Assessing potential legal responses to medical ghostwriting: effectiveness and constitutionality

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ABSTRACT

Pharmaceutical companies are extensively involved in shaping medical knowledge to market their products to physicians and consumers. Specialized planning is undertaken to produce scientific articles driven by commercial interests. Rather than the listed authors, hidden analysts and publication management firms hired by pharmaceutical companies are often responsible for the content of scientific articles. Such ghostwriting practices raise serious concerns regarding the integrity of knowledge and thus demand urgent attention.

This paper analyses the strategies of legal regulation on medical ghostwriting and their comparative advantages and disadvantages. Many of regulatory proposals suffer from a lack of effectiveness, whereas others are subject to constitutional concerns. The analysis in this paper offers insights into framing adequate regulation; it supports the strategy for reforming the structure of information production while calling for cautiousness in shaping its regulatory outline. In addition, this paper contributes to the analysis of First Amendment jurisprudence, suggesting that the judiciary should allow a certain amount of leeway for political branches to develop effective regulation.

KEYWORDS: ghostwriting, ghost management, medical knowledge, First Amendment, commercial speech doctrine

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INTRODUCTION

The influence of the pharmaceutical industry on the production of medical knowledge has received increasing attention in recent years. With the potential for substantial profits, the industry has assumed a major role in many aspects of society. Regarding the formation of knowledge, many studies have disclosed that pharmaceutical companies are extensively involved in shaping medical knowledge to market their products to physicians and consumers. Specific specialized planning is conducted to produce scientific articles driven by commercial interests. Rather than the listed authors, hidden analysts and medical communication firms hired by pharmaceutical companies are often responsible for the content of such articles. Such ghostwriting practices raise serious concerns regarding the integrity of knowledge, and thus demand urgent attention.

The case of Merck’s rofecoxib (Vioxx) represents a pertinent example of such practices and their harmful consequence. A ghostwritten article published in the Annals of Internal Medicine reported on the results of a Vioxx trial without mentioning the deaths of the participants. Jeffrey Lisse, the first author of the article, admitted that the ‘initial paper was written at Merck, and then it was sent to me for editing’. The subsequent widespread use of Vioxx, which the ghostwritten article contributed to, was disastrous, resulting in numerous cardiovascular events including many fatalities.

The ghostwriting practices discussed in this paper are those practiced by pharmaceutical companies (ie medical ghostwriting). Medical ghostwriting has been defined as ‘the practice of pharmaceutical companies secretly authoring journal articles published under the byline of academic researchers’. Although the concept of ghostwriting is sufficiently broad to include the context in which researchers hire professional writers to help draft manuscripts, the concern of distorted reporting arises primarily in the context of commercial entities employing publications as a marketing tool. Therefore, in this paper, ghostwriting refers exclusively to medical ghostwriting as defined above. Ghost management is another concept that warrants attention. Some studies have used this term instead of ghostwriting to reveal and emphasize that such

1 See eg Marc A. Rodwin, Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform, 40 J. L. MED. & ETHICS 511, 512–19 (2012) [hereinafter Institutional Corruption]; Marc A. Rodwin, Five Un-easy Pieces of Pharmaceutical Policy Reform, 41 J. L. MED. & ETHICS 581, 581 (2013) [hereinafter Pharmaceutical Policy Reform]; Marc-André Gagnon, Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health, 41 J. L. MED. & ETHICS 571, 573 (2013).
2 Leemon McHenry, Of Sophists and Spin-Doctors: Industry-Sponsored Ghostwriting and the Crisis of Academic Medicine, 8 MENS SANA MONOGRAPHS 129, 135 (2010).
3 In one study, researchers assessed the public-health effects of rofecoxib and revealed that

Using the relative risks from the abovementioned randomized clinical trials and the background rates seen in NSAID risk studies, an estimated 88,000–140,000 excess cases of serious coronary heart disease probably occurred in the USA over the market life of rofecoxib. The US national estimate of the case-fatality rate (fatal acute myocardial infarction plus sudden cardiac death) was 44%, which suggests that many of the excess cases attributable to rofecoxib use were fatal.

David J. Graham et al., Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-Oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Nested Case-Control Study, 365 LANCET 475, 480 (2005).
4 Jonathan Leo & Jeffrey R. Lacasse, Ghostwriting, in ENCYCLOPEDIA OF CRITICAL PSYCHOLOGY 802 (T. Teo ed., 2014).
5 Simon Stern & Trudo Lemmens, Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwriting Articles, 8 PLoS MED. e1001070, at 1 (2011).
practices involve not only writing but also the planning and management involved in publication. This paper acknowledges that ghost management refers to the nature of the practice more comprehensively than does ghostwriting. However, this paper uses ghostwriting because it is a more commonly used term for discussing the issue.

Although various responses to medical ghostwriting have been proposed, the potential effects of such responses remain questionable. Many of them call for the reform of journals, editing organizations, professional societies, or academic institutions. However, incentives must be considered when initiating self-disciplinary actions. The conflicts of interest originating from the commercial influence of the industry tend to hinder reforms or even drive those actors toward the opposite direction. Consequently, expecting self-disciplinary actions to be sufficient constitutes wishful thinking. Some commentators have concluded that self-regulation has thus far been completely ineffective.

For the studies that use the term ghost management, see eg, Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLoS Med. e286, at 1429 (2007) [hereinafter *Ghost Management*]; Sergio Sismondo, *Ghost in the Machine: Publication Planning in the Medical Sciences*, 39 SOC. STUD. SCI. 171, 172 (2009) [hereinafter *Ghost in the Machine*].

For example, Alastair Matheson, *How Industry Uses the ICMJE Guidelines to Manipulate Authorship—And How They Should Be Revised*, 8 PLoS MED. e1001072, at 3–4 (2011) (suggesting the revision of the ICMJE authorship guidelines) [hereinafter *Manipulate Authorship*]; Alastair Matheson, *The ICMJE Recommendations and Pharmaceutical Marketing—Strengths, Weaknesses and the Unsolved Problem of Attribution in Publication Ethics*, 17 BMC MED. ETHICS e1001072, at 8 (2016) (suggesting the revision of the ICMJE Recommendations) [hereinafter *Unsolved Problem*]; Joel Lexchin & Donald W. Light, *Commercial Influence and the Content of Medical Journals*, 332 BMJ 1444, 1446 (2006) (calling for the action of journals, editors’ organizations, and professional societies); Peter C. Gotzsche et al., *What Should Be Done To Tackle Ghostwriting in the Medical Literature?*, 6 PLoS MED. e1000023, at 123–25 (2009) (suggesting the use of a checklist to facilitate editors detect ghostwriting); The PLoS Medicine Editors, *Ghostwriting: The Dirty Little Secret of Medical Publishing That Just Got Bigger*, 6 PLOS MED. e1000156, at 2 (2009) (calling for the action of journals); Sismondo, *Ghost Management*, supra note 6, at 1432 (calling for action of journals, universities, and medical centers); Alastair Matheson, *Corporate Science and the Husbandry of Scientific and Medical Knowledge by the Pharmaceutical Industry*, 3 BIOSOCIETIES 355, 375 (2008) (suggesting the establishment of an International Standard of Integrity in Science by leading journals, professional societies, and teaching institutions) [hereinafter *Corporate Science*]; Jeffrey R. Lacasse & Jonathan Leo, *Ghostwriting at Elite Academic Medical Centers in the United States*, 7 PLOS MED. e1000230, at 3 (2010) (calling for the action of academic medical centers); Jonathan Leo et al., *Why Does Academic Medicine Allow Ghostwriting? A Prescription for Reform*, 48 SOCIETY 371, 374–75 (2011) (suggesting the revision of the ICMJE policies).

See infra part I paras 4–5. See also Matheson, *Unsolved Problem*, supra note 7, at 8 (discussing the factors underlying the weakness of the ICMJE Recommendations and mentioning that ‘[m]ost obviously, it might be considered inevitable that medical publishing’s financial dependency on the pharmaceutical industry should lead to timid editorial standards and incomplete measures’).

Stern & Lemmens, supra note 5, at 1–2.

Xavier Bosch et al., *Challenging Medical Ghostwriting in US Courts*, 9 PLoS MED. e1001163, at 1 (2012). For example, although the International Committee of Medical Journal Editors (ICMJE) Recommendations have long been considered a core action of self-regulation that promotes publication ethics, they have been consistently described as ineffective in responding to industry marketing practices. For example, Matheson, *Unsolved Problem*, supra note 7, at 9 (examining 2015 Recommendations and concluding that ‘much of the ICMJE guidance with respect to industry remains weak and incomplete, and advocacy-based marketing is directly facilitated’); Matheson, *Manipulate Authorship*, supra note 7, at 3 (examining 2011 guidelines and concluding that the ‘current guidelines are therefore not an obstacle but a vehicle through which origination and authorship can be misrepresented to readers in the services of marketing, while enabling the companies involved to claim their conduct is compliant and ethical’); Leo et al., supra note 7, at 374 (commenting on 2009 policies and stating that ‘use of the ICMJE criteria may facilitate ghostwriting while creating the impression that medical journals have strict policies on authorship’). The staff report of the Senate Committee on Finance, followed
In light of such deficiencies, some commentators have suggested resorting to legal restraints.11

Before analysing such proposals, current regulatory efforts and their deficiency should be introduced. Recently, efforts have been undertaken to ensure the integrity of the medical profession, such as the enactment of the Physician Payments Sunshine Act in 2010. Through this act, the legislature has attempted to increase the transparency of the overall financial relationship between physicians and the pharmaceutical industry.12 This act requires applicable manufacturers to submit information regarding their payments or other transfers of value to physicians to the Centers for Medicare and Medicaid Services annually.13 The Centers for Medicare and Medicaid Services then provides this information to the public online.14 In doing so, potential conflicts of interest can be exposed and the readers of academic publications may have more information that could assist them in assessing the credibility of the publications.

However, the disclosure of the financial relationship between physicians and the pharmaceutical industry does not necessarily lead to any changes in ghostwriting practices and their effects. Industry funding permeates medical education and research; in particular, continuing medical education is substantially supported by industry funding. Consequently, many members of the medical community consider some kinds of relationships with the industry as acceptable and do not value the authorship in some way connected with the industry any less than independent resources.15 Therefore, the transparency promoted by the Physician Payments Sunshine Act, though producing many merits, may have only a limited effect on eliminating ghostwriting.16

Efforts should be undertaken toward introducing innovative legal responses. Therefore, the purpose of this paper is to explore the regulatory strategies of existing and potential proposals, including the proposal offered in this paper, and to analyse their comparative advantages and disadvantages. After revealing the challenges that those proposals encountered, this paper asserts that the judiciary should allow a certain amount of leeway for political branches to adopt the regulatory strategy to reform the structure of information production, which is the fundamental method of countering problems with ghostwriting.

The exploration described in this paper consists of three parts. Part I describes the practice of ghostwriting in the pharmaceutical industry and the specific problems involved. Part II describes the regulatory strategies for responding to ghostwriting and

11 See infra part II. 1.
12 Sergio Sismondo, Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won’t Cast Light On, 41 J. L. MED. & ETHICS 635, 635 (2013).
13 42 U.S.C. § 1320a–7h (2016).
14 Centers for Medicare and Medicaid Services, Open Payments, https://www.cms.gov/openpayments/index.html (accessed Nov. 20, 2017).
15 Sismondo, supra note 12, at 639–40.
16 Id. at 640.
presents related proposals. Part III compares the proposals and analyses their major strengths and weaknesses. Based on the findings, this paper concludes by reflecting on the First Amendment jurisprudence and the potential for allowing for adequate legislative discretion.

I. Problems of Ghostwriting

In recent decades, pharmaceutical companies have increasingly exploited research for marketing purposes. They produce academic publications by using the names of guest authors to influence the opinions of medical practitioners and scholars as a form of product promotion. Furthermore, they nurture researchers to become key opinion leaders by inviting the researchers as guest authors and later gain greater influence over medical opinions by publishing articles that the researchers lend their names to. Unfortunately, such practices often result in distorted information and the corruption of relationships between academia and industry.

Pharmaceutical companies purposefully utilize academic publications, especially journal papers, as tools to deliver messages that serve the marketing strategies for their products. Because these papers are written and managed toward publication by people (representing the interests of pharmaceutical companies) hidden from the public, the activities involved in producing them have been referred to as ghostwriting and ghost management. Ghostwriting involves systematic and professional effort. Typically, pharmaceutical companies hire medical communication firms or public relations firms to assist in formulating and executing publication plans that steer the processes and results to comply with their commercial interests. Company statisticians analyze data obtained from company-sponsored clinical trials, professional medical writers draft papers, and other staff members review the papers and contribute marketing perspectives. These industry-produced publications usually avoid listing company-related authors. To adorn publications with an academic appearance, independent researchers become the ‘authors’ of the publications, despite their contributions being limited to the extent of them not qualifying as authors.

Although ghostwriting is conducted in secret, the number of studies exposing it has gradually increased over the years. Through individual case studies, reports of personal experiences, and extensive investigations and observations, studies have demonstrated the pervasiveness of ghostwriting. Conducting a comprehensive review of those

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17 Sismondo, *Ghosts in the Machine*, supra note 6, at 171; Donald W. Light et al., *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 41 J. L. MED. & ETHICS 590, 594–95 (2013); Gagnon, supra note 1, at 572.

18 Matheson, *Corporate Science*, supra note 7, at 362.

19 Sismondo, *Ghosts in the Machine*, supra note 6, at 171–72; Matheson, *Corporate Science*, supra note 7, at 362–63; Sismondo, *Ghost Management*, supra note 6, at 1429; McHenry, supra note 2, at 129–30.

20 See eg Peter C. Gotzsche et al., *Ghost Authorship in Industry-Initiated Randomised Trials*, 4 PLoS MED. e19 (2007); David Healy & Dinah Cattell, *Interface between Authorship, Industry and Science in the Domain of Therapeutics*, 183 BRET. J. PSYCHIATRY 22 (2003); Sismondo, *Ghost Management*, supra note 6, at 1429–31; McHenry, supra note 2, at 134–38; Adrian J. Fugh-Berman, *The Haunting of Medical Journals: How Ghostwriting Sold ‘HRT’*, 7 PLoS MED. e1000335 (2010); Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation*, 299 JAMA 1800 (2008); S. Swaroop Vedula, *Implementation of a Publication Strategy in the Context of Reporting Biases. A Case Study Based on New Documents from Neurontin Litigation*, 13 TRIALS 136 (2012); Lindsey Gabrielsen, *Bias at the Gate?: The Pharmaceutical Industry’s Influence on the Federally Approved Drug Compendia*, 40 AM. J. L. & MED. 141, 159
empirical studies goes beyond the task of this paper; however, discussing a case herein illustrates the process and consequences of ghostwriting.

The popularization of numerous modern medicines such as Vioxx, Avandia, Paxil, Zoloft, Zyprexa, Prempro, Fen-Phen, and Neurontin has reportedly involved ghostwriting. Vioxx manufactured by Merck & Co. is a compelling example, which has been previously described. Another representative case is Study 329, which examined the use of paroxetine (Paxil, Seroxat) to treat adolescent depression. Documents released following litigation disclosed the following story. The results of the trial for efficacy and safety were negative. Particularly, regarding safety, significantly more participants in the paroxetine group than the placebo group engaged in self-harmed or reported emergent suicidal tendencies. Despite this evidence, the manufacturer SmithKline Beecham (SKB) (later GlaxoSmithKline (GSK)) evidently attempted to manage the dissemination of data for the commercial interests of the company. They hired Scientific Therapeutics Information (STI), a medical communication firm, to prepare a manuscript and manage the publication process. Consequently, an article was published in the *Journal of the American Academy of Child and Adolescent Psychiatry*, despite the journal having reasons based on specific submitted information and the opinions of one reviewer to question the validity of the conclusion. Many of the named authors actually made minor, even no recognizable, contributions, while the major drafter of the article, Sally Laden, an employee of STI, was acknowledged only for editorial assistance and several SKB employees who contributed substantially were not even acknowledged. The published article, which concealed and misrepresented data, had a considerable impact on medical practices and academia. The article was distributed among doctors by SKB to promote the off-label use of paroxetine. Moreover, the article was cited in a positive light in numerous subsequent medical articles.

A further aspect of ghostwriting practices is that the pharmaceutical industry develops and maintains dynamic cooperative relationships with key opinion leaders. First, pharmaceutical companies groom rising talent in research fields as key opinion leaders by discovering them, connecting with them, and helping them to expand the scope of their influence. Because the evaluation of a scholar's publications has a major effect on a his or her reputation, allowing junior researchers to join the list of authors of ghostwritten papers that appear in prestigious journals effectively enhances their degree of influence and gradually elevates them to the position of key opinion leader. Second, pharmaceutical companies purposefully manage and utilize their relationships with key

(2014); Linda Logdberg, *Being the Ghost in the Machine: A Medical Ghostwriter’s Personal View*, 8 PLoS MED. e1001071 (2011).

21 Leo & Lacasse, *supra* note 17, at 802; Leo et al., *supra* note 7, at 371; McHenry, *supra* note 2, at 135–38. See also Jon N. Jureidini & Leemon B. McHenry, *Conflicted Medical Journals and the Failure of Trust*, 18 ACCOUNT. RES. 45, 45 (2011).

22 For the report of this case, see eg Leemon B. McHenry & Jon N. Jureidini, *Industry-Sponsored Ghostwriting in Clinical Trial Reporting: A Case Study*, 15 ACCOUNT. RES. 152 (2008); Jureidini & McHenry, *supra* note 21; McHenry, *supra* note 2, at 136; Leo & Lacasse, *supra* note 17, at 802–3.

23 Jureidini & McHenry, *supra* note 21, at 46.

24 McHenry & Jureidini, *supra* note 22, at 153–60.

25 McHenry, *supra* note 2, at 136; McHenry & Jureidini, *supra* note 22, at 160–61.

26 Sismondo, *supra* note 12, at 636–37.

27 Healy & Cattell, *supra* note 20, at 25. See also Stern & Lemmens, *supra* note 5, at 1 (ghostwritten publications give credibility to guest authors in the legal setting).
opinion leaders.\textsuperscript{28} They pay key opinion leaders to speak to influence other physicians, researchers, and even agencies and consumers. Moreover, they invite key opinion leaders to serve as guest authors for ghostwritten publications, thereby increasing the credibility of the intended messages of the publications.\textsuperscript{29} In summary, ghostwriting is a highly useful device used by the pharmaceutical industry to maintain relationships with academic figures, nurture junior researchers, and grow in influence unjustly by exploiting the names of researchers they have invested in.

The influence of the pharmaceutical industry over medical journals further reinforces ghostwriting practices. Assuming that industry-produced materials are published because they successfully deceive editors by meeting high scientific standards and leaving no traces of being ghostwritten would be naïve. Journals often have conflicts of interest regarding the publication of industry-produced materials because the evidence has shown that publishing reports of industry-supported clinical trials may increase a journal’s impact factor and revenue.\textsuperscript{30} A crucial reason why industry-supported trials attract more citations than do independent studies is that pharmaceutical companies endeavor to raise attention to their studies for commercial reasons through such means as producing ghostwritten study reviews, purchasing and disseminating reprints, and gaining media exposure.\textsuperscript{31} Such actions directly and indirectly influence journal finances through the increase in the journal’s impact factor. In some cases, ‘a single trial may lead to an income of US$1 million for a journal from reprint sales, and with a large profit margin of around 70%’.\textsuperscript{32} Consequently, publication decisions made by journals are not completely free from the influence of the pharmaceutical industry.

Furthermore, ‘predatory’ journals and publication practices that they conduct to facilitate medical ghostwriting have become widespread phenomena. Such journals focus on commercial profit, and thus are more likely to abandon their duty of ensuring quality in their publications. Some even provide channels for commercial editing agents and companies to publish articles.\textsuperscript{33} Consequently, ghostwritten articles easily acquire the appearance of scholarly works.

Ghostwriting practices engender serious, undesirable consequences. First, ghostwriting practices produce key opinion leaders with false research experience attached to them.\textsuperscript{34} Second, such practices corrupt the academia–industry relationship and threaten public trust in the academic community. Third and most crucially, ghostwriting damages the integrity of science. Ghostwritten publications, which frequently appear in influential journals, significantly shape medical knowledge. However, such publications are largely driven by marketing purposes rather than genuine scientific curiosity to explore truths. Strong and concentrated commercial interests distort the content of ghostwritten articles and consequently, the information that they impart is not

\textsuperscript{28} Matheson, \textit{Corporate Science}, supra note 7, at 369–71; Sismondo, supra note 12, at 637.
\textsuperscript{29} Sismondo, supra note 12, at 638–39.
\textsuperscript{30} Andreas Lundh et al., \textit{Conflicts of Interest at Medical Journals: The Influence of Industry-Supported Randomised Trials on Journal Impact Factors and Revenue – Cohort Study}, 7 PLoS MED. e1000354 (2010). See also Harvey Marcovitch, Editors, Publishers, Impact Factors, and Reprint Income, 7 PLoS MED. e1000355 (2010).
\textsuperscript{31} Lundh et al., supra note 30, at 4–5.
\textsuperscript{32} Id. at 5.
\textsuperscript{33} Armen Yuri Gasparyan et al., \textit{Statement on Publication Ethics for Editors and Publishers}, 31 J. KOREAN MED. SCI. 1351, 1353 (2016).
\textsuperscript{34} Healy & Cattell, supra note 20, at 25.
trustworthy.\textsuperscript{35} Furthermore, the manipulation of academic publications endangers not only the abstract notion of scientific integrity but also the concrete interests of public health and safety. Previous studies have revealed cases where ghostwritten publications have concealed or misrepresented information related to drugs. In some cases, falsely presented data on drugs have led to injuries and even deaths among patients.\textsuperscript{36} Considering that people’s lives and health are at stake, the fight against ghostwriting constitutes an essential task for governments.

\section*{II. Regulatory Proposals}
Commentators have proposed various legal responses to ghostwriting. From the perspective of regulatory strategies, these proposals can be categorized under three main types. One regulates the content of disseminated information, one attacks the false representation of authorship, and the third reforms the structure of information production.

\subsection*{1. Regulating the Content of Disseminated Information}
The most straightforward strategy to ensure the quality of information is to regulate the adequacy of disseminated scientific information. The following proposals, drawing support from existing laws, are categorized under this strategy type.

Some commentators have suggested borrowing the prohibition of off-label marketing,\textsuperscript{37} which itself represents a concern of the Food and Drug Administration (FDA) for the content of industry-disseminated information, to suppress the ghostwriting practices.\textsuperscript{38} If ghostwritten academic articles advocate unapproved drug use, they might constitute illegal off-label promotion. In that case, the False Claims Act, which has been a powerful mechanism for preventing off-label marketing, could impose civil liabilities on not only the pharmaceutical company but also the guest authors involved.\textsuperscript{39}

\begin{thebibliography}{99}
\bibitem{35} Healy & Cattell, \textit{ supra note} 20, at 26; McHenry, \textit{ supra note} 2, at 138; Sismondo, \textit{ Ghosts in the Machine, supra note} 6, at 193–94; Light et al., \textit{ supra note} 17, at 595; Gagnon, \textit{ supra note} 1, at 574; Stern & Lemmens, \textit{ supra note} 5, at 1; Trudo Lemmens, \textit{ Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene}, 32 \textit{J. L. Med. & Ethics} 641, 646 (2004); Gotzsche et al., \textit{ supra note} 7, at 122; Tore Scherstén, \textit{ Medical Research and Publication for Sale: Ghostwriting, Ghost Management and ‘Spin’, in Trust and Confidence in Scientific Research} 47, 48–49 (Göran Hermerén et al. eds., 2013).
\bibitem{36} Lacasse & Leo, \textit{ supra note} 7, at 1; Trudo Lemmens, \textit{ Pharmaceutical Knowledge Governance: A Human Rights Perspective}, 41 \textit{J. L. Med. & Ethics} 163, 165 (2013); Scherstén, \textit{ supra note} 35, at 49–50; McHenry, \textit{ supra note} 2, at 139. See also Gabrielsen, \textit{ supra note} 20, at 159; Healy & Cattell, \textit{ supra note} 20, at 26.
\bibitem{37} Regarding the federal prohibition of off-label marketing and the constitutional controversy caused by the prohibition, see Stephanie M. Greene & Lars Noah, \textit{Debate: Off-Label Drug Promotion And The First Amendment}, 162 \textit{U. Pa. L. Rev. Online} 239 (2014), \url{http://www.pennlawreview.com/online/162-U-Pa-L-Rev-Online-239.pdf} (accessed Jan. 30, 2018); Coleen Klasmeier & Martin H. Redish, \textit{ Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection}, 37 \textit{Am. J. L. & Med.} 315 (2011); Kate Greenwood, \textit{The Ban on ‘Off-Label’ Pharmaceutical Promotion: Constitutionally Permissible Prophylaxis against False or Misleading Commercial Speech?}, 37 \textit{Am. J. L. & Med.} 278 (2011); Michael A. Walsh, \textit{The FDA and the First Amendment: Off-Label Promotion, Due Process, and the Commercial Speech Doctrine}, 2012 \textit{Wl. 497}1934 (2012); Jennifer L. Herbst, \textit{Off-Label ‘Promotion’ May Not Be Merely Commercial Speech}, 88 \textit{Temp. L. Rev.} 43 (2015); William S. Comanor & Jack Needleman, \textit{The Law, Economics, and Medicine of Off-Label Prescribing}, 91 \textit{Wash. L. Rev.} 119 (2016).
\bibitem{38} Bosch et al., \textit{ supra note} 10, at 3. See also Stern & Lemmens, \textit{ supra note} 5, at 3.
\bibitem{39} Bosch et al., \textit{ supra note} 10, at 3.
\end{thebibliography}
Another proposal, directly criticizes problematic ghostwritten publications, appeals to tort claims of personal injury and wrongful death.\(^{40}\) Where ghostwritten articles manipulate data and present false information (for example, concealing severe side effects of drugs) and patients suffer from injuries or even die because of the prescriptions that rely on the ghostwritten articles, patients or their families certainly have a cause of action against pharmaceutical companies. In addition, guest authors, who provide false information to others, may also be liable, according to the Restatement of Torts sections 310 and 311, because they have the duty to exercise reasonable care to ascertain the accuracy of the information.\(^{41}\)

2. Attacking the False Representation of Authorship

In contrast to the aforementioned proposals, which target the content of disseminated information, some proposals aim to enhance the quality of information by eliminating the false representation of authorship. This approach emphasizes the illegality of the false representation of authorship and avoids the burden of proving the falsity of disseminated information.

One study proposed that guest authorship constitutes fraud.\(^{42}\) The false representation of authorship by unqualified guest authors misleads journals and their readers, who decide to publish articles and read and use the information contained in journal articles, respectively. Furthermore, guest authors receive the credit of authorship through having articles published in academic journals. Therefore, courts may find fraud has been committed upon journals and their readers.\(^{43}\)

The doctrine of ‘fraud on the court’ also provides a potential legal ground.\(^{44}\) The doctrine imposes disadvantages or sanctions on a party or its counsel for intentionally or recklessly providing false averments or concealing truth that should be disclosed, thereby deceiving the court. Accordingly, when pharmaceutical company lawyers cite ghostwritten articles, which present false warranties of authorship, fraud on the court may be raised against said companies and their lawyers.\(^{45}\)

3. Reforming the Structure of Information Production

Some proposals seek solutions from a more fundamental angle, redirecting regulatory attention to the structure of information production. The previous two strategies mainly focus on false or misleading information (occurring in either publication content or representation of authorship), which is the outcome or appearance of ghostwriting. By contrast, with an eye on the root of the ghostwriting problem, another potential strategy is to exclude the pharmaceutical industry from the process of knowledge production, thereby fundamentally stripping pharmaceutical companies of the ability to conduct ghostwriting practices. The following two proposals exemplify this strategy.

Learning from legislations regulating corporate speech in public elections, this paper offers a new proposal, suggesting to bar pharmaceutical companies from engaging in

\(^{40}\) Id. at 2.
\(^{41}\) Id.
\(^{42}\) Stern & Lemmens, supra note 5, at 3.
\(^{43}\) Id. For a further development of this argument, see Deanna Minasi, Note: Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters, 86 FORDHAM L. REV. 299 (2017).
\(^{44}\) Id. at 4.
\(^{45}\) Id.
the activities of academic publication in connection with specific products (hereafter proposal A). To combat corruption and distortion, there have been federal and state statutes that prohibit corporations from spending in support of or against a candidate or political party, with variations in aspects such as the amount of spending, duration of prohibition, and methods of information dissemination. Using these legislations as a model, ghostwriting regulation may prohibit pharmaceutical companies from making contribution or expenditure on initiating, drafting, writing, or publishing any academic journal articles in connection with a specific product. In this basic form, law makers may further consider the specific scope of the restriction through means such as imposing the ban only for a certain period of a drug’s life cycle, only on certain types of drugs, or on publishing in certain types of journal. Such regulation could largely free the production of academic knowledge from unavoidable bias inherent in industry-produced materials.

Another proposal, which intervenes even more deeply in industry activities, advocates the establishment of an independent mechanism for clinical trials (hereafter proposal B). Supporters of proposal B suggest, for example, that governments could designate independent institutes and researchers to design and conduct clinical trials, paid by pharmaceutical companies, rather than rely on pharmaceutical companies to produce the necessary data for drug approval. In separating research from the industry with such an evident conflict of interest, this independent drug testing could fundamentally safeguard research integrity. Although proposal B does not aim to eliminate ghostwriting by design, the significant decrease in industry-conducted research would naturally result in a significant decrease in ghostwriting.

III. Comparison: Effectiveness and Constitutionality

Although all three strategies are valuable in responding to ghostwriting and could be adopted simultaneously by regulators, exploring their comparative merits would contribute richly to the policymaking, particularly because although the third strategy appears to be a critical addition to the proposed ghostwriting regulation, people may be

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46 Sismondo proposed a similar idea by calling for voluntary action from universities and academic health centers to prohibit sponsors from intervening in publication. Sismondo, Ghost Management, supra note 6, at 1432. In addition, Gagnon suggested the regulatory solution of imposing ‘an outright ban on pharmaceutical promotion deemed to be harmful to prescribing habits’. Gagnon, supra note 1, at 578.

47 The federal campaign law that was the subject of the infamous Supreme Court decision of Citizen United v FEC presents a notable example. As summarized by the Court opinion, the Act ‘prohibits corporations and unions from using their general treasury funds to make independent expenditures for speech defined as an “electioneering communication” or for speech expressly advocating the election or defeat of a candidate’ and ‘[a]n electioneering communication is defined as “any broadcast, cable, or satellite communication” that “refers to a clearly identified candidate for Federal office” and is made within 30 days of a primary or 60 days of a general election’. 558 U.S. 310, 318, 321 (2010). See also 2 U.S.C. § 441b (2006); 2 U.S.C. § 434 (2006). At state level, for example, Massachusetts law provides that no corporation ‘shall directly or indirectly give, pay, expend or contribute, or promise to give, pay, expend or contribute, any money or other valuable thing for the purpose of aiding, promoting or preventing the nomination or election of any person to public office, or aiding or promoting or antagonizing the interest of any political party’. M.G.L.A. 55 § 8 (2014).

48 For example, Marc A. Rodwin, Independent Drug Testing to Ensure Drug Safety and Efficacy, 18 J. HEALTH CARE L. & POL’Y 45 (2015) [hereinafter Independent Drug Testing]; Marc A. Rodwin, Independent Clinical Trials to Test Drugs: The Neglected Reform, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 113 (2012) [hereinafter Independent Clinical Trials]; Light et al., supra note 17, at 597; Lemmens, supra note 35, at 653.

49 Rodwin, Independent Drug Testing, supra note 48, at 55–57; Rodwin, Independent Clinical Trials, supra note 48, at 119, 126–27; Lemmens, supra note 35, at 653.
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considerably more hesitant to embrace it than the first two strategies. Few would object to eliminating false or misleading information in publication content (first strategy) or in representation of authorship (second strategy), especially when this goal can be achieved through current laws. However, the third strategy, which demands new legislation and serves to significantly alter the status quo, has thus far not gained strong support. Against this backdrop, the comparison described in terms of effectiveness and constitutionality in the following subsection could help to consider whether the ghostwriting regulation should include the third strategy.

1. Effectiveness

The difference in the approach between the first two strategies and the third strategy causes a difference in their degrees of effectiveness in dealing with ghostwriting. The first two strategies focus on preventing the noticeable outcome or appearance of ghostwriting, while the third strategy redirects attention to the root of the ghostwriting problem (i.e., the commercial bias behind industry-produced materials). The structural change engendered by the third strategy could fundamentally undermine ghostwriting practices. By comparison, the first two strategies may have only limited regulatory effectiveness.

Each proposal in the first two strategies has its own disadvantages. First, the approach that borrows the restriction on off-label marketing does not directly target ghostwritten publications and only affects ghostwritten articles that promote unapproved drug use. Moreover, the FDA regulation on off-label marketing itself has come under attack as a violation of the First Amendment. After United States v Caronia, the FDA’s prohibition of off-label promotion is considered restricted under the jurisdiction of the Second Circuit, and pharmaceutical companies may continue to test their First Amendment theory in other courts. Second, regarding the approach that appeals to tort claims of personal injury and wrongful death, establishing a causal link between physical harm and ghostwritten articles is extremely difficult. Even if courts accept the theory, very few cases are likely to be successful. Moreover, the approach responds only to a limited range of situations, where notable physical harm can be traced to the products of pharmaceutical companies. Third, the approach that applies the fraud claim poses only a trivial threat to pharmaceutical companies in the form of low damages. Although this approach has the potential to deter guest authors, because of ‘the transactional costs of such an endeavor, the novelty of the theories, and the nominal damages at issue’, the possibility of any law firm filing such a case is low. If courts have no or very few chances to enforce the theory, the approach would not be a deterrent. Fourth, although the approach that applies the doctrine of fraud on the court may restrict pharmaceutical companies from citing ghostwritten articles in judicial proceedings, it does

50 For example, Greene & Noah, supra note 37, at 248–54, 261–67; Klasmeier & Redish, supra note 37, at 342–49; Herbst, supra note 37, at 71–89.
51 703 F.3d 149 (2d Cir. 2012).
52 The most recent development was that of a manufacturer who sought a preliminary injunction preventing the FDA from bringing misbranding action against its modified off-label communications. The application was granted by the United States District Court for the Southern District of New York. Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F.Supp.3d 196 (S.D. New York, 2015).
53 Stern & Lemmens, supra note 5, at 4.
54 Bosch et al., supra note 10, at 1–2.
not prevent pharmaceutical companies from using those articles for marketing, which is the primary purpose of such articles. Consequently, even if pharmaceutical companies cannot present such articles in court, they still have strong incentives to continue ghostwriting.

Notably, all proposals in the first two strategies face a fundamental challenge; that is, attacking the quality of ghostwritten research is difficult. With the help of professional analysts and publication planners, ghostwritten articles easily meet scientific standards and, on the surface, can even exhibit high academic quality. In fact, ghost-managed articles exhibit higher citation rates than do independent studies. Given this context, the strategy of fighting ghostwriting through attacking its false content is confronted with the formidable challenges of discovering and proving the existence of problematic content. The strategy of targeting false representation of authorship may face fewer barriers, but discovering and proving the existence of ghostwriting remains a difficult task. The endeavor on the fraud claims could possibly expose only the tip of the ghostwriting iceberg. Broadly speaking, because none of these proposals intervene in the basis of ghostwriting practices, they are unlikely to substantially diminish such practices.

The third strategy reforms the structure of information production and has the potential to bring about major change. Specifically, the danger of ghostwriting practices is that the pharmaceutical industry, with its immense aggregations of wealth, intervenes in the production of academic publications and, consequently, manipulates medical knowledge. Industry-produced material unavoidably contains biases motivated by commercial interests and is fundamentally in conflict with the spirit of science in the pursuit of truth. This underlying commercial bias naturally distorts the presentation of scientific information, impedes the formation of trustworthy knowledge, and could lead to compromised health and safety. Moreover, immense aggregations of wealth empower the industry to systematically and extensively influence knowledge production. Therefore, the overall effect is enormous. This more comprehensive and institutional understanding leads to the conclusion that isolating the production of medical knowledge from the influence of the pharmaceutical industry, beyond merely focusing on false information in individual publications, is the fundamental solution.

Some might be skeptical of the ease of enforcement of the regulation under this strategy. However, it should be noted that, at the very least, such regulation is easier to enforce than the proposals under the first two strategies. Specifically, proposal A has the support of existing securities regulation, rather than seeking enforcement on its own. Pharmaceutical companies are generally publicly traded corporations. They are obligated to disclose detailed financial information. Because the regulation targets the spending of companies, with the aid of the disclosure requirements and external audits undertaken by the accounting profession, the violation of such regulation would be exposed more readily than other regulatory alternatives. Regarding proposal B, its enforcement is even less problematic because the FDA only accepts information from

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55 Sismondo, supra note 12, at 640. See also Lundh et al., supra note 30, at 3–4.

56 Cf. Marc A. Rodwin, Rooting out Institutional Corruption to Manage Inappropriate Off-Label Drug Use, 41 J. L. MED. & ETHICS 654, 657 (2013) (mentioning that it is difficult to discover off-label promotion activities and the legal sanctions and liabilities do not stop pharmaceutical companies from continually engaging in off-label promotion).

57 See eg 15 U.S.C. § 78m (2016).
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independent sources for drug approval. In addition, although pharmaceutical companies are required to pay for the execution of clinical trials, the FDA, rather than pharmaceutical companies, designates and contracts with independent testing institutes. This proposed design considerably dispels the concern that the independent testing mechanism might be captured by the pharmaceutical industry.

The regulation that embodies the third strategy would attack ghostwriting considerably more severely than would other regulatory options because it negates the ability of pharmaceutical companies to conduct ghostwriting, regardless of whether a ghostwritten article causes any proven harm. Thus, the overall regulatory scheme should include the third strategy if effectiveness is the only concern. However, legal responses to ghostwriting raise constitutional issues because they impinge on protected rights, especially freedom of speech and research.

2. Constitutionality

The proposed regulation’s impact on the free marketplace of scientific information should be cautiously considered from a constitutional perspective. With an abundance of available clinical data, the pharmaceutical industry plays a major role in supplying scientific information regarding drugs and health. Some might be concerned that a restriction on the research and publication activities of the industry may significantly reduce the quantity of scientific information. The longstanding First Amendment jurisprudence formed on the basis of judicial decisions prioritizes protection of the free marketplace of ideas, and it is fair to say that the analytic framework established by the First Amendment jurisprudence for judicial review has well accounted for protecting the value of free speech. Therefore, testing the regulation through such an analytical framework would be an appropriate approach to clarify concerns on the restrictions of free speech.

The first two strategies could easily survive constitutional scrutiny. Academic publications produced by pharmaceutical companies in connection with their products fall within the scope of commercial speech, which receives weaker constitutional protection.\(^58\) Although the exact boundary of commercial speech is not completely clear under Supreme Court precedents,\(^59\) *Bolger v Youngs Drug Products Corp.*\(^60\) laid a strong foundation to support such a finding. Similar to the informational pamphlets in *Bolger*,\(^61\) ghostwritten articles produced by pharmaceutical companies discuss specific products that the companies have an economic motivation to promote. Therefore, such articles should be considered commercial speech. Under the commercial speech doctrine, the First Amendment does not extend protection to false or misleading

\(^{58}\) See Bosch et al., *supra* note 10, at 3–4 (identifying medical ghostwriting as commercial speech).

\(^{59}\) DANIEL A. FARBER, THE FIRST AMENDMENT 157 (2d ed., 2003); EUGENE VOLOKH, THE FIRST AMENDMENT AND RELATED STATUTES 190 (3d ed. 2008); JEROME A. BARRON & C. THOMAS DIENES, FIRST AMENDMENT LAW 171 (4th ed. 2008). The Supreme Court in *In re Primus* also admits that the line between commercial speech and noncommercial speech ‘will not always be easy to draw’. 436 U.S. 412, 438 n. 32 (1978).

\(^{60}\) 463 U.S. 60, 66 (1983).

\(^{61}\) In *Bolger*, presented with the case of a company distributing informational pamphlets discussing the desirability of prophylactics and mentioning specific products sold by the company, the Court categorized the pamphlets as commercial speech despite them not containing any clear transaction proposals. *Id.* at 62, 66–67.
commercial speech. Because the first two strategies target false or misleading information in ghostwritten works, not many constitutional concerns would be raised.

The third strategy would encounter a real challenge in relation to the First Amendment. The proposal A regulation clearly suppresses free expression of the pharmaceutical industry. Regarding the proposal B regulation, whether it concerns the First Amendment requires further discussion. This regulation requires data for drug approval come from independent drug testing. Effectively, it amounts to preventing pharmaceutical companies from conducting clinical drug trials because such trials are extremely expensive, the produced data are largely worthless, and the companies have already shouldered the financial burden for independent testing. Consequently, this regulation appears to restrict free research of pharmaceutical companies even more profoundly than does the proposal A regulation. Although some might argue that the proposal B regulation constrains conduct rather than speech and thus does not implicate the First Amendment, this view should be rejected. The First Amendment guarantees freedom of not only the publication or presentation but also the planning and implementation of research because research planning and implementation activities are essential preconditions of producing research results. This understanding of the coverage of research freedoms has been supported extensively by scholars.

Under the analytical framework of the First Amendment jurisprudence, the two steps, determining the nature of the regulation and applying a corresponding standard of review, follow. First, the regulations of proposals A and B should be considered content-based because such regulations are established out of fear of the negative communicative impact of pharmaceutical companies’ study results. Similar to the first two strategies, with economic motivation and connection to specific products, the subject matters of the regulations of proposals A and B (the academic publications and

62 Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 771 (1976); Central Hudson Gas & Elec. v. Public Serv. Comm’n, 447 U.S. 557, 566 (1980).
63 Some commentators have argued that the medical ghostwriting is fraud, which the First Amendment does not protect. Bosch et al., supra note 10, at 3–4.
64 Chung-Lin Chen, Constitutional Analysis of Research Ethics Review Laws: The United States and Beyond, 16 COLUM. SCI. & TECH. L. REV. 248, 260–61 (2015); James R. Ferguson, Scientific Inquiry and the First Amendment, 64 CORNELL L. REV. 639, 649–54 (1979); John A. Robertson, The Scientist’s Right to Research: A Constitutional Analysis, 51 S. CAL. L. REV. 1203, 1216–18 (1977); Roy G. Spece Jr. & Jennifer Weinzierl, First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature, 8 S. CAL. INTERDISC. L. J. 185, 213–19 (1998); Michael Davidson, First Amendment Protection for Biomedical Research, 19 ARIZ. L. REV. 893, 899–900 (1977); Richard Delgado et al., Can Science Be Inopportunely Constitutional Validity of Governmental Restrictions on Race-IQ Research, 31 UCLA L. REV. 128, 160–62 (1983).

Nevertheless, notably, the Supreme Court has not clarified whether it embraces this view of research freedom.
65 The analytical framework consists of two major elements: the content-based and content-neutral distinction and the high-value and low-value speech distinction. In short, content-neutral regulation of speech triggers intermediate scrutiny, whereas content-based regulation requires strict scrutiny unless the regulated speech falls under the category of low-value speech. See generally, BARRON & DIENES, supra note 59, at 28–44; LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW 789–94, 832–41 (2d ed. 1988); KEITH WERHAN, FREEDOM OF SPEECH 72–79 (2004); DAVID M. O’BRIEN, CONGRESS SHALL MAKE NO LAW: THE FIRST AMENDMENT, UNPROTECTED EXPRESSION, AND THE U.S. SUPREME COURT 11–13 (2010); Geoffrey R. Stone, Content Regulation and the First Amendment, 25 WM. & MARY L. REV. 189, 190–97 (1983); Geoffrey R. Stone, Content-Neutral Restrictions, 54 U. CHI. L. REV. 46, 47–48 (1987).
66 Regarding the meaning of content-based regulation, see eg TRIBE, supra note 65, at 789–90.
clinical study data produced by pharmaceutical companies, respectively, in connection with their products) fall within the scope of commercial speech. Therefore, the commercial speech doctrine governs constitutional analysis. However, in contrast to the first two strategies, the third strategy does not specifically target ghostwritten works, but rather extensively curtails the power of pharmaceutical companies to produce academic publications or clinical study data. Pharmaceutical companies may argue that the regulation suppresses the dissemination of truthful and non-misleading information, which warrants constitutional protection. Consequently, the fate of the third strategy is much more heavily shadowed than those of the first two strategies.

The regulation under the third strategy has two possible grounds for survival, but the Supreme Court is likely to reject both of them. First, industry-produced academic publications and clinical study data might be considered inherently misleading, thereby rendering them ineligible for constitutional protection, because they are naturally driven by economic motivation and their commercial nature is veiled by their academic appearance. In sustaining this argument, the proponents may contend that based on the evidence provided in part I of this paper, ‘experience has proved that in fact such [form of commercial speech] is subject to abuse’. However, pharmaceutical companies may counterargue that their publications and data can be presented without any misleading content or false authorship, and the Supreme Court precedents have established that suppressing such expression, even though the potential for deception is high in the context of such expression, must overcome the scrutiny that commercial speech is ordinarily subjected to. Considering only a small portion of industry-produced academic publications and clinical study data have been proven harmful, courts would likely hesitate to conclude that sufficient evidence exists for a history of abuse.

Second, if the courts reject the ‘inherently misleading’ argument and decide to introduce the Central Hudson test, the regulation, when it is carefully formulated, might be considered as a necessary means of pursuing substantial governmental interests. In terms of the end prong, the regulation could easily reach the required threshold to be passed because its ultimate goal, safeguarding the life, health, and safety of the people, is apparently a substantial, even compelling, interest. Regarding the means prong, the requirement that the regulation be ‘no more extensive than necessary’ raises a high standard, especially when it is construed as the ‘least restrictive means’ requirement.

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67 In re R. M. J., 455 U.S. 191, 203 (1982) (‘But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions.’); see also Id. at 202 (citing Ohralik v. Ohio State Bar Assn. and Friedman v. Rogers as examples that the Court upholds the prohibitions on ‘the particular advertising is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive’).

68 See Id. at 203–7 (1982).

69 The Supreme Court has developed a special standard, the Central Hudson test, for reviewing commercial speech restrictions. Central Hudson Gas & Elec. v. Public Serv. Comm’n, 447 U.S. 557 (1980).

70 Id. at 566 (‘not more extensive than is necessary’), 569–70 (‘no more extensive than necessary’), 572 (‘no more extensive than is necessary’).

71 For example, Id. at 564 (‘if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.’); Thompson v. Western States Medical Center, 535 U.S. 357, 371 (2002) (‘we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.’). However, this is once construed as a less rigid requirement. For example, Board of Trustees of the State University of New York
One could argue that other regulatory options and designs less intrusive upon speech do not serve governmental interests as effectively as the regulation, if the legislature designs the regulation carefully to avoid unnecessary restriction by narrowing the regulatory scope to include, such as, only a certain period of a drug life cycle and only a high-risk drug. Nevertheless, the recent trend of Supreme Court precedents on cases of commercial speech favors a more demanding review, especially in relation to not only the language used to describe the standard of review but also the overall outcomes of judgments. This trend of the judicial attitude considerably disadvantages the possibility of the regulation passing the means inquiry.

Although acknowledging the current situation in relation to the commercial speech doctrine, this paper seriously doubts the wisdom of affording such strong protection to the commercial speech of the pharmaceutical industry when the regulation is aimed at preventing the manipulation of scientific information. First, commercial speech is motivated toward distortion. The market force naturally drives commercial entities to pursue profit maximization rather than make autonomous choices. This thus leads to an increased threat of misconduct than other types of speech. The publication practices of the pharmaceutical industry revealed in this paper exemplify such tendencies toward distortion. Second, as Virginia State Board of Pharmacy v Virginia Citizens Consumer Council, Inc. identifies, commercial speech has greater objectivity and hardness. Its disseminators can more easily verify the truth of the speech regarding their products than other types of speakers, and the driving force of profit pursuit makes it more durable than other types of speech when confronted with regulation. Therefore, the regulatory efforts toward ensuring the accuracy of commercial speech should receive more judicial support than those in other contexts. Third, the remedy of ‘more speech’ is less available in responding to commercial speech and, therefore, the core premise for granting the protection of the First Amendment to other types of speech is

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72 See Nat Stern, Commercial Speech, ‘Irrational’ Clients, and the Persistence of Bans on Subjective Lawyer Advertising, 2009 B.Y.U. L. REV. 1221, 1248–51, 1253–56 (2009); David C. Vladeck, Lessons From a Story Untold: Nike v. Kasky Reconsidered, 54 CASE W. RES. L. REV. 1049, 1059 (2004); Tamara R. Piety, Market Failure in the Marketplace of Ideas: Commercial Speech and the Problem that Won’t Go Away, 41 LOY. L.A. L. REV. 181, 185 (2007); Samantha Rauer, Note and Comment, When the First Amendment and Public Health Collide: The Court’s Increasingly Strict Constitutional Scrutiny of Health Regulations that Restrict Commercial Speech, 38 AM. J. L. & MED. 690, 702–06 (2012).

73 For the standpoints opposing affording commercial speech strong constitutional protection or any constitutional protection, see eg C. Edwin Baker, Commercial Speech: A Problem in the Theory of Freedom, 62 IOWA L. REV. 1 (1976) [hereinafter Theory of Freedom]; C. Edwin Baker, The First Amendment and Commercial Speech, 84 IND. L. J. 981 (2009) [hereinafter The First Amendment]; Thomas I. Emerson, First Amendment Doctrine and the Burger Court, 68 CAL. L. REV. 422, 460–61 (1980); ERIC BARENDT, FREEDOM OF SPEECH 399–406 (2d ed. 2007); Victor Brudney, The First Amendment and Commercial Speech, 53 B.C.L. REV. 1153 (2012); Reza R. Dibadj, The Political Economy of Commercial Speech, 58 S.C.L. REV. 913 (2007); James Weinstein, Fools, Knaves, and the Protection of Commercial Speech: A Response to Professor Redish, 41 LOY. L.A. L. REV. 133 (2007); Tamara R. Piety, supra note 72, at 181; R. George Wright, Freedom and Culture: Why We Should Not Buy Commercial Speech, 72 DENV. U. L. REV. 137 (1994); Samantha Rauer, supra note 72, at 690, 706–11 (2012).

74 Baker, The First Amendment, supra note 73, at 985–87. See also Piety, supra note 72, at 198–217.

75 425 U.S. 748, 771 n.24 (1976).

76 Id. See also C. Edwin Baker, Paternalism, Politics, and Citizen Freedom: The Commercial Speech Quandary in Nike, 54 CASE W. RES. L. REV. 1161, 1169 (2004).
generally absent.\textsuperscript{77} Third parties cannot compete with commercial disseminators in offering counterinformation, considering the imbalance between them and commercial disseminators in terms of the possibility of access to the truth regarding products and, particularly, financial resources invested in the marketplace of ideas.\textsuperscript{78} This market failure, especially in the context of the pharmaceutical industry having considerable wealth, justifies increased regulatory power to counteract information manipulation. Therefore, the Court should lower its standard of review in examining the proposed regulation. Actually, the Court itself once construed the means prong of the \textit{Central Hudson} test as only seeking a ‘reasonable fit’ between the end and the means\textsuperscript{79} or even completely excluded commercial speech from the domain of constitutional protection.\textsuperscript{80}

The following point, which has not received sufficient attention, further supports the inclination to reject the introduction of a stringent review standard. That is, when initiating regulation on the pharmaceutical industry in order to safeguard public health and safety, political processes inherently suffer from minoritarian bias—a type of political malfunction resulting from the overrepresentation of concentrated interest groups and the underrepresentation of dispersive members of the public.\textsuperscript{81} First, the interests of the pharmaceutical industry are generally overrepresented. Its vast potential interests motivate it to actively participate in political processes. Moreover, the industry possesses substantial economic resources, usually maintains good connections with politicians, and therefore occupies a privileged position in politics.\textsuperscript{82} Second, the health and safety interests of the public are naturally underrepresented. Although the interest of public health and safety should be weighed heavily in regulatory decision-making, each individual who shares that public interest has too little at stake to be motivated toward effective action in political processes. Moreover, the ‘public good problem’—the factors of transaction costs and free-riding—and the lack of expertise and resources to understand and examine scientific information further hinder individuals from engaging in effective participation. Consequently, in general, the decision-making in political processes disproportionately advantages the pharmaceutical industry, and the resulting regulatory scheme is unlikely to unduly burden the industry.\textsuperscript{83} For this reason, the judiciary should not stand to impede the regulatory efforts in restraining the industry in the pursuit of public health and safety. Applying a stringent standard of review is therefore inadequate.

\begin{itemize}
\item \textsuperscript{77} Brudney, \textit{supra} note 73, at 1154, 1167–68.
\item \textsuperscript{78} Piety, \textit{supra} note 73, at 224–25; Dibadj, \textit{supra} note 73, at 920; Baker, \textit{The First Amendment}, \textit{supra} note 73, at 994.
\item \textsuperscript{79} Fox, 492 U.S., at 469.
\item \textsuperscript{80} Prior to the 1976 \textit{Virginia State Board of Pharmacy} decision, commercial speech did not receive the protection afforded by the First Amendment.
\item \textsuperscript{81} Regarding minoritarian bias, see NEIL K. KOMESAR, \textsc{Imperfect Alternatives: Choosing Institutions in Law, Economics, and Public Policy} 75–76, 81–82 (1994); NEIL K. KOMESAR, \textsc{Law’s Limits: The Rule of Law and the Supply and Demand of Rights} 57, 59–60 (2001).
\item \textsuperscript{82} Paul D. Jorgensen, \textit{Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda}, 41 J. L. MED. & ETHICS 561, 561–63 (2013).
\item \textsuperscript{83} See Jorgensen, \textit{supra} note 82, at 563–64. The rise and fall of the legislative proposal for independent drug testing as an example, see Rodwin, \textit{Institutional Corruption}, \textit{supra} note 1, at 514; Light et al., \textit{supra} note 17, at 597; Rodwin, \textit{Independent Drug Testing}, \textit{supra} note 48, at 58–77; Rodwin, \textit{Independent Clinical Trials}, \textit{supra} note 48, at 119, 126–59.
\end{itemize}
In summary, while legal regulation for ghostwriting necessarily involves limiting the free flow of information, the implications to the First Amendment differ among the various approaches. The first two strategies would easily pass judicial inspection because the targeted speech falls beyond constitutional protection. By contrast, the third strategy, which aspires to eradicate not only proven deception but also hidden commercial bias in knowledge production, extends its impact zone to a wide range of research implementation and publication of the pharmaceutical industry and raises considerable concerns related to the First Amendment. Under the current judicial tendency to grant substantial protection to commercial speech, policymakers must consider constitutional concerns when designing the regulation that embodies the concept of the third strategy. In the meantime, courts should account for the nature of the context to leave sufficient discretion to policymakers to realize that strategy.

**CONCLUSION**

Many studies have demonstrated the pervasiveness of medical ghostwriting and the need for urgent action. Ghostwriting practices systematically influence the integrity of medical knowledge and ultimately endanger people’s lives, health, and safety. However, although ethical norms and legal rules condemn ghostwriting, they have so far proven ineffective in suppressing the practice. Commentators have suggested various solutions to the ghostwriting problem. From the perspective of regulatory strategies, this paper categorizes these suggestions into three approaches, aimed at regulating the content of disseminated information, attacking the false representation of authorship, and reforming the structure of information production.

The implications of the strategy that directs attention to the structure of information production are particularly notable. On the one hand, this strategy precedes the other regulatory options in effectiveness because it seeks to solve the root of the problems. On the other hand, in contrast to the other regulatory options, it faces constitutional challenges because its restrictions go beyond unprotected speech. In light of the urgent need to address ghostwriting problems, the enhanced potential effectiveness of this strategy urges policymakers to incorporate it into the regulatory scheme. In doing so, First Amendment-related concerns require caution from the policymakers in shaping the regulatory outline. Because the constitutionality of a law partially depends on how the law is designed, the legislature should endeavor to formulate tailored restrictions to prevent unnecessary casualties.

In addition to offering insights into framing the regulation, the constitutional analysis in this paper contributes to reflecting on the First Amendment jurisprudence. The fate of a law is influenced by not only the action of the legislature but also the attitude of the judiciary, and the current development of Supreme Court precedents appears to considerably narrow the scope of legislative discretion. In particular, when the overall outcome of these precedents is accounted for, they almost serve to burden the disputed regulation with a tendency toward unconstitutionality. However, because of the seriousness of the ghostwriting problem and difficulty in fighting it, a certain amount of leeway should be allowed for political branches to develop effective regulation. Moreover, even intrusive regulation may merit judicial support because the disproportionate power balance between the pharmaceutical industry and dispersive individuals in the general public demands modification.
The amount of leeway granted to the legislature depends on how the courts choose to protect corporations or commercial entities, how they determine what information is misleading, how they evaluate the appropriation of the relationship between the end and the means, and how they interpret the means prong of the Central Hudson test. If, as suggested by many scholars, the courts declined to extend the same First Amendment protection to corporations or commercial entities as they do to individuals, the question of constitutionality surrounding the regulation would be largely dismissed. However, the Supreme Court does not adopt that stance; therefore, analysis of the First Amendment is transferred to the realm of the commercial speech doctrine. Despite the trend of precedents leaning toward stringent examination, the instability and ambiguity of the doctrine still leave a possibility for the survival of even an intrusive regulation. Essentially, courts should not afford strong protection to the commercial speech of the pharmaceutical industry when the regulation is aimed at ensuring the integrity of scientific information. If the legislature has shaped the regulatory scope carefully, courts may rule in favor of the regulation based on construing the applied test as a less stringent requirement and finding the regulation an adequate means. That is the direction in which the courts should work to protect public health and safety.

ACKNOWLEDGEMENTS
The author thanks Dominique Sprumont for his help and comments. This study was supported by a grant from the Ministry of Science and Technology, Taiwan (MOST-103–2410-H-007–017-MY2).

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84 For example, C. Edwin Baker, supra note 73, at 981, 987–90 (2009); C. Edwin Baker, Realizing Self-Realization: Corporate Political Expenditures and Redish's The Value of Free Speech, 130 U. PA. L. REV. 646 (1982); Amy J. Sepinwall, Citizens United and the Ineluctable Question of Corporate Citizenship, 44 CONN. L. REV. 575 (2012); Daniel J. H. Greenwood, Essential Speech: Why Corporate Speech Is Not Free, 83 IOWA L. REV. 995 (1998). See also Ronald J. Colombo, The Corporation as a Tocquevillian Association, 85 TEMP. L. REV. 1 (2012); Anne Tucker, Flawed Assumptions: A Corporate Law Analysis of Free Speech and Corporate Personhood in Citizens United, 61 CASE W. RES. L. REV. 495 (2011).

85 First Nat'l Bank of Bos. v. Bellotti, 435 U.S. 765, 777–84 (1978); Citizens United, 558 U.S. 310, 342–43 (2010).