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Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters

Deanna Minasi
Fordham University School of Law

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CONFRONTING THE GHOST: LEGAL STRATEGIES TO OUST MEDICAL GHOSTWRITERS

Deanna Minasi*

Articles published in medical journals contribute significantly to public health by disseminating medical information to physicians, thereby influencing prescribing practices. However, the information guiding treatment decisions becomes distorted by selective publishing and medical ghostwriting, which negatively affects overall patient care. Although there is general consensus in the medical community that these practices of publication bias represent a moral failing, the issue is rarely framed as a wrong that necessitates legal consequences.

This Note takes the stance that medical ghostwriting constitutes an act prohibited under the Racketeer Influenced and Corrupt Organizations Act (RICO) and argues that physicians fraudulently named as authors should be held civilly liable under RICO. This Note explores civil RICO, its origin, its legislative and judicial history, and the evolution of RICO to areas beyond traditional organized crime. By applying the elements of civil RICO to medical ghostwriting, this Note argues that physicians named as authors who knowingly fail to fulfill journal authorship criteria should be held accountable for their role in disseminating misleading medical information. This Note argues that, at the very least, current regulations governing the medical publication framework should be better enforced and revised to mandate authorship disclosure.

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* J.D. Candidate, 2018, Fordham University School of Law; B.S., 2012, Fordham University. I would like to thank Professor Olivier Sylvain and the editors and staff of the *Fordham Law Review* for their valuable guidance and assistance throughout the process. I would also like to thank my family for their unwavering support.

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INTRODUCTION

“[T]he medical journal, like the newspaper, is an ever-present friend whose influence and advice are potent for good or evil.”¹ This statement, made by a Chicago physician in 1906, reveals that physicians have long recognized the importance of medical journals. Since their development, medical journals have done more than simply disseminate new knowledge of medical treatments or therapeutic breakthroughs. These journals have articulated norms of professional and social responsibility, established standards for ethical research, and served as platforms for public health discussion.² Yet, like anything of great power, medical journals have the potential for evil—a potential that, while articulated over a century ago, only recently fully emerged.

By shaping medical knowledge, medical journals can play a direct role in patient health. A 2014 study showed that nearly 75 percent of physicians change their clinical practices quarterly or monthly based on reading the results of medical research, and 16 percent of physicians reported saving a patient’s life in the last year as a result of reading information in medical

1. Scott H. Podolsky et al., *The Evolving Roles of the Medical Journal*, 366 NEW ENG. J. MED. 1457, 1457 (2012) (quoting J.H. Salisbury, *The Subordination of Medical Journals to Proprietary Interests*, 4 CAL. ST. J. MED. 247, 247 (1906)).

2. See *id.* at 1457–59.

literature.³ As such, the research published in medical journals significantly impacts physician treatment decisions. Medical research is not merely an abstract scholarly pursuit; rather, it functions as a powerful tool used directly to affect people's lives.

To complicate matters, there is a tremendous amount of research conducted in the United States. An estimated \$59 billion is invested annually by biopharmaceutical companies in research and development alone.⁴ This vast amount of research is made accessible to physicians via medical journals, which rely on peer review to ensure that manuscripts submitted for publication are scientifically sound and accurate.⁵ While steps are in place to promote accuracy and transparency, publishing bias is all too common, which poses a major threat to public health.

Publication bias is driven by the tendency of physicians, reviewers, and editors to submit or accept manuscripts for publication based on the direction or strength of a study's findings.⁶ Thus, authors and editors are more likely to submit and publish, respectively, studies with positive results rather than studies with negative results and are more likely to omit negative data.⁷ Drug companies have an obvious financial interest in how their products are presented in research publications, and the selection of positive trial results is one way to present the product in a more favorable light. Further, authorship of publications is highly sought after by physicians. For academic investigators (physicians who serve as lead researchers), academic tenure frequently depends on securing multiple publications in leading journals, and collaboration with industry professionals heightens prestige and can result in additional grant support.⁸ This combination of industry gain and personal benefit creates an incentive to engage in practices of publication bias.

Misleading publications go far beyond simply misinforming doctors about the benefits and harms of medical interventions. Through the doctors, these articles leave patients exposed to potentially ineffective, unnecessary, or harmful treatments. In a discipline grounded in principles of objective science and ideals of nonmaleficence, the information underlying treatment decisions has become muddled, which negatively affects patient care.

3. *Survey: How Doctors Read and What It Means to Patients*, BUS. WIRE (July 22, 2014), <http://www.businesswire.com/news/home/20140722005535/en/Survey-Doctors-Read-Means-Patients> [https://perma.cc/8V3Z-J797].

4. Press Release, Pharmaceutical Research and Manufacturers of America, PhRMA Member Companies Invested \$58.8 Billion in 2015 R&D (May 11, 2016), <http://phrma.org/press-release/phrma-member-companies-invested-58-8-billion-in-randd-in-2015> [https://perma.cc/GU8W-VSM2].

5. See, e.g., *Media Center Publication Process*, NEW ENG. J. MEDICINE, <http://www.nejm.org/page/media-center/publication-process> [https://perma.cc/5DTS-NSY2] (last visited Sept. 21, 2017).

6. See Kay Dickersin, *The Existence of Publication Bias and Risk Factors for Its Occurrence*, 263 J. AM. MED. ASS'N 1385, 1385 (1990).

7. See *id.* at 1385–86.

8. Xavier Bosch & Joseph S. Ross, *Commentary, Ghostwriting: Research Misconduct, Plagiarism, or Fool's Gold?*, 125 AM. J. MED. 324, 324 (2012).

While there is a general consensus that publication bias constitutes a moral failing,⁹ the issue is rarely framed as a wrong deserving of legal consequence. Indeed, those who have been exposed for engaging in these practices have suffered only minimal professional or academic consequences,¹⁰ creating a culture of permissible dishonesty. Drawing on the few articles that merge law and medicine in the realm of publication, this Note argues that certain biased practices constitute fraudulent behavior.

Part I of this Note explores the connected practices of selective publishing and medical ghostwriting and their real-world effect on public health. This Part also introduces the Racketeer Influenced and Corrupt Organizations Act (RICO) and discusses how the statute's legislative and judicial history mandates a liberal interpretation, promoting applicability to areas beyond traditional organized crime. Part II argues that medical ghostwriting constitutes an act prohibited under civil RICO and that physicians fraudulently named as authors should be held civilly liable. While acknowledging civil RICO as a viable tool to combat medical ghostwriting, Part III proposes less drastic solutions to the current medical publication framework that avoid placing liability on physicians. This Part offers greater enforcement of current Food and Drug Administration (FDA) regulation and the implementation of a mandatory disclosure rule as possible solutions. While avoiding constitutional concerns, these solutions consider the practical needs of the pharmaceutical industry and offer a realistic means of addressing medical publication bias.

I. PUBLISHING BIAS IN MEDICAL RESEARCH AND AN INTRODUCTION TO CIVIL RICO

Part I.A provides a basic overview of the FDA's drug approval process.¹¹ Next, Parts I.B and C address industry practices that contribute to medical publication bias: the selective publication of medical research and medical ghostwriting. Part I.D then explains that a litigatory approach to combating publication bias is possible.

A. *The Approval Process for FDA-Regulated Drugs*

To market a drug for human use in the United States, a manufacturer (typically a pharmaceutical or biotechnology company) needs the approval of the FDA, the federal agency that determines whether available evidence demonstrates that a drug is safe and efficacious.¹² The approval process begins with the manufacturer submitting an application to the FDA that contains the results of preclinical animal tests, manufacturing information,

9. See *id.* (explaining that the practice of ghostwriting is perceived as a "slight, easily comprehensible moral failing, rather than as unethical").

10. *Id.*

11. For a more detailed explanation of the drug approval process, see Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. PRAC. 362 (2001).

12. See Gerrit M. Beckhaus, *A New Prescription to Balance Secrecy and Disclosure in Drug-Approval Processes*, 46 U. MICH. J.L. REFORM 135, 135 (2012).

investigator information, and clinical protocols.¹³ The application proceeds if “sufficient hints of drug efficacy” are shown to warrant human testing.¹⁴

The drug then enters three phases of clinical trials.¹⁵ If the drug passes the third extensive phase of testing, a new drug application (NDA) is submitted to the FDA for approval.¹⁶ The NDA contains detailed information regarding the drug’s composition, results of preclinical and clinical trials, the drug’s behavior in the body, and how the drug is manufactured, processed, and packaged.¹⁷ At that stage, the FDA can approve or reject the application or request further study before making a decision.¹⁸ On average, the entire process takes eight to twelve years and may cost over \$500 million.¹⁹ But the development of new drugs is an important part of modern medicine, and clinical trials are an essential aspect of that development.

B. *Selective Publishing of Clinical Trial Results*

Publication bias favors the dissemination of information about medical interventions that show a statistically significant benefit.²⁰ One form of publication bias is selective publishing, which occurs when journals publish favorable clinical trials that promote the use of a drug but fail to publish trials yielding unfavorable results.²¹ This practice not only has the potential to lead to preferential prescribing of drugs with underestimated harms but also limits the number and scope of studies available for review by clinicians.²² Ultimately, through selective publication, unrealistic estimates of drug effectiveness may alter a drug’s apparent risk-to-benefit ratio, leading to inappropriate treatment decisions.²³

Many reports illuminate the existence of selective publishing, suggesting that it represents a deeply rooted problem in the medical community.²⁴ These reports show that published literature conveying drug efficacy does not accurately reflect drug efficacy according to FDA reviews, which contain

13. *See id.* at 138.

14. *See id.* at 139.

15. *See id.* Phase I determines the drug’s general safety and profile by testing the drug on twenty to eighty healthy volunteers. *Id.* If not inordinately toxic, the drug moves on to Phase II, where well-controlled clinical studies are conducted on several hundred patients with the condition the drug is intended to improve. *Id.* These studies obtain data on the drug’s effectiveness, common short-term side effects, and risks. *Id.* In Phase III, large-scale, randomized trials are conducted on several hundred to several thousand people to gather additional information on effectiveness and safety. *Id.* at 139–40.

16. *Id.* at 139.

17. *Id.* at 139–40.

18. Lipsky & Sharp, *supra* note 11, at 364.

19. *Id.*

20. Kristin Rising et al., *Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation*, 5 PLOS MED. 1561, 1562 (2008).

21. *Id.*

22. *Id.*

23. Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 259 (2008).

24. *See* Dickersin, *supra* note 6, at 1386 (noting that the first professional critique of the problem of publishing positive results and rejecting negative findings arose in the 1950s).

information on all trials submitted to the regulator.²⁵ In a study published in *The New England Journal of Medicine*, researchers reviewed clinical trials of twelve antidepressant drugs approved by the FDA between 1987 and 2004 and compared the results of the FDA-reviewed trials to those published in medical journals.²⁶ If selective publishing did not exist, the FDA reviews and the publications would contain the same information. Yet the findings revealed a bias toward the publication of positive results.

According to the FDA review, seventy-four studies were conducted representing 12,500 patients' worth of data, while the published literature presented a total of only fifty-one studies.²⁷ No evidence of publication was found for twenty-three of the FDA-reviewed studies, accounting for data from 3449 study participants.²⁸ Out of the FDA-reviewed studies, thirty-eight were deemed to have positive results.²⁹ The published literature, however, reported forty-eight of the studies positively.³⁰ Thus, according to the published literature, the results of all but three studies were positive.³¹ The study also found that the published literature presented an effect size, or assessment of treatment efficacy, nearly one-third larger than the effect size from the FDA data.³²

A comparative analysis in the *Stanford Law and Policy Review* explored the specific strategies employed by industries to manipulate the reporting of research.³³ The analysis found that, in comparison to other industries, the pharmaceutical industry publishes more research that supports its interests and suppresses more research in cases where the results do not support the industry's interests.³⁴ The article concluded that pharmaceutical companies used peer-reviewed publications as a marketing tool.³⁵ After all, once a drug

25. See, e.g., Rising, *supra* note 20, at 1562 (presenting findings from an observational study of efficacy trials of approved NDAs for New Molecular Entities from 2001 to 2002 and noting that (1) many trials had not been published and (2) discrepancies existed between the FDA-reviewed trial information and information found in publications, leading to more favorable presentations of the NDA drugs in the publications); see also Turner, *supra* note 23, at 259.

26. Turner, *supra* note 23, at 253.

27. *Id.* at 255 tbl.1.

28. *Id.* The researchers noted there may be many reasons why study results are not published. *Id.* at 259.

29. *Id.* at 254.

30. *Id.* at 254–55.

31. *Id.* at 256 figs.1–2.

32. *Id.* at 255–56.

33. See generally Jenny White & Lisa A. Bero, *Corporate Manipulation of Research: Strategies Are Similar Across Five Industries*, 21 STAN. L. & POL'Y REV. 105 (2010) (providing a systematic examination of the strategies industries use to manipulate research to promote the industry's products, thereby enhancing credibility and profits).

34. *Id.* at 109 tbl.1. The study also included the tobacco, lead, vinyl chloride, and silicosis-generating industries. *Id.* at 106. The categories of research manipulation studied were (1) funding of research that supports industry interests, (2) publication of research that supports industry interests, (3) suppression of industry-sponsored research when results do not support industry interests, (4) distortion of public discourse on research, (5) setting of scientific standards favorable to the industry, and (6) dissemination of favorable research directly to the public. *Id.* at 108.

35. *Id.* at 130.

is approved for sale, the pharmaceutical company is tasked with selling its drug to the only people who can make it available to patients—physicians, who turn to the published medical research for guidance.

While these reports demonstrate that selective publishing exists, they fail to show the consequences of the biases. It is therefore necessary to identify concrete examples of the resulting harm. From the mid-1990s to the early 2000s, a number of highly publicized incidents occurred involving attempts to manipulate clinical research publication.³⁶ Of particular importance is the 2004 litigation between New York Attorney General Eliot Spitzer and drug giant GlaxoSmithKline (“Glaxo”).³⁷

As the first suit to allege the illegality of data suppression, Spitzer accused Glaxo of “repeated and persistent fraud” in violation of New York consumer protection law.³⁸ Specifically, the complaint identified five studies of Paxil use among children and adolescents.³⁹ It alleged that two of Glaxo’s studies failed to show that the drug was more effective than a placebo for treating depression, and three showed that suicide-related behaviors were twice as likely among Paxil users.⁴⁰ However, out of the five studies, only one study was published in a prominent journal, and it suggested favorable results.⁴¹

Not long after the complaint was filed, Glaxo settled for \$2.5 million and agreed to post all clinical trial results on its website, an unusual move for a pharmaceutical company.⁴² Even with a quick settlement, the suit established a new standard with regard to disclosure, drastically altering the nature of the industry’s handling of clinical trial results.⁴³ Perhaps in direct response, the International Committee of Medical Journal Editors (ICMJE) announced that their journals⁴⁴ would require registration in a public clinical

36. See Laurence J. Hirsch, Commentary, *Conflicts of Interest, Authorship, and Disclosures in Industry-Related Scientific Publications: The Tort Bar and Editorial Oversight of Medical Journals*, 84 MAYO CLINIC PROC. 811, 812 (2009). Manipulations included blocking of publication by contractual means, withholding study data from investigators, and reporting a twelve-month study as a six-month trial that provided misleading favorable results without explanation of the changed reporting period. *Id.*

37. Complaint, *People v. GlaxoSmithKline, PLC* (N.Y. Sup. Ct. June 2, 2004), <http://news.findlaw.com/wsj/docs/glaxo/nyagglaxo60204cmp.pdf> [<https://perma.cc/E4N3-GCFK>].

38. *Id.* at 1; see Barbara Martinez, *Spitzer Charges Glaxo Concealed Paxil Data*, WALL ST. J. (June 3, 2004), <http://www.wsj.com/articles/SB108618482620826827> [<https://perma.cc/GB5S-99UQ>].

39. Complaint, *supra* note 37, at 5; see also Martinez, *supra* note 38.

40. Complaint, *supra* note 37, at 5; see also Martinez, *supra* note 38. According to the complaint, one unpublished study showed that 7.7 percent of the youth on Paxil had suicidal thinking and acts compared with 3 percent of the placebo group. Complaint, *supra* note 37, at 11; see also Martinez, *supra* note 38.

41. Martinez, *supra* note 38.

42. See Jaime Holguin, *Glaxo Settles Paxil Lawsuit*, CBS NEWS (June 3, 2004), <http://www.cbsnews.com/news/glaxo-settles-paxil-lawsuit/> [<https://perma.cc/Y5NN-4HYH>].

43. Press Release, Office of N.Y. State Attorney Gen. Eliot Spitzer, Settlement Sets New Standard For Release of Drug Information (Aug. 26, 2004), <http://www.ag.ny.gov/press-release/settlement-sets-new-standard-release-drug-information> [<https://perma.cc/R249-SZZ7>].

44. Almost 3000 journals are listed as following the ICMJE guidance. *Journals Following ICMJE Recommendations*, INT’L COMMISSION MED. J. EDITORS,

trials registry as a condition of publication consideration.⁴⁵ The ICMJE asserted the policy was necessary to establish full transparency with respect to the performance and reporting of clinical trials.⁴⁶ Indeed, one of the explicit purposes of clinical trial registration is to prevent selective publication and selective reporting of research outcomes.⁴⁷

These events likely contributed to the passage of Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA),⁴⁸ which established legal requirements for study sponsors and investigators to report specified clinical trial information for certain applicable clinical trials on the online national registry, managed by the National Library of Medicine at the National Institutes of Health (NIH).⁴⁹ Specifically, the statute requires registration at the outset of the study⁵⁰ and disclosure of trial results within twelve months of study completion.⁵¹ Congress' main intention in enacting Title VIII was doubtless to improve transparency of clinical research. During a 2007 House of Representatives hearing, Senator Charles Grassley testified that the bill would

expand an existing public data base by mandating the registry of all clinical trials and the results of those trials. This reform is key to establishing greater transparency regarding clinical trials, the good ones and the bad ones, and to hold drug makers and drug regulators accountable and to give doctors all the information they can to their patients.⁵²

The statute established registration requirements and provided a legally defined timeline with specific mandates for the reporting of trial results.⁵³ Because publication bias is still prevalent years after the FDAAA's enactment, however, compliance with Title VIII remains an issue.

<http://www.icmje.org/journals-following-the-icmje-recommendations/>
[<https://perma.cc/RD7S-ZLBS>] (last visited Sept. 21, 2017).

45. Catherine D. DeAngelis et al., Editorial, *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, 351 NEW ENG. J. MED. 1250, 1250–51 (2004).

46. *Id.* at 1251.

47. *Clinical Trial Registration*, INT'L COMMISSION MED. J. EDITORS, <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html> [<https://perma.cc/U9BF-GRN8>] (last visited Sept. 21, 2017).

48. Pub. L. No. 110-85, § 801, 121 Stat. 823, 904 (2007) (codified at 42 U.S.C. § 282(j) (2012)).

49. Deborah A. Zarin et al., *Trial Reporting in ClinicalTrials.gov—The Final Rule*, 375 NEW ENG. J. MED. 1998, 1998 (2016).

50. 42 U.S.C. § 282(j)(2)(C). Information to be reported in the registry includes descriptive information regarding study design and recruitment, as well as contact and administrative information. *Id.* § 282(j)(2)(A)(i).

51. *Id.* § 282(j)(4)(C)(i)(I). The completion date is defined as the date that the “final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome” and thus, does not include time or care related to secondary outcomes. *Id.* § 282(j)(1)(A)(v). Additionally, because the completion date relates to last patient care date, the FDAAA applies to discontinued trials. *Id.*

52. *The Adequacy of FDA to Assure the Nation's Drug Supply: Hearings Before the Subcomm. on Oversight and Investigations of the S. Comm. on Energy & Commerce*, 110th Cong. (2007) (statement of Sen. Charles Grassley), <https://www.gpo.gov/fdsys/pkg/CHRG-110hrg35502/html/CHRG-110hrg35502.htm> [<https://perma.cc/RYT6-KHS2>].

53. Zarin, *supra* note 49, at 1998.

According to a recent report, the national registry currently has more than 224,000 study records⁵⁴ but compliance with the reporting requirements has been low, partly due to ambiguous statutory requirements.⁵⁵ One study showed that after twelve months, the end of the statutory reporting period, results were reported for only 17 percent of trials funded by the industry, 8.1 percent of trials funded by the NIH, and 5.7 percent of trials funded by other government or academic institutions.⁵⁶ In an effort to promote compliance, the FDA issued a final rule⁵⁷ in September 2016, which clarified the registration and reporting requirements for the regulated community,⁵⁸ interpreted ambiguous key statutory provisions, and developed additional requirements necessary to further the goal of transparency.⁵⁹

The enactment of the final rule validates the FDAAA's commitment to maintaining public trust and encouraging advances in the design, conduct, and oversight of clinical trials.⁶⁰ Organizations will need to ensure that their systems and procedures promote complete and timely clinical trial reporting. Yet the specifics of how and under what circumstances the agencies will seek to enforce the requirements are not included in the final rule.⁶¹ Instead, the NIH stated that it expects the "clarification of responsibilities and obligations in this final rule will lead to a high level of voluntary compliance with these requirements."⁶² In an effort to raise awareness of the procedures and penalties of noncompliance, the final rule describes the potential legal consequences of violating Title VIII, which include civil damages.⁶³

While the effects of the final rule are not yet known, compliance with Title VIII is merely the first step in addressing bias in publication. In theory,

54. *Id.*

55. *Id.*

56. Monique L. Anderson et al., *Compliance with Results Reporting at ClinicalTrials.gov*, 372 *NEW ENG. J. MED.* 1031, 1034–37 (2015). After five years, these numbers only marginally increased. Results had been reported by 41.5 percent of trials funded by industry, 38.9 percent of those funded by the NIH, and 27.7 percent of those funded by other government or academic institutions. *Id.* at 1034.

57. *See generally* Clinical Trials Registration and Results Information Submission, 81 *Fed. Reg.* 64,982 (Sept. 21, 2016) (to be codified at 42 C.F.R. pt. 11). For discussion of the key issues that the final rule addresses, see Zarin, *supra* note 49, at 1998.

58. Additionally, the NIH—the largest public funder of clinical trials in the United States, which invests more than \$3 billion annually—has issued a complementary policy to cover all NIH-funded trials, including those not subject to regulation. *See* Kathy L. Hudson et al., *Opinion, Toward a New Era of Trust and Transparency in Clinical Trials*, 316 *J. AM. MED. ASS'N* 1353, 1353–54 (2016). Requirements include submitting applications that contain specific information about protocols and other information necessary for effective peer review. *Id.* Noncompliance will result in the NIH withholding funding to grantee institutions. *Id.*

59. *See* Zarin, *supra* note 49, at 1999.

60. Hudson, *supra* note 58, at 1354.

61. *See* 42 C.F.R. pt. 11 (2016).

62. Clinical Trials Registration and Results Information Submission, 81 *Fed. Reg.* at 65,117.

63. 42 C.F.R. § 11.66. Specifically, if the secretary of the Department of Health and Human Services determines that any clinical trial information was not submitted as required or was false or misleading, the secretary must notify the responsible party and give it an opportunity to remedy the noncompliance within thirty days. *Id.* § 11.66(a)(2). If the violation is not corrected within that time, the person is subject to a civil monetary penalty of not more than \$10,000 per day until the violation is corrected. 21 U.S.C. § 333(a)(2) (2012).

complete disclosure of clinical trial results grants physicians access to both negative and positive results, allowing for informed treatment decisions; in practice, however, physicians rely on medical journals for this information.⁶⁴ Regulating the published information and ensuring the validity of that information must therefore be a goal of reform.

C. Ghostwriting in Medical Journals

Medical ghostwriting is the practice of hiring medical education, marketing, or communications companies to draft articles that are presented to prominent physicians⁶⁵ to sign on as authors.⁶⁶ Ghostwritten articles can be drafted by pharmaceutical companies that are not acknowledged in final publication and include review articles,⁶⁷ editorials, and primary research papers.⁶⁸ These ghostwritten articles contravene journal authorship requirements but are nevertheless published.⁶⁹ Physicians who agree to serve as authors may be unfamiliar with underlying data or relevant research and may have provided only limited input.⁷⁰ While the manufacturer benefits from the promotion of its product, the authors also benefit, as successful publications increase their prestige and may lead to promotions or more research funding opportunities.⁷¹

Because ghostwritten articles often contain selective clinical trial results, they can have a significant impact on physician prescribing practices. When a prominent physician lends his or her name to such an article, the perceived credibility of the findings and conclusions is heightened, thereby influencing

64. See *supra* note 1 and accompanying text.

65. The term “physicians” in this Note refers not only to practicing physicians but also to scientists and medical academics.

66. SEN. CHARLES E. GRASSLEY, S. COMM. ON FIN., 111TH CONG., GHOSTWRITING IN MEDICAL LITERATURE 1, 2 (2010) [hereinafter GRASSLEY REPORT], <http://www.grassley.senate.gov/sites/default/files/about/upload/Senator-Grassley-Report.pdf> [https://perma.cc/C3EB-HKU8].

67. A review article is an article in which an author examines a large body of medical research and offers a bottom-line judgment about how to treat a particular ailment. See Natasha Singer, *Medical Papers by Ghostwriters Pushed Therapy*, N.Y. TIMES (Aug. 4, 2009), <http://www.nytimes.com/2009/08/05/health/research/05ghost.html?pagewanted=all> [https://perma.cc/P8X3-5VQ2].

68. See GRASSLEY REPORT, *supra* note 66, at 2.

69. ICMJE recommends that authorship be based on the following four criteria: (1) “[s]ubstantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work”; (2) “[d]rafting the work or revising it critically for important intellectual content”; (3) “[f]inal approval of the version to be published”; and (4) “[a]greement 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.” *Defining the Role of Authors and Contributors*, INT’L COMMITTEE MED. J. EDITORS, <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> [https://perma.cc/D5KP-9LLQ] (last visited Sept. 21, 2017). The ICMJE further recommends that “authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged.” *Id.*

70. GRASSLEY REPORT, *supra* note 66, at 2.

71. See *id.* at 15.

readers' treatment decisions.⁷² The warranty of authorship influences the article's integrity and quality, making it unsurprising that knowledge of ghostwriting reduces the credibility of the publication.⁷³ It is therefore in the pharmaceutical company's best interest not to disclose true authorship, since these articles play an important role in the marketing and sale of their drugs. Ghostwriting functions as a way for pharmaceutical companies to "covertly shape the medical literature in favor of [their] commercial interests."⁷⁴

To assess the prevalence of inappropriate authorship in the form of honorary and ghost authors, editors of *The Journal of the American Medical Association (JAMA)* surveyed authors published in six leading medical journals in 2008.⁷⁵ Online questionnaires completed by 630 authors show that the prevalence of articles with honorary authorship, ghost authorship, or both was 21 percent.⁷⁶ Specifically, ghostwriting was reported at a rate of 7.9 percent in *JAMA*, 7.7 percent in *PLOS Medicine*, 7.6 percent in *The Lancet*, 4.9 percent in *The Annals of Internal Medicine*, and 2.1 percent in *Nature Medicine*.⁷⁷ *The New England Journal of Medicine* reported the highest rate among the journals at 11 percent.⁷⁸ The reported rates increased for honorary authorship, with *Nature Medicine* reporting the highest rate at 29.3 percent and *The New England Journal of Medicine* reporting the lowest rate at 12.2 percent.⁷⁹ Less than one-fifth of the articles surveyed included acknowledgment sections that identified contributions such as review, comments, and analysis.⁸⁰ While these statistics may seem insubstantial, the six journals examined are considered to be among the most influential journals in medicine and all have rigorous authorship guidelines.⁸¹ Thus, the editors who conducted the study suspect that the prevalence of inappropriate authorship could be higher in journals with more relaxed standards.⁸²

72. *Id.* at 2.

73. See, e.g., Jeffrey R. Lacasse & Jonathan Leo, *Knowledge of Ghostwriting and Financial Conflicts-of-Interest Reduces the Perceived Credibility of Biomedical Research*, BMC RES. NOTES, Jan. 2011, at 1 (assessing the impact of several conflicts of interest, including ghostwriting, on the perceived credibility of biomedical research among practicing clinicians). Two versions of a fictional antidepressant study were presented to hospital personnel—one disclosed conflicts of interest and the other did not. *Id.* at 2. Perceived credibility ratings were lower in the study that disclosed conflicts of interests, and clinicians relying on that study were less likely to recommend the antidepressant. *Id.* at 3–4.

74. See Jeffrey R. Lacasse & Jonathan Leo, *Ghostwriting at Elite Academic Medical Centers in the United States*, PLOS MED., Feb. 2010, at 1.

75. See Joseph S. Wislar et al., *Honorary and Ghost Authorship in High Impact Biomedical Journals: A Cross Sectional Survey*, BMJ, Oct. 2011, at 1. ICMJE authorship criteria was used to define honorary authors as individuals who are named as authors but who have not met authorship criteria and ghost authors as individuals who have made substantial contributions to the work reported in an article but who are not named as authors. *Id.* at 1–2. For the purposes of this Note, "ghostwriting" includes both honorary authors and ghost authors.

76. *Id.* at 3.

77. *Id.* at 7 tbl.1.

78. *Id.*

79. *Id.*

80. *Id.* at 4.

81. *Id.*

82. *Id.*

Additionally, while respondents were assured confidentiality, underreporting of honorary and ghost authorship was expected, indicating that the results do not reveal the true extent of inappropriate authorship.⁸³

The prevalence of ghostwriting fails to give credence to its dangerous consequences. The highly publicized Merck case provides an example. Before the pharmaceutical giant Merck voluntarily pulled its multibillion-dollar drug Vioxx from the market, the FDA warned Merck that its promotional campaign minimized potentially serious cardiovascular risks.⁸⁴ The FDA instructed the company to contact physicians to “correct false or misleading impressions and information” that it had disseminated through advertisements and publications.⁸⁵ Despite these warnings, the drug remained on the market for three more years, possibly contributing to nearly 28,000 heart attacks and deaths over four years.⁸⁶

Merck’s handling of Vioxx spurred litigation that triggered the medical community to examine Merck’s internal documents in an effort to better understand collaborations between the pharmaceutical industry and medical profession.⁸⁷ After reviewing 250 documents, a pattern emerged demonstrating that Merck prepared manuscripts for its own clinical trials and recruited external, academically affiliated physicians to be honorary authors.⁸⁸ The documents revealed that the clinical trials and analyses of manuscripts were completed before the physicians became involved.⁸⁹ Documents also described contracts between Merck employees and medical publishing companies providing for ghostwriting, reviews, and recruitment of external physician as authors.⁹⁰ Merck compensated some physicians who agreed to serve as authors of ghostwritten manuscripts with honoraria ranging from \$750 to \$2500.⁹¹

Another example of how the consequences of ghostwriting are not known until thousands of patients’ lives are negatively affected involves Wyeth’s treatment of its hormone drugs. Documents unveiled during litigation show that Wyeth paid ghostwriters to produce twenty-six articles that were

83. *Id.*

84. After spending only a few years on the market, Vioxx was voluntarily pulled after outside researchers continuously raised the possibility that Vioxx might be a danger to the heart, linking the painkiller to an increased risk of heart attacks, strokes, and deaths. See Alex Berenson et al., *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES (Nov. 14, 2004), <http://www.nytimes.com/2004/11/14/business/despise-warnings-drug-giant-took-long-path-to-vioxx-recall.html> [<https://perma.cc/978Q-B8SF>].

85. *Id.*

86. See Bloomberg News, *F.D.A. Releases Memo on Vioxx*, N.Y. TIMES (Nov. 3, 2004), <http://www.nytimes.com/2004/11/03/business/fda-releases-memo-on-vioxx.html> [<https://perma.cc/644W-M2ET>].

87. See generally Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 J. AM. MED. ASS’N 1800 (2008).

88. *Id.* at 1801–02. Specifically, a Merck employee was found to be the author of the first draft of the manuscript; however, in the published articles, the first author was an external, academically affiliated investigator. *Id.* at 1803.

89. *Id.* at 1802.

90. *Id.* at 1803–04.

91. *Id.* at 1806.

published in eighteen medical journals between 1998 and 2005.⁹² These articles emphasized the benefits and deemphasized the risks of its hormone drugs without disclosing Wyeth's role in initiating or financing the studies.⁹³ The true nature of these risks, however, were disclosed to the public after a 2002 federally funded study found that the hormones increased the risk of breast cancer, heart disease, and stroke in menopausal women, leading to the filing of nearly 8000 lawsuits.⁹⁴

Practices like those of Merck and Wyeth led to a report by the Senate Finance Committee, helmed by Senator Charles Grassley, that described a two-year investigation into pharmaceutical industry influence over academia and medical ghostwriting.⁹⁵ The report found that, despite past litigation exposing ghostwriting, pharmaceutical companies' role in medical publications remained veiled or undisclosed.⁹⁶ The report also focused on academia, finding that, while their ability to detect ghostwriting is limited, only a small number of major medical schools have explicitly banned the practice.⁹⁷ Similarly, it found that journal criteria on authorship requirements had a limited effect on ghostwriting despite journals' explicit prohibition of the practice.⁹⁸

Dr. Joseph S. Ross, an assistant professor at Mount Sinai School of Medicine, likened the practice of medical ghostwriting to "steroids and baseball," stating, "You don't know who was using and who wasn't; you don't know which articles are tainted and which aren't."⁹⁹ Ghostwriting raises concerns for physicians who rely on medical literature to inform their practice. Because patient care is guided by these publications, this Note explores ways to ensure the validity of the literature used by prescribing physicians. While regulatory reform of the current medical publication framework will be addressed, the practice of ghostwriting presents an opportunity for a litigatory approach to the issue.

D. The Potential for Legal Action Against Medical Ghostwriting

Although the practice of ghostwriting is well known in the medical community, the legal world has been slow to address the issue. With few legal avenues available and no precedent to support a claim, two law

92. See Singer, *supra* note 67.

93. See *id.*; see also Duff Wilson, *Wyeth's Use of Medical Ghostwriters Questioned*, N.Y. TIMES (Dec. 12, 2008), <http://www.nytimes.com/2008/12/13/business/13wyeth.html> [<https://perma.cc/FZ8S-EYM6>] (explaining that documents revealed a "publication plan tracking report" by Wyeth showing "articles in which manuscripts were completed by the company before they were sent to the putative author for review, and any revisions were subject to final approval from the company").

94. See Singer, *supra* note 67.

95. See generally GRASSLEY REPORT, *supra* note 66.

96. See *id.* at 4–7.

97. See *id.* at 7–11. Out of the ten leading medical schools the report examined, six had policies explicitly prohibiting ghostwriting: Columbia, Johns Hopkins, Stanford, University of California, San Francisco, University of Washington, and Washington University. *Id.* at 7.

98. See *id.* at 11–14.

99. See Singer, *supra* note 67.

professors published an article that proposed using civil RICO to combat ghostwriting.¹⁰⁰ At first glance, RICO seems an unlikely statute to be discussed in the same breath as medical publishing, but an understanding of civil RICO's application and history can help to illustrate how the statute can be applied to areas beyond traditional organized crime.

Congress enacted RICO as part of Title IX of the Organized Crime Control Act of 1970 (OCCA) to combat the influence of organized crime on interstate commerce.¹⁰¹ The statute provides for both criminal and civil penalties for acts performed as part of an ongoing criminal enterprise.¹⁰² RICO permits the government and private plaintiffs to bring civil actions in either state or federal court,¹⁰³ and, under § 1964(c), is available to "[a]ny person injured in his business or property by reason of a violation" of RICO.¹⁰⁴ Those found civilly liable must pay treble damages, as well as attorney's fees and costs.¹⁰⁵ The availability of treble damages, combined with the statute's broad and liberal construction, has turned civil RICO into the weapon of choice for plaintiffs. It has the potential to serve as a valuable tool for medical ghostwriting plaintiffs as well.

II. PUBLICATION BIAS AS A VIOLATION OF CIVIL RICO

Though it was first enacted in response to growing crime syndicates, civil RICO has been stretched to areas far beyond traditional organized crime. This Part explores how a broad application of RICO could include medical ghostwriting. Part II.A describes how, historically, the pharmaceutical industry has been held liable for medical ghostwriting, while individual physicians have escaped liability. Next, Part II.B examines the history of RICO and the support for a liberal interpretation of the statute. Finally, Part II.C discusses the elements under § 1962(c) that a plaintiff must prove to pursue a successful RICO claim and applies those elements to the practice of medical ghostwriting.

A. *The Sole Wrongdoer: Pharmaceutical Industry Is Held Liable*

The Glaxo, Merck, and Wyeth examples demonstrate that issues of publication bias are only brought to light after public health has been

100. See generally Simon Stern & Trudo Lemmens, *Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles*, PLOS MED., Aug. 2011.

101. Organized Crime Control Act of 1970, Pub. L. No. 91-452, 84 Stat. 922 (codified as amended in scattered sections of 18 U.S.C.).

102. 18 U.S.C. §§ 1963–1964 (2012). RICO may provide equitable relief through divestiture of the defendant's interest in the enterprise, restrictions on the defendant's future activities or investments, and dissolution or reorganization of the enterprise. *Id.* § 1964(a).

103. *Id.* § 1964(b)–(c); see also *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990) (holding that state and federal courts have concurrent jurisdiction over claims arising under § 1964(c)).

104. 18 U.S.C. § 1964(c).

105. A successful plaintiff may recover three times the damages sustained and the cost of the suit, including a reasonable attorney's fee. *Id.*

compromised. Typically, however, the manufacturer is held solely responsible for its wrongdoing, as healthcare fraud allegations and subsequent payouts are commonplace in the pharmaceutical world.¹⁰⁶ For example, in addition to paying \$4.85 billion to settle thousands of personal injury suits, Merck paid \$950 million and pleaded guilty to a criminal misdemeanor charge for its illegal promotion¹⁰⁷ of Vioxx to treat rheumatoid arthritis before the FDA approved it for that purpose.¹⁰⁸ Merck also faced civil claims under the False Claims Act for making false statements to state Medicaid agencies about Vioxx's cardiovascular safety and for making "inaccurate, unsupported, or misleading" statements to increase sales of the drug, resulting in payments by the federal government.¹⁰⁹ Most recently, Merck settled a securities class action suit brought by its shareholders for \$830 million.¹¹⁰ Although the total costs to Merck exceed \$6 billion, litigation of this nature is viewed merely as "a cost of doing business."¹¹¹ Further, while publishing bias necessarily functions as a factor in these claims, neither selective publishing nor ghostwriting were identified as acts of fraudulent behavior. And, perhaps most alarmingly, no individual was held responsible.

Noticeably absent from litigation involving the pharmaceutical industry is any mention of the physicians who agreed to author ghostwritten papers. While the pharmaceutical industry is surely at fault for facilitating the drafting of the articles, the authors who fail to fulfill authorship criteria should also face legal liability.

B. A Liberal Interpretation of Civil RICO Facilitates Its Broad Application

An examination of RICO's legislative and judicial history is essential to understanding how civil RICO can stretch beyond traditional organized crime to apply to medical publishing.

106. In 2011, the *Wall Street Journal* stated that a recent Merck settlement was the "latest big payout by a drug company to settle health-care fraud allegations," noting that GlaxoSmithKline PLC, Pfizer Inc., Eli Lilly & Co., and AstraZeneca PLC have also reached costly settlements in recent years. See Peter Loftus & Brent Kendall, *Merck to Pay \$950 Million in Vioxx Settlement*, WALL ST. J. (Nov. 23, 2011), <http://www.wsj.com/articles/SB10001424052970204531404577054472253737682> [https://perma.cc/5UY2-GU4X].

107. Under the Food, Drug and Cosmetic Act, manufacturers are prohibited from marketing drugs for any uses except those the FDA has determined are safe. See 21 U.S.C. § 331 (2012).

108. See Duff Wilson, *Merck to Pay \$950 Million Over Vioxx*, N.Y. TIMES (Nov. 22, 2011), <http://www.nytimes.com/2011/11/23/business/merck-agrees-to-pay-950-million-in-vioxx-case.html> [https://perma.cc/79CW-XMPC].

109. Press Release, U.S. Dep't of Justice, Justice Department Announces Nearly \$1 Billion Civil and Criminal Resolution with Merck Sharp and Dohme Over Promotion of Vioxx (Nov. 22, 2011), <http://www.fda.gov/ICECI/CriminalInvestigations/ucm280985.htm> [https://perma.cc/A7HR-G7QQ].

110. See Peter Loftus, *Merck to Pay \$830 Million to Settle Vioxx Shareholder Suit*, WALL ST. J. (Jan. 15, 2016), <http://www.wsj.com/articles/merck-to-pay-830-million-to-settle-vioxx-shareholder-suit-1452866882> [https://perma.cc/ADY8-JL8V].

111. See Wilson, *supra* note 108.

1. Legislative History

This Part explores civil RICO's legislative history by dividing it into two time periods of statutory construction surrounding the enactment of § 1962(c): preliberalization and postliberalization.

Congress originally enacted RICO to combat the criminal infiltration of American business and trade.¹¹² By the 1950s, concern about the national reach of crime syndicates became pervasive, leading Congress to investigate the nature of these networks.¹¹³ The congressional investigations revealed for the first time that the suspected crime syndicates were operating through infiltration, a novel form of criminal activity in which the profits of organized crime were used to buy and operate legitimate business enterprises, reaching across almost every business sector.¹¹⁴ These alarming results led to the establishment of the Commission on Law Enforcement and the Administration of Justice, which issued a task report focusing on the organized nature of the crime syndicates rather than trying to prevent individual crimes from occurring.¹¹⁵ This focus on the infiltration of legitimate business proved foundational for RICO, spurring a series of legislative measures that eventually led to the statute's enactment.¹¹⁶

The original legislation that evolved into RICO attempted to punish either the investment of illegitimate profits into legitimate businesses or the acquisition of an interest in legitimate businesses by illegitimate means.¹¹⁷ Recognizing that the imprisonment of an organized crime leader did not eradicate a syndicate, RICO targeted the economic base to drain the organization's source of income.¹¹⁸ This purpose is explicit in the first two substantive crimes created by RICO. Section 1962(a) prohibits the use of income derived from a pattern of racketeering activity to acquire an interest in an enterprise.¹¹⁹ Section 1962(b) prohibits the acquisition or maintenance of an interest in or control of an enterprise through a pattern of racketeering activity.¹²⁰

Congress radically expanded RICO beyond its original intent with the addition of subsection (c),¹²¹ which made it a crime not only to acquire an enterprise by racketeering but also to conduct the affairs of an enterprise by

112. See, e.g., 115 CONG. REC. 9569 (1969) (noting the Senate Committee's determination that "organized crime in the United States is a highly sophisticated, diversified, and widespread activity that annually drains billions of dollars from America's economy").

113. Miranda Lievsay, Note, *Containing the Uncontainable: Drawing RICO's Border with the Presumption Against Extraterritoriality*, 84 FORDHAM L. REV. 1735, 1739 (2016).

114. *Id.* at 1739–40. Major industries such as banking and insurance, as well as small businesses such as restaurants and hotels were involved in this infiltration. *Id.* at 1740.

115. *Id.* at 1740.

116. *Id.* at 1741.

117. Gerard E. Lynch, *A Conceptual, Practical, and Political Guide to RICO Reform*, 43 VAND. L. REV. 769, 770, 773 (1990) (dismantling the myth that the original package of legislation was aimed at punishing membership in organized crime).

118. Lievsay, *supra* note 113, at 1741.

119. Lynch, *supra* note 117, at 770; see also 18 U.S.C. § 1962(a)–(b) (2012).

120. Lynch, *supra* note 117, at 770; see also 18 U.S.C. § 1962(b).

121. Lynch, *supra* note 117, at 774.

a pattern of racketeering.¹²² Thus, § 1962(c) makes anyone who engages in a pattern of criminal acts while managing any legitimate enterprise guilty of a RICO offense.¹²³ While the other provisions have limited application, § 1962(c) “has proved almost infinitely adaptable” and has been used in the overwhelming majority of RICO cases.¹²⁴

Since the inception of § 1962(c), courts have broadly interpreted RICO to include defendants who do not fit the conventional conception of a participant in organized crime. Rather than curtail this judicial interpretation, Congress extensively revised RICO in 1984 to broaden the law, including the addition of forfeiture provisions.¹²⁵ By this time, the use of RICO in white-collar and political corruption cases, as well as the widespread use of civil RICO, was well established.¹²⁶ While today’s uses may not have been foreseeable, Congress was aware of RICO’s application beyond traditional notions of organized crime when it revised the law in 1984.¹²⁷

The liberal construction clause of the OCCA, section 904(a), further supports a broad interpretation by expressly providing that “[t]he provisions of [RICO] shall be liberally construed to effectuate its remedial purposes.”¹²⁸ Adding strength to this directive is the fact that no other statute in the U.S. Code that imposes criminal penalties mandates liberal construction.¹²⁹ Thus, this congressional directive specifically requires courts to adopt a liberal approach when construing ambiguities within RICO.¹³⁰ Despite its rather clear instruction, this clause has been met with some resistance.¹³¹ The early history of civil RICO is marked by certain courts’ unwillingness to apply the statute to cases involving persons other than the stereotypical “mobster.”¹³²

2. The Liberal Judicial Interpretation

The unwillingness to use RICO broadly came to a halt after the U.S. Supreme Court undertook the task of clarifying the scope of civil RICO, heeding the congressional mandate. The Supreme Court specifically

122. 18 U.S.C. § 1962(c).

123. Lynch, *supra* note 117, at 774.

124. *Id.* Section 1962(d) prohibits conspiracy to violate any of the three preceding subsections and is also often used. 18 U.S.C. § 1962(d).

125. Lynch, *supra* note 117, at 775.

126. *Id.*

127. Under the doctrine of legislative acquiescence, Congress’s failure to enact opposing legislation is an indication of its implied agreement with the statute’s interpretation. *See, e.g.,* Bob Jones Univ. v. United States, 461 U.S. 574, 601 (1983) (“Congress’ failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the IRS rulings . . .”).

128. 21 U.S.C. § 853(o) (2012).

129. Craig W. Palm, *RICO and the Liberal Construction Clause*, 66 CORNELL L. REV. 167, 168 n.6 (1980).

130. *Id.* at 175 (finding no constitutional impediments to the express liberal construction mandate).

131. For a general discussion of the principles of statutory construction and the controversy over the constitutionality of the liberal construction clause, see *id.*

132. Anne Melley, *The Stretching of Civil RICO: Pro-Life Demonstrators Are Racketeers?*, 56 UMKC L. REV. 287, 291 (1988) (discussing the judicial interpretation of civil RICO).

addressed the liberal construction clause in *United States v. Turkette*,¹³³ where the Court considered whether the term “enterprise” as used in RICO encompasses both legitimate and illegitimate enterprises. While the Court determined that the plain language and structure of the statute did not limit its application to legitimate enterprises, it nevertheless followed the directive set forth in section 904(a) of the OCCA.¹³⁴ Using legislative history as guidance, the Court determined that RICO was both a preventive and remedial measure to deal with organized crime infiltrating legitimate businesses and should be interpreted to include a broader definition of “enterprise.”¹³⁵

Following suit, the Court in *Sedima, S.P.R.L. v. Imrex Co.*¹³⁶ reiterated that RICO should be read broadly. Rejecting the Second Circuit’s narrow reading of the statute, the Court refused to find that a criminal conviction on the underlying predicate offenses was a prerequisite to bringing a civil RICO action.¹³⁷ The Court also refused to require a “racketeering injury” separate from the harm from the predicate acts.¹³⁸ At the end of its opinion, the Court recognized that civil RICO had evolved into something different from its original conception and that almost all actions were being brought against defendants other than the “archetypal, intimidating mobster.”¹³⁹ Yet, the Court concluded that this “defect—if defect it is—is inherent in the statute as written, and its correction must lie with Congress.”¹⁴⁰

The Supreme Court’s liberal pronouncement of civil RICO’s application has made it “a formidable weapon for plaintiffs in civil litigation” and has fostered widespread application of the statute to matters beyond traditional organized crime.¹⁴¹ For example, in 1989, a women’s health center successfully instituted a private civil RICO action against antiabortion protesters.¹⁴² Despite the defendants’ argument that the center’s application of RICO exceeded the statute’s purpose, the Third Circuit held that civil

133. 452 U.S. 576 (1981). The enterprise in this case was a group of individuals associated-in-fact for the purpose of engaging in criminal activities, including arson, insurance fraud, and illegal trafficking in drugs. *Id.* at 579.

134. *Id.* at 580–87; *see also* 21 U.S.C. § 853(o) (2012).

135. *Turkette*, 452 U.S. at 588–93; *see also* H.J. Inc., v. Nw. Bell Tel. Co., 492 U.S. 229 (1989) (reiterating that RICO was broadly written to encompass a wide range of criminal activity and noting that narrow construction of the statute would be contrary to congressional intent).

136. 473 U.S. 479 (1985). In this case, the Court adjudicated a dispute over a joint venture in which Sedima alleged the respondent presented inflated bills, cheating Sedima out of a portion of its proceeds by collecting for nonexistent expenses. *Id.* at 483.

137. *Id.* at 493.

138. *Id.* at 495.

139. *Id.* at 499–500.

140. *Id.* at 499.

141. Ann K. Wooster, Annotation, *Validity, Construction, and Application of Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C.A. §§ 1961 et seq.—Supreme Court Cases*, 171 A.L.R. Fed. 1st, § 2 (2001).

142. *See generally* Ne. Women’s Ctr., Inc. v. McMonagle, 868 F.2d 1342 (3d Cir. 1989) (holding that activists could be liable under RICO for their intimidation and harassment of the center resulting in destruction of its property).

RICO could appropriately be applied to the defendants' intimidation and harassment.¹⁴³

3. Civil RICO Efforts to Combat Health-Care Fraud

Using civil RICO to combat health-care fraud is not novel.¹⁴⁴ Since 2010, civil RICO has been repeatedly employed in class action suits against pharmaceutical companies,¹⁴⁵ allowing for further expansion of the statute's application. These cases provide significant guidance for plaintiffs who sue pharmaceutical companies under civil RICO.¹⁴⁶ Although this Note seeks to place civil RICO liability on authors involved in publishing bias rather than pharmaceutical companies, this guidance is useful insofar as it stresses the importance of the theory of liability.¹⁴⁷

In *UFCW Local 1776 v. Eli Lilly & Co.*,¹⁴⁸ a number of unions and insurers brought a putative class action against Eli Lilly claiming civil RICO predicated on mail fraud and conspiracy to violate RICO.¹⁴⁹ These claims were based on the plaintiffs' contention that Eli Lilly made false statements and omitted material information concerning the safety and efficacy of its drug, Zyprexa, including disseminating false information about the drug's risks.¹⁵⁰

The plaintiffs alleged a chain of causation in which Lilly distributed misinformation about Zyprexa that the physicians relied upon in prescribing the drug, which caused the plaintiffs, as third-party payors (TTPs), to overpay.¹⁵¹ However, the Second Circuit found that this narrative "obscures the more attenuated link between the alleged misrepresentations made to doctors and the ultimate injury."¹⁵² It fails to consider that the TTPs relied on advice from other parties to place Zyprexa on their lists of approved medications and then failed to negotiate the drug's price below the level set

143. *Id.* at 1357. The court found that the defendants' description of their conduct as "civil disobedience" did not immunize them from statutes that prohibit the very acts that the defendants were found to have committed and that the tangible damage to the center's medical equipment resulting from the protesters' forcible entry was all that RICO required to establish injury. *Id.* at 1348–49.

144. See Pamela Bucy Pierson, *RICO Trends: From Gangsters to Class Actions*, 65 S.C. L. REV. 213, 258 (2013) (noting that more than half of RICO class actions allege some type of health-care fraud).

145. See, e.g., *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1357 (11th Cir. 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 123 (2d Cir. 2010); *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 256 (9th Cir. 2010).

146. See Pierson, *supra* note 144, at 256.

147. See *id.*

148. 620 F.3d 121 (2d Cir. 2010).

149. *Id.* at 121–37.

150. *Id.* at 129. Plaintiffs argued that they were injured by paying for Zyprexa prescriptions that (1) would not have been issued but for the alleged misrepresentations and (2) that were at a higher price than would have been charged absent the alleged misrepresentations. *Id.* at 123.

151. *Id.* at 134.

152. *Id.*

by Eli Lilly, leading to overpayment.¹⁵³ Thus, the chain of causation “rests on the independent actions of third and even fourth parties,” and therefore must fail.¹⁵⁴

Similarly, in *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*,¹⁵⁵ a welfare fund, which reimbursed plan members for covered medical expenses, brought a RICO class action against Bayer. The complaint alleged that Bayer, aware of the adverse effects of its drug, Trasyolol, launched an aggressive marketing campaign containing false or misleading statements to justify the drug’s price of over \$1000 per dose.¹⁵⁶ The Eleventh Circuit held that the fund failed to explain how or why Bayer’s alleged suppression of information caused it to pay for Trasyolol.¹⁵⁷ That is, the fund failed to demonstrate that it would have independently determined that the drug was not “medically necessary”—a requirement for payment—if Bayer had disclosed the allegedly suppressed information.¹⁵⁸ If the fund had stated facts plausibly demonstrating that it would not have bought Trasyolol had it known the true information, a direct relation would have been established. Without such facts, the complaint failed to meet the direct relation requirement.¹⁵⁹

While the courts above found the plaintiffs’ injuries too attenuated to constitute proximate cause, this issue can be avoided. This Note focuses on a class of plaintiffs—the medical journal and its subscribers—who are directly injured by publication bias and whose rights may be vindicated by civil RICO.

C. Elements of Civil RICO and Their Applicability to Medical Ghostwriting

Medical journals publish articles that fail to accurately represent the results of clinical trials, which are ghostwritten by outside companies and authored by prominent physicians.¹⁶⁰ Because the medical journals do not intend to publish misleading information, they cannot have the requisite intent necessary to withstand an allegation of fraud under civil RICO. Even so, the physicians who sign their names to articles they had little to no part in drafting may have the required intent. This Part applies the elements of civil RICO to physicians who sign on to ghostwritten articles and considers whether such a theory is viable.

153. *Id.* The court found that the evidence in the record supported the conclusion that prescribing doctors generally do not consider the price of a medication when deciding what to prescribe for an individual patient. *Id.* at 133–34. Thus, any reliance by doctors on misrepresentations as to the efficacy and side effects of a drug was not a but for cause of the price that TTPs ultimately paid for each prescription. *Id.*

154. *See id.* at 134 (quoting *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 11 (2010)).

155. 444 F. App’x 401 (11th Cir. 2011).

156. *Id.* at 403.

157. *Id.* at 410.

158. *See id.*

159. *Id.*

160. *See supra* Part I.C.

1. Who Can Bring the Civil RICO Claim?

To bring suit in federal court, plaintiffs must have standing.¹⁶¹ “Standing” refers to whether a litigant is entitled to have a court decide the merits of the particular issue or dispute.¹⁶² While a claim may have merit, the claimant may nevertheless be denied access to the courts because he or she is not the proper party to bring the suit.¹⁶³ In that case, the claimant lacks standing.

The plain language of civil RICO permits “[a]ny person” injured to bring a claim.¹⁶⁴ This general grant of statutory standing, combined with the statute’s plaintiff-enticing treble damages, caused courts to fashion a variety of standing requirements intending to limit access to the federal courts.¹⁶⁵

In *Holmes v. Securities Investor Protection Corp.*,¹⁶⁶ the Supreme Court established proximate cause as the appropriate standard for civil RICO standing.¹⁶⁷ This standard demands that the plaintiff prove a direct relation between the asserted injury and the alleged conduct.¹⁶⁸ It is not enough to allege that a defendant’s acts were the but-for cause of a plaintiff’s injuries.¹⁶⁹

The Court used the proximate cause standard to permit the flexible judicial tools in determining a person’s responsibility for the consequences of that person’s actions.¹⁷⁰ The Court noted that its concept of proximate cause reflected both a notion of justice and judicial convenience.¹⁷¹ The direct relation requirement is a central element because when injury is less direct, (1) it becomes more difficult to “ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors”; (2) courts are forced “to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts”; and (3) an interest in deterring injurious conduct is not justified because “directly injured victims can generally be counted on to vindicate the law as private attorneys general” without incurring the problems faced by remotely injured plaintiffs.¹⁷² The Court determined that focusing upon the direct relationship

161. Ryan C. Morris, *Proximate Cause and Civil RICO Standing: The Narrowly Restrictive and Mechanical Approach in Lerner v. Fleet Bank and Baisch v. Gallina*, 2004 BYU L. REV. 739, 745.

162. Morris, *supra* note 161, at 745.

163. *Id.* at 746.

164. 18 U.S.C. § 1964(c) (2012).

165. See Morris, *supra* note 162, at 755–59.

166. 503 U.S. 258 (1992).

167. *Id.* at 268; see also, e.g., *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 481 (1985) (rejecting the argument that RICO claims could only be brought against defendants convicted of criminal charges who sustained a racketeering injury, which was distinct from the injury occurring as a result of the predicate acts themselves).

168. *Holmes*, 503 U.S. at 268. Looking to RICO’S legislative history, the Supreme Court found it significant that the Clayton Act, upon which RICO was based, was interpreted at the time of RICO’S enactment as requiring proximate cause. *Id.* at 267. The Court reasoned that Congress knew of this interpretation when it passed RICO and thus intended for proximate cause to be required to prevail on a RICO claim. *Id.* at 268.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.* at 269–70.

between the conduct and the harm avoids these complications.¹⁷³ This direct relation requirement prevents uncertain inquiries from overrunning RICO litigation.¹⁷⁴

A direct relationship may be shown where a plaintiff is able to demonstrate that factors other than the alleged RICO conduct did not contribute to her injury.¹⁷⁵ While this establishes a high standard for the plaintiff to meet, it is not necessary for the plaintiff to prove she relied on the alleged predicate acts.¹⁷⁶ The statute's broad language of "any person" suggests a "breadth of coverage not easily reconciled with an implicit requirement that the plaintiff show reliance in addition to injury."¹⁷⁷ Thus, proximate cause requires only a showing that someone relied on the defendant's misrepresentation leading directly to the plaintiff's injury.¹⁷⁸

Section 1964(c) requires a person to be "injured in his business or property."¹⁷⁹ While society should be most concerned with the physical injury to patients resulting from treatment decisions influenced by medical literature, this injury is too attenuated from the alleged fraud to satisfy RICO's standing requirement.¹⁸⁰ Instead, the direct injury resulting from fraudulent authorship is to the medical journal and its subscribers.¹⁸¹ The harm to the medical journal involves the cost of publishing the fraudulent article.¹⁸² The harm to the subscribers involves the monetary value of the journal subscription containing the fraudulently authored article.¹⁸³

A journal subscription price¹⁸⁴ represents a compilation of articles that adhere to the journal's guidelines, since the journal would refuse to publish an article if it were known that the article failed to meet its publication

173. *Id.*

174. *See* *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006) (declining to find proximate cause after finding that the direct victim of the alleged RICO violation involving tax fraud was the State of New York, not the plaintiff, and further, plaintiff's loss of market share could have been caused by a number of factors independent of the alleged tax fraud).

175. *See id.* at 459.

176. *See* *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 657–58 (2008) (finding that first-party reliance is not necessary to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy the proximate cause principles).

177. *Id.* at 649.

178. *See id.* at 659.

179. 18 U.S.C. § 1964(c) (2012).

180. *See supra* Part II.B.3.

181. Although there is also reputational harm to the medical journal itself, such harm is considered a personal injury and is therefore not an injury recognized under civil RICO. *See, e.g.,* *Santana v. Cook Cty. Bd. of Review*, 679 F.3d 614, 623 (7th Cir. 2012) (noting that statements, which may amount to defamation under state law, do not advance a viable claim under § 1964(c), even if the defamation results in a loss of income).

182. With annual revenue of \$9.4 billion in 2011, analysts estimate profit margins at 20–30 percent for the science-publishing industry, so the average cost to the publisher of producing an article is likely to be around \$3500 to \$4000. *See* Richard Van Noorden, *Open Access: The True Cost of Science Publishing*, 495 *NATURE* 426, 427 (2013).

183. *See* Stern & Lemmens, *supra* note 100, at 3.

184. For example, an annual regular membership to the American Medical Association, which grants access to *JAMA*, is \$420 for physicians. *See* AMA MEMBERSHIP DUES, <https://www.ama-assn.org/membership/ama-membership-dues> [https://perma.cc/TT4L-2D9D] (last visited Sept. 21, 2017).

requirements. However, an author's false claim of authorship deceives the journal into believing the article has met authorship requirements and induces the journal to publish the article, thereby occupying valuable journal space.¹⁸⁵ The subscribers then lose the opportunity to read a legitimate article that satisfies the journal's publication requirements, diminishing subscription value.¹⁸⁶ The plaintiffs would only need to allege facts showing that the ghostwritten article was fraudulently authored and subsequently published in a journal that the subscribers paid for.¹⁸⁷ While the individual claim of a subscriber or medical journal may be insignificant, treble damages for the aggregate claims of all subscribers and the medical journal have the potential to be substantial.¹⁸⁸

Failure to allege a viable theory of proximate cause has been the downfall of civil RICO actions by medical journals against pharmaceutical companies.¹⁸⁹ To prevail on proximate causation, the medical journal must show a direct relationship between the cost of publication and the physician's alleged fraudulent authorship. Specifically, it must demonstrate that it would not have published the article had it known of the fraudulent authorship. Fraudulently authored articles fail to meet journals' publication requirements and therefore would not be considered for publication, providing useful support for this theory.

Likewise, the subscribers must sufficiently allege a direct relationship between their overpayment for the medical journal subscription and the physician's alleged fraudulent authorship. The subscribers must demonstrate that they would not have paid the same price for a journal that contains a fraudulent article as they would have for a journal that contains articles that meet authorship requirements. Stern and Lemmens argue that knowledge of ghostwriting undermines the ghostwritten article's credibility.¹⁹⁰ Because these articles have the potential to influence treatment decisions, an article with less credibility is necessarily less valuable to the reading physician. Yet it is irrelevant whether the subscriber even reads the fraudulent article.¹⁹¹ The fraudulent article replaces a more creditable article that would have conformed to the journal's requirements, thereby depriving the subscriber of the full value of the subscription.¹⁹²

Additionally, the subscribers do not have to demonstrate that they relied on the fraudulent authorship due to the Supreme Court holding that civil RICO does not require the plaintiff to show first-hand reliance.¹⁹³ The direct relationship between the plaintiffs' injury and the physician's fraudulent conduct is clear: a physician fraudulently authors an article that is subsequently published by a journal, thereby decreasing the value of the

185. See Stern & Lemmens, *supra* note 100, at 3.

186. See *id.*

187. See *id.* at 4.

188. See *id.* at 3.

189. See, e.g., *supra* Part II.B.3.

190. See Stern & Lemmens, *supra* note 100, at 3.

191. *Id.*

192. *Id.*

193. See *supra* notes 175–83 and accompanying text.

journal subscription. The plaintiffs, therefore, have the requisite proximate cause standing required under § 1962(c) to bring a claim against the physicians for decreasing the value of the journal subscription.

2. The Elements of Civil RICO

RICO's operative section sets forth four substantive offenses prohibiting forms of enterprise activity.¹⁹⁴ Along with at least one substantive offense, a civil RICO violation requires, by a preponderance of the evidence, a showing of (1) a person participating in (2) a pattern of racketeering activity (3) in connection with the acquisition, maintenance, conduct, or control of an enterprise.¹⁹⁵

a. Racketeering Activity

An act of "racketeering activity" is the predicate act that forms the foundation of a civil RICO claim. The plaintiff must first prove the elements of the crime alleged as the racketeering activity. Congress defined "racketeering activity" as any act "chargeable" under state or federal law, any act "indictable" under federal criminal provisions, and any offense under federal law involving bankruptcy fraud, securities fraud, or drug-related activities.¹⁹⁶ This includes a vast list of prohibited acts that Congress has incorporated by reference in the requisite provision.¹⁹⁷ In particular, mail fraud and wire fraud are included in the statutory definition,¹⁹⁸ helping to facilitate the expansive application of civil RICO in litigation.

With regard to medical ghostwriting, the predicate act that forms the foundation of a plaintiff's civil RICO claim is mail fraud.¹⁹⁹ Mail fraud occurs whenever a person, "having devised or intending to devise any scheme or artifice to defraud" uses the mail "for the purpose of executing such scheme or artifice or attempting so to do."²⁰⁰ In interpreting this statute, the Supreme Court held that any mailing that is incident to a fraudulent scheme satisfies the mailing element.²⁰¹ Further, the plaintiff does not need to prove intent or that the defendant engaged in the physical act of mailing.²⁰² It is sufficient that the defendant knew or should have known that the use of the mail would follow in the ordinary course of business.²⁰³

Here, a physician who authored an article she did not significantly contribute to had a scheme to defraud plaintiffs. Indeed, a physician agrees

194. See 18 U.S.C. § 1962(a)–(d) (2012).

195. *Id.* § 1962(c); see also Lievsay, *supra* note 113, at 1742.

196. 18 U.S.C. § 1961(1).

197. See *id.*

198. *Id.*

199. See 18 U.S.C. § 1341.

200. *Id.*

201. See *Pereira v. United States*, 347 U.S. 1, 8 (1954) (holding that the mail fraud statute was violated where a scheme to defraud was established and the mailing of a check by the bank was an "essential part of that scheme").

202. *Id.* at 8–9.

203. *Id.*

to authorship so the journal and its readers believe that the physician significantly contributed to the work illustrated in the publication. This is precisely what the warranty of authorship conveys. The scheme to defraud is bolstered by the potential impact publication has on a physician's career.²⁰⁴ The recognition and prestige that flow from publication incite a physician to make others believe she contributed substantially to a published work. Even if a defendant-physician did not physically mail the fraudulently authored publication, she would have known journals would be mailed to subscribers in the ordinary course. In fact, authorship only becomes meaningful to a physician once it is disseminated to the public. Therefore, the mailing, as a way to convey this information to the public, is not merely incidental—it is essential to the fraudulent scheme.²⁰⁵

As a procedural matter, under Federal Rule of Civil Procedure 9(b), the act of mail fraud must be alleged with particularity.²⁰⁶ To satisfy this rule, a plaintiff must identify the statements or representations made by the defendant that were actually false or misleading at the time they were made.²⁰⁷ Thus, rather than broadly alleging that a physician engaged in fraudulent authorship, plaintiffs must point to the specific articles that contain fraudulent authorship to satisfy Rule 9(b).

b. Pattern of Racketeering Activity

A defendant's engagement in racketeering activity is not enough to satisfy the statute. RICO further requires that a defendant act through a "pattern of racketeering activity."²⁰⁸ Congress defined "pattern of racketeering activity" as "at least two acts of racketeering activity, one of which occurred after [October 15, 1970] and the last of which occurred within ten years . . . after the commission of a prior act."²⁰⁹ Thus, every RICO claim must involve at least two predicate acts occurring within ten years.

While it was generally accepted that the commission of any two predicate acts constituted a pattern, the Supreme Court in *Sedima, S.P.R.L. v. Imrex Co.*²¹⁰ expressed in dicta its dissatisfaction with courts' broad construction of the pattern requirement.²¹¹ In a footnote that ultimately did little to guide

204. *See supra* note 8 and accompanying text.

205. Today, articles published in medical journals are often available on a journal's website, changing the predicate act from mail fraud to wire fraud. *See* 18 U.S.C. § 1961(1) (2012).

206. FED. R. CIV. P. 9(b).

207. *See, e.g.,* *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 256 (9th Cir. 2010). Here, a welfare fund alleged that the defendant pharmaceutical company violated RICO by engaging in deceptive advertising that misrepresented the safety of off-label uses. *Id.* at 257. The court held that the plaintiff failed to plead its allegations of fraud under RICO, emphasizing that a mere assertion that a company promoted its drug for ineffective or unapproved uses will not satisfy Rule 9(b). *Id.* Instead, the plaintiff must point to specific misrepresentations made by the defendant. *Id.* at 257–58.

208. 18 U.S.C. § 1962(a).

209. *Id.* § 1961(5).

210. 473 U.S. 479 (1985).

211. *Id.* at 496 n.14.

lower courts,²¹² the Court attempted to refine RICO by holding that the predicate acts must show continuity and relatedness.²¹³ These two prongs were later clarified in *H.J. Inc. v. Northwestern Bell Telephone Co.*²¹⁴ Because Congress was concerned with long-term concerted criminal conduct, the Court held that the pattern requirement necessitates (1) a relationship between activities, established by a series of factors²¹⁵ and (2) the threat of continuing activity.²¹⁶ Because most predicate acts are sufficiently related, the continuity prong frequently proves most challenging to a plaintiff asserting a civil RICO claim.

The key factor in determining whether the threat of continuing activity exists is the duration of the alleged racketeering activity.²¹⁷ The prong is adequately pleaded only where the plaintiff has alleged “closed-ended” or “open-ended” continuity, referring to either a closed period of repeated conduct or to past conduct that by its nature projects a threat of future repetition.²¹⁸ To demonstrate continuity over a closed period, the plaintiff must provide a series of related predicates that have extended over a substantial period of time.²¹⁹ Acts extending over a few weeks or months, without the threat of future criminal conduct, will not satisfy the requirement.²²⁰ In fact, even two years of related predicates may not be long enough to constitute continuity.²²¹

While closed-ended continuity is primarily a temporal concept, courts consider a number of factors in determining whether the requirement is met.²²² The factors include the number and variety of predicate acts, the

212. Patrick J. Ryan, Note, *The Civil RICO Pattern Requirement: Continuity and Relationship, a Fatal Attraction?*, 56 FORDHAM L. REV. 955, 964 (1988). For a discussion of the lower courts’ confusion over what constitutes a pattern within the meaning of § 1962(c) that spawned from *Sedima*, see *id.* at 64–65.

213. See *Sedima, S.P.R.L.*, 473 U.S. at 496 n.14.

214. 492 U.S. 229 (1989).

215. See *id.* at 239–40. The Court turned to another provision of the OCCA, Title X, where “pattern” was defined as “acts that have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events” and determined that there was no reason to believe RICO’s pattern component required a more “constrained” notion of relationship. *Id.*

216. See *id.* at 240 (“RICO’s legislative history tells us, however, that the relatedness of racketeering activities is not alone enough to satisfy § 1962’s pattern element. To establish a RICO pattern it must also be shown that the predicates themselves amount to, or that they otherwise constitute a threat of, continuing racketeering activity.”).

217. See Pierson, *supra* note 144, at 230 (discussing the importance of longevity in establishing a pattern under RICO).

218. *H.J. Inc.*, 492 U.S. at 241 (asserting that “continuity is both a closed-ended and open-ended concept”).

219. *Id.* at 242.

220. *Id.*

221. See, e.g., *Roger Whitmore’s Auto. Servs., Inc. v. Lake City*, 424 F.3d 659, 673 (7th Cir. 2005) (noting that the court has not hesitated to find that closed periods of several months to several years did not qualify as “substantial” enough to satisfy continuity).

222. See *H.J. Inc.*, 492 U.S. at 242 (“Whether the predicates proved establish a threat of continued racketeering activity depends on the specific facts of each case.”).

length of time over which they were committed, the number of victims, the presence of separate schemes,²²³ and the distinct injuries involved.²²⁴

To demonstrate open-ended continuity, a plaintiff must show that the predicate acts establish a threat of continued racketeering activity projecting into the future.²²⁵ Both the nature of the predicate acts and the nature of the alleged enterprise are relevant. Where the enterprise primarily conducts a legitimate business, the plaintiff must show the predicate acts were the regular way the enterprise conducts its business or that the predicate acts, by their very nature, threaten continued criminal activity.²²⁶

A plaintiff alleging a civil RICO violation against a medical ghostwriting first must identify a physician who engaged in at least two acts of fraudulent authorship within ten years. Proving that the acts satisfy relatedness is relatively straightforward. The relatedness factors of purpose, victims, and method involved, are similar in every act of fraudulent authorship.²²⁷ When a physician lends her name to an article, her purpose is to be published. The victims are the medical journals and deceived readers. And the method involved is a drafted manuscript presented to a physician for written approval.²²⁸ Multiple instances of fraudulent authorship, therefore, likely can be connected to one another.

The continuity prong of the pattern requirement may be more difficult to establish. Yet the factors that courts consider when determining closed-ended continuity may be a viable method of establishing continuity for a

223. While the number of schemes may be a factor, the Supreme Court has explicitly rejected the rigid notion that a pattern is formed only when predicate acts are part of separate schemes. *Id.* at 236–37. Instead, multiple predicate acts within a single scheme may constitute criminal activities that have long-term and widespread consequences. *See id.*

224. *Park v. Jack's Food Sys., Inc.*, 907 F. Supp. 914, 920 (D. Md. 1995) (noting that the Fourth Circuit has adopted a “case-by-case, fact specific approach” in determining whether the continuity requirement is met). Other circuit courts look to similar factors in assessing whether the closed-ended concept of continuity has been satisfied. *See, e.g.*, *Columbia Nat. Res., Inc. v. Tatum*, 58 F.3d 1101, 1110 (6th Cir. 1995) (noting that factors include the duration of the racketeering activity, the number of different schemes, the number of predicates, the types of injury, and the number of victims and perpetrators); *Bartcheck v. Fid. Union Bank/First Nat'l State*, 832 F.2d 36, 38–39 (3d Cir. 1987) (applying factors including the number of unlawful acts, the length of time over which they were committed, the similarity of the acts, the number of victims and perpetrators, and the character of the unlawful activity); *Morgan v. Bank of Waukegan*, 804 F.2d 970, 975 (7th Cir. 1986) (noting that factors include the number and variety of predicate acts, the length of time over which they were committed, the number of victims, the presence of separate schemes, and the occurrence of distinct injuries); *Gross v. Waywell*, 628 F. Supp. 2d 475, 486 (S.D.N.Y. 2009) (applying factors such as the number and variety of predicate acts, the number of participants and victims and the presence of separate schemes).

225. *See H.J. Inc.*, 492 U.S. at 241.

226. *See, e.g.*, *Cofacredit, S.A. v. Windsor Plumbing Supply Co.*, 187 F.3d 229, 243–44 (2d Cir. 1999) (finding insufficient evidence to support a claim that mail and wire fraud were a regular means of doing business).

227. *See supra* note 215 and accompanying text.

228. Documents revealed in relation to Wyeth's hormone replacement therapy show that “company executives came up with ideas for medical journal articles, titled them, drafted outlines, paid writers to draft the manuscripts, recruited academic authors and identified publications to run the articles—all without disclosing the companies' roles to journal editors or readers.” *Wilson, supra* note 93.

plaintiff. Because of the importance of publication to physicians' careers and the relationship between physicians and pharmaceutical companies,²²⁹ it is reasonable to assume that physicians agree to author numerous articles throughout their careers. One doctor even reported that the request to author ghostwritten articles "happens all the time."²³⁰ The authoring of numerous articles spanning over a physician's career would constitute a large number of predicate acts lasting well beyond two years, favoring plaintiffs. While there are similar injuries and a similar goal of obtaining publication, each act of authoring a ghostwritten article represents a distinct scheme. Further, the vast number of victims—the duped medical journals and overpaying subscribers—may tip the scale toward finding that series of related predicates extended over a substantial period of time.

Alternatively, the plaintiffs would need to show a threat of continuing criminal activity beyond the period during which the predicate acts were performed. The strongest evidence of continued future activity would be an agreement between the authoring physician and pharmaceutical company showing an ongoing understanding that the physician's name would be used to author future ghostwritten articles. This does not necessarily have to be a formal contract but may be in the form of emails between a pharmaceutical company and a physician eliciting authorship for future publications. Indeed, this would be an explicit threat that likely would satisfy the continuity prong necessary to establish a pattern of racketeering activity.

c. Enterprise

The conduct prohibited in § 1962 is unlawful only if it occurs in connection with an "enterprise." RICO generally targets the bad actors who misuse a legitimate enterprise rather than the enterprise itself. RICO defines enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity."²³¹ Through its broad statutory language void of limiting or restrictive provisions, this definition recognizes both formal structures and groups of individuals as enterprises.²³² However, this definition takes on a distinct meaning when referred to under § 1962(c). Unlike the other types of conduct covered under civil RICO, a person under § 1962(c) is limited to someone who is employed by or associated with an enterprise.²³³ Because § 1962(c) is used to pursue individuals who use an organization and its resources to

229. A 2007 survey showed that 94 percent of physicians reported having a relationship with pharmaceutical companies. Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 *NEW ENG. J. MED.* 1742, 1743 (2007).

230. See Natasha Singer, *Senator Moves to Block Medical Ghostwriting*, *N.Y. TIMES* (Aug. 18, 2009), <http://www.nytimes.com/2009/08/19/health/research/19ethics.html?fta=y> [<https://perma.cc/H9HL-D9E6>].

231. 18 U.S.C. § 1961(4) (2012).

232. See *United States v. Turkette*, 452 U.S. 576, 580 (1981) ("There is no restriction upon the associations embraced by the definition: an enterprise includes any union or group of individuals associated in fact.").

233. Any person may be charged with violations of § 1962(a), (b), or (d). See 18 U.S.C. § 1962(a)–(b), (d).

commit racketeering activity, courts have required that the defendant be separate and distinct from the enterprise where the alleged racketeering was conducted.²³⁴ Indeed, “enterprise” connotes the vehicle through which the pattern of racketeering activity is committed.²³⁵

Many of the physicians solicited to author ghostwritten articles are affiliates of hospitals or, more commonly, academic institutions.²³⁶ The affiliation with a hospital or academic institution contributes to the physician’s prestige, which facilitates the solicitation to author an article in the first place. These institutions therefore serve as the enterprise in which the pattern of racketeering activity occurs. Therefore, physicians are “employed by or associated with” their respective institutions within the meaning of § 1962(c).

III. REVISING THE CURRENT MEDICAL PUBLICATION FRAMEWORK

Given the challenges of bringing a successful civil RICO claim, revising the current medical publication framework offers a better means of addressing publication bias in medical research. To combat such bias, this Part proposes greater enforcement of FDAAA disclosure requirements, as well as the implementation of a mandatory disclosure rule.

A. Challenges to Bringing a Civil RICO Claim

While this Note proposes a viable cause of action under civil RICO against physicians who lent their names to ghostwritten articles, the claim nevertheless poses an uphill battle for plaintiffs. Establishing a pattern of racketeering activity likely presents the greatest challenge to a successful claim. Although there is speculation that many physicians engage in ghostwriting practices throughout their careers, generating proof of such engagement will be difficult.²³⁷

A RICO claim against a physician necessarily rests on establishing, by a preponderance of the evidence, that articles are ghostwritten. These articles are not typically exposed until an investigation has been conducted through litigation. Ideally, a civil RICO action would be brought against the involved physician alongside a larger action against the pharmaceutical company whose activities drew attention from regulators or the press. Because of the vast amount of time involved in drug development, an investigation into a specific pharmaceutical company’s handling of a drug may reveal numerous articles from the same author spanning over many years. Even so, such

234. Pierson, *supra* note 144, at 237; *see, e.g.*, United States v. Goldin Indus., Inc., 219 F.3d 1268, 1270 (11th Cir. 2000) (noting that, consistent with every other circuit that has addressed the question, the defendant in a § 1962(c) claim must be separate and distinct from the “enterprise” named therein).

235. Nat’l Org. for Women, Inc. v. Scheidler, 510 U.S. 249, 259 (1994).

236. *See* Singer, *supra* note 230 (noting the growing body of evidence that suggests doctors at top medical schools have been attaching their names to scientific papers that were drafted by ghostwriters working for drug companies).

237. *See supra* text accompanying note 230.

litigation is uncommon. A drug first must cause considerable harm to the public to initiate litigation.

To make matters worse, even after ghostwriting is exposed, physicians who have served as authors often remain unnamed. Thus, although many articles may be ghostwritten, the majority of these articles will go unnoticed, and the fraudulent authors will remain unknown. Because civil RICO requires pattern of fraudulent activity, only repeat offenders—the physicians who regularly engage in ghostwriting practices—can be found liable. This insulates a large number of physicians from civil RICO liability, even though their ghostwriting undoubtedly negatively affects public health.

In addition to these substantive issues, litigation costs may dissuade plaintiffs from bringing civil RICO claims. The potential of recovery, even if aggregated and trebled, may be nominal compared to the transaction costs inherent in such a claim.²³⁸

There have also been many critiques of expanding civil RICO beyond its legislative intent.²³⁹ In fact, the Supreme Court expressed its concern that the statute was being used in ways that Congress may not have envisioned.²⁴⁰ Holding physicians liable under civil RICO may therefore be met with harsh criticism because of reluctance to link physicians to a statute originally intended for criminals.

In response to these criticisms, employing civil RICO to hold ghostwriting physicians liable is necessary to stop biased practices that harm public welfare. Journal authorship requirements and academic bans on ghostwriting have not fully eradicated this harmful practice. Thus, the deterrent effect that the threat of litigation carries becomes appealing when the health of the nation is at stake. Holding physicians responsible for their contributions to ghostwriting will likely promote self-policing in the medical community. Physicians, who have taken an oath to do no harm, may be less likely to engage in a practice that is now a cognizable harm and may urge their fellow colleagues to do the same. The threat of liability will shift the current culture of permissible dishonesty to a culture of transparency. Even if problematic, this is a valuable and necessary threat. Enforcement and revision of the current regulations governing medical publication, combined with the threat of civil RICO liability, stands the best chance at effectively stemming the continued practice of medical ghostwriting.

238. See, e.g., Xavier Bosch et al., *Challenging Medical Ghostwriting in U.S. Courts*, PLOS MED., Jan. 2012, at 1 (arguing that the costs of bringing a RICO claim would likely discourage law firms from prosecuting such cases because of “the novelty of the theories, and the nominal damages at issue”).

239. See generally Tricia Bozyk, *Disgorging American Business: An Examination of Overbroad Remedies in Civil RICO Cases*, 59 RUTGERS L. REV. 129 (2006) (arguing that the remedies available to the government and private plaintiffs bringing civil RICO claims should be limited); Eric Lloyd, *Making Civil RICO “Suave”: Congress Must Act to Ensure Consistent Judicial Interpretations of the Racketeer Influenced and Corrupt Organizations Act*, 47 SANTA CLARA L. REV. 123 (2007) (discussing the rise in civil RICO claims and federal courts’ attempts to limit its scope).

240. See *supra* notes 139–42 and accompanying text.

B. Enforcement of FDAAA Disclosure Requirements

Enforcing compliance with the FDAAA requirements for clinical trial results is the first step in addressing issues of publication bias.²⁴¹ While the effects of the most recent final rule are still unknown, the FDA must take more active measures in regulating the national registry. Any study that is registered on the FDAAA website must also disclose the results, and the FDA must promptly notify noncompliant parties and enforce applicable penalties.²⁴² Interestingly, the penalty for noncompliance was not increased in the final rule.²⁴³ While civil monetary penalties of up to \$10,000 per day may cripple a study run by an independent researcher, studies funded by pharmaceutical companies will likely be unaffected by such a low penalty. A separate penalty should therefore be placed on studies funded by drug companies in an amount that will sufficiently deter the companies from noncompliance.

However, the clinical trial results, even if disclosed, would do little to protect public health if prescribing physicians fail to see them. To make the clinical trial results accessible to physicians, medical journals should provide a citation to the relevant results on the national registry within the drug's publication. The reading physician, at her own discretion, will then be prompted to review the full clinical trial results of the particular drug under consideration. Physicians will, at the very least, be aware that the publication does not explain the full story and will tailor their practices accordingly.

C. Mandatory Disclosure of Authorship

Ghostwriting involves fraudulent authorship, but the pharmaceutical industry's practice of hiring external companies to draft manuscripts for publication is not, in itself, fraudulent. In fact, it is a necessary industry practice. Because of the volume of results generated in the development of a new drug, pharmaceutical companies and investigators are unable to draft all the literature associated with the results on their own.²⁴⁴ Professional communication agencies therefore play an important role in the effective and ethical promotion of a product.²⁴⁵ The needs of the pharmaceutical industry must be taken into consideration when deciding how to resolve this public health issue.

1. Mandatory Disclosure Rule

Rather than restricting pharmaceutical companies from outsourcing manuscripts for publication or requiring that the researchers involved in the original clinical trials draft the manuscripts, the less burdensome solution lies

241. See *supra* notes 49–64 and accompanying text.

242. See *supra* note 63 and accompanying text.

243. See *supra* note 63 and accompanying text.

244. Mark Hughes, *Careers in Medical Writing: Regulatory Writing—What's That Then?*, SCIENCE (May 4, 2001), <http://www.sciencemag.org/careers/2001/05/careers-medical-writing-regulatory-writing-whats-then> [https://perma.cc/2C6V-8YQ6].

245. See *id.*

in disclosure. Indeed, ghostwriting only becomes ghostwriting, and consequentially fraudulent, when there is a lack of authorship disclosure. To avoid issues of fraud, the FDA should institute rulemaking to enforce mandatory disclosure of authorship. Authors should be required to disclose the role they played in drafting the manuscript, and any author, whether pharmaceutical company, medical communication agency, or physician, should be acknowledged in the final publication. While the private ordering by the ICMJE in recommending such disclosure provides certain protection,²⁴⁶ public ordering in the form of a rule promulgated by the FDA would create a uniform standard for all medical journals. A lack of authorship disclosure would signal to physicians serving as authors and editors of medical journals that an FDA violation likely occurred. All parties would then have the opportunity to ensure that compliance is met. A rule promulgated by the FDA would also announce to the medical community that ghostwriting is not a mere moral failing but rather a legal violation deserving of regulatory action.

Such regulation aimed at reducing biased prescribing practices is not novel. Along with the enactment of the FDAAA, the FDA has imposed advertising limitations on pharmaceutical companies.²⁴⁷ Additionally, in response to the growing concern that gifts from pharmaceutical companies to physicians distort judgment in prescribing practices, several state legislatures have imposed limitations on gift giving.²⁴⁸ These limitations are justified because gifts have been shown to entice health professionals into relationships that subtly call for reciprocity, thereby influencing prescribing behaviors.²⁴⁹ Similarly, the chance to author a prominent publication without having to satisfy authorship criteria should be examined because it can be seen as a gift from a drug company. Scrutiny here is justified because a publication supporting the use of a particular drug authored by a prominent physician entices other physicians to prescribe the drug. The ethical concern in both situations is the same—distortion of physicians' judgment in

246. See *supra* note 69.

247. See Shena T. Wheeler, Note, *Under the Influence: An Examination of the Tactics Pharmaceutical Companies Use to Manipulate Physicians*, 7 IND. HEALTH L. REV. 89, 102–03 (2010) (discussing the external factors influencing physicians' prescribing habits—including advertising and gifts from pharmaceutical companies—and current regulations designed to curb such practices).

248. For example, Massachusetts prohibits the exchange of all gifts from pharmaceutical companies to physicians. MASS. GEN. LAWS ANN. ch. 111N, § 2 (West 2008). Minnesota prohibits pharmaceutical companies from giving physicians gifts with a total annual combined retail value in excess of \$50, subject to a few exceptions. MINN. STAT. ANN. § 151.461 (West 2008). Vermont bans gifts from drug manufacturers to healthcare professionals and requires disclosure of allowable expenditures by manufacturers to the Attorney General. VT. STAT. ANN. tit. 18, § 4632 (West 2009). Most recently, using the Vermont law as an example, the California Senate passed a bill in May 2017 that would ban drug companies from giving gifts to physicians. See Sophia Bollag, *California Bill Would Ban Drug Company Gifts to Doctors*, U.S. NEWS (May 18, 2017), <https://www.usnews.com/news/best-states/california/articles/2017-05-18/california-may-bar-drug-makers-from-giving-doctors-gifts> [https://perma.cc/D756-LWB3] (noting that drug companies spend more than \$1.4 billion a year on gifts to California doctors).

249. See Wheeler, *supra* note 247, at 113.

prescribing medicine. A similar solution should therefore be imposed in the form of mandatory disclosure.

2. Constitutional Concern

One constitutional concern regarding mandatory disclosure is whether it impedes on the exercise of free speech. In 1976, the Supreme Court determined that the First Amendment protects commercial speech.²⁵⁰ Since then, the FDA has had to confront the free speech rights of its regulated entities. The extent of these rights, however, depends on whether the speech is commercial or noncommercial, as the government enjoys much more freedom to regulate the former.²⁵¹ This disparity arises from the different tests courts apply. For laws targeting commercial speech, courts apply intermediate scrutiny, whereas laws targeting noncommercial speech receive more stringent scrutiny.²⁵² Intermediate scrutiny allows courts to ask whether the content of commercial speech is false or misleading, opening the door for content-based objections generally forbidden in noncommercial contexts.²⁵³

The prevailing test to determine whether speech is commercial or not asks (1) whether the speech is an advertisement, (2) whether it refers to a specific product, and (3) whether the speaker has an economic motive.²⁵⁴ While seemingly straightforward, this test becomes complicated in the context of scientific speech, where companies make scientific claims about the health and safety of their products. Courts have traditionally noted that scientific articles, published for educational purposes, are a protected form of noncommercial speech.²⁵⁵ Thus, the publication of an article addressing scientific findings in a peer-reviewed journal generally does not constitute commercial speech.

But at what point is protected scientific inquiry transformed into commercial speech subject to stricter scrutiny? Courts have often found that a scientific article becomes commercial speech when, for example, it contains favorably false information about a product and is written by the company that manufactures the product.²⁵⁶ Courts have adopted a skeptical view

250. *See generally* Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (applying the First Amendment to commercial speech and striking down a Virginia statute prohibiting pharmacies from advertising prescription drug prices).

251. *See generally* Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?*, 37 AM. J.L. & MED. 388 (2011) (arguing for a framework that identifies relevant factors courts can use to distinguish commercial from noncommercial speech). If speech is commercial, the FDA can ensure that it is not false or misleading by requiring certain speech or imposing certain limitations. *Id.* at 388. The FDA has much less control over noncommercial speech. *See id.*

252. *Id.* at 390–91.

253. *Id.* at 390.

254. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66–67 (1983).

255. *See, e.g.,* Bracco Diagnostics, Inc. v. Amersham Health, Inc., 627 F. Supp. 2d 384, 456 (D.N.J. 2009) (noting an “abundance of case law to support the proposition that a scientific article is protected noncommercial speech despite the potential for erroneous content”).

256. *See id.* (citing *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 112 (6th Cir. 1995)); *see also* Cortez *supra* note 251, at 405 (“There is a good argument that drug companies that hire

towards FDA-regulated bodies, heeding Justice William Brennan's warning that "those who seek to convey commercial messages will engage in the most imaginative of exercises to place themselves within the safe haven of noncommercial speech, while at the same time conveying their commercial message."²⁵⁷ Professor Nathan Cortez found that out of twenty-four cases where FDA-regulated entities claimed First Amendment protection, courts categorized the speech as commercial in all but two.²⁵⁸

Pharmaceutical companies clearly engage in practices of publication bias and increasingly use medical journals as a platform for marketing and selling their products.²⁵⁹ The prevalence of publication bias demands that articles published in medical journals be treated as commercial speech subject to regulation by the FDA.²⁶⁰

While the government may protect consumers from false or misleading information,²⁶¹ it generally may not prohibit truthful and nondeceptive claims in pursuit of other valuable ends.²⁶² If the FDA goes beyond guarding against the dissemination of false or misleading information and seeks to promote broader public health goals, the agency will likely violate the First Amendment. Therefore, the question this Note seeks to answer is whether requiring mandatory disclosure of authorship protects consumers from false or misleading information.

The answer to this question is yes. Requiring authors of ghostwritten publications to disclose their level of involvement protects journals and their subscribers from the false or misleading information conveyed through the false warranty of authorship. Claiming authorship of an article that the physician had no involvement in writing is neither a truthful nor a nondeceptive claim. Without disclosing the author's level of involvement, the reader is led to believe that the physician named as the author is responsible for the information conveyed. This, of course, would be false. Therefore, the FDA has the constitutional authority to promulgate a mandatory disclosure rule in an effort to protect the readers from false or misleading information.

'ghostwriters' to publish positive scientific articles about their products are engaged in commercial speech.").

257. See Cortez *supra* note 251, at 392–93 (footnote omitted); see also *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 778 (1969) (noting "the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health").

258. See Cortez *supra* note 251, at 390.

259. See *supra* Part I.

260. See *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) ("In concluding that commercial speech, like other varieties, is protected, we of course do not hold that it can never be regulated in any way. Some forms of commercial speech regulation are surely permissible.").

261. See *id.* at 771 ("Untruthful speech, commercial or otherwise, has never been protected for its own sake.").

262. See *id.* at 773. See generally Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31 (2011) (discussing the constitutionality of the FDA's restrictions on the advertising of therapeutic products to physicians and patients).

While mandating disclosure of authorship is not a panacea for all misleading articles, disclosure of ghostwriting will signal to readers that an article must be read with caution. There is the hope that, if legitimate authors are held accountable for the content of a publication, all parties involved will ensure that articles convey the most accurate representation of the results on which they are based.

CONCLUSION

Medical journals contribute significantly to public health by disseminating medical information to physicians, thereby influencing prescribing practices. Yet, through selective publishing and medical ghostwriting, the information guiding treatment decisions has become polluted and distorted, negatively affecting patient care. Through the selective publication of clinical trial results that show positive findings in support of a particular drug, prescribing physicians are blind to the true effects of the medications they prescribe. Worse yet, prescribing physicians can be unaware of the true author of a publication, giving undue credence to an article based on the prestige of an author recruited by a pharmaceutical company to serve as nothing more than a mere signature.

While the medical community and regulators have made efforts to reduce publication bias in medical research, this Note advocates a novel approach by imposing civil RICO on physicians involved in medical ghostwriting. Although Congress enacted RICO in response to the destruction caused by organized crime's infiltration of legitimate businesses, the statute's broad and liberal construction has facilitated its use to areas beyond traditional organized crime, including its use in claims against the pharmaceutical industry.

By applying the elements under § 1962(c), this Note concludes that using civil RICO against physicians involved in ghostwriting is a viable. However, because the pattern requirement under § 1962(c) will render a civil RICO claim challenging, this Note also proposes alternative approaches to addressing publication bias. By enforcing FDAAA compliance and imposing a mandatory disclosure rule for authorship, prescribing physicians will have access to all clinical trial results and will be made aware of potential bias in the medical publications that guide their practices. The culture of transparency that is created through the threat of litigation and regulatory reform will ultimately lead to more informed, and consequently superior, patient care, positively affecting public health.