the entity to directly commit RM, for instance through the Bayh-Dole Act that permits not-for-profit organizations such as academic institutions to patent products they develop from federally sponsored research.[71] University officials could identify promising projects, then direct and incentivize investigators to design and execute those studies most likely produce the desired outcomes regardless of their veracity. It has been suggested that incentives in academia have become increasingly perverse, becoming a system that 'selectively weeds out ethical and altruistic actors, while selecting for academics who are more comfortable and responsive to perverse incentives from the point of entry'.[72]

2. Authorship

Authorship likewise illuminates the distinction between corporations versus individuals in RM. To be an 'author' is to be the creator, source, or originator of a work.[73] If the organization *authored* the study, then it should be the entity directly accountable.[74]

International Committee of Medical Journal Editors (ICMJE) guidelines are followed by myriad medical journals:

> The ICMJE recommends that *authorship* be based on the following 4 criteria: [1] Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND [2] Drafting the work or revising it critically for important intellectual content; AND [3] Final approval of the version to be published; AND [4] Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.[75]

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70 See Responsibilities of Institutions, 42 C.F.R. §93.300.

71 Patent and Trademark Law Amendments (Bayh–Dole) Act, Pub. L. No. 96-517, 94 Stat. 3015, 3019 (1980).

72 M.A. Edwards & S. Roy, *Academic Research in the 21st Century: Maintaining Scientific Integrity in a Climate of Perverse Incentives and Hypercompetition*, 34 Envtl. Eng. Sci. 51, 52 tbl.2 (2016).

73 *Authorship*, Merriam-Webster, https://www.merriam-webster.com/dictionary/authorship (last accessed Mar. 5, 2021).

74 Conversations about authorship often concern investigators who may want undeserved credit for others' work. But here our interest is the reverse: when does the organization deserve (for better or worse) to be deemed the author of a study. For further discussion, see R. Smith, *The Trouble with Medical Journals*, 99 J.R. Soc. Med. 115, 115–119 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1383755/; ALLEA, *supra* note 15; J.M. McClellan et al., *Courtesy Authorship in Academic Surgery Publications*, 154 JAMA Surg. 1110, 1110–1116 (2019); P. Fontanarosa et al., *Authorship and Team Science*, 318 JAMA 2433, 2433–2437 (2017); J.M. McClellan et al., *Courtesy Authorship in Academic Surgery Publications*, 2019 JAMA Surgery Online 1, 1–7 (2019); S.D. Mentzelopoulos & S.G. Zakynthinos, *Research Integrity, Academic Promotion, and Attribution of Authorship and Nonauthor Contributions*, 318 JAMA 1221, 1221–22 (2017).

75 Int'l Comm. of Med. Journal Editors, Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals 2 (2019), http://www.icmje.org/recommendations/.

The first two criteria are particularly relevant: [1] substantial contribution to conception/design *or* data acquisition/analysis/interpretation and [2] drafting/critically revising the work.

Regarding [1]: as noted above, organizations can and do undertake activities. They need not literally 'hold the pen' with which bogus data are created. It is sufficient that they direct someone to. Indeed, in one of the ORI's earliest findings of research misconduct, Dr. Roger Poisson was found guilty of fabrication and/or falsification because '[i]nterviews with the project staff revealed that *the actual data changes had been made by the data management staff at the direction of the Principal Investigator,* Dr. Roger Poisson.'[76]

Broadly, much of medical researchers' authoring is quite indirect. In large clinical trials the clinician–investigator often is not the one who actually screens potential subjects, provides the intervention, and records the data. She/he may do some of these things, but much of the work may be done by a research nurse coordinator, or outsourced to a CRO.[77] Nurse coordinators and CROs generally are not on the list of authors even though they do much or most of the actual data gathering. The one who hired them will ordinarily be deemed author.

In 'bench research', again the named investigators may not be the ones to pour chemicals into beakers, handle lab mice, or record numbers in notebooks. Lab techs often do much or all of this.[78] The investigator is author because she/he is the one who initiated such work and engaged the lab techs, or who agreed with colleagues to participate in the collaborative effort to gather such data according to the agreed-on methodology for the agreed-on purpose.

Regarding [2]: similarly, the process of drafting, critiquing, and editing manuscripts is often not entirely done by named authors. Many universities, for instance, provide services for scientific writing.[79] While such an office might require a first draft capturing the overall gist of the research, much of the further drafting and editorial refinement may be done by such services.[80] Scientists, after all, are not always the most lucid writers.

Moreover, medical science often requires numerous collaborators across many sites, hence numerous authors.[81] Realistically, it is simply not feasible for every one of, say, 30 authors to 'draft[] the work or revis[e] it critically for important intellectual

76 *ORI Newsletter*, Office Res. Integrity, Apr. 1993, at 3, https://ori.hhs.gov/sites/default/files/vol1_no2.pdf. (emphasis added)

77 K. Stone, *What are Contract Research Organizations—CRO: CROs Play a Major Role in Drug Development*, the balance small bus. (July 24, 2019), https://www.thebalancesmb.com/contract-research-organizations-cro-2663066.

78 Of note, staff are 'usually not members of the scientific community. They were not bound by a standard of professional ethics and usually did not have any personal investment in the validity of the study's outcome. They were also less likely to understand the significance of their misconduct on the research objectives and the subsequent impact of their actions'. Kornfeld, *supra* note 11, at 2.

79 See, e.g., *Office of Scientific Writing*, UTHSC, https://www.uthsc.edu/research/scientific-writing/index.php (last accessed Mar. 6, 2021).

80 See, e.g., L.K. Woolley, *Goodbye Ghostwriters! How to Work Ethically and Efficiently With Professional Medical Writers*, 130 CHEST 921, 921–23 (2006).

81 From 1975–2016, the average number of authors listed in major medical journals increased from 1.9 to 5.67 per article. Actual author numbers can range far higher. In three leading general medical journals (*JAMA*, *The Lancet*, and *New England Journal of Medicine*), tracked 'in 2005, 2010, and 2015[, the] median number

content'.[82] If the initial draft is solid, there is no reason for 30 people to demand 'change this!' or 'change that' sentence, simply to retain the status of 'author'. Rather, each author's draft/revise contribution will more likely be to agree with what someone else wrote.

The upshot: if individual persons can be authors by hiring others to do the actual work or by affirming what others wrote or revised, then organizations are capable of the same kinds of authorship. Hence, in the end we must look to see which entity is the driving force conceiving the project and directing its execution.

IV. CASE STUDIES: RESEARCH MISCONDUCT BY CORPORATIONS

It is one thing to show that organizations such as corporations can directly commit RM and quite another to show they actually have. As discussed in Part II, the most common offenses are fabrication or falsification 'such that the research is not accurately represented in the research record',[83] done knowingly, intentionally, or recklessly.[84]

Part IV describes several cases in which a corporation arguably committed RM. At the corporate level the greater challenge is not so much to show, e.g., data were manufactured or falsified, as to prove knowledge, intent, or recklessness.[85] This latter is not ordinarily exposed unless litigation and extensive discovery provide access to communication among upper-level management. Here we discuss five litigated cases: two pharmaceutical seeding trials, concealment of adverse events in a drug trial, ghost-writing, and finally a case from the fitness industry.[86] Legal claims in these cases included False Claims Act violations, off-label marketing, anti-competitive behavior,

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of authors per article increased in all three journals (from a range of 8–11 in 2005 to 11–18 in 2015)'. Fontanarosa et al., *supra* note 74, at 2433. See also Hussinger & Pellens, *supra* note 23.

82 Int'l Comm. of Med. Journal Editors, *supra* note 75, at 2.

83 42 C.F.R. § 93.103. Plagiarism is not considered here, as it is more common among individual scientists than among corporations.

84 42 C.F.R. § 93.104.

85 Exemplifying a nonlitigated example, a Novartis subsidiary admitted submitting manipulated data for its new drug, Zolgensma, which treats children born with spinal muscular atrophy. The FDA concluded that the false information involved mouse data and did not alter conclusions regarding the drug's safety and effectiveness. L. McGinley, *FDA: Gene Therapy Maker Submitted Manipulated Data Before Drug was Approved*, Wash. Post (Aug. 6, 2019), https://www.washingtonpost.com/health/2019/08/06/gene-therapy-maker-knew-data-manipulation-before-fda-approval-agency-says/. K. Thomas, *Novartis Hid Manipulated Data While Seeking Approval for $2.1 Million Treatment*, N.Y. Times (Aug. 6, 2019), https://www.nytimes.com/2019/08/06/health/novartis-fda-gene-therapy.html.

86 These are not the only examples. Another concerns Johnson and Johnson's pelvic mesh device. Trial testimony suggests potential RM:

> Dr. Adriane Fugh-Berman, professor of pharmaceutical and medical practices with the Georgetown University School of Medicine, said the altering of reports to support industry goals in marketing of pelvic mesh devices extended to making an addition or editing out of one line of information. 'People (mesh device industry insiders) are hired just to write the last line of an abstract for an article,' Fugh-Berman said.

J. Sammon, *State Witness in J&J Pelvic Mesh Trial Says Doctors Get Doctored Studies About Mesh Devices*, N. Cal. Rec. (Aug. 15, 2019), https://norcalrecord.com/stories/513056657-state-witness-in-j-j-pelvic-mesh-trial-says-doctors-get-doctored-studies-about-mesh-devices. Studies regarding antipsychotic medications, particularly as used in children, may also exemplify. See, e.g., Lemmens, *supra* note 20, at 641–42 (regarding the use of Zoloft, and applications Paxil for children); see also Sismondo, *supra* note 27; K. Applbaum, *Getting to Yes: Corporate Power and the Creation of a Psychopharmaceutical Blockbuster*, 33 Cult Med. Psychiatry 185, 199 (2009) (promotion of Zyprexa for myriad long-term uses, outside of label-approved short-term use in acute mania).

and the like. However, in no case was research misconduct specifically alleged. As discussed here, it could rightly have been on the table.

IV.A. Seeding Trial: Neurontin

> Seeding trials are clinical trials, deceptively portrayed as patient studies, which are used to promote drugs recently approved or under review by the [FDA] by encouraging prescribers to use these medications under the guise of participating as an investigator in a clinical trial. . . . [M]arketing departments, rather than clinical research departments, are known to design and conduct these trials . . . [whose] primary goal is to expose physicians to a new drug and have them interact with the pharmaceutical company sponsor and its sales representatives, in order to influence prescribing decisions, independent of any findings from the actual study. In addition, physician 'investigators' are the actual trial subjects, and this information is neither disclosed to them nor the [patients].[87]

Gabapentin, patented in 1977 and approved in 1993 as adjunctive therapy for partial complex seizures, became a surprise blockbuster in the 2000s when off-label marketing promoted its use for myriad other uses such as pain, bipolar disorder, and migraine.[88] Inside details were described by consultants who had access to all documents and depositions in two lawsuits, *Harden Manufacturing v Pfizer* and *Franklin v Warner-Lambert*. 'Documents included internal and external correspondences, internal planning documents and presentations, clinical research reports, and market research analyses', mostly between 1990 and 2009.[89]

The trial recruited 772 investigators who enrolled 2759 patients, about four patients per investigator. All were told the study was 'designed to assess the safety and tolerability of doses of Neurontin (gabapentin) from 900 to 3600 mg daily whose partial seizures are not completely controlled by other drugs'.[90]

The company 'recruited site investigators with little or no clinical trial experience, provided insufficient training, and did not audit study sites prior to the beginning of the trial, which led to poor trial data quality'.[91] Per an in-house April 1996 memo:

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87 Krumholz et al., *supra* note 35, at 1100; see also K.P. Hill et al., *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 Anns. Internal Med. 251, 251 (2008):

> Seeding trials are designed to appear as if they answer a scientific question but primarily fulfill marketing objectives. Kessler and colleagues portrayed seeding trials as 'attempts to entice doctors to prescribe a new drug being marketed by the company' while the company puts its product in the hands of practicing physicians, hoping that the experience of treating patients with the study drug and a pleasant, even profitable, interaction with the company will result in more loyal physicians who prescribe the drug.

88 Landefeld & Steinman *supra* note 35, at 103–06.

89 Krumholz et al., *supra* note 35, at 1101. Per Landefeld & Steinman, *supra* note 35, at 104: 'The *Franklin* case placed more than 8000 pages of corporate documents in the public domain; these documents are now available in a searchable digital library at the University of California, San Francisco (www.dida.library.ucsf.edu). The class-action suit also generated detailed testimony and reports that are available through the Federal Judiciary's Public Access to Court Electronic Records Service Center.'

90 Krumholz et al., *supra* note 35, at 1101 ('Patients were initially given Neurontin, 900 mg/d, during the first week and then were to have their doses titrated up to 1800 mg/d, 2400 mg/d, and ultimately to 3600 mg/d. Deviation from the rigid titration schedule led to exclusion from the study's primary analysis. Titration stopped if the patient developed dose-limiting adverse effects or if the physician judged that the patient had reached an efficacious dose.').

91 *Id.* at 1102.

> Investigators are inexperienced with conducting clinical trials, investigators do not have study coordinators, up-front training for completing Case Report Forms (CRFs) was minimal at the video-conferenced investigator meeting, and the CRF does not have annotated pages included for reference.[92]

Thus, management knew, perhaps intended that, the trial was poorly designed. Independent sources questioned the trial's scientific validity before it was initiated. The Johns Hopkins University IRB, for instance, rejected the application for the trial, both initially and on appeal, stating 'the board in its deliberation, voted to disapprove the protocol, since we believe that the entry criteria and outcome measures are too vague to allow any scientific conclusions to be reach [sic]'.[93] Moreover, following the trial's completion, some of the corporate customer business units—'autonomous, regionally focused branches of Warner–Lambert that planned and implemented marketing strategies [–] conceded that the study design was not rigorous enough for dissemination'.[94]

Statistical analysis also was problematic. Site investigators did not adhere to the follow-up protocol, so that fewer than 25% of patients were assessed during the requisite time-frame. 'There were no mentions of data irregularity in either the internal research report or the published articles.'[95]

Even from this brief summary, it appears that the Neurontin seeding trial clearly departed from established scientific norms in its design, execution, data analysis, and research report, arguably committing falsification. Additionally, the company's knowledge of these departures is evident from in-house communications. RM could reasonably be ascribed.

IV.B. Seeding Trial: Vioxx

Merck's seeding trial for Vioxx likewise is best explored through confidential internal documents exposed by litigation, particularly *Cona v Merck and Co., Inc*., and *McDarby v Merck and Co., Inc*. and made directly available to litigation consultants.[96] Even prior to FDA approval for Vioxx, Merck launched a trial ostensibly comparing Vioxx (rofecoxib) with naproxin for people with osteoarthritis.[97] Merck recruited 600 investigators and over 5500 patients—just a few patients per investigator—in this three-month trial.[98]

As with the Neurontin seeding trial, the objective was not science, but marketing: introduce as many physicians and patients to the drug as possible, prior to its FDA approval.

> Although ADVANTAGE was called a seeding trial in many internal documents, the marketing objectives of the trial were not described on the informed consent form. 'The

92 *Id*.

93 'The Johns Hopkins University IRB . . . rejected the application for the STEPS trial, both initially and on appeal, stating 'the board in its deliberation, voted to disapprove the protocol, since we believe that the entry criteria and outcome measures are too vague to allow any scientific conclusions to be reach [sic].' *Id*. at 1101.

94 *Id*. at 1102.

95 *Id*.

96 K.P. Hill et al., *supra* note 87, at 251.

97 The completed study was published in a well-regarded medical journal. J.R. Lisse et al., *ADVANTAGE Study Group. Gastrointestinal Tolerability and Effectiveness of Rofecoxib Versus Naproxen in the Treatment of Osteoarthritis: A Randomized, Controlled Trial*, 139 Anns. Internal Med. 539, 539–46 (2003).

98 K.P. Hill et al., *supra* note 87, at 252.

> objectives were to provide [a] product trial among a key physician group to accelerate uptake of VIOXX as the second entrant in a highly competitive new class and gather data important to this customer group.'[99]

However, that aim was actively concealed in the publication's stated objectives and conclusion:

> **Objective:** To assess the tolerability of rofecoxib compared with naproxen for treatment of osteoarthritis.
> **Conclusions:** In patients with osteoarthritis treated for 12 weeks, rofecoxib, 25 mg/d, was as effective as naproxen, 500 mg twice daily, but had statistically significantly superior GI tolerability and led to less use of concomitant gastrointestinal (GI) medications. Benefits of rofecoxib in subgroup analyses were consistent with findings in the overall sample.[100]

This falsification of the research record is accompanied by evidence of knowledge and intent. Per a marketing division in-house email: 'It may be a seeding study, but let's not call it that in our internal documents'.[101] Hence, RM could reasonably be ascribed.

IV.C. Concealing Adverse Events: Vioxx

Merck's considerably more consequential act of likely RM involved concealing heart attack data from its main study to secure FDA approval for Vioxx: the VIGOR trial.[102] As with the other examples in Part IV, litigation provided the otherwise-unavailable in-house documents necessary to complete the case for RM, documenting knowledge and/or intent. Among various accounts,[103] perhaps the clearest is a narrative from a litigation consultant.[104]

Early in Vioxx's development, Merck's scientists 'were concerned that the drug might adversely affect the cardiovascular (CV) system by altering the ratio of prostacyclin to thromboxane, which act in opposition, balancing blood flow and clotting.'[105] Their investigations continued, ultimately helping clarify the pathways by which the drug

99 *Id*. at 255 (quoting Merck Clinical Study Report).

100 The completed study was published in a well-regarded medical journal. R. Lisse et al., *supra* note 97.

101 K.P. Hill et al., *supra* note 87, at 255. 'A Merck marketing slide set used for the company's internal purposes stated that a goal of ADVANTAGE was for investigators to "[g]ain experience with Vioxx prior to and during the critical launch phase".' *Id*. at 252.

102 The two trials described here were not Merck's only acts of likely RM. Another study, examining the effects of rofecoxib for Alzheimer disease on cognitive impairment, involved concealing a switch during data analysis, from an intention-to-treat analysis to an on-treatment analysis, which effectively obscured the trial's mortality. If true, this would represent falsification in which the research report did not reflect the actual data. See B.M. Psaty & R.A. Kron, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents from Rofecoxib Litigation*, 299 JAMA 1813, 1817 (2008).

103 D.S. Egilman & A.H. Presler, Letter, *Report of Specific Cardiovascular Outcomes of the ADVANTAGE Trial*, 144 Anns. Internal Med. 781 (2006); G.D. Curfman et al., *Expression of Concern:* Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 353 New Eng. J Med. 2813, 2813–14 (2005); C. Bombardier et al., *Response to Expression of Concern Regarding VIGOR Study*, 354 New Eng. J Med. 1196, 1196–99 (2006); A. Reicin & D. Shapiro, *Response to Expression of Concern Regarding VIGOR Study*, 354 New Eng. J. Med. 1198, 1198–99 (2006); G.D. Curfman et al., *Expression of Concern Reaffirmed*, 354 N. Eng. J. Med. 1193 (2006).

104 H. M Krumholz et al., *What Have We Learnt From Vioxx?*, 334 Brit. Med. J. 120, 120–23 (2007).

105 *Id*. at 120.

causes CV events. Despite knowing the drug could increase thrombus formation, Merck included none of this information in its application to the FDA.[106]

The VIGOR trial, designed to measure upper gastrointestinal toxicity of rofecoxib versus naproxin in patients with rheumatoid arthritis, 'was designed to continue until a predetermined number of confirmed uncomplicated or complicated gastric perforations, ulcers, or bleeds had occurred.'[107] Despite Merck scientists' concern for potential CV events, the trial's Data Safety Monitoring Board (DSMB) had no cardiologist, and the trial had no standard procedure for collecting information on CV events.[108]

In its second safety analysis, the DSMB found elevated CV risk in one group and recommended adding an analysis plan to capture that data. Noting this increased risk of myocardial infarction (MI), Merck's chief scientist emailed colleagues that this increased risk apparently had a 'mechanism based as we worried it was', namely the prostacyclin findings.[109]

Nevertheless, published reports obscured the trial's adverse MI data. Although the cut-off date for enumerating adverse GI events was March 9, 2000, the cut-off date chosen for adverse CV events was set a month earlier, at February 10, 2000—thereby excluding three MIs that would otherwise have been counted.[110] Moreover, per the editors of *New England Journal of Medicine*, litigation documents showed that 'at least two of the authors knew about the three additional myocardial infarctions at least two weeks before the authors submitted the first of two revisions and 4 1/2 months before publication of the article'.[111]

Issues associated with the VIGOR trial and the two seeding trials are considerably more complex than these brief summaries suggest.[112] Here, suffice it to say that the underlying research processes and data were evidently manipulated so that the 'research was not accurately represented in the research record',[113] hence falsified, and that corporate management knew this to be the case, thus supporting an inference of RM.

IV.D. Ghostwriting: Merck and Vioxx

Part III discussed ghostwriting as a fairly common, distinctively corporate form of RM. Several Vioxx trials exemplify. As above, litigation revealed the in-house documents attesting to Merck's commission of ghostwriting, and its managerial knowledge and intent.

'When publishing their own clinical trials (designed, conducted, and sponsored by Merck), documents were found describing Merck scientists often working to prepare manuscripts and subsequently recruiting external, academically affiliated investiga-

106 *Id.*
107 *Id.*
108 *Id.*
109 *Id.* at 121.
110 C. Bombardier et al., *supra* note 103, at 1196.
111 G.D. Curfman et al., *supra* note 103, at 2813. See also G.D. Curfman et al., *supra* note 103.
112 H.M. Krumholz et al., *supra* note 104, at 121 (discussing further obscuring of the adverse CV data by inserting, e.g., post-hoc subgroup analyses concerning which patients were at risk for CV incidents via indications for aspirin prophylaxis, and a proposal that naproxin somehow had a CV protective effect, to suggest that Vioxx did not cause CV harm, but simply lacked naproxin's (fictional) protective effect).
113 Per 42 C.F.R. § 93.103(b): 'Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.'

tors to collaborate on the manuscript as guest authors.' [114] 'Documents were found describing Merck employees contracting with medical publishing companies to ghost-write review manuscripts focused on rofecoxib and subsequently recruiting external, academically affiliated investigators to be guest authors.'[115] Indeed, the lead 'author' of Merck's seeding trial[116] expressly acknowledged that he played no role in data collection or analysis, stating:

> Merck designed the trial, paid for the trial, ran the trial. Merck came to me after the study was completed and said, 'We want your help to work on the paper'. The initial paper was written at Merck, and then it was sent to me for editing.[117]

Inasmuch as bogus ascriptions and deletions of authorship are falsifications of the research record—much like plagiarism is a falsification of authorship attribution—and given that Merck executives clearly acted intentionally, RM can reasonably be concluded.

IV.E. CrossFit v NSCA

The final case study, also in bioscience, comes from the fitness industry. Here too, details became available only through years of litigation for which this author served as a paid consultant. The story adds value because it exposes management machinations in great detail, and because it describes somewhat less obvious forms of RM, aside from common data manipulation. Here, because the corporation owned the scientific journal publishing fabricated data, its 'corrections' of the research record actually re-entrenched the earlier fabrications.

The saga begins with an apparently simple story about graduate students run amok and the defendant organization's failure properly to address allegations of RM. The realities in *CrossFit, Inc. v National Strength and Conditioning Association* (NSCA)[118] eventually exposed multiple acts of RM undertaken at the highest levels of the corporation.[119]

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114 J.S. Ross et al., *supra* note 58, at 1802; see also Landefeld & Steinman, *supra* note 35, at 105.

115 J.S. Ross et al., *supra* note 58, at 1805. For instance, Ross et al. displays 'an e-mail from representatives of Scientific Therapeutics Information to Merck employees providing an update on the development and estimated delivery dates for 8 manuscripts related to rofecoxib that the company was preparing, including intended titles, authors, and journals'. *Id*; see also the ghostwriting evidenced by legal documents for studies extolling paroxetine, an antidepressent, for adolescents. Lacasse & Leo, *supra* note 59.

116 Lisse et al., *supra* note 97.

117 K.P. Hill et al., *supra* note 87, at 253 (quoting statement by Jeffrey Lisse in the New York Times (A. Berenson, *Evidence in Vioxx Suits Shows Intervention by Merck Officials*, N.Y. Times, Apr. 24, 2005, at A1).

118 No.: 14cv1191-JLS(KSC), 2018 WL 3491854 (S.D. Cal. July 18, 2018).

119 The author acknowledges that many of the evidence documents described in this article will not be accessible to the reader. However, much of the evidence is at least indirectly available via descriptions in various court adjudications. See: Report by E. H. Morreim, JD, PhD, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 3:14-cv-01191-JLS-KSC, (submitted 4/1/16; filed S.D. Cal. May 8, 2017), https://s3.amazonaws.com/crossfitpubliccontent/Morreim_Initial_Report.pdf. Supplemental Report by E. H. Morreim, JD, PhD, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 3:14-cv-01191-JLS-KSC, (filed S.D. Cal. Feb. 22, 2018), https://s3.amazonaws.com/crossfitpubliccontent/Morreim_Supp_Report.pdf. Declaration of E. H. Morreim, JD, PhD, In Support of CrossFit, Inc.'s Renewed Motion for Terminating Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 3:14-cv-01191-JLS-KSC, (S.D. Cal. June 20, 2019), https://s3.amazonaws.com/crossfitpubliccontent/330_PUBLIC-DECLARATION-of-EH-Morreim-JD-PhD-ISO-MOTION-for-Sanctions-Renewed-Motion-for-Terminating-Sanctions.pdf; Order Granting in Part and Denying in Part Plaintiff CrossFit, Inc.'s Renewed Motion

The NSCA is a research-based nonprofit corporation providing educational services, trainer certifications, and publications.[120] Of its several peer-reviewed scientific journals, premier is the *Journal of Strength and Conditioning Research* (*JSCR*).[121]

CrossFit, Inc., a privately owned company, uses a somewhat unconventional approach to fitness, including high-intensity interval training, weightlifting, gymnastics, and calisthenics with an emphasis on everyday functional movement. In an intensely competitive market, CrossFit became very popular internationally, in military as well as civilian markets, posing a significant challenge for NSCA as both offer similar products—training seminars, coaching, certifications, etc.[122]—in the same markets.

In 2011 three Ohio State graduate students studying exercise physiology linked up with a local CrossFit gym as it was about to launch a 10-week fitness challenge. The students proposed taking before/after measurements of such parameters as body fat and VO_2Max. The gym owner and participants agreed.

Finding that everyone who completed the program showed strong improvement regardless of age, gender, or prior fitness, the students wrote up their findings. With faculty advisor Dr. Steven Devor as last author, they submitted their manuscript to NSCA's *JSCR* (the 'Devor article'). Although the initial manuscript said nothing about injuries or risk, after multiple rounds of revision the authors stated in the final publication that, of 54 people who began the program, nine cited injury or overuse as their reason for not completing it. The authors emphasized that the benefits of CrossFit may not be worth the risk.[123]

When the article appeared online in February 2013 the gym owner, startled to see injury data because to his knowledge nobody had been hurt, contacted CrossFit headquarters. CrossFit sought out the nonfinishing participants and, after contacting

for Terminating Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 3:14-cv-01191-JLS-KSC, (S.D. Cal. Dec. 4, 2019). Order (1) Denying Defendant's Motion to Appoint Special Master, and (2) Setting Scheduling Order. Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 14cv1191-JLS(KSC) (S.D. Cal. Oct. 19, 2018). Order Granting in Part and Denying in Part Defendant's Motion to Amend the Scheduling Order to Allow Additional Expert Discovery, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 14cv1191-JLS(KSC), 2018 WL 3491854 (S.D. Cal. July 18, 2018). Order No. 6: Ruling re: Discoverability of Identity of Peer Reviewers, Nat'l Strength and Conditioning Ass'n v. Glassman, No. 37-2016-00014339-CU-DF-CTL (Cal. App. Dep't Super. Ct. Dec. 5, 2017). Order Granting in Part and Denying in Part Motion for Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No. 14-cv-01191-JLS (KSC), 2017 WL 2298473 (S.D. Cal. May 26, 2017). Order (1) Granting CrossFit, Inc.'s Partial MSJ and (2) Granting in Part and Denying in Part National Strength and Conditioning Association's MSJ, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 14cv1191 JLS (KSC), 2016 WL 5118530 (S.D. Cal. Sept.16, 2016). Numerous additional documents are available at https://www.crossfit.com/battles/public-documents-compilation.

120 *NSCA Responds to CrossFit Lawsuit*, NSCA, https://www.nsca.com/media-room/news-andannouncements/nsca-responds-to-crossfit-lawsuit/, (last accessed March 27, 2021); see also *Education Overview*, NSCA, https://www.nsca.com/education/education-overview/, (last accessed Mar. 9, 2021).

121 *Journal of Strength Conditioning Research: Online Submission and Review System*, http://edmgr.ovid.com/jscr/accounts/ifauth.htm, (last accessed Mar. 9, 2021) ('Since 1978 the NSCA has attempted to "bridge the gap" from the scientific laboratory to the field practitioner .... This journal wishes to promote the publication of peer-reviewed manuscripts that add to our understanding of conditioning and sport through applied exercise and sport science.').

122 *Crossfit, Inc.*, Bloomberg, https://www.bloomberg.com/profile/company/7616723Z:US (last accessed Mar. 9, 2021).

123 Michael M. Smith et al., *Crossfit-Based High Intensity Power Training Improves Maximal Aerobic Fitness and Body Composition*, 27 J. Strength & Conditioning Res. 3159, 3159–72 (2013) (retracted).

four of them, published online that none of the four had been injured or spoke with anyone about why they didn't complete the study.[124] CrossFit shared this finding with NSCA's Board of Directors, adding that the study coordinator believed the injury data were fabricated. Neither the NSCA nor the editor of *JSCR* responded.

In the fitness industry, a purportedly scientific claim that a particular workout approach has a high rate of injury can be economically devastating. Hence, with evidence the injury claims were fraudulent and with no response from NSCA, CrossFit sued in federal court in May 2014.[125]

The following January, 10 of the 11 nonfinishers provided sworn declarations. Not one had been injured by the workouts, and not one had told anyone why they did not finish.[126] Although those declarations clearly showed the injury data were false, NSCA did nothing until September 2015, when *JSCR* published a brief Erratum.[127]

At this point, the story depicts graduate students fabricating data and NSCA responding poorly to an allegation of RM.[128] The story soon became much more complicated.

Amidst both sides' preparations for federal trial, NSCA separately sued CrossFit in state court for defamation.[129] Discovery for that case revealed that NSCA had withheld numerous documents and committed perjury in depositions for the federal case.[130]

The federal court granted significant sanctions against NSCA in May 2017, including a requirement that NSCA hire a neutral forensic evaluator to find whatever evidence had been withheld or destroyed.[131] That effort unearthed vast discovery abuse. Among many other offenses, NSCA had withheld nearly 280,000 relevant documents and lost or destroyed over 200 devices and 16 separate servers.[132]

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124 R. Berger, *NSCA 'CrossFit Study' Fraud?*, The CrossFit J. at 4 (May 2013), http://library.crossfit.com/free/pdf/05_2013_ACSM_Berger_FINALS.pdf.

125 Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 14cv1191 JLS (KSC), 2016 WL 5118530 (S.D. Cal. Sept.16, 2016).

126 Declaration of Paul A. Serritella in Support of Plaintiff's Motion for Partial Summary Judgment on the Element of Falsity, Exhibits D–N, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 14cv1191 JLS (KSC), 2016 WL 5118530 (S.D. Cal. Sept.16, 2016) (submitted Jan, 20, 2015). Two people experienced injuries during the relevant time-period, but those were unrelated to CrossFit workouts.

127 See *infra* note 150 and accompanying text.

128 Among other problems, NSCA and *JSCR* failed to follow internationally accepted standards for addressing an allegation of fabrication in a published manuscript. *Fabricated Data in a Published* Article, COPE, https://publicationethics.org/resources/flowcharts/suspected-fabricated-data-published-manuscript (last accessed Mar. 9, 2021). See Report by E. H. Morreim, JD, PhD, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No.: 3:14-cv-01191-JLS-KSC, (submitted 4/1/16; filed S.D. Cal. May 8, 2017), https://s3.amazonaws.com/crossfitpubliccontent/Morreim_Initial_Report.pdf

129 NSCA's claims concerned trade libel, defamation and unfair business practices. See National Strength and Conditioning Association v. Glassman, No. 37-2016-00014339-CU-DF-CTL (S.D. Super. Ct. filed May 2, 2016). See also Discoverability of Identity of Peer Reviewers, Nat'l Strength and Conditioning Ass'n v. Glassman, No. 37–2016-00014339-CU-DF-CTL (Cal. App. Dep't Super. Ct. Dec. 5, 2017).

130 Reflecting an earlier distinction between corporations' direct versus indirect liability, see *supra* note 66 and accompanying text, in these cases the corporation did not merely suborn perjury; arguably it directly committed perjury, as the persons in question were acting under the direction and in accordance with the overall plan of top management.

131 Order Granting in Part and Denying in Part Motion for Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n No. 14-cv-01191-JLS (KSC), 2017 WL 2298473 (S.D. Cal. May 26, 2017).

132 NSCA's senior management had deleted numerous documents (e.g., the Executive director deleted 1378 documents, the Publications Director 1251); the EiC of *JSCR* had wiped several NSCA-owned cell

Granting in December 2019 the severest sanction—termination of the suit in CrossFit's favor—the Southern District of California was not amused. '[I]n twenty-five years on the bench, this is the first case that the Court has ever had that has gotten to this point . . . . [T]he severity and frequency of defendant's bad faith misconduct is as egregious as anything this Court has ever seen or read in any of the cases.'[133]

More important here, final tranches of evidence arguably reveal research misconduct—by the definition—orchestrated at the highest levels of NSCA management: fabrication of the injury data, falsification in the Erratum, and falsification in the article's eventual Retraction.

1. Research Misconduct: Fabricating injury data

Well before the Devor manuscript was submitted to *JSCR*, NSCA management discussed the need for science to combat CrossFit's competition. 'Crossfit is growing at an astronomical rate and is one of the hottest trends; if the NSCA is to be viewed as an industry leader information needs to be developed and released assessing the strengths of the programs, strategies to capitalize on what Crossfit does well, and arming NSCA-CPT's with scientific rationale as to the weaknesses of Crossfit.'[134] However, at the time no science whatever existed regarding CrossFit; hence, there could not possibly have been science showing its purported weaknesses.

In June 2012, the Devor authors submitted their manuscript, drawing robustly favorable conclusions regarding CrossFit and saying nothing about injuries because the authors had gathered no injury data.

Nevertheless, as *JSCR*'s Editor-in-Chief (EiC) sent the manuscript to the Senior Articles Editor who would shepherd the piece through peer review, he made his expectations clear: 'so we put it in your good hands to get it ok, so a lot of context is needed for this, fit but at what cost etc. . . . . get some good reviewers to take a close look at this as catabolism will break you down but while fit are you in a catabolic state etc.'[135] As subsequent emails made clear, 'context' was the EiC's code-word for CrossFit's alleged propensity to cause injury ('fit but at what cost').

Two months later, although the peer reviewers said nothing about injury, the EiC warned authors the piece could not be published until review comments were taken into account:

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phones and "lost" more than one NSCA-owned computer (with NSCA's knowledge); NSCA was busily destroying documents and devices even while the forensic neutral was scampering to find them. CrossFit, Inc. v. National Strength and Conditioning Association, Order Granting in Part and Denying in Part Plaintiff CrossFit, Inc.'s Renewed Motion for Terminating Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No. 3:14-cv-01191-JLS (KSC) at 5–6 (S.D. Cal. Dec. 4, 2019).

133 Plaintiff CrossFit, Inc. was additionally awarded some $4million for attorney fees generated in pursuing NSCA's discovery abuses, reserving for a final phase the issue of compensatory and punitive damages. *Id.* at 47.

134 2012 Fitness Industry Trends & NSCA Positioning (June 15, 2012) (on file with the author). Management also discussed 'canned' presentations for trade shows. They could '[d]iscuss the good and bad from P90X, Crossfit, Bootcamps, etc. this would be a review of the programs based on science . . . ' Emails between Nick Clayton (Education Coordinator) and Scott Douglas (Marketing Director) (May 23–24, 2012) (emphasis added).

135 Email sent from William Kraemer to Travis Triplett (June 20, 2012) (emphasis added).

> You also need to caution readers as to the context of your findings due to the fact many people do get injured doing these types of workouts. Typically a lack of general preparation is seen or people do to [sic] much to [sic] quickly and get hurt so how this was dealth [sic] with is of particular importance.[136]

The revised manuscript still said nothing about injury. The EiC again emphasized the article could not be published unless it incorporates review comments, noting CrossFit supervision is 'not too well done in most CrossFit gyms for exercise technique, Y-Tube is full of this'.[137]

The authors' third version stated that, of the 54 subjects who began, nine cited injury or overuse for quitting. The EiC demanded more. 'This [injury rate] is very important and needs to be emphasized,' because overuse injuries come from 'too much too soon' and participants must be 'properly screen[ed].'[138] He added an entirely new criticism: 'CrossFit certification is not a certification that has met certification standards in Washington DC as American College of Sports Medicine (ACSM) and NSCA certifications and this needs again to be established as to the qualifications of the trainers in more detail as this is important.'[139] The final publication added a strong paragraph emphasizing that CrossFit's benefits may not be worth the risks.[140]

NSCA senior management, already looking for science discrediting CrossFit, welcomed the article. From Marketing Director observed to Executive Director: 'I do believe we have research that speaks to the benefits and concerns of CrossFit—this is the work that [EiC] Bill Kraemer did in the *JSCR*.'[141]

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136 Review comments from EiC William Kraemer to Devor authors. The EiC cited, as though it were science, a nonscientific article (co-authored by the EiC) speculating that CrossFit and other high-intensity workouts cause injury. See M.F. Bergeron et al., *Consortium for Health and Military Performance and American College of Sports Medicine Consensus Paper on Extreme Conditioning Programs in Military Personnel* 10 Curr Sports Med. Rep. 383, 383–89 (2011), https://pubmed.ncbi.nlm.nih.gov/22071400/ [hereinafter Champ Paper]. The authors did cite it in the Devor article's final published version.

137 EiC Email to Devor Article Authors (Oct. 13, 2012) (on file with author). In the fitness industry, a lack of supervision is commonly said to be associated with increased risk of injury, particularly for newcomers.

138 EiC Email to Devor Article Authors (Nov. 23, 2012) (on file with author).

139 EiC email to Devor Article Authors (Oct. 13, 2012) (on file with author). Note, peer reviewers' comments and the EiC's correspondence with the Devor authors were provided to CrossFit, Inc. in 2015 or 2016, prior to tranches of additional discovery documents uncovered by the forensic neutral engaged pursuant the court's mandate of May 26, 2017. Other documents discussed here were largely provided following that mandate.

140 In their Discussion section the Devor authors opine:

> A unique concern with any high-intensity training program such as HIPT or other similar programs is the risk of overuse injury. Despite a deliberate periodization and supervision of our Crossfit-based training program by certified fitness professionals, a notable percentage of our subjects (16 per cent) did not complete the training program and return for follow-up testing. Although peer-reviewed evidence of injury rates pertaining to high-intensity training programs is sparse, there are emerging reports of increased rates of musculoskeletal and metabolic injury in these programs (1). This may call into question the risk–benefit ratio for such extreme training programs, as the relatively small aerobic fitness and body composition improvements observed among individuals who are already considered to be 'above average' and 'well-above average' may not be worth the risk of injury and lost training time. Further work in this area is needed to explore how to best realize improvements to health without increasing risk above background levels associated with participation in any nonhigh intensity-based fitness regimen.

Michael Smith et al., *supra* note 123, at 3171–72 (the reference noted as (1) refers to the CHAMP Paper, *supra* note 136).

141 Emails from March 6, 2014.

This richer story suggests fabrication, directly committed by NSCA: 'making up data or results and recording or reporting them,'[142] at least knowingly if not outright intentionally.[143]

Admittedly this was not literal gun-to-the-head coercion, and the student authors who invented injury data arguably likewise committed fabrication. But coercion appears real[144] and, as noted above,[145] data fabrication can arise via directing others, not just by making up numbers oneself. Students are vulnerable to Academia's well-known 'publish or perish' mandate, and perhaps also naïvely saw guidance from long-experienced mentors. Every review piled on more: the students must 'caution readers [that] many people do get injured doing these types of workouts'; 'lack of general preparation'; supervision is 'not too well done . . . for exercise technique, Y-Tube is full of this'; the belated injury data are 'very important and need[] to be emphasized'; overuse injuries come from 'too much too soon'; and CrossFit trainers' certification is dubious. In the end it appears that NSCA, seeking 'science' with which to discredit its competitor and acting through its premier journal's EiC, pushed until it got what it wanted.

The Southern District of California agreed. 'It is taken as established that: . . . the NSCA made the false statement [injury claim] in the Devor Study with the intention of disparaging CrossFit and thereby driving consumers to the NSCA'[146] and thereby 'have deceived and continue to deceive the public and consumers regarding the safety and effectiveness of CrossFit training . . . [The statements] were willful and malicious. . . . CrossFit's evidence . . . is appalling.'[147]

2. Research Misconduct: Falsification in the Erratum

Nine months after 10 of the 11 nonfinishers swore under oath they had neither been injured by CrossFit workouts nor told anyone their reasons for not finishing[148] NSCA, which owns *JSCR*, published an Erratum.

> [T]he authors have stated that the reasons for participants not completing follow-up testing, as reported in the article, were provided to the authors by the club owner. The club owner has denied that he provided this information. After the article was published, 10 of the 11 participants who did not complete the study have provided their reasons for

142 42 C.F.R. § 93.103(a).

143 42 C.F.R. § 93.104(b).

144 *Coerce*, Merriam-Webster, https://www.merriam-webster.com/dictionary/coerce (last accessed Mar. 10, 2021).

145 See *supra* note 76 and accompanying text.

146 Order Granting in Part and Denying in Part Motion for Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No. 14-cv-01191-JLS (KSC), 2017 WL 2298473 at *7 (S.D. Cal. May 26, 2017).

147 Order Granting in Part and Denying in Part Plaintiff CrossFit, Inc.'s Renewed Motion for Terminating Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No. 3:14-cv-01191-JLS (KSC) at 28, 39–40, 46 (S.D. Cal. Dec. 4, 2019) (order of statements is somewhat rearranged). The court encompassed related fraudulent 'science' in NSCA's other publications, including not just the Devor article, but also the Erratum, Hak Study, various TSAC Report articles about CrossFit, content promoted at NSCA events referencing CrossFit-related injuries, *Id*.

148 Declaration of Paul A. Serritella in Support of Plaintiff's Motion for Partial Summary Judgment on the Element of Falsity, Exhibits D–N, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n (S.D. Cal. Jan. 30, 2015).

> not finishing, with only 2 mentioning injury or health conditions that prevented them from completing follow-up testing. In light of this information, injury rate should not be considered a factor in this study. This change does not affect the overall conclusion of the article.[149]

This erratum falsifies the research record, first, by falsely reducing the injury data question to a squabble between gym owner and student-authors—'He said, they said.' Second, by stating that two people mentioned injury, NSCA falsely implies that the CrossFit workouts had caused their injuries—which they did not.[150] Third, it leaves intact the article's overall conclusion warning readers that CrossFit's benefits may not be worth its risks of injury, thereby tacitly reinforcing the injury claims rather than correcting the research record.

The erratum emerged from the highest levels of management. When allegations of data fabrication first emerged, NSCA management collectively agreed not to respond.[151] Later amidst litigation, NSCA's Publications Director created a two-person panel[152] that recommended the erratum.[153]

NSCA knew the Erratum was misleading but chose not to amend it: 'we did not clarify that the injury and medical condition were not associated with the their workouts at the club[;] people are assuming that they were'.[154] Per the court: 'the Erratum's statement, that two participants were injured during the course of the Study, misled

149 *Erratum*, 29 J. Strength & Conditioning Res. e1 (Sep. 21, 2015), http://journals.lww.com/nsca-jscr/Fulltext/2015/10000/Erratum.39.aspx.

150 One person had a preexisting condition (Sealed Participants' Declarations: Exhibit E), whereas the other was injured during ordinary weight-lifting (Sealed Participants' Declarations: Exhibit F). See *supra* note 126.

151 The initial May 2013 email went from Russell Berger of CrossFit to Brenda McQuay, Executive Assistant to Dr. Carwyn Sharp, NSCA's chief science officer, who then forwarded it to Keith Cinea, NSCA Publications Director. Keith Cinea, 30-b-6 deposition 7/16/15, at 237; Keith Cinea, 30-b-6 deposition 10/23/15 at 44, 46–47. Not long after, in a document dated Aug. 6, 2014, publications director Cinea acknowledged direct awareness that no participants had been injured, yet still opted not to pursue the allegation of fabrication:

> The only proof offered in Berger's paper that the Devor study had inaccurate data: I asked [gym owner] Potterf if he could remember who the individuals were and contact them for me. He did, and after about a week of emails, he had documented each person's reason for not attending the re-test. Not one reason included injury. Skeptical of Potterf's own potential bias, I checked in with a few of the subjects on Potterf's list, and they all confirmed that they were not injured but had failed to show up to the final test due to a lack of time or interest. . . . All communications that are sent by Crossfit just offer a link to an article they already wrote. Never have they just submitted a formal letter (or email) listing their complaint. It always points back to an article they want us to read NSCA-STROZ000004794_native. (emphasis added)

Ultimately NSCA's chief science officer, Executive Director, publications director, and *JSCR*'s EiC collectively declined to respond.

152 Ordinarily a journal's EiC could and would decide what to do about an allegation of misconduct. NSCA overruled this avenue. See emails among Keith Cinea, Jeff Chandler, Tom James, Levi Boren, & Michael Hobson (May 26–August 25, 2015); 4833-001 (collected emails, NSCA—00170305, 001834-36, 001864, 001884). The two-person panel was Travis Triplett, who had served as Senior Articles Editor for the Devor article, and Jeff Chandler, editor of NSCA's *Strength & Conditioning Journal*. Keith Cinea Deposition, 304–308 (July 16, 2015). Per Cinea deposition of 10/23/15, Kraemer as Editor in Chief of *JSCR* was expressly kept out of this decision-making. The two-person panel was tasked to find out whether participants were injured by the training—odd, given that sworn depositions had answered that question clearly.

153 After debating debating how much information to provide, management chose a limited description, hoping to limit criticism. Keith Cinea Deposition (Oct. 23, 2015).

154 Email from Michael Hobson, NSCA's Media Relations Manager, to Keith Cinea et al. (Sept. 23, 2015).

the public and harmed CrossFit'; 'the NSCA was aware of the misleading nature of the Erratum.'[155]

Falsification is 'changing or omitting data or results such that the research is not accurately represented in the research record'.[156] Here, instead of plainly renouncing the fabricated injury data, the company's move to 'correct' the research record in its wholly owned scientific journal actually perpetuated the conclusion that CrossFit's risks may outweigh its benefits. Per in-house communications, senior management's conduct quite clearly appears intentional. RM can reasonably be inferred.

3. Research Misconduct: Falsification in the Retraction

NSCA arguably also committed falsification in finally retracting the article. Over one year following the Erratum and nearly two years after sworn declarations proved no one had been injured, NSCA's Publications Director finally asked Ohio State University's Office of Responsible Research Practices (ORRP)[157] to investigate the Devor article. Focusing solely on the Devor authors' failure to obtain proper IRB oversight, the letter expressly presupposed the bogus injury data were actually truthful.

> Of those [54 initial participants], . . . nine subjects cit[ed] overuse or injury for failing to complete the program and finish follow-up testing. It is our understanding that the overuse and injury published in the Article was an 'unanticipated event.' However, to the NSCA's knowledge, the Authors did not alert the participants of the article to the possibility of overuse or injury when obtaining their informed consent.[158]

Unsurprisingly, the ensuing OSU investigation focused on the Devor authors' false statement of IRB approval,[159] having been expressly steered away from data fabrication.

NSCA's subsequent Retraction Notice[160] misled and obfuscated. The entire first paragraph emphasized IRB problems and left injury claims on the table. The second paragraph's final sentence states '*a federal judge ruled* . . . the injury data

155 Order Granting in Part and Denying in Part Motion for Sanctions, Crossfit, Inc. v. Nat'l Strength and Conditioning Ass'n, No. 14-cv-01191-JLS (KSC), 2017 WL 2298473 at ∗12 (S.D. Cal. May 26, 2017).

156 42 C.F.R. § 93.103(b).

157 Letter from Keith Cinea, NSCA Publications Director, to OSU's IRB c/o ORRP (Dec. 20, 2016) (but without response). The letter initially went to the Ohio Attorney General in June 2016. Letter from Keith Cinea, NSCA Publications Director, to Daniel Forsythe, Senior Assistant Attorney General for Ohio (June 10, 2016).

158 Letter from Keith Cinea, NSCA Publications Director, to OSU's IRB c/o ORRP (Dec. 20, 2016) (emphasis added).

159 Michael M. Smith et al., *supra* note 123 [retracted] (claiming on page 3168 that IRB approval had been secured).

160 The full Retraction Notice, published in May 2017:

> The *Journal of Strength and Conditioning Research* has retracted the article entitled 'CrossFit-based High Intensity Power Training Improves Maximal Aerobic Fitness and Body Composition' by Smith, MM, Sommer, AJ, Starkoff, BE, and Devor, ST, published in the November 2013 issue of the *Journal of Strength and Conditioning Research* (Vol. 27, pp. 3159–3172). The *Journal of Strength and Conditioning Research* was advised on May 4, 2017 by one of the authors that the study was not conducted under an IRB approved protocol for that study, as was stated in the article. Because the study was performed without proper IRB approval, the article has been retracted.
>
> This retraction follows the October 2015 erratum which stated that 'after the article was published, 10 of the 11 participants who did not complete the study have provided their reasons for not finishing, with only 2 mentioning injury or health conditions that prevented them from completing follow-up testing.' The injury and health conditions that prevented the participants from completing follow-up testing were not caused by participation in the CrossFit-related study, and a federal judge ruled in September of 2016 that the injury data reported by the authors in the article was [sic] false.

. . . was [sic] false',[161] implying the injury data might still be true notwithstanding such a ruling.[162]

The retraction thus abjures any straight statement that the injury data were completely fabricated and that no one was harmed by the workouts. Hence, we see falsification: 'changing or omitting data or results such that the research is not accurately represented in the research record'.[163] NSCA's retraction added to the research record and, by failing to state clearly that injury data were fabricated, it further entrenched discrepancies between the research and the record.

Ample evidence attests that the concealment was committed 'knowingly, intentionally or recklessly'.[164] Indeed, NSCA's Publications director admitted in deposition that he knew the 2016 letter failed to notify OSU that NSCA possessed clear evidence the injury data were likely fraudulent.[165] Clearly, such dishonesty also represented a 'significant departure from accepted practices of the research community'.[166]

V. IMPLICATIONS

Although research misconduct has not been attributed to organizations,[167] the foregoing analysis shows that clearly it can be and what RM looks like on the corporate level, systematically orchestrated by management. Other types of organization are likewise capable of committing RM, such as universities[168] or government agencies.[169] As

Retraction: CrossFit-based High Intensity Power Training Improves Maximal Aerobic Fitness and Body Composition, 31 J. Strength & Conditioning Res. e76 (July 2017). (emphasis added) https://journals.lww.com/nsca-jscr/Fulltext/2017/07000/CrossFit_based_High_Intensity_Power_Training.37.aspx.

161 *Id*. (emphasis added)

162 In a subtler smokescreen the Retraction, *supra* note 160, states '[t]he injury and health conditions that prevented the participants from completing follow-up testing were not caused by participation in the CrossFit-related study'. *Id*. (emphasis added). At various points during litigation, NSCA suggested that the 'study' consisted only of the before/after measurements of body fat, VO_2max, etc. To the extent that NSCA invites readers to conclude that no one was harmed by the before/after measuring processes, they leave open the possibility that participants were nevertheless injured by the CrossFit workouts.

163 42 C.F.R. § 93.103(b).

164 42 C.F.R. § 93.104(b).

165 Deposition of the NSCA's 30(b)(6) Representative, Keith Cinea, NSCA Education and Publications Director, Potterf, v. Nat'l Strength and Conditioning Ass'n, No. 14CV003292 at ∗74, ∗77–78 (Ct. of Common Pleas of Franklin City, Ohio, May 11, 2017). Cinea also acknowledges, *Id*. at 81 ff, that although his letter alluded to the Belmont Report, he personally had no knowledge of that document. The letter was largely written by NSCA's counsel.

166 42 C.F.R. § 93.104(a).

167 In 2014 David Lewis, PhD, provided a sobering account of problematic science within the federal Environmental Protection Agency, coining the term 'institutional research misconduct'. His term did not invoke the federal, or any other, definition of research misconduct, nor did it distinguish between research misconduct and broader kinds of *scientific misconduct* as the latter is defined in this article. As a result, some instances he dubs 'institutional research misconduct' are more appropriately deemed scientific misconduct. That said, his discussion has greatly enriched our understanding of the potential for misdeeds in science at the government level. See David L. Lewis, Science for Sale: How the US Government Uses Powerful Corporations and Leading Universities to Support Government Policies, Silence Top Scientists, Jeopardize Our Health, and Protect Corporate Profits (2014).

168 As discussed above, universities' incentive to commit RM might come through the Bayh–Dole Act. See *supra* notes 71–72 and accompanying text.

169 Government agencies' incentives are largely political rather than financial, yet the mechanisms of organization-level RM are essentially the same. See Lewis, *supra* note 167; see also M.A. Edwards, *Institutional Scientific Misconduct at U.S. Public Health Agencies: How Malevolent Government Betrayed Flint, MI*,

discussed in Part III, key criteria for determining who committed RM—individuals versus an organization—concern who initiated the research, whose purposes are being served, who has primary control over choice of project, research design, data collection, analysis, and reporting. Although this article does not purport to provide an exhaustive analysis, several major implications can be highlighted.

Initially, we should amend the current 'bad apples' view of RM, as something committed only by individual persons, and recognize a system-level perspective. Over 30 years ago health policy analysts began to recognize that a focus on individual miscreants could not adequately explain how errors happen in healthcare. Rather, we needed also to recognize the role of organizational culture, and structural factors such as 'latent errors' that can render adverse outcomes more likely.[170]

Here, however, we add a dimension. Whereas errors in healthcare are ordinarily unintentional and a systems-approach looks for multifactorial explanations and solutions,[171] RM is indeed intentional, knowing or reckless. So we do still look for bad actors. But the foregoing says we must elevate the search for RM to encompass organizations, not just wayward individuals.

As adequately pursuing and penalizing organizations committing RM will require adjustments throughout civil and criminal law, a useful beginning comes from federal regulations regarding RM.

V.A. Recognizing and Pursuing Organization-Level Research Misconduct

Current regulations governing federally funded research regard organizations exclusively as funding conduits and as supervisors to foster scientific integrity and investigate RM where indicated, not as entities capable of committing RM.[172] This must change, for several reasons.

FlintWaterStudy (Feb. 3, 2016); *Testimony to the U.S. Cong. Committee on Oversight and Government Reform on Examining Federal Administration of the Safe Drinking Water Act in Flint, Michigan*, 112th Cong. A42–A53 (Feb. 3, 2016).

170 Lucian Leape pointed out in 1994 that health system errors caused some 180,000 deaths per year, or 'the equivalent of three jumbo-jet crashes every [two] days'. Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1851 (1994); see also Linda T. Kohn et al., Inst. of Med., To Err is Human (Nat'l Acad. Press 2000); Thomas Bodenheimer, *The American Health Care System. The Movement for Improved Quality in Health Care*, 340 New Eng. J. Med. 488, 488–92 (1999); Mark R. Chassin. *Is Health Care Ready for Six Sigma Quality?* 76 Milbank Q. 565, 565–91 (1998); Glenn Laffel & David Blumenthal, *The Case for Using Industrial Quality Management Science in Health Care Organizations*, 262 JAMA 2869, 2869–73 (1989); Avedis Donabedian, *The Quality of Care: How Can it Be Assessed?* 260 JAMA 1743, 1743–48 (1988).

171 As observed by Dauer and Marcus:

> Individuals do make errors and should be responsible for the quality of their work. Nevertheless, the 'bad apple' approach of the tort system focuses on outliers rather than on more pervasive influences. It looks at outliers as if they were significant when in fact they are most often highly unusual and sometimes random events. The strategy of quality improvement system design, by contrast, is to recognize that errors occur, to recognize that people work within systems, and to design the systems to do two things: (1) to make it difficult for individuals to make errors and (2) to make the whole system capable of 'absorbing' individuals' errors when they occur by identifying and correcting errors before they can be harmful. Even when a doctor has committed an error of judgment or skill, a systems approach demands to know how and why that infraction came about.

Edward A. Dauer & Leonard J. Marcus, *Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement*, 60 L. & Contemp. Probs. 185, 195 (1997).

172 42 C.F.R. §93.200; see also *Policies—Regulations Q&A: Question and Answers—42 CFR Part 93*, Office Res. Integrity, https://ori.hhs.gov/QA-Reg-6-05 (last accessed Mar. 10, 2021); NIH Policy Statement, *supra* note 9.

First, the temptation to cheat has grown stronger with evolution of FDA approval processes.[173] In response to corporate and public demand for speedier approval of new products, numerous new tracks have been developed, including accelerated approval, breakthrough therapies, expanded access, fast-track, and priority review.[174] Particularly, in 1997 Congress permitted the FDA to approve a drug on the basis of just one research trial rather than the usual two or more. By 2015–17, nearly half of all new drug approvals were granted on the basis of just one pivotal trial.[175] Those trials, in turn, are now increasingly based on surrogate endpoints (e.g., particular lab values or tumor shrinkage) rather than actual clinical outcomes.[176] Although surrogate endpoints can be valuable and sometimes unavoidable, they do not always correlate with clinical benefit.[177]

The results are concerning.

> Scientists at biotech pioneer Amgen, for instance, reported in 2011 that they could confirm only 6 of 53 landmark studies in cancer biology. Researchers at pharma giant Bayer announced in 2012 that only 14 of 67 attempts to confirm claims in oncology, women's health and cardiovascular disease succeeded. Officials at Novartis and AstraZeneca told a recent cancer meeting that they encountered the same problem.[178]

Similarly, although the FDA often requires postmarketing research as a condition of speedier approval, enforcement is limited. '[A] study of 614 postapproval requirements and commitments imposed in 2009 and 2010 found that by the end of 2015, 20% had not been started, 25% were delayed or ongoing, and only 54% were completed.'[179]

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173 Universities and other not-for-profit organizations are susceptible alongside corporations. As noted *supra* notes 71–72, 168, and accompanying text, universities can produce patentable drugs or devices and, like corporations, seek FDA approval.

174 J.J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 JAMA 164, 164 (2020). The stakes are high. In 2016, over $400 billion was spent on prescription drugs. *Id*.

175 *Id*. at 168 ('The proportion of new drugs supported by at least 2 pivotal trials decreased from 80.6 per cent in 1995–1997 to 52.8 per cent in 2015–2017.').

176 *Id*. at 169.

> Under the Accelerated Approval program, use of surrogate measures that are not yet designated as well established increased from 9% (28/313) in 1993-2001 to 13% (39/309) in 2011-2018. When these measures do reliably predict how a patient feels, functions, or survives, their use to approve new drugs can accelerate the availability of useful medications. By contrast, a surrogate measure that does not predict actual patient benefit may accelerate approval of a drug that presents risk but could be of little clinical use.

Id. at 173.

177 *Id*. at 173.

178 S. Begley, *U.S. Science Officials Take Aim at Shoddy Studies*, Reuters (Jan. 27, 2014), https://www.reuters.com/article/idUSL2N0KX18S20140127. In their related article in Nature, Collins and Tabak note that irreproducibility is particularly a problem in preclinical studies. F.S. Collins & L.A. Tabak, *Policy: NIH Plans to Enhance Reproducibility*, 505 Nature 612, 612–13 (2014), https://www.nature.com/news/policy-nih-plans-to-enhance-reproducibility-1.14586.

179 *Id*. at 172 (trial statistics omitted). Consider one postmarketing study of Makena, a drug to prevent or delay preterm birth. Approved in 2011 under accelerated approval regulations, the drug became best seller for its manufacturer, AMAG Pharmaceuticals. The required postparketing studies, not completed until 2019, showed the drug to be no more effective than placebo. Sixteen FDA panelists voted unanimously that Makena did not provide verifiable benefits for neonatal outcomes, and 13 of those 16 agreed that Makena did not provide substantial evidence of effectiveness. Nevertheless, Makena remains on the market. R. Rubin, *Confirmatory Trial for Drug to Prevent Preterm Birth Finds No Benefit, So Why Is It Still Prescribed?*, 323 JAMA 1229 (Mar. 18, 2020), https://jamanetwork.com/journals/jama/fullarticle/2763422?guestA

Additionally, although the FDA Amendments Act of 2007[180] requires investigators to register their clinical trials and post data on a federal website within a year of a trial's completion, historically the latter provision has not been well-enforced.[181] As a result, even if hypothetically a manufacturer tests its new drug in 10 trials, of which nine produce dismal results, the company has been able to report only the lone favorable trial and keep quiet the overall negative results. That is now set to change, as a federal court ruled in February 2020 that the Department of Health and Human Services must begin enforcement.[182] However, time will tell how vigorously that is undertaken.

In the end, corporations face significant temptation to cut corners, given that: (i) a new drug or device might be approved on the basis of just one study; (ii) that lone study may not need any control group; (iii) the outcomes measured may not be actual improvements in human health and function; (iv) the requirement to post negative trial results may not be vigorously enforced; (v) FDA inspection-detected RM may never be pursued; and (vi) any negative results or reviews might simply be blended into an overall document that may tend to mask doubts or scientific challenges.[183]

Nevertheless, some ingredients for federal recognition of corporate RM are already in place. In suspected RM with PHS funds, for instance, a 'charge letter'[184] is sent to the 'respondent', defined as a 'person'.[185] Likewise, ORI can 'propose administrative

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180 42 U.S.C. §§ 282(i)(1)(A), 282(i)(1)(A)(2).

181 A recent study concluded that:

> [O]f 184 sponsor organizations with at least five trials due as of 25 September 2019, 30 companies, universities, or medical centers never met a single deadline (see https://scim.ag/ctgov). As of that date, these habitual violators had failed to report any results for 67% of their trials and averaged 268 days late for those and all trials that missed their deadlines .... In all 4768 trials Science checked, sponsors violated the reporting law more than 55% of the time. And in hundreds of cases where the sponsors got credit for reporting trial results, they have yet to be publicly posted because of quality lapses flagged by ClinicalTrials.gov staff.

C. Piller, *Transparency on Trial: Many Clinical Trial Results Aren't Posted Publicly, as U.S. Law Requires—and a Promised Crackdown has Fizzled*, 367 Science 240, 241 (2020), https://www.sciencemag.org/news/2020/01/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law.

182 *Seife v U.S. Dep't of Health and Human Servs.*, No. 18 Civ. 11462 (NRB) (S.D.N.Y. Feb. 24, 2020).

183 The FDA is moving away from its traditional publication of all review documents prepared by various scientific disciplines (e.g., toxicology, statistical, clinical review) and instead will replace these individual scientific reviews with a single collective, integrated review. Although the avowed goal is to enhance clarity, in reality such 'integrated reviews are unlikely to achieve the agency's stated goals and likely to introduce new problems'. M. Herder et al., *Integrated Drug Reviews at the US Food and Drug Administration—Legal Concerns and Knowledge Lost* 180 JAMA Internal Med. 629, 629–30 (2020). Important questions, cautions, and contrary information may be lost, to the potential detriment of public health. *Id*. The authors provide several examples to illustrate the potential loss of important information and argue why the FDA's new approach may indeed be illegal.

184 *Charge letter* means the written notice, as well as any amendments to the notice, which are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official. 42 C.F.R. §93.202.

185 '*Respondent* means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.' 42 C.F.R. §93.225; see also 42 C.F.R. §93.405:

> Notifying the respondent of findings of research misconduct and HHS administrative actions. (a) When the ORI makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, other than debarment or suspension, it notifies the respondent in a charge letter. In cases involving a debarment or suspension

actions against any person to the HHS'.[186] Both potentially apply to a corporate person, given that corporations as well as individuals are legally deemed persons.

Similarly, since 1977 the FDA has had authority to inspect investigators and sites doing research subject to FDA oversight, to ensure regulatory and ethical compliance.[187] Those inspections encompass organizations' as well as individuals' actions and can flag certain situations as 'Official Action Indicated'—essentially, RM.[188] Relevant offenses include: deviation from investigational plan; failure to maintain adequate/accurate source documentation; violations related to investigational product; failure to personally supervise the study; submission of false information to the FDA and sponsor; failure to communicate with sponsor.[189] These and other offenses could be more expressly labeled as potential research misconduct.

That said, clearer guidance is needed regarding who/what entity should pursue allegations or suspicions of RM. For federally funded research, the standard presumption is that the funding recipient will undertake RM investigations.[190] Plainly this is untenable where the organization itself is the likely perpetrator. Even so, ORI already in fact has authority to undertake direct investigations;[191] hence, it needs only to exercise that authority where an organization, rather than individual persons, is the target of suspicion. But that authority needs to be supplemented with specific provisions for recognizing and pursuing organization-level RM.

For FDA-governed research, better guidance for pursuing corporate-level RM, e.g., during site inspections, must likewise be developed. Although FDA visits several hundred research sites every year and periodically detects misconduct, often little or nothing is done other than sometimes to delete the corrupt data from analysis. RM is rarely pursued, nor are such findings noted in the resultant scientific literature.[192] This is seriously problematic, because knowingly permitting corrupt data to remain in a research record can more broadly corrupt the scientific literature—*scientific* misconduct.

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action, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter includes the ORI findings of research misconduct and the basis for them and any HHS administrative actions. The letter also advises the respondent of the opportunity to contest the findings and administrative actions under Subpart E of this part.

186 Per 42 C.F.R. §93.400: 'General statement of ORI authority. (c) HHS administrative actions. (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions. (2) ORI may propose to the HHS debarring official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative actions within the components' authorities'.

187 Horowitz, *supra* note 34, at 110. The FDA uses the same definitions, rules and regulations regarding research misconduct as other federal agencies; see U.S. Food & Drug Admin., 09–10–0020 FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC (last updated Aug. 8, 2014), https://www.fda.gov/regulatory-information/privacy-act/09-10-0020-fda-records-related-research-misconduct-proceedings-hhsfdaoc; see also Office Sci. & Tech. Policy, Federal Policy on Research Misconduct; U.S. Food & Drug Admin., *Kefauver–Harris Amendments Revolutionized Drug Development* (Sept. 10, 2012), https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development; Garamendia et al., *supra* note 24.

188 Garamendia et al., *supra* note 24, at 593–94.

189 *Id*. at 596–98.

190 See sources cited *supra* note 172.

191 See 42 C.F.R. §93.400.

192 C. Seife, *Research Misconduct Identified by the US Food and Drug Administration Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature*, 175 JAMA Internal Med. 567, 567–77 (2015).

V.B. Penalizing Organization-Level Research Misconduct

Penalties for RM must likewise be adjusted to penalize organizations expressly as perpetrators and to do so proportionately to the offense. Currently, the avowed purpose of PHS administrative sanctions for RM is just remedial.[193] And many PHS administrative actions inherently apply mainly to individuals, e.g., letters of reprimand, supervision requirements, exclusion from serving as advisor to PHS.[194] Hence, greater force, clarity, and options are needed for sanctioning corporate-level RM.

Options are readily available. FCA[195] actions are already applied in the setting of RM, as noted above.[196] However, FCA claims have not, to date, expressly been tied to organizations as direct perpetrators of RM, a deficit that could be remedied by statute or by regulation, or by expressly alleging RM in complaints and identifying it in court rulings. Additionally, although many RM penalties for federally funded research focus on individuals, some could also apply to organizations, e.g., debarment from future federal funding.[197] Given ORI's history of finding only natural persons guilty of RM, however, sanctions applicable to corporate persons need to be made more explicit. Finally, although historically there have been few direct criminal prosecutions for RM, in late 2020 the Department of Justice's Consumer Protection Branch began stepping

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> Fifty-seven published clinical trials were identified for which an FDA inspection of a trial site had found significant evidence of 1 or more of the following problems: falsification or submission of false information, 22 trials (39%); problems with adverse events reporting, 14 trials (25%); protocol violations, 42 trials (74%); inadequate or inaccurate recordkeeping, 35 trials (61%); failure to protect the safety of patients and/or issues with oversight or informed consent, 30 trials (53%); and violations not otherwise categorized, 20 trials (35%). Only 3 of the 78 publications (4%) that resulted from trials in which the FDA found significant violations mentioned the objectionable conditions or practices found during the inspection. No corrections, retractions, expressions of concern, or other comments acknowledging the key issues identified by the inspection were subsequently published . . . . When the FDA finds significant departures from good clinical practice, those findings are seldom reflected in the peer-reviewed literature, even when there is evidence of data fabrication or other forms of research misconduct.

Id. at 567. A subsequent inquiry found numerous episodes of protocol aberration and research misconduct. See R. Dal-Ré et al., *Increasing Access to FDA Inspection Reports on Irregularities and Misconduct in Clinical Trials*, 2020 JAMA e1, e1–e2; see also Garamendia et al., *supra* note 24.

193 'The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds.' Office of Research Integrity. Policies—Regulations Q&A; Question and Answers—42 CFR Part 93; available at https://ori.hhs.gov/QA-Reg-6-05.

194 See *Policies - Regulations Q&A: Question and Answers - 42 CFR Part 93*, Off. Res. Integrity, https://ori.hhs.gov/QA-Reg-6-05 (last accessed Mar. 2, 2021); see also 42 C.F.R. §93.200 '(Administrative action means—(a) an HHS action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds or (b) an HHS action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.'); *Case Summaries*, Off. Res. Integrity, https://ori.hhs.gov/content/case_summary (last accessed Mar. 2, 2021).

195 31 U.S.C. § 3729.

196 See *supra* note 12 and accompanying text as Duke University was held vicariously—not directly—liable for its employees' RM.

197 42 C.F.R. §93.205 ('Debarment or suspension. Debarment or suspension means the Government-wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).').

up fraud enforcement actions in this area. Enforcement is anticipated to focus, *inter alia*, on Covid-19 research.[198]

FDA penalties for improper research conduct already apply to organizations—albeit not under the express heading of 'RM'. They include warning letters, disqualifications,[199] rejections of data, injunctions, civil money penalties, and the like.[200] Analogous actions are likewise applied to CROs for such violations as failure to select qualified clinical investigators, failure to adequately monitor the study, failure to bring noncompliant investigators into compliance, and the like.[201] Where research misconduct is applicable, these failings should be expressly labeled, and penalized, as forms of RM.

In the end we may ask why it matters what we call yet another episode of fast-and-loose-in-science—RM, scientific misconduct, or just bad science—and why does it matter whether we pin RM on organizations as well as on individuals.

Classification matters because individual research projects, and the data and methodology on which they are founded, are the bedrock of science. They are what we use to prove or disprove broader factual claims or to show that the scientific literature has been distorted. These individual research projects are the domain of research misconduct. If a high-quality research project is completed but withheld from publication for wrongful reasons we may have scientific misconduct, but there is still a chance it will be published one day.[202] But if the underlying research has itself been

198 Jessica Heim, Evan Seeder & Daniel Wallmuth. *Data Corruption: DOJ Targets Fraud In Medical Research Trial In The Era Of COVID-19*. JDSupra (March 23, 2021) https://www.jdsupra.com/legalnews/data-corruption-doj-targets-fraud-in-2120391/ (last visited March 27, 2021). See also Department of Justice. *Medical Doctor and Study Coordinator Sentenced to Prison in Scheme to Falsify Clinical Trial Data* (March 22, 2021); https://www.justice.gov/opa/pr/medical-doctor-and-study-coordinator-sentenced-prison-scheme-falsify-clinical-trial-data (last accessed March 28, 2021).

199 'Disqualification', or A Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE), for instance, refers to 'a clinical investigator has: a. Repeatedly or deliberately failed to comply with the requirements of 21 CFR 312, 511, and/or 812, as appropriate, and/or 21 CFR 50 or 56 or b. Repeatedly or deliberately submitted false information to FDA or to the sponsor in any required report'. This could be attributed to an organization, just as to natural persons.

200 US Food & Drug Admin., Compliance Program 7348.811: Chapter 48-Bioresearch Monitoring: Clinical Investigators and Sponsor-Investigators, at 54–55 (July 22, 2020), http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/ucm133773.pdf; see also Food & Drug Admin. Office Regulatory Affairs, ORA-WIDE PROCEDURE; FMD 86: Establishment Inspection Report Conclusions and Decisions 11(Jan. 28, 2014), https://www.fda.gov/media/87643/download.

201 US Food & Drug Admin., Compliance Program 7348.811: Chapter 48-Bioresearch Monitoring: Sponsors, Contract Research Organizations and Monitors at pt. V (Apr. 19, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/compliance-program-7348810-bioresearch-monitoring.

202 Over 20 years ago the pharmaceutical firm that makes Synthroid, a synthetic thyroid replacement, undertook a head-to-head research study, hypothesizing that its product was superior to generics. The study was completed and accepted for publication in *The Journal of the American Medical Association*. However, because the science showed the brand name product to be no better, the company blocked the paper from publication. Several years later the study—and the block—came to light and publication followed. As did profuse apologies from the company. See L.K., *Drug Firm, Relenting, Allows Unflattering Study to Appear*, N.Y. Times (Apr. 16, 1997), https://www.nytimes.com/1997/04/16/us/drug-firm-relenting-allows-unflattering-study-to-appear.html; B.J. Dong et al., *Bioequivalence of Generic and Brand-Name Levothyroxine Products in the Treatment of Hypothyroidism* 277 JAMA 1205, 1205–13 (1997); see also *Letters by Martin JB (Chancellor, University of California, San Francisco) and Spigelman MK (Vice President of Research and*

corrupted at the core, we have nowhere else to turn.[203] Now, more than ever, we need to be able to trust science. But now, more than ever, corruption of science is a problem that must be addressed forthrightly and precisely.

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CONFLICT OF INTEREST

The author filed one report and one declaration as an expert on behalf of Plaintiff CrossFit, Inc. in Part IV's final case study.

Development, Knoll Pharmaceutical Company), and Replies by Dong et al., 277 JAMA 1199, 1199–1201 (1997); M. Wadman, *$100m Payout After Drug Data Withheld*. 388 Nature (1997).

203 There is a reason, for instance, why most statutes begin with definitions. We need to know as exactly as possible how and to what that statute applies, so that it will hit and not miss its intended mark. Indeed, the federal definition of 'research misconduct' helps us reach this article's conclusions.