Alternative Resolution Centers
Hon. Vincent J. O'Neill (Ret.)
ARC Case No. _____

DR. JAMES STUDNICKI, DR. DONNA J. HARRISON, DR. DAVID C. REARDON, DR. JOHN W. FISHER, DR. INGRID SKOP, DR. MAKA TSULUKIDZE, DR. CHRISTINA CIRUCCI, DR. SHARON J. MACKINNON, CHRISTOPHER CRAVER, AND TESSA COX,

Claimants,

v.

SAGE PUBLICATIONS, INC.,

Respondent.

DEMAND FOR ARBITRATION

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INTRODUCTION

1. "When you mix science and politics, you get politics."[1] That is what Respondent Sage Publications, Inc. did when it retracted Claimants' scientific articles to pursue a political agenda.

2. Claimants are 10 professional researchers who co-authored three scientific studies in 2019, 2021, and 2022 about the characteristics of certain abortion providers (those who lack admitting privileges) and the relative risks of abortion procedures (chemical-induced abortions).[2] Sage conducted thorough peer reviews of the Articles, accepted them for publication in one of its medical journals, *Health Services Research and Managerial Epidemiology* ("HSRME"), and publicly praised them for their scientific rigor.

3. But Sage's commitment to science—to publish research on controversial topics like abortion—disappeared after the Supreme Court ruled in *Dobbs v. Jackson Women's Health Organization* that the federal Constitution does not confer a right to abortion and that the American people and their elected representatives have broad legal authority to regulate abortion. 597 U.S. 215 (2022). After *Dobbs*, a federal court cited two of the Articles in support of its ruling that the FDA had improperly approved the chemical abortion drug, mifepristone, and later unlawfully removed the in-person dispensing requirement to protect the women who take it. *See All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 524 n.9, 537 n.22 (N.D. Tex. 2023).

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[1] John M. Barry, *The Pandemic Could Get Much, Much Worse. We Must Act Now*, The New York Times (July 14, 2020), perma.cc/3495-FERX.

[2] For ease of reference, Claimants are referred to as "the Authors," and the three scientific studies at issue are referred to as "the Articles."

4. A pro-abortion advocate then filed a complaint with Sage about the 2021 Article and the Authors' affiliations with the Charlotte Lozier Institute ("CLI"), a research organization that conducts scientific, statistical, and medical research to educate the public on abortion and the value of life from fertilization to natural death; the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), a nonprofit organization that equips medical practitioners to defend the lives of pregnant mothers and their unborn children; and the Elliot Institute, a research organization that studies the effects of abortion. Sage and its journal responded by retracting all three Articles and removing the lead Author, Dr. James Studnicki, from HSRME's editorial board.

5. Sage's reasons for retracting the Articles were pretextual. Sage did not point to anything that could justify the rare and severe measure of retraction under prevailing professional guidelines, such as a major error or falsification. Instead:

(A) Sage cited limitations in the Authors' research, but the Authors had expressly disclosed those limitations in the Articles.

(B) Sage complained about the way the Authors chose to display some data in one graphic chart, but that chart was not misleading. Moreover, the Authors listed all the data shown in the chart in a separate table, making it easy for any reader to directly reference and analyze it.

(C) Sage asserted that the Authors did not declare their pro-life affiliations as conflicts of interest—a standard that Sage never applies to authors with pro-abortion affiliations—but the Authors disclosed

their affiliations and fully complied with Sage's conflict of interest declaration requirements.

(D) Sage also claimed that its double-blind peer-review process for the Articles was flawed because one of the peer reviewers who recommended publication was affiliated with CLI. But Sage selected this reviewer; neither the Authors nor the reviewer was aware of each other's identity during the double-blind review process; and the other reviewers who did not have pro-life affiliations also recommended publication. Moreover, the mere fact that a peer reviewer has pro-life affiliations is not a valid reason for retracting an article under prevailing professional guidelines.

6. In other words, Sage did not articulate any scientific basis or legitimate editorial policy for retracting the Articles.

7. Sage's retractions breached the Publishing Agreements that Sage entered with the Authors in 2019, 2021, and 2022. The Agreements were unequivocal: Sage could retract the Articles only if the Authors "infring[ed] th[e] Agreement." But the Authors fully complied with the Agreements, and Sage never showed otherwise. Sage thus had no contractual basis to retract the Articles.

8. Sage also acted with bad faith and unfair dealing throughout the retraction process. It gave specious reasons for its retractions, ignored the Authors' detailed responses to Sage's concerns, refused to respond to the Authors' correspondence, conducted an unauthorized post-publication review process to undermine its own peer reviews approving the Articles, showed political bias, and did

not pursue less burdensome measures than retraction, which violated the very industry standards for retraction that Sage claimed to follow.

9. Sage's retractions also contradicted the representations it had made to the Authors. Before entering the Agreements to publish the Articles, Sage informed the Authors that it had performed a "rigorous" double-blind peer-review process. But when Sage retracted the Articles, it claimed to do so based on flaws in the peer-review process. If that is true, then Sage bears legal responsibility, because it induced the Authors to publish with HSRME based on misrepresentations that its peer-review process was sound. The Authors' reliance on those misrepresentations then led to the Articles being retracted, causing them enormous and ongoing reputational and financial harm.

10. Sage's retractions were also an act of invidious discrimination. Sage applied inconsistent retraction standards to the Authors based on Sage's perception of the Authors' pro-life beliefs and affiliations. This is unlawful under California anti-discrimination law.

11. Finally, Sage had no justification for removing the lead Author, Dr. James Studnicki, from the board of HSRME. Sage took this action for the same reason it retracted the Articles—invidious discrimination.

12. The combined reputational and economic harm to the Authors from these unlawful actions is enormous and incalculable. Because of Sage's retractions, the Authors and their research have been attacked by the media, by other authors, and even by a Justice of the U.S. Supreme Court, and the Authors have had new

research proposals inexplicably turned away by other journals that now fear associating with them. The Authors have years—even decades—of fruitful research ahead of them, but they are now being treated as pariahs.

13. The Authors are entitled to declaratory and monetary relief for these harms, as well as injunctive relief requiring Sage to rescind the retractions. The Authors seek the full benefit of their bargain with Sage and to remedy the ongoing harms to their well-earned reputations as objective, honest, and highly qualified scientists and researchers.

PARTIES

14. The Authors are nationally recognized and credentialed scientists associated with CLI, a research organization that conducts scientific, statistical, and medical research to educate the public on abortion and the value of life from fertilization to natural death; AAPLOG, a nonprofit organization that encourages and equips its members and other concerned medical practitioners to provide an evidence-based rationale for defending the lives of both the pregnant mother and her unborn child; and the Elliot Institute, one of the leading organizations producing original research on the impact of abortion on women, men, families, and society. The Authors have authored or contributed to hundreds of peer-reviewed articles in biomedicine and public health systems, and not one of those articles (except for the three at issue here) has ever been retracted.

15. James Studnicki, Sc.D., M.P.H., M.B.A., is Vice President and Director of Data Analytics at CLI and lead Author of the retracted Articles. Dr. Studnicki holds both Doctor of Science (Sc.D.) and Master of Public Health (M.P.H.) degrees from

Johns Hopkins University and a Master of Business Administration (M.B.A.) degree from George Washington University. Dr. Studnicki's 50-year academic career has encompassed appointments at the nation's premier institutions for public health and health services research, including the Johns Hopkins School of Hygiene and Public Health, the top public health school in the country, where he was the first Director of its Master of Health Science Program in Health Finance and Management. Dr. Studnicki has authored over 100 peer-reviewed articles in health services research and has published in some of the most influential medical journals, including the *New England Journal of Medicine*, the *Journal of the American Medical Association*, the *American Journal of Preventive Medicine*, and the *American Journal of Public Health*. Dr. Studnicki's Articles make up three of HSRME's top ten most-read publications.

16. Donna J. Harrison, M.D., is Director of Research for AAPLOG and has been a board-certified physician in obstetrics and gynecology for over 30 years. Dr. Harrison received her Honors undergraduate degrees in Biochemistry and Chemistry at Michigan State University. She received her Doctor of Medicine (M.D.) degree from the University of Michigan, with additional training in international medicine at the University of Arizona in Tucson, Arizona. She did her residency training in obstetrics and gynecology at a University of Michigan affiliate hospital, where she then served as Associate Professor in Obstetrics and Gynecology. While in private practice she worked in underserved areas of Haiti and served as Chair of the Department of Obstetrics and Gynecology as well as Chair of Quality Control at her health system. She currently serves as Associate Professor at Trinity International University. She

has authored numerous peer-reviewed papers, including on maternal mortality, mifepristone mortality and morbidity, and the FDA approval of mifepristone and ulipristal.

17. David C. Reardon, Ph.D., is the founder and director of the Elliot Institute. Dr. Reardon is widely recognized as one of the leading experts on the effects of pregnancy loss on women. Dr. Reardon is the author of numerous books and peer-reviewed articles on this topic, including a comprehensive summary of the medical literature on abortion and mental health. Dr. Reardon's studies have been published in prestigious medical journals such as the *British Medical Journal* and the *American Journal of Obstetrics and Gynecology*. He has also served as a peer reviewer on abortion-related research for each of the following journals: *JAMA Psychiatry*, *British Medical Journal*, *Acta Paediatrica*, *Medical Science Monitor*, *Archives of General Psychiatry*, *Social Science Quarterly*, *BMC Women's Health*, *BMC Pregnancy and Childbirth*, *Mayo Clinic Proceedings*, *Lancet Psychiatry*, *Drug and Alcohol Dependence*, *Frontiers in Psychiatry*, *Frontiers Public Health*, and *Annals of Internal Medicine*.

18. John W. Fisher, Ph.D., J.D., M.S., M.A., is a retired U.S. Navy submarine commander and Senior Associate Scholar at CLI. Dr. Fisher earned a Ph.D. in Information Systems and Decision Sciences from the University of South Florida, a Juris Doctor degree from the Massachusetts School of Law, and five masters' degrees. Dr. Fisher has developed and taught graduate courses on Information Management at Troy University and the University of North Carolina,

Charlotte, where he spearheaded efforts to create a data-based community assessment portal for North Carolina Health Departments. At CLI, Dr. Fisher has co-authored peer-reviewed research examining pregnancy outcomes, abortion mortality, maternal mortality, and other public health topics.

19. Ingrid Skop, M.D., FACOG, is Vice President and Director of Medical Affairs for CLI. Dr. Skop received her medical degree from the Washington University School of Medicine and has practiced as a board-certified obstetrician/gynecologist for over 30 years in San Antonio, where she has delivered more than 5,000 babies. She is a member of the Texas Maternal Mortality and Morbidity Review Committee and has also served as board member and medical director for pregnancy resource centers in San Antonio, Austin, and Houston. Dr. Skop's research on maternal mortality, abortion, and women's health has been published in multiple peer-reviewed journals.

20. Maka Tsulukidze, M.D., Ph.D., M.P.H., is an Associate Professor at Florida Gulf Coast University (FGCU), Marieb College of Health & Human Services, and an Associate Scholar for CLI. Before joining FGCU, Dr. Tsulukidze was a Postdoctoral Fellow at the Dartmouth Center for Health Care Delivery Science. She earned a Ph.D. from the University of North Carolina, Charlotte, and an M.D. from Tbilisi Medical Academy. Dr. Tsulukidze has co-authored studies published in the academic journals *Patient Education and Counseling*, *PLOS ONE*, *Archives of Surgery*, *Joint Commission Journal on Quality and Patient Safety*, *American Journal of Alzheimer's Disease & Other Dementias*, and *Educational Gerontology*.

21. Christina Cirucci, M.D., FACOG, is a board-certified OB/GYN and has practiced medicine for twenty years. Dr. Cirucci received her medical degree from Thomas Jefferson University (Sidney Kimmel Medical College) and completed her OB/GYN residency at the Medical College of Virginia. She is a diplomate of the American Board of Obstetrics and Gynecology, a Life Fellow of the American College of Obstetricians and Gynecologists, and a National Certified Menopause Practitioner with the North American Menopause Society. Dr. Cirucci also serves on AAPLOG's board of directors and is an Associate Scholar with CLI. She has published peer-reviewed articles in the medical literature on the complications of chemical abortion. She has also served as a peer reviewer for each of the following journals: *Obstetrics and Gynecology*, *HSRME*, *Annals of Pharmacotherapy*, *Issues in Law and Medicine*, and *Cureus*. Dr. Cirucci has volunteered her medical skills in various third-world countries in Africa and Asia.

22. Sharon J. MacKinnon, Ph.D., RN, FNP, has over 25 years of experience on the front lines of health care serving predominantly low-income patients in urban and rural settings in the South, first as a nurse and then as a family nurse practitioner. Dr. MacKinnon obtained her Ph.D. in Health Services Research at the University of North Carolina, Charlotte. As a CLI associate scholar, she has contributed to several abortion research publications.

23. Christopher Craver, M.A., is an independent health services researcher affiliated with CLI. His research focuses on the use of secondary healthcare data sources in population-based scientific research. Mr. Craver is widely published on

many healthcare topics including cancer treatment, rare disease populations, and the efficacy of surgical services.

24. Tessa Cox (née Longbons) is a Senior Research Associate at CLI where her research focuses on abortion statistics at the state and national levels and the changing landscape of abortion policy, provision, and access in the United States. Ms. Cox has appeared on CBN News and EWTN News Nightly; she has testified before members of Congress on the Born-Alive Abortion Survivors Protection Act; and her work has been featured by national media outlets. She has contributed to peer-reviewed research on women's experiences with chemical abortion and the impact of abortion on women enrolled in Medicaid.

25. Respondent Sage Publications, Inc. is a Delaware corporation with its principal place of business located in Thousand Oaks, California. It is one of the largest academic publishers in the world, with offices spanning four continents, and it has been a major influence in global academic publishing and scientific research since its founding in 1965. It is the publisher of more than 1,000 journals and over 800 new books each year. In 2023 alone, Sage published over 71,000 articles that were downloaded over 29 million times. Those same articles were featured in over 14,000 news stories and cited in 286 policy documents from governments all over the world. Sage stocks the shelves of schools, libraries, and universities, and it touts its ability to use its size to create "pathways from the ivory tower to the public sphere" and make "an outsized impact on public policy." Sage, *Independence with Impact Report*

2023, bit.ly/4diOyJG. Sage is the proprietor of the scientific journal *Health Services Research and Managerial Epidemiology*.

BACKGROUND

I. The Authors write three Articles on abortion.

26. In 2018, *Roe v. Wade* was the law of the land. The Supreme Court had for decades held that the U.S. Constitution guaranteed a woman's right to have an abortion. It would be years before the Court in June 2022 would shock the nation by overruling *Roe* in *Dobbs v. Jackson Women's Health Organization*. 597 U.S. 215 (2022). It would also be years before national medical associations and individual doctors in 2023 would sue the FDA to challenge its approval of chemical abortion drugs and subsequent removal of established safeguards.

27. Given the legality and prevalence of abortion, the Authors conducted scientific research to better understand the health risks of contemporary abortion practices. In 2019, six of the Authors published *Doctors Who Perform Abortions: Their Characteristics and Patterns of Holding and Using Hospital Privileges* (the "2019 Article"). This Article was the first published peer-reviewed study on the characteristics of doctors who perform abortions and the extent to which they hold and use hospital admitting privileges. Hospital admitting privileges are essential for surgeons who require the necessary technology, personnel, and support services found in the inpatient setting to practice their specialty. The process of credentialing and hospital privileging for physicians enhances their competency and the quality of care rendered to patients. Therefore, hospital admitting privileges are valued as a sign of competency and a reassurance to women that a physician can secure their

admission to a hospital if a procedure goes wrong. The study found that nearly half the doctors studied lacked such privileges. The 2019 Article highlighted the dearth of research on the medical qualifications of abortion doctors and posed questions for future research. The 2019 Article is attached as Exhibit A.

28. In 2021, eight of the Authors continued their scientific research into abortion safety with a groundbreaking article, *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015* (the "2021 Article"). This article was a longitudinal cohort study of emergency room use following chemical and surgical abortions. It examined Medicaid claims data, which is the largest database of pregnancy outcomes in the U.S. The Authors recognized and disclosed in the Article that this dataset was not perfect, but the relative completeness of Medicaid data allowed them to make discoveries about abortion safety that no other researchers had previously been able to investigate with other available datasets. The 2021 Article is attached as Exhibit B.

29. Among other things, the 2021 Article found that the rate of abortion-related emergency room visits following chemical abortion increased by 507% from 2002 through 2015, but by only 315% for abortion-related ER visits after surgical abortions over the same period. It found that "an ER visit is significantly more likely to occur following a prior chemical abortion than following a prior surgical abortion." Ex. B at 5.

30. The timing of the 2021 Article was significant. Chemical abortion was on the rise. It constituted 6% of all abortions in 2001, but it had steadily risen to 53%

of all abortions by 2020. With chemical abortions increasingly becoming the most common method, the 2021 Article's findings about the relative dangers of chemical abortion posed a threat to proponents of the procedures.

31. The 2021 Article was widely circulated and read online, and it remains the single most-read article in HSRME's history. Its findings were a signal scientific achievement, both for the Authors and for HSRME, in advancing women's health and in demonstrating the practical value of fearless scientific inquiry into matters of social controversy. In 2022, HSRME's Editor-in-Chief, Dr. Gregory M. Garrison, praised the 2021 Article for fulfilling the scientific "vision" of HSRME. Dr. Garrison also emphasized the Article's scientific contribution to women's health. The Article's finding "that chemical abortions were associated with more emergency department visit morbidity than surgical abortions" showed "the need to objectively evaluate [medical] interventions for potential unintended effects." Gregory M. Garrison, *We Live in Interesting Times: How Health Services Research and Managerial Epidemiology Helps Point the Way Forward*, HSRME (Mar. 1, 2022), bit.ly/4a5xuUI.

32. Nine of the Authors continued their research into chemical abortion with a follow-up article in May 2022 entitled *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization* (the "2022 Article"). This Article reported that by 2015, 60.9% of abortion-related ER visits following chemical abortion were being miscoded as a miscarriage due to patient concealment or ER staff mischaracterization, likely resulting in "sub-optimal care and, subsequently, an increased likelihood of

hospital admission." Disturbingly, the study found that an ER physician's misclassification of a failed induced abortion as miscarriage was correlated with higher rates of hospitalization and surgical intervention. The study also identified patient concealment of a chemical abortion and/or ER staff failure to identify a failed abortion attempt increased the risk for multiple hospital admissions and delayed provision of necessary surgical treatment. The 2022 Article concluded that these increased risks highlight the importance of abortion providers advising women that they may face increased medical risks if they do not inform medical personnel that they are experiencing an abortion complication. The 2022 Article is attached as Exhibit C.

33. The Authors' goal in publishing these articles was simple: to expand scientific research into these important and controversial issues. Like most researchers who publish academic articles, the Authors had no idea how their research might be used by members of the public, or whether it would be used in future litigation.

II. The Authors submit the Articles to HSRME for publication.

34. The submission and peer-review process for the three Articles went smoothly.

35. HSRME required the Authors to disclose their "financial support" and provide a Declaration of Conflicts of Interest statement in the Article manuscripts that declared "[a]ny *commercial* or *financial* involvements that might present an appearance of a conflict of interest." (emphasis added).

36. The Authors submitted their manuscript of the 2019 Article to HSRME for publication on January 24, 2019; their manuscript of the 2021 Article on September 10, 2021; and their manuscript of the 2022 Article on April 20, 2022. To comply with the submission guidelines and facilitate a double-blind peer-review process, the Authors submitted the title pages of these manuscripts to HSRME separately. On that page, the Authors disclosed to HSRME their affiliations with CLI, AAPLOG, and the Elliot Institute, provided a declaration that they did not have any financial or commercial conflicts of interest, and disclosed any financial support they received.

37. For the 2019 Article, the Authors declared no actual or potential financial or commercial conflicts and that they did not receive any financial support for the research, authorship, or publication. For the 2021 and 2022 Articles, the Authors declared no actual or potential financial or commercial conflicts and that they had received financial support for the research, authorship, and publication from CLI.

38. For each submission, the Authors provided their affiliations, declaration of conflicts, and statement of financial support to HSRME through its online submission portal. For correspondence purposes, many of the Authors also provided HSRME with their institutional email addresses, which identified them to HSRME as employees or affiliates of CLI and AAPLOG.

39. Following each submission, HSRME conducted a double-blind peer review of each Article. The 2019 and 2021 Articles were judged by three reviewers.

The 2022 Article was judged by two reviewers, with the editor also providing comments. Neither the reviewers nor the Authors knew each other's identities. Sage assured the Authors that this process was thorough and rigorous. *See, e.g.*, Sage, *Resources for Reviewers*, bit.ly/3wFNz5U. A guide that Sage provides to peer reviewers describing the peer-review process is attached as Exhibit D.

40. For each Article, the reviewers submitted comments and recommended publication. HSRME provided the Authors with the reviewers' comments and instructed the Authors to address each comment and revise the Articles accordingly. In each instance, the Authors addressed the reviewers' comments and submitted a revised manuscript. HSRME reviewed the revisions and accepted the Articles for publication.

41. If the Authors had not adequately addressed all concerns highlighted by the reviewers in any of these peer-review processes, HSRME would have informed them and withdrawn the Article from consideration. For example, HSRME "unsubmitted" the 2019 Article when it mistakenly believed that the Authors had not "address[ed] comments from reviewer 1 as well as reviewer 2." The Authors' initial response had addressed each reviewer's comments, but their response did not identify which reviewer made each comment. When the Authors revised their response to identify which reviewer had written each comment, HSRME accepted the 2019 Article for publication.

42. Thus, in accepting the three Articles for publication, HSRME expressed its satisfaction with the Authors' revisions and responses to the reviewers' comments.

43. For each Article, after the peer-review process but before publication, Sage sent page proofs to the Authors with several queries for them to address. These queries included requests that the Authors "confirm that all author information, including names, affiliations, sequence, and contact details, is correct," and "confirm that the Funding and Conflict of Interest statements are accurate."

44. The Authors confirmed all these details. The Authors also included a statement at the end of each manuscript that they had no potential financial or commercial conflicts of interest with respect to the research, authorship, and/or publication of the Articles. They disclosed their affiliations with CLI, AAPLOG, and the Elliot Institute and reported funding from CLI for the 2021 and 2022 Articles. The Authors also volunteered short biographies that provided more details about their roles within their respective organizations. All this information—which would be included in the final published Articles—was provided to HSRME before it approved the Articles for publication. In short, Sage was fully aware of the Authors' affiliations with CLI, AAPLOG, and the Elliot Institute before publication and were satisfied with the Authors' disclosures.

45. Thus, the Authors completely and accurately disclosed all affiliations, conflicts, and financial support required by HSRME.

46. Following review of the Authors' revisions to the Articles, HSRME accepted the Articles for publication.

47. Upon HSRME's acceptance of the 2021 and 2022 Articles for publication, the Editor-in-Chief emailed lead author Dr. James Studnicki, thanking him and praising both Articles as a "fine contribution" to the journal.

III. Sage agrees to limit retraction to narrow circumstances.

48. After accepting each Article but before publishing them, Sage and the Authors entered into a Publishing Agreement. The Agreements for the 2019, 2021, and 2022 Articles are identical in substance and attached as Exhibits E, F, and G, respectively.

49. Importantly, the Agreements authorized Sage to take "corrective action," which includes "retracting the [Article]," only when the contribution is "found to be infringing this Agreement." This limitation on retraction and the other provisions in the Agreements "constitut[e] the entire agreement between the parties."

50. The Agreements required the Authors to certify that: (1) the Articles represent "the[ir] original work"; (2) they have "the right to enter into [each] Agreement and to convey the rights granted … to [Sage]"; (3) the Articles are "not being considered for publication elsewhere"; (4) the Authors obtained and disclosed all copyright permissions; (5) the Articles contain "no violation of any existing copyright, other third party rights or any defamatory or untrue statements and do[] not infringe any rights of others"; (6) any studies that the Articles were directly based on "compli[ed] with the governing Institutional Review Board (IRB) standards"; (7) the Authors acknowledged "[a]ll forms of financial support" and declared "[a]ny commercial or financial involvements that might present an appearance of a conflict of interest related to the [Articles]"; and (8) the Authors have not signed an agreement

with a sponsor prohibiting them from "publishing both positive and negative results." Ex. E at 1-2; *see* Ex. F at 1-2; Ex. G at 1-2. For all three Articles, the Authors satisfied these requirements and certified their compliance.

51. The Authors paid an article processing charge of $1,200, $1,200, and $1,280 to Sage for publication of the Articles under the 2019 Agreement, 2021 Agreement, and 2022 Agreement, respectively.

52. The Agreements provide that Sage "will publish the [Articles] under the Creative Commons license selected by you." Ex. E at 1; *see* Ex. F at 1; Ex G at 1.

53. Each Agreement conferred on the Authors a Creative Commons Attribution-NonCommercial license (CC BY-NC 4.0) to share and adapt the Articles. This license is "irrevocable" if the Authors follow the license terms. Each Agreement conferred on Sage an exclusive commercial license to "produce, publish, sell and sub-license [the] article[s] and any accompanying abstract or Supplemental Material[.]" Sage retains these exclusive commercial rights.

54. Sage published the 2019 Article in HSRME on April 15, 2019, the 2021 Article in HSRME on November 9, 2021, and the 2022 Article in HSRME on May 20, 2022.

IV. A federal court cites the 2021 Article in support of its ruling on chemical abortion.

55. One month after the Authors published the 2022 Article, the Supreme Court issued its historic decision in *Dobbs*. Now, for the first time in decades, the American people and their elected representatives could freely regulate—and even ban—abortion practices that they believe are harmful. The Articles thus became

dangerous to pro-abortion political interests because they provided scientific evidence that chemical abortions have serious risks and can be harmful to women.

56. In November 2022, a group of national medical associations and individual doctors sued the FDA in the U.S. District Court for the Northern District of Texas to reverse its approval of the chemical abortion drug mifepristone and removal of critical safeguards for the drug. The plaintiffs cited the 2021 and 2022 Articles in support of their position. On April 7, 2023, the Court temporarily enjoined the FDA's approval and subsequent elimination of certain regulatory safeguards that the FDA had previously implemented. Among many other authorities and studies, the District Court cited the 2021 and 2022 Articles in support of its ruling that the plaintiffs had standing because of, among other things, the "'enormous pressure and stress'" that chemical abortions place on ER doctors. *See All. for Hippocratic Med.* 668 F. Supp. at 523-24 & n.9, 537 & n.22 (N.D. Tex. 2023).

57. This case was highly publicized and fast-moving. The Fifth Circuit partially affirmed the District Court's ruling in August 2023, and the Supreme Court granted certiorari and heard oral argument on March 26, 2024. *Food & Drug Admin. v. All. for Hippocratic Med.,* 144 S. Ct. 537 (2023).

V. Pro-abortion advocates criticize and pressure Sage.

58. Media attention surrounding the mifepristone case began to focus on the Authors' 2021 and 2022 Articles. For example, *The New York Times* described them as a minority position in the scientific literature and unreliable. *See* Amy Schoenfeld Walker, et al., *Are Abortion Pills Safe? Here's the Evidence*, The New York Times (Apr. 1, 2023), perma.cc/S5K8-UYHT. Other articles were less diplomatic. One

accused the Authors, CLI, and AAPLOG as sources of "[s]uspect science" behind a "false … narrative" about the dangers of mifepristone. Sofia Resnick, *Suspect Science and Claims at Center of Abortion-Pill Lawsuit*, Indiana Capital Chronicle (Feb. 13, 2023), bit.ly/3JFr4Rm.

59. After the District Court's April 2023 ruling, *The Washington Post* criticized the 2021 Article as "flawed science" that "exaggerate[s] the negative physical and psychological effects" of mifepristone. *See* Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, The Washington Post (Apr. 13, 2023), perma.cc/VB6B-CHL8. Because the Authors were "affiliated with [CLI]," *The Washington Post* accused the 2021 Article of not being "evidence-based medicine" or reflecting "the gold standard of research design." *Id.* *The Washington Post* quoted Ushma Upadhyay, Ph.D. M.P.H.—a professor at the University of California, San Francisco's abortion training and advocacy center, Advancing New Standards for Reproductive Health (ANSIRH)—in support of its accusations.

60. In April 2023, a professor at South University and pro-abortion advocate named Chris Adkins, Ph.D., submitted a complaint to HSRME about the 2021 Article. Although he submitted the complaint anonymously, Adkins later publicly revealed himself to the media. *See* Sofia Resnick, *Retracted Studies the Latest in a Decades-Long Abortion-Science Fight*, Arkansas Advocate (Feb. 26, 2024), bit.ly/3JOVgd3.

VI. Sage retracts the Articles.

61. After receiving Adkins' complaint, Sage decided that it would retract the Authors' Articles. Sage made up its mind to retract the Articles—and ruled out any

lesser measure—before it even began the retraction process. Given scholars' influence on abortion policy, Sage did not want to provide a platform for researchers whom it perceived to be pro-life or advancing pro-life views or causes, or whose articles could be used by courts and litigators to protect women from unsafe abortion procedures or otherwise advance pro-life positions.

A. Sage ignores contractual and ethical limits on retraction.

62. Sage was undeterred by the contractual limits on its ability to retract the Authors' Articles. Sage's contracts with the Authors allowed it to retract the Articles only if they were "found to be infringing th[e] [publishing] Agreement." Ex. E at 1; *see* Ex. F at 2; Ex. G at 2. Sage is also governed by the retraction guidelines published by the Committee on Publication Ethics (COPE). COPE is a nonprofit organization that provides advice and guidance to its over 12,500 member journal editors and publishers on best practices in the ethics of scholarly publishing. HSRME is a member of COPE, and Sage requires its journals and editors to consult COPE's ethical guidelines for guidance on publishing ethics.

63. The COPE Retraction Guidelines are formal COPE policy and are intended to advise editors and publishers on when a retraction is appropriate. *See* COPE, *Retraction Guidelines*, bit.ly/3wo26mF. These guidelines recognize the severe impact that retraction has on an author's reputation. They thus emphasize that retraction is reserved only for articles that contain "such seriously flawed or erroneous content or data that their findings and conclusions cannot be relied upon." The COPE Retraction Guidelines are attached as Exhibit H.

64. Publishers must consider whether a lesser measure, such as correction, "could sufficiently address errors or concerns" with an article. *Id.* The Guidelines emphasize that retractions are "not usually appropriate" if "[t]he main findings of the work are still reliable[.]" Correction "may be best" if "only a small part of an article reports flawed data or content[.]" For example, "if only a small section of an article" is plagiarized, editors should consider a correction by "not[ing] that text was used without appropriate acknowledgement and cite the source," "rather than retracting the entire article," which "may contain sound, original data." The Guidelines also provide that "a previously corrected article may be further corrected[.]" *Id.* at 3, 6. In other words, even errors that persist after correction may still not warrant retraction.

65. For example, in 2017 HSRME chose not to retract the paper of another group of researchers for an undisclosed conflict of interest but only published a correction. *See* HSRME, *Correction Notice*, Sage Journals (Aug. 25, 2017), bit.ly/4dJJHBn. Other Sage journals have taken similar actions. *See, e.g.*, Journal of Primary Care & Community Health, *Correction Notice*, Sage Journals (Sept. 14, 2017), bit.ly/4bK4Nhv.

66. The Guidelines provide that publishers should "consider" retraction in cases of "redundant publication, plagiarism, peer review manipulation, reuse of material or data without authorisation, copyright infringement or some other legal issue (eg, libel, privacy, illegality), unethical research, and/or a failure to disclose a major competing interest that would have unduly influenced interpretations or recommendations." *Id.* at 3.

67. Even when a publisher determines that retraction is warranted, COPE cautions publishers that "[t]he main purpose of retraction is to correct the literature and ensure its integrity rather than to punish the authors." *Id.* In furtherance of this purpose, the Guidelines instruct publishers on how to conduct the retraction process and outline the content that retraction notices should include.

68. The Guidelines provide that "[w]henever possible, editors should negotiate with authors and attempt to agree on a form of wording [of the retraction notice] that is clear and informative to readers and acceptable to all parties." *Id.* at 4. The Guidelines also emphasize that removal of the retracted articles from the publisher's website is only permissible "[i]n extremely limited cases," such as when "the article is clearly defamatory, violates personal privacy, is the subject of a court order, or might pose a serious health risk to the general public." *Id.* at 5. Even in these circumstances, however, COPE instructs publishers to retain "the metadata (title and authors)" and "clearly state why the full article has been removed" in the retraction notice. *Id.*

B. Sage gives pretextual reasons for retracting the Authors' 2021 Article.

69. Sage began its retraction efforts on June 28, 2023, when one of its representatives emailed the Authors to inform them that Sage had received an anonymous concern from a reader regarding the 2021 Article. The Authors were so surprised by this email that they thought it was a prank and immediately contacted Sage to ask whether it was real.

70. Sage confirmed that it was real and outlined four concerns with the

"representation of data in the [2021] article and author conflicts of interest." On July 13, the Authors responded to each of these concerns in a lengthy and thorough email, ***a simplified summary of which is included below in bold italics.***

71. *First*, Sage expressed concern about how the Article used a dual y-axis graph to show how the rate of ER visits for chemical abortions increased at a steeper rate than ER visits for non-chemical abortions.

(A) By using a dual y-axis graph, the Authors were able to visualize for readers how the rates of ER visits between 2002 and 2015 for *non*-chemical abortion increased by 315%, while visit rates for chemical abortion increased by 507%. The dual y-axis graph also enabled the Authors to separate and compare the rate of increase for different types of abortion-related ER visits.

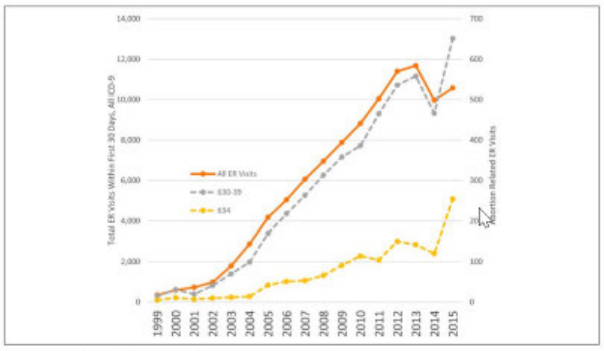


Figure 2. Emergency room (ER) use following surgical abortion, 1999-2015.

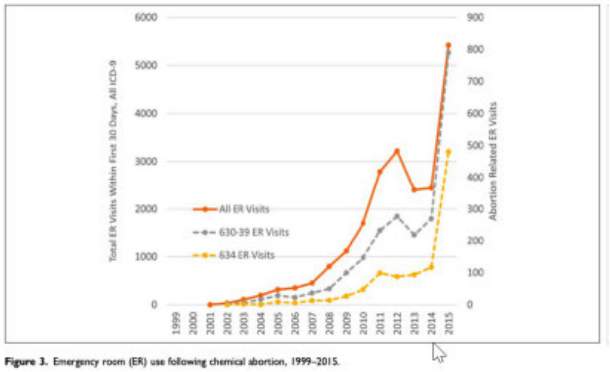
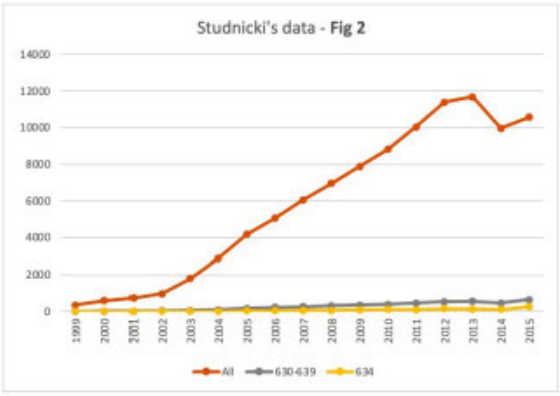
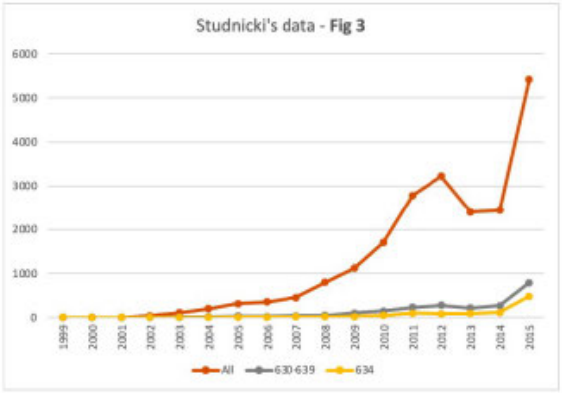


Figure 3. Emergency room (ER) use following chemical abortion, 1999–2015.

(B) Sage asked the Authors why they didn't use a single y-axis graph. When Sage converted the same data into a single y-axis graph, it visualized something very different—a comparison of all ER visits with

two subsets of abortion-related visits. A single y-axis graph showed that these abortion-related visits were only a small fraction of total ER visits.





(C) ***In response, the Authors explained that a single y-axis graph "hides important variations over time" between the rate of non-chemical abortion and chemical abortion ER visits, which was the main point of the article. The dual y-axis graph was not misleading, either, because the Authors set forth the data behind the graph in a separate table.*** (Sage later admitted that the use of a dual y-axis graph here was "not unusual.")

72. *Second*, Sage expressed concern about how the 2021 Article gathered data on abortion-related ER visits. The article collected data on abortion-related ER visits by including any ER visit coded between ICD-9 630 and ICD-9 639—that is, visits related to abnormal pregnancy, spontaneous abortion, or induced abortion, and complications arising from any of these conditions—that occurred within 30 days of an abortion paid by a Medicaid claim.

(A) Gathering this data allowed the Authors to determine for the first time the total ER burden on women following an abortion.

(B) Sage asked why the Authors collected data on abnormal pregnancies (ICD-9 630 through 633).

(C) ***In response, the Authors explained that the data on abnormal pregnancies was abortion-related because the coded abnormality occurred within 30 days of a confirmed abortion.***

73. *Third*, Sage expressed concern that the 2021 Article only considered ER visits for Medicaid patients and not all patients.

(A) By using Medicaid data, the Authors were not only able to collect detailed and reliable data on ER visit trends over time, but they could also collect data on ER visits that occurred within 30 days of an abortion confirmed by a Medicaid claim. No other data source in the United States, including the CDC's Abortion Surveillance Reports, has such detail or reliability due to "voluntary" and "piecemeal" data reporting, "methodological inadequacies," and the "absence of a comprehensive national reporting system of pregnancy outcomes." Ex. B at 2. Moreover, while this data set was limited to a subset of the population, it is common for epidemiological studies—including those that portray abortion in a positive light—to analyze population subgroups and extrapolate findings from those subgroups to the broader population.

(B) Sage expressed concern that Medicaid data might not be "associated with the general population" because Medicaid patients are "generally of poorer health and more likely to have comorbidities and/or

preexisting conditions" and "more likely to visit the ER to seek a smaller co-payment, when eligible."

(C) ***In response, the Authors explained that their Article already disclosed these limitations of the data, stating that "'Medicaid eligible beneficiaries are by definition financially disadvantaged and are not representative of all women experiencing abortion.'"***

74. *Fourth*, Sage expressed concern that the Authors did not "declar[e] in the article" that they "belong[ed] to [the] Charlotte Lozier Institute" or that Dr. James Studnicki was "an Editorial board member of the journal."

(A) ***In response, the Authors explained that they disclosed their affiliation with CLI and the funding support they received from CLI for their research.***

(B) ***The Authors also responded that "publication by editorial board members is not considered a conflict of interest as long as the member is not involved in the review of his/her own paper." The Authors pointed out that it was Sage's express policy that "'[e]ditorial board members should be encouraged to contribute articles to the journal, either by submitting their own work (subject to rigorous peer review) or soliciting articles from their colleagues.'"***

C. Sage acts with bad faith in the retraction process.

75. Sage never replied to the Authors' July 13 response. In fact, Sage never once discussed with the Authors the concerns it had with their Articles, its expression of concern, or its eventual retractions. While Sage sent brief confirmation emails acknowledging the Authors' repeated attempts to discuss the issues, Sage never engaged with the Authors. In a subsequent letter to the Authors' legal counsel, Sage brushed off the Authors' correspondence with Sage as "attempt[s] to dismiss [Sage's] raised concerns without providing sufficient detail to appropriately assess them." In short, after the Authors sent their July 13 response, it was radio silence from Sage.

76. On July 25, 2023, Sage posted an Expression of Concern ("EOC") online stating that Sage had been "alerted to potential issues regarding the representation of data in the article and author conflicts of interest" and that "an investigation is underway." Sage reported that it had "contacted the authors," but it did not acknowledge or describe the Authors' detailed July 13 response.

77. The EOC's negative effect on the Authors' reputation was immediate. Beginning on August 1, 2023, numerous media outlets published articles reporting on the EOC, characterized the Authors as "activists" funded by "powerful anti-abortion political groups," and impugned the Authors' integrity. Sofia Resnick, *Study Cited by Texas Judge in Abortion-Pill Case Under Investigation*, News From The States (Aug. 1, 2023), bit.ly/4b79VMe; *see* Alabama Reflector (Aug. 1, 2023), bit.ly/49YL0tj; Johns Hopkins Population Center (Aug. 2, 2023), bit.ly/4aWmTwH; Kansas Reflector (Aug. 2, 2023), bit.ly/3wdM6Dx; NC Newsline (Aug. 2, 2023), bit.ly/3UmWReM; Nevada Current (Aug. 3, 2023), bit.ly/3UDQDZl; New Jersey

Monitor (Aug. 2, 2023), bit.ly/44kslXv; Tennessee Lookout (Aug. 3, 2023), bit.ly/3UcCbWU; Georgia Recorder (Aug. 9, 2023), bit.ly/3xUdTJU. One interviewee was quoted saying: "'I can't prove that there was intent to deceive, but I struggled to find an alternative reason to present your data in such a way that exaggerates the magnitude.'" *Id.*

78. On August 4, 2023, the Authors wrote to Sage explaining how the media was beginning to "accus[e] our research team of deception and misrepresentation" based on Sage's July 25 EOC. The Authors explained that "[e]very day, as a result of the EOC and the distribution of the defamatory article, damage is being inflicted on the reputation of each member of our professional research group." The Authors asked Sage to "expedite its investigation and announce its findings as soon as possible." Sage never responded to this email.

79. On August 14, 2023, the Authors again wrote to Sage emphasizing how "the mere existence" of the complaint and SAGE's issuance of the EOC were being used "as weapons to undermine the veracity of [their] work and inflict harm on the[ir] reputation." The Authors pleaded with Sage to respond to their communications and "expedite" its review.

80. On August 15, 2023, Sage emailed this response: "Thank you for contacting Sage. I'm acknowledging receipt of your email and will endeavour to send a full response in the next few days. Thank you for your patience." Then, on August 17, Sage sent the Authors a short email informing them that Sage was "unable to provide a timeline" for the completion of the investigation and that Sage was awaiting an

"editorial review of the concerns that were raised" and the additional information that Authors had provided.

81. On October 12, 2023, nearly three months after Sage publicized the EOC, the Authors wrote Sage once again requesting that the investigation be completed, that the EOC be removed, and that Sage issue a "suitable apology" for the reputational harm caused by the EOC. A Sage representative sent a brief email response that she would "obtain an update on the investigation" and "will be in contact again shortly." The Authors did not hear back from her.

82. On October 30, 2023, the Authors sent Sage a follow-up email asking that both "the original complaint" and the Authors' "complete response to the complaint" be published along with the EOC. The Authors emphasized "the accumulating and unwarranted damage to the[ir] reputations … caused by the EOC and Sage's decision to post it without [their] response in full." On November 1, Sage responded that the investigation "is ongoing" and that Sage would "be in touch" as soon as it had an update. Sage never got back in touch with them about this request.

83. Frustrated, Dr. Reardon responded to Sage's November 1 communication inquiring why Sage's investigation involved such "lengthy delays." Dr. Reardon reiterated the Authors' responses to Sage's concerns and reminded Sage that their 2021 Article was "supported by the reviewers and editor." Sage never responded to Dr. Reardon's email.

84. Sage's posting of the EOC on its website has foreseeably resulted in the Authors' ongoing loss of subsequent business and scientific publishing opportunities.

D. Sage expands its retraction to all three of the Authors' Articles on abortion.

85. On November 13, 2023, although the anonymous concern and EOC targeted only the 2021 Article, Sage sent the Authors a Retraction Notice informing them that Sage had decided that *all three Articles* "must be retracted."

86. The November 13 Retraction Notice was the first time Sage had raised *any* issues with the 2019 and 2022 Articles and thus was issued before the Authors had any opportunity to address concerns about them. Because of Sage's persistent bad faith and unfair dealing, the Authors began to communicate with Sage through legal counsel.

87. Sage initially gave the Authors until November 16, or just three days, to respond to the Retraction Notice. Sage extended the deadline to November 29 after receiving a letter from the Authors' counsel, David A. Shaneyfelt, criticizing the "unreasonable, unrealistic, and highly prejudicial" nature of the three-day deadline.

88. Now that a lawyer was involved, Sage finally responded to the Authors on November 21, 2023, with a blistering letter from its attorney Ronni Sander. The letter was defensive and combative, denied any wrongdoing, and even accused the Authors of defamation for challenging Sage's conduct. This letter marked the only time that Sage provided a response of any substance to the Authors' concerns. But the letter did not engage with the Authors on the science or the merits of the EOC or the Notice. Sander invited the Authors to "respond with any new evidence that impacts the underlying retraction decision."

89. The Authors responded to this invitation with a detailed scientific response on November 29, 2023. Sage acknowledged receipt on December 6 but then ignored the response and never responded to it or addressed it.

90. The November 13 Retraction Notice gave three reasons for retraction, none of which show that the Authors violated any provisions of the Agreements or that retraction was warranted under the COPE Guidelines.

91. *First*, Sage claimed that the Authors had failed to declare the "pro-life political advocacy of author affiliations" such as CLI, AAPLOG, and the Elliot Institute in the Declaration of Conflicting Interests. Sage maintained that this failure "undermined the objective editorial assessment of the Articles during the peer review process, violated [Sage's] submission policy and ICMJE [International Committee of Medical Journal Editors] guidance and potentially misled readers."

(A) But the Authors disclosed all of their affiliations and funding sources to Sage before and after the peer-review process, and the Authors fully set forth all affiliations, positions, and funding sources in the published Articles so that readers would be aware of them.

(B) Moreover, neither Sage's Agreements with the Authors nor its submission policy required the Authors to declare the "political advocacy" of their affiliations as conflicts. Sage required only disclosure of "financial" and "commercial" conflicts, potential conflicts, or funding sources. Indeed, Sage routinely publishes articles that do not contain disclosures of the "political advocacy" of the authors' affiliations. *See, e.g.*,

Zelly Marti et al., *Embodied Political Influencers: How U.S. Anti-Abortion Actors Co-Opt Narratives of Marginalization*, Social Media + Society (Apr. 18, 2024), bit.ly/4b9HmxG [3]; Carmela Zuniga et al., *Breaking Down Barriers to Birth Control Access: An Assessment of Online Platforms Prescribing Birth Control in the USA*, J. of Telemedicine & Telecare (Jan. 21, 2019), bit.ly/4b6uSav [4]; Moria Mahanaimy & Heidi Moseson, *The Need for Social Support During Unintended Pregnancy Decision-Making: A Qualitative Analysis of In-Depth Interviews With Young People in California*, Emerging Adulthood (Mar. 14, 2022), bit.ly/3UqbQVq[5]; Stephanie Andrea Küng et al., *Factors Affecting the Persistent Use of Sharp Curettage for Abortion in Public Hospitals in Mexico*, Women's Health (July 15, 2021), bit.ly/44vVOxT[6]; Anuradha Kumar, *Disgust, Stigma, and the Politics of Abortion*,

[3] The authors of a pro-abortion article did not declare their funding from the Open Society Foundations, a 501(c)(3) like CLI, as a conflict of interest, even though the Open Society Foundations was founded by George Soros and donates primarily to progressive causes.

[4] The authors of an article on contraception did not declare their affiliations with Ibis Reproductive Health as a conflict of interest, even though Ibis Reproductive Health "seeks to ensure all people have the right and ability to access safe, affordable, quality abortion care" and uses its research to "advocate" for and "integrate" abortion as a "necessary part of reproductive health care."

[5] The author of a study on the decision-making process of women who experienced unintended pregnancies did not declare an affiliation with Ibis Reproductive Health as a conflict of interest.

[6] The authors of study on abortion methods used in Mexico did not declare an affiliation with Ipas as a conflict of interest, even though Ipas is an NGO with a "singular commitment to expand access to abortion."

Feminism & Psych. (Apr. 19, 2018), bit.ly/3JRl2xa[7]; Jorge Eduardo Sanchez-Morales et al., *Cost Analysis of Surgical and Medical Uterine Evacuation Methods for First-Trimester Abortion Used in Public Hospitals in Mexico*, Health Services Insights (Sept. 23, 2022), bit.ly/4acD1cd[8]; Susheela Singh, *Global Consequences of Unsafe Abortion*, Women's Health (Nov. 1, 2010), bit.ly/4b64E8b[9]; Rachel K. Jones et al., *"I Would Want to Give My Child, Like, Everything in the World": How Issues of Motherhood Influence Women Who Have Abortions*, J. Family Issues (Oct. 16, 2007), bit.ly/4b6R1Wg[10]; Malcolm Potts et al., *Criticism of Misguided Chu et al. Article*, J. Royal Soc'y of Med. (Nov. 1, 2012), bit.ly/3URYId2[11]; Gretchen Sisson & Katrina

[7] The author of a study on the stigma over abortion did not declare affiliation with Ipas as a conflict of interest.

[8] The authors of a cost analysis criticizing the Mexican public health system's "expensive" abortion procedures did not declare affiliation with Ipas as a conflict of interest.

[9] The author of an article on the consequences of unsafe abortion declared "no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript," including "employment," despite her role as Vice President for Global Science & Policy Integration at the Guttmacher Institute, a pro-abortion research and policy organization "committed to advancing sexual and reproductive health and rights worldwide," including "safe abortion care."

[10] The authors of a study demonstrating how "decisions to terminate pregnancies are often influenced by the desire to be a good parent" did not declare an affiliation with the Guttmacher Institute as a conflict of interest.

[11] The authors of an article advocating for the use of misoprostol did not declare an affiliation with the Bixby Center as a conflict of interest, even though the Bixby Center is an organization whose members "believe comprehensive family planning includes access to safe abortion" and designs its research to "increase access by expanding those who provide care and removing barriers to service."

Kimport, *Depicting Abortion Access on American Television, 2005–2015*, Feminism & Psych. (Feb. 1, 2017), bit.ly/3JTLGWf[12]; Aleta Baldwin et al., *U.S. Abortion Care Providers' Perspectives on Self-Managed Abortion*, Qualitative Health Rsch. (Mar. 24, 2022), bit.ly/3ybVJmU[13].

(C) In any event, CLI, AAPLOG, and the Elliot Institute do not engage in "pro-life political advocacy"—so there was nothing for the Authors to declare. These institutions are 501(c)(3)s that perform only educational and research activities. *See, e.g.*, Chuck Donovan, *Scholarship, Not Politics*, Accountability in Rsch. (Apr. 23, 2024), bit.ly/4bm8sC0 (explaining why characterization of CLI's work as "political" is "legally and factually false").

(D) Further, the COPE Guidelines make clear that retraction is not the appropriate action for the failure that Sage alleged. The Guidelines recommend publishing a new conflict of interest statement as an alternative to retraction. The Guidelines also provide that retraction is not appropriate if "[a]uthor conflicts of interest have been reported to the journal after publication, but in the editor's view these are not likely

[12] The author of a study on the "underrepresentation of the difficulty of obtaining abortion care" in American television did not declare an affiliation with Advancing New Standards in Reproductive Health (ANSIRH), which is run by Bixby, as a conflict of interest, even though ANSIRH "envision[s] a world in which all people have the resources, support, and freedom to achieve reproductive wellbeing" and believes that "[a]bortion is an essential part of reproductive health care."

[13] The authors of an article calling for strategies "to expand access to a spectrum of options for medication abortion" did not declare its funding from the Society of Family Planning as a conflict of interest, even though the Society of Family Planning is an organization that advocates for "just and equitable abortion and contraception."

to have influenced interpretations or recommendations, or the conclusions of the article." Ex. H at 3. Sage's practice is to follow these guidelines and at most issue a correction instead of retraction. *See, e.g.*, HSRME, *Correction Notice*, Sage Journals (Aug. 25, 2017), bit.ly/4dJJHBn. Sage has never explained why these alternatives were insufficient, why the drastic measure of retraction was required for the Articles, and why Sage did not follow its own precedent of correcting instead of retracting. In any event, even these alternatives were not warranted because the Authors disclosed their affiliations upon submission.

92. *Second*, Sage claimed that its own peer-review processes for the Articles were flawed. According to Sage, its peer review for each article included a reviewer holding an "honorary affiliation" with CLI "at the time the review was provided." Sage claimed that this alleged conflict "compromised" the entire peer-review process. Sage, however, has not revealed this reviewer's identity to the Authors, preventing them from confirming the veracity of this claim. In any event, Sage's argument fails to justify retraction for several reasons:

(A) A flawed peer-review process is not a basis for retraction under the Agreements.

(B) It is not a basis for retraction under the COPE Guidelines, either. Even if the inclusion of the CLI-affiliated reviewer somehow tainted the peer-review process, the fault lies with Sage, not the Authors. It would

thus be inappropriate to punish the Authors with retraction instead of simply posting a notice of Sage's own failures.

(C) Including a CLI-affiliated reviewer in a peer-review process of an article written by CLI-affiliated researchers does not compromise the process. Sage, who selected and vetted the reviewer, uses a "double-anonymized peer review" for all research submissions. Neither the Authors nor the reviewer was aware of the other's identities. And the mere fact that a reviewer has connections to an organization that is concerned about abortion safety does not mean that the reviewer is unable to objectively review research concerning abortion or unconcerned about the robustness and reliability of the analysis.

(D) Sage used multiple peer reviewers for each article, and the CLI-affiliated reviewer reached the same conclusion as the other, non-affiliated reviewers: that the Articles were quality scholarship and should be published.

(E) Finally, the Authors are unaware of Sage applying this standard in other contexts—for example, by disqualifying reviewers affiliated with pro-abortion organizations from reviewing papers with findings favorable to pro-abortion organizations' policy objectives.

93. *Third*, Sage claimed that there were fundamental problems "with the study design, methodology, assumptions about healthcare indicators and analyses, such that the conclusions may not be adequately supported by the results."

(A) None of this is true, but errors in methodology, assumptions, data analysis, data presentation, and scientific opinion are not justifications for retraction under the Agreements regardless. At most, per COPE Guidelines, any perceived errors merited a correction or post-publication amendment.

(B) Moreover, Sage's post-publication review was pretextual and done in bad faith. It was improper, unscientific, and performed with the express purpose of justifying retraction—that is, of giving a patina of legitimacy to Sage's biased precommitment to retract the Authors' Articles. Sage did not even let the Authors review and respond to the reviewers' comments. Instead, Sage provided the Authors with only excerpts of the reviewers' comments, and only after Sage informed the Authors that it was moving forward with retraction.

(C) Nothing in the Agreements authorized post-publication review.

(D) Unlike the original peer review, Sage's post-publication review was biased from the start. Sage specifically hired "[t]wo subject matter experts" to determine whether an article that had already satisfied peer review was flawed. These reviewers knew that Sage wanted them to find (or manufacture) any errors that they could, and they knew what Sage wanted—retraction. And Sage provided no assurance that they were unbiased and unaffiliated with pro-abortion organizations.

(E) Contrary to standard practice, the Authors were not provided with the opportunity to respond to the post-publication reviewers or address any concerns before Sage issued its retraction notice.

(F) Sage's contrived post-publication review also did not produce any findings that warranted retraction under the COPE Guidelines. The reviewers did not explicitly challenge, let alone invalidate, a single specific finding in any of the three Articles. Nor did they allege—much less provide evidence—that the Authors' findings were unreliable under the COPE Guidelines, "either as a result of major error (eg, miscalculation or experimental error), or as a result of fabrication (eg, of data) or falsification (eg, image manipulation)." Ex. H at 2. Moreover, the Authors' results are replicable and accurately reported, and the COPE Guidelines state that retractions are "not usually appropriate" if "[t]he main findings of the work are still reliable and correction could sufficiently address errors or concerns." *Id.* at 3.

94. As noted, on November 29, 2023, the Authors provided Sage with a detailed, scientific response to the Notice that empirically and objectively addressed each of the post-publication reviewers' concerns and confirmed the scientific validity of the Authors' underlying findings. *See* Letter from David Shaneyfelt to Ronni Sander (Nov. 29, 2023), bit.ly/3wdh92m. To this day, Sage has never responded to the Authors' scientific rebuttal of the post-publication reviewers.

E. Sage removes the lead author of the Articles, Dr. James Studnicki, from HSRME's editorial board.

95. On November 14, 2023, the day after Sage issued its Retraction Notice, Dr. Gregory M. Garrison, HSRME's Editor-in-Chief, emailed the lead author of the Articles, Dr. James Studnicki, removing him from the HSRME editorial board.

96. Dr. Studnicki's termination came without any notice, conversation, or expression of dissatisfaction, from Dr. Garrison or anyone else, about Dr. Studnicki's service during his four years on the board.

97. In his email, Dr. Garrison cited "the decision to retract [the Articles]" as the reason for Dr. Studnicki's removal. According to Garrison, the retractions meant Dr. Studnicki could no longer "uphold the highest standards of quality and integrity in scholarly publishing." But the retractions had not yet been finalized; they were based on reasons that were pretextual; and they were issued without giving the Authors a chance to respond. In reality, Sage terminated Dr. Studnicki for the same reason it retracted the Authors' Articles—political bias and discrimination against persons whom Sage perceived to be pro-life or advancing pro-life views or causes, or else affiliated with organizations that Sage perceived to be pro-life or advancing pro-life views or causes.

F. Sage retracts the Articles.

98. On February 5, 2024, Sage officially retracted the Articles.

99. Sage posted the retractions on its website, along with an additional public notice that the Articles had been retracted because Sage identified "unsupported assumptions" and "misleading presentations of the findings" that

demonstrate "a lack of scientific rigor" and "render the authors' conclusion unreliable." Sage also cited the same flawed reasoning that it provided to the Authors in November. By using inflammatory language to describe its reasoning, such as saying that the Articles were "misleading" and "demonstrate[d] a lack of scientific rigor," Sage violated the COPE Guidelines yet again. *See* Sage Perspectives, *A Note From Sage on Retractions in Health Services Research and Managerial Epidemiology*, (Feb. 5, 2024), bit.ly/4k1fSj1 (using similar inflammatory language).

100. Contrary to standard industry practice under the COPE Guidelines, Sage made no effort to negotiate with the Authors on the wording of the Retraction Notice. Indeed, Sage never addressed or even acknowledged the Authors' November 29 scientific response detailing how Sage's methodological concerns did not "explicitly challeng[e]," let alone "invalidat[e]" a "single specific finding in any of the three papers" and failed to provide "evidence of a major error, miscalculation, fabrication, or falsification." Moreover, the February 5 Retraction Notice that Sage eventually published on its website had substantially different language than the November 13 Notice that Sage initially shared with the Authors. For example, the November 13 Notice admitted that Sage's statistical expert determined that the Authors' dual y-axis chart in the 2021 Article was "not unusual." But this important admission was not included in the public-facing February 5 Notice.

101. On February 6, 2024, contrary to standard industry practice under the COPE Guidelines, as well as its Publishing Agreements with the Authors, Sage removed the original versions of the Articles from its website. *See* Ivan Oransky,

Papers Used by Judge to Justify Abortion Pill Suspension Retracted, Retraction Watch (Feb. 6, 2024), bit.ly/4gM4pAY.

VII. Sage's actions cause incalculable harm to the Authors' reputations as professional researchers and objective scientists.

102. The harm caused by Sage's July 25 EOC, Sage's retraction of all three Articles, and Sage's publicization of its pretextual claims about the Authors and their scientific work, was profound, immediate, and foreseeable. Because the mifepristone litigation was ongoing, the media, litigants, and judges immediately noticed and discussed the retractions, touting them as proof that the case against mifepristone was scientifically flawed.

103. Various news outlets reporting on the retractions referred to the Articles as "junk science." *See* Jessica Glenza, *How Rightwing Groups Used Junk Science to Get An Abortion Case Before the US Supreme Court*, The Guardian (Mar. 23, 2024), bit.ly/3Wlg6YT; Nicole Karlis, *Three "Junk Science" Abortion Pill Studies Were Just Retracted. Will the Supreme Court Notice?*, Salon (Feb. 8, 2024), bit.ly/4dmPUTV; Michael Hiltzik, *Column: Two Key Antiabortion Studies Have Been Retracted As Junk Science. Will the Supreme Court Care?*, Los Angeles Times (Feb. 8, 2024), lat.ms/3UEqAkM (also reported in the Hawaii Tribune Herald (Feb. 10, 2024), *see* bit.ly/3UQ8fkN); Angie Jaime, *Republicans Move to Restrict Abortion Pill with 'Zombie Law' and 'Junk Science'*, Teen Vogue (Mar. 4, 2024), bit.ly/49XeVSK; Andrew Chung, *US Supreme Court Abortion Pill Fight Brings Claims of Distorted Science*, Reuters (Mar. 25, 2024), reut.rs/4aVoEdl; Madison Pauly, *The Supreme Court Abortion Pill Case Is Based on Imaginary Patients and Shoddy Science*, Mother Jones

(Mar. 25, 2024), bit.ly/4dcPvmV; Josh Numainville, *5th Circuit Used 'Junk Science' in Abortion Drug Ruling, Brief Tells SCOTUS*, 31 No. 11 Westlaw J. Health Law 05 (Feb. 2, 2024); *see also* Ja'han Jones, *Conservative Judge Relied on Now-Retracted Studies to Outlaw Mifepristone*, MSNBC (Feb. 7, 2024), on.msnbc.com/3D0OG3h (calling the studies "pseudoscientific").

104. Most of the coverage quoted Sage's unsubstantiated claims in the Retraction Notice that the Articles had "fundamental problems," "misleading presentations of the data," and a "lack of scientific rigor."

105. On February 23, 2024, *The Hill* published an opinion piece entitled "Why a Flawed Study on Medication Abortion Was Retracted," by members of the Guttmacher Institute, a pro-abortion advocacy organization. *See* Rachel K. Jones & Kelly Baden, *Why a Flawed Study on Medication Abortion Was Retracted*, The Hill (Feb. 23, 2024), bit.ly/3w4PEIr. The piece lauded Sage for its "justified" retraction of the Authors' "unsound science." *Id.* It further connected the Articles and the Authors to the promotion of "[f]aulty science … to attack not just Americans' right to health care and bodily autonomy, but also to undermine the integrity of the scientific process and our entire judicial system." *Id.*

106. Professor Chris Adkins, the pro-abortion advocate who made the initial anonymous complaint to Sage that precipitated the retraction, and Professor Ushma Upadhyay, who had openly criticized the Authors and their Articles in the press, were emboldened by the retraction. In March, they published their own analysis of the Articles, accusing the Authors of "[d]eception." Chris E. Adkins & Ushma D.

Upadhyay, *Deception by Obfuscation: Studnicki et al.'s Retracted Longitudinal Cohort Study of Emergency Room Utilization Following Abortion*, Contraception (Mar. 16, 2024), bit.ly/3wp4NEi. Adkins and Upadhyay alleged that the Authors "obfuscated and misrepresented" the safety of medication abortion with mifepristone. *Id.*

107. Other media outlets accused the Authors of deception. In June 2024, *The Washington Post* published a piece about the retractions stating that the Articles' "findings were presented in … deceiving ways." Katelyn Jetelina & Heidi Moseson, *A Scientific Controversy at the Supreme Court*, The Washington Post (June 10, 2024), bit.ly/413liRS. The piece also insinuated that the Articles must have been seriously flawed. *Id.* ("Removing a published article from a scientific journal doesn't happen because of some small error. It's unusual for a paper to be retracted.").

108. Sage's retraction even made waves at the U.S. Supreme Court during oral argument in *FDA v. Alliance for Hippocratic Medicine*. Jessica L. Ellsworth, counsel for Petitioner Danco Laboratories, quoted verbatim Sage's inflammatory language in its public retraction notice, telling the Court that the Articles had been retracted for "lack of scientific rigor and for misleading presentations of data." Tr. of Oral Arg. at 59, *FDA v. All. for Hippocratic Med.*, No. 23-235 (Mar. 26, 2024), bit.ly/4i7isCp. Ms. Ellsworth added that the "errors" in the studies "can infect judicial analyses." *Id.*

109. During oral argument, Justice Ketanji Brown Jackson noted her concern that the lower courts had relied on the Authors' studies that have since been found to be "discredited and removed." *Id.* at 99.

110. The media coverage of the retractions picked up again following the oral argument. In June 2024, *The Wall Street Journal* published an article titled "Antiabortion Lawsuits Leaned on Discredited, Disputed Research." Nidhi Subbaraman, *Antiabortion Lawsuits Leaned on Discredited, Disputed Research*, The Wall Street Journal (June 18, 2024), bit.ly/4bdw6S7. The piece cited the retractions and highlighted that the Authors' articles had been "disputed, disavowed[,] [and] subsequently retracted." *Id.*

111. This highly publicized retraction has foreseeably resulted in the ongoing loss of subsequent business and scientific publishing opportunities.

112. For example, on March 26, 2024, medRxiv, a free online archive and distribution server for complete but unpublished, non-peer-reviewed manuscripts ("preprints") in the medical, clinical, and related health sciences, refused to post one of the Authors' manuscripts, "*Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004–2015*." Such rejections are unheard of for researchers with the Authors' well-earned reputations as researchers and scientists.

113. On April 9, 2024, the Online Journal of Public Health Informatics rejected the same manuscript, citing "methodological weaknesses" and the "major conflict of interest" that the Authors are affiliated with AAPLOG, which espouses the

"religious belief" that "human life begins at the moment of fertilization." But the rejected study did not deal with, or depend on, any conclusion regarding when human life begins. It examined Medicaid claims data to identify pregnancy outcomes (*i.e.* birth, chemical abortion, or surgical abortion), the Current Procedural Terminology (CPT) acuity code assigned to the outcome, and any emergency department visits within 30 days of a pregnancy outcome to analyze the influence of a pregnancy outcome on the likelihood of an emergency department visit as well as the relative acuity of visits following different outcomes. The Online Journal's reasons were thus entirely pretextual—and similar to the reasons HSRME used in its retraction. When the Authors objected, the Online Journal responded by quoting the Retraction Notice, specifically the language alleging the "defects in the selection of the cohort data," and how the Authors' affiliations with "pro-life advocacy organizations, including Charlotte Lozier Institute," present conflicts of interest. The HSRME retraction has thus encouraged and created a template for other journals to refuse to publish the Authors' scholarly work.

114. Similarly, on April 22, one of the Authors, Dr. Reardon, received an email from the journal BMC Women's Health, rejecting his research article studying the prevalence and effects of unwanted abortions in Canada. To support the rejection, the journal cited Dr. Reardon's "multiple studies retracted in the past."

115. These rejections are just the tip of the iceberg and reveal the enormous and incalculable harm that Sage's retraction has inflicted on the Authors' reputations and their ability to publish research and scholarship. Journal editors, who are less

likely to publish authors with retracted articles, can use an online database operated by Retraction Watch to search for the Authors' names and identify any past articles they have written that were retracted. *See* Retraction Watch Database, bit.ly/3D5elaU. Searching the term "Studnicki" immediately identifies all three retracted articles and lists the reasons for the retractions, including: "Bias Issues or Lack of Balance," "Concerns/Issues About Data … [and] Results," "Conflict of Interest" "Error in Analyses … Data … [and] Results and/or Conclusions," and "Unreliable Data … [and] Results." *Id.* Thus, these retractions will adversely affect the Authors every time they submit a new article to a journal and the journal editors review their retraction history.

116. Because of their vast experience and knowledge, some of the Authors also provide compensated consulting services in their areas of expertise, such as serving as expert witnesses. But the retractions undermine these and other professional opportunities.

117. As scientists, the Authors' credibility is their lifeblood. The retractions themselves and their subsequent publicization have destroyed the Authors' hard-earned professional reputations. Only rescission of the retraction—in accordance with the terms of the Agreements—can remedy the ongoing harms to the Authors' credibility as professionals and objective scientists.

JURISDICTION

118. The Agreements provide that "[a]ny controversy or claim arising out of or relating to this Agreement, or the breach thereof, which the parties cannot settle

themselves or through mediation, shall be settled by arbitration." Ex. E at 3; Ex. F at 3; Ex. G at 3.

119. On October 3, 2024, the Authors filed a Petition to Compel Arbitration in the Superior Court of the State of California for the County of Ventura pursuant to the Agreements. *See Studnicki v. Sage Publ'ns Inc.*, 2024CUPA031167 (Cal. Sup. Ct.). The Agreements provide that "[t]he validity, interpretation, performance[,] and enforcement of this Agreement shall be governed ... where the Journal is published by Sage's offices in the United States, by the laws of the State of California and subject to the jurisdiction and venue of the courts of the State of California located in Ventura County." Ex. E at 3; Ex. F at 3; Ex. G at 3.

120. On November 21, 2024, Judge Ronda McKaig granted the Authors' Petition. The order is attached as Exhibit I.

121. On January 31, 2025, pursuant to Cal.C.C.P. §1281.6, the Court appointed Judge Vincent J. O'Neill to serve as the arbitrator of the parties' dispute. The order is attached as Exhibit J.

CONDITIONS PRECEDENT TO FILING ACTION

122. The Authors have complied with all required conditions precedent before filing this action.

123. The Authors have complied with the provision of the Agreements requiring the parties to "first make a good-faith effort" to resolve among themselves a dispute arising out of or relating to the Agreements. Ex. E at 3; Ex. F at 3; Ex. G at 3.

124. The parties have agreed to waive the Agreements' mediation

prerequisite requiring that the parties "shall engage in non-binding mediation." *Id.*

125. The Superior Court of California for the County of Ventura has ordered the parties to submit the Authors' claims to binding arbitration with Judge Vincent J. O'Neill. Ex. J.

LEGAL CLAIMS

FIRST CLAIM
(BREACH OF CONTRACT)

126. The Authors incorporate by reference the factual allegations of the preceding paragraphs as though fully restated herein.

127. On March 6, 2019, October 11, 2021, and May 10, 2022, the Authors and Sage entered into Agreements under which Sage agreed to publish three Articles written by the Authors in HSRME and confer on the Authors a Creative Commons Attribution-NonCommercial license (CC BY-NC 4.0). These agreements are binding contracts. The Agreements were both reasonable and supported by adequate consideration.

128. Pursuant to the Agreements, Sage was prohibited from retracting the Articles unless the Authors violated the Agreements.

129. The Authors performed all conditions, covenants, and promises required on their part in accordance with each Agreement, except for any conditions which the Authors were prevented or relieved from performing by the acts and omissions of Sage.

130. Sage breached the Agreements by (1) retracting the Authors' Articles on terms and for reasons other than those permitted by the Agreements; (2) conducting

a post-publication review of the Articles; and (3) failing to honor its obligations to continue to publish the Authors' Articles. Sage's failure to perform its obligations under the Agreements constituted a material breach thereof.

131. As a direct and proximate result of Sage's contractual breaches, the Authors suffered direct financial losses in an amount to be proven at the Hearing.

132. As a direct and proximate result of Sage's contractual breaches, the Authors have been harmed through loss of their reputation as credible scientists, public acclaim, goodwill, and business opportunities. The full extent of this harm is difficult, if not impossible to calculate. As such, there is no adequate remedy at law available to fully compensate the Authors for their losses caused by Sage's breach.

133. Based on Sage's breach of the Agreements, the Authors request specific performance of the Agreements, namely, that the Arbitrator, consistent with Sage's express promise under the Agreements to not retract the Articles without authorization, order Sage to rescind the retractions.

SECOND CLAIM
(BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING)

134. The Authors incorporate by reference the factual allegations of the preceding paragraphs as though fully restated herein.

135. On March 6, 2019, October 11, 2021, and May 10, 2022, the Authors and Sage entered into Agreements under which Sage agreed to publish three Articles written by the Authors in HSRME and confer on the Authors a Creative Commons Attribution-NonCommercial license (CC BY-NC 4.0). These agreements are binding

contracts that are reasonable and supported by adequate consideration, and they contain an implied covenant of good faith and fair dealing.

136. The Agreements gave Sage discretion to take corrective action, including retraction, in the limited circumstances when a violation of the Agreements occurred. Sage had a duty to exercise this discretion in good faith and through objectively reasonable conduct.

137. In addition to breaching its express contractual obligations to the Authors, Sage also acted in a manner that demonstrates bad faith and unfair dealing through a failure or refusal to discharge its contractual responsibilities, an unfair frustration of the agreed common purposes of the Agreements, and an interference with the reasonable expectations of Authors—all of which deprived the Authors of the benefits of the Agreements. These actions include, but are not limited to, the following:

(A) Deciding to retract the Articles—and ruling out any lesser measures, such as correction—before it even began the retraction process;

(B) Providing pretextual reasons for the EOC and retraction notice;

(C) Refusing to communicate with the Authors during the EOC and retraction process;

(D) Publicly posting the EOC and retraction without referencing or including the Authors' scientific rebuttals; and

(E) Violating the COPE Guidelines to which Sage had bound itself, including by failing to negotiate with the Authors on a form of wording of the retraction notice that is "clear and informative to readers and acceptable to all parties," using inflammatory language in the retraction notice, and removing the retracted Articles from the publisher's website.

138. As a direct and proximate result of Sage's breaches of the implied covenant of good faith and fair dealing, the Authors suffered direct financial losses in an amount to be proven at the Hearing.

139. As a direct and proximate result of Sage's breach, the Authors have been harmed through the loss of their reputation as credible scientists, public acclaim, goodwill, and business opportunities. The full extent of this harm is difficult, if not impossible to calculate. As such, there is no adequate remedy at law available to fully compensate the Authors for their losses caused by Sage's breach.

140. Based on Sage's breach of the Agreements, the Authors request specific performance of the Agreements, namely, that the Arbitrator, consistent with Sage's express promise under the Agreements to not retract the Articles without authorization, order Sage to rescind the retractions.

THIRD CLAIM
(NEGLIGENT MISREPRESENTATION)

141. The Authors incorporate by reference the factual allegations of the preceding paragraphs as though fully restated herein.

142. As part of the Agreements between the Authors and Sage, Sage promised to conduct a peer-review process for each Article in a thorough and

definitive manner before publication and to make publication decisions based on the results of its peer review. Sage had a duty to not misrepresent the quality and reliability of this peer-review process.

143. Sage informed the Authors before the Authors entered the Agreements that the peer-review process was properly conducted and offered to publish the Articles on that basis.

144. The Authors, justifiably relying on Sage's representations about its peer-review process, agreed with Sage to publish their 2019, 2021, and 2022 Articles with HSRME.

145. Sage later retracted the Authors' 2019, 2021, and 2022 Articles based on the claim that its peer review was flawed due to Sage selecting an associate scholar of CLI as one of the double-blind reviewers.

146. If Sage's claim about the flawed nature of the peer-review process is true, then Sage had no reasonable grounds to believe that the peer review was properly conducted when it made that representation to the Authors. Sage was fully aware of the Authors' affiliation with CLI before conducting the peer review and selecting the reviewers. Sage thus misrepresented the quality and reliability of the peer-review process to induce the Authors to agree to publish their Articles in HSRME.

147. Sage's retraction caused the Authors to suffer direct financial losses and damaged the Authors' reputation and careers as credible scientists, public acclaim, goodwill, and business opportunities, in an amount to be proven at the Hearing.

FOURTH CLAIM
(NEGLIGENCE)

148. The Authors incorporate by reference the factual allegations of the preceding paragraphs as though fully restated herein.

149. As the publisher of the Articles, Sage owed the Authors a duty of care to properly conduct the peer-review process, to exercise reasonable care when handling complaints about the Articles, to conform any investigation or corrective action to publishing industry standards as outlined by the COPE Guidelines, to communicate with the Authors and update them as to the progress of the EOC and retraction investigation, and to timely respond to the Authors' questions and complaints.

150. Sage breached these duties as set forth above by, among other things:

(A) Failing to conform its investigation of the Articles and its responsive actions to the COPE Guidelines, including by: misconstruing the data and findings set forth in the Articles; improperly taking any corrective action; ruling out any lesser measures; deciding to retract the Articles before Sage even began the retraction process; giving pretextual reasons for the EOC and the retractions; publicly posting the EOC and retractions without referencing or including the Authors' scientific rebuttals; failing to communicate with the Authors about the wording of the retraction notice; using inflammatory language in the retraction notice; and removing the retracted Articles from the publisher's website;

(B) Refusing to communicate with the Authors during the EOC and retraction investigation, as well as after the retraction decision; and

(C) Failing to properly evaluate the Articles and the Authors' affiliations, including without limitation by directing a flawed post-publication peer-review process.

151. Sage retracted the Authors' 2019, 2021, and 2022 Articles based on its claim that its peer-review process was flawed due to Sage selecting an associate scholar of CLI as one of the double-blind reviewers.

152. If Sage's claim about the flawed nature of the peer-review process is true, then Sage breached its duty to the Authors by failing to conduct the peer-review process with reasonable care before publication of the Articles.

153. Sage's EOC and retraction caused the Authors to suffer direct financial losses and damaged the Authors' reputation and careers as credible scientists, public acclaim, goodwill, and business opportunities, in an amount to be proven at the Hearing.

FIFTH CLAIM
(VIOLATION OF THE UNRUH CIVIL RIGHTS ACT,
CAL. CIV. CODE §51, *ET SEQ.*)

154. The Authors incorporate by reference the factual allegations of the preceding paragraphs as though fully restated herein.

155. The Unruh Act prohibits invidious discrimination in all business establishments. *See* Cal. Civ. Code §51(b). That includes discrimination based on religion or political affiliation or a "perception" of religion or political affiliation.

156. The Unruh Act defines "religion" to include "all aspects of religious belief, observance, and practice." Cal. Civ. Code §51(e)(4).

157. Discrimination based on "religion" also includes discrimination based on the "perception" that a person is religious or that the person is associated with a person who is, or is perceived to be, religious. Cal. Civ. Code §51(e)(6). It also includes discrimination based on the "perception" that a person holds a political affiliation or is associated with a person who holds, or is perceived to hold, a political affiliation.

158. Therefore, Sage could not discriminate against the Authors based on a perception that the Authors held pro-life views, that their Articles advanced pro-life views or causes, or that they were affiliated with organizations that held or advanced pro-life views or causes.

159. But from the moment Sage received an anonymous complaint about the "pro-life political advocacy" of the Authors and their affiliations, Sage decided that it would treat the Authors unequally based on its perception that the Authors held pro-life views, that their Articles advanced pro-life views or causes, or that the Authors were affiliated with organizations that held or advanced pro-life views or causes.

160. Sage has not and does not investigate or retract articles about abortion written by authors it perceives to be pro-abortion, advancing pro-abortion views or causes, or affiliated with entities that espouse pro-abortion views or engage in pro-abortion political advocacy.

161. Sage has not and does not remove individuals from its journal editorial boards whom it perceives to be pro-abortion, advancing pro-abortion views or causes, or affiliated with entities that espouse pro-abortion views or engage in pro-abortion political advocacy.

162. Sage breached the Agreements and breached the implied covenant of good faith and unfair dealing based in part on its perception that the Authors held, advanced, or affiliated with those who held or advanced pro-life views or causes.

163. By retracting the Articles and engaging in bad faith and unfair dealing based on the Authors' perceived pro-life views, activities, or affiliations, Sage denied the Authors full and equal services and discriminated against the Authors on the basis of a perception of religion and/or political affiliation.

164. Sage's retraction of the Articles is thus religious and political affiliation discrimination in violation of California Civil Code §51(b).

165. Sage's removal of Dr. Studnicki from HSRME's Editorial Board is also religious and political affiliation discrimination in violation of California Civil Code §51(b) for the same reasons.

166. Sage's retraction caused the Authors to suffer direct financial losses and damaged the Authors' reputation and careers as credible scientists, public acclaim, goodwill, and business opportunities.

167. Sage's discriminatory practices caused the Authors considerable harm, including reputational harm. Therefore, the Authors seek compensatory relief, injunctive relief, and statutory damages under the Unruh Act in the amount of $4,000 for each instance of discrimination, in an amount to be proven at the Hearing.

RELIEF REQUESTED

168. For the reasons stated here and those to be presented during the Hearing, the Authors respectfully request an award granting the following relief:

(A) A declaration that Sage's retractions of the Authors' Articles breached Sage's Agreements with the Authors;

(B) A declaration that Sage's retractions of the Authors' Articles breached the implied covenant of good faith and fair dealing;

(C) A declaration that Sage was negligent in its handling of the investigation and retractions and failed to conform its investigation and retractions to publishing industry standards as outlined by the COPE Guidelines;

(D) A declaration that Sage's retractions of the Authors' Articles violated the Unruh Act;

(E) A declaration that Sage's removal of Dr. Studnicki from the board of HSRME violated the Unruh Act;

(F) An injunction requiring Sage to rescind the retractions;

(G) An award of monetary damages, including, but not limited to, money damages for costs and fees incurred in publishing the Articles, damage to reputation and careers as credible scientists, loss of public acclaim, loss of goodwill, and loss of business opportunities, and an award of $4,000 in statutory damages under the Unruh Act for each instance of Sage's discrimination, in an amount to be proven at the Hearing;

(H) Attorneys' fees and arbitration costs; and

(I) Such other and further relief as the Arbitrator may deem just and proper.

Dated: February 21, 2025

Respectfully submitted,

/s/ Philip A. Sechler

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CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2025, this Demand for Arbitration was served upon the Respondents via email, as follows:

Caroline Petro Gately
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Attorneys for Respondent

Dated: February 21, 2025

/s/ Steven C. Begakis
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EXHIBIT A

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SAGE

Doctors Who Perform Abortions: Their Characteristics and Patterns of Holding and Using Hospital Privileges

James Studnicki[1], Tessa Longbons[1], John W. Fisher[1], Donna J. Harrison[2], Ingrid Skop[2], and Sharon J. MacKinnon[1]

Abstract

Controversy exists regarding whether doctors who perform abortions should be required to hold hospital admitting privileges, but no research exists as to the extent to which they actually hold and use such privileges. Extensive Internet and government data sources were used to identify and verify abortionists in Florida. All medical and osteopathic abortion doctors who were licensed to practice at any time during the period 2011 to 2016 were included in the study (n 85). Every abortionist hospital admission of a female patient aged 15 to 44 occurring during the 6-year study period was identified (n 21 502). Abortionist physicians are 74.1% male, 62% have been in practice for 30 years or longer, 27.1% are graduates of foreign medical schools, and 55.3% are board certified. Nearly half (48.2%) of the abortionists had at least 1 malpractice claim, public complaint, disciplinary action, or criminal charge. Half (50.6%) of the abortionists reported hospital privileges, but only 32 (37.6%) admitted at least 1 patient to a hospital. Seven physicians accounted for 68.2% of all the admissions, and 79.6% of all admissions were related to a live birth. Black was the modal race (47.6%) and Medicaid the most frequent (64.9%) pay source. Nearly one-fifth (19.4%) of admissions came through the emergency department. Physicians who hold hospital privileges are significantly ($P < .05$) more likely to be board certified and to be approved for Medicaid payment than their colleagues without privileges. Of those doctors who hold and use hospital privileges, the lowest admission volume physicians are significantly less likely to be involved in live births, more likely to admit commercially insured and white inpatients, and much more likely to use the emergency room as the route to hospital admissions for their Medicaid-eligible and black patients. Further study of abortionist physicians is indicated regarding their heterogeneous personal and professional characteristics; their career pathways and practice concentrations; their relative integration with or isolation from peers and the professional network; the importance of black and poor induced abortion patients in their total caseload; and, especially for abortionists without hospital privileges, the means by which their patients requiring emergency care and hospitalization are accommodated.

Keywords

hospital privileges, abortionist physicians, emergency room admissions, racial disparities, emergency visits

Introduction

Hospital Privileges, Abortion, and the Need for Research

Within the past few years, a number of state laws were enacted which required that physicians who provide abortions have admitting privileges at a hospital within 30 miles of the location of abortion. The justification offered by proponents of this legislation was that it would reduce the risk factor for patients who had potentially deadly complications during or after an abortion by expediting their emergency treatment and admission, if necessary, at a hospital. Opponents of these state laws argued, by contrast, that admitting privileges were medically unjustified largely based upon the opinion that abortion was a relatively safe procedure and that adverse events requiring a

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hospital admission or emergency department (ED) visit were rare.[1,2] From a research perspective, it is clear that findings concerning the incidence and outcomes of abortion complications remain inconclusive, largely because of the demonstrably inadequate systems of abortion certification and reporting in the United States.[3] Research from Finland and Denmark, countries with comprehensive systems for reporting abortions and other pregnancy outcomes, concluded that there is a 4 times greater risk of mortality following abortion than childbirth.[4,5] These findings contrast with the often-referenced conclusion that childbirth-related mortality is 14 times that of abortion.[6]

Similarly, no research exists on the comparative outcomes of women who experience complications of an induced abortion performed by providers with and without hospital admitting privileges. More fundamentally, there has been no research at all on the extent to which abortionists actually hold and use hospital privileges. In particular, the question of whether and how often abortion doctors utilize the ED as a pathway to hospital admission is relevant to the legal issue of requiring privileges for abortionists.

The objectives of this analysis, therefore, were to describe the characteristics of physicians who perform induced abortions and to describe the extent to which they hold and use hospital admitting privileges, with an emphasis on the involvement of the ED in the admission. Specific foci of the analyses were on the differences in physicians with and without privileges and the differences in patient and practice characteristics associated with the volume of hospital admissions accounted for by each doctor. In a domain with literally no preceding research, this analysis was intended to explore and formulate important research questions and to inform the design and data needs of future hypothesis testing studies.

There is a broad professional consensus that the process of credentialing and hospital privileging for physicians enhances their competency and the quality of care rendered to patients. Hospital admitting privileges are obviously essential for surgeons who require the necessary technology, personnel, and support services found in the inpatient setting to practice their specialty. Many insurance companies require that a physician hold admitting privileges as a condition of participation in their provider networks.[7] The benefits of obtaining hospital privileges do not, however, accrue only to those physicians who practice exclusively within the inpatient setting. The American College of Surgeons and the American Medical Association produced 10 core principles for patient safety for office-based surgery and practice. The principles were approved by more than 3 dozen interested parties including the major accrediting organizations for ambulatory and office-based surgery (Joint Commission on the Accreditation of Healthcare Organization, Accreditation Association for Ambulatory Health Care, Inc, American Association for Accreditation of Ambulatory Surgical Facilities, Inc); surgical and medical specialty societies, including the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine; and various state medical associations (Massachusetts, New York, Kansas, Indiana, and Missouri). Two of the 10 core principles relate directly to the process of securing and maintaining hospital admitting privileges. Core principle No. 4 states that "physicians performing office based surgery must have admitting privileges at a nearby hospital . . . or a transfer agreement with another physician who has admitting privileges at a nearby hospital." Core principle No. 8 states that "a physician may show competency by maintaining core privileges at an accredited licensed hospital or ambulatory surgery center."[8] Finally, it is clear that hospital privileges are valued and sought in some form not only by physician–surgeons but also by nonsurgical primary care physician–practitioners such as family practice doctors, and even by nonphysician practitioners such as psychologists, optometrists, nurse-midwives, and others.[9-11] Hospital privileges also provide an opportunity for physicians to gain access to important diagnostic and treatment technology as well as a diverse network of provider specialists, which should enable each privileged physician to play a more complete and integrated role in optimizing the care delivered to each patient.

Methods

Abortion Physician Identification, Verification, and Inclusion Process

Abortionist physicians licensed in Florida between 2011 and 2016 were selected for the study using a 3-step process (Figure 1). First, a complete list of Florida abortion facilities was compiled using lists published by the Florida Department of Health (FDoH) and organizations interested in abortion provision. Second, the websites of these facilities were checked for physician names and Internet searches were performed to find physicians associated with the facilities. Third, each physician was associated with abortion by at least 2 different sources and then each physician's FDoH practitioner profile was checked to ensure that he or she was a medical doctor or osteopathic physician who was licensed in Florida between 2011 and 2016. Physicians who self-identified as board certified by the American Board of Obstetricians and Gynecologists (ABOG) were validated by the ABOG Diplomate Verification Search System.

The Florida Practitioner Profile

The primary source of physician characteristics for this analysis is the Florida Practitioner Profile (FPP), maintained by the Division of Medical Quality Assurance. Required by law since 1997, all medical doctors; osteopathic, chiropractic, and podiatric physicians; and licensed advanced registered nurse practitioners must report their profiles. Data elements residing in the FPP include practice address; participation in Medicaid; hospitals and other provider facilities at which the doctor holds privileges; other state licensures; year licensed in any jurisdiction; education and training, including postgraduate and professional (including dates); specialty certification; and proceedings and actions such as medical sanctions and termination, criminal offenses, and disciplinary actions undertaken against them by various organizations.

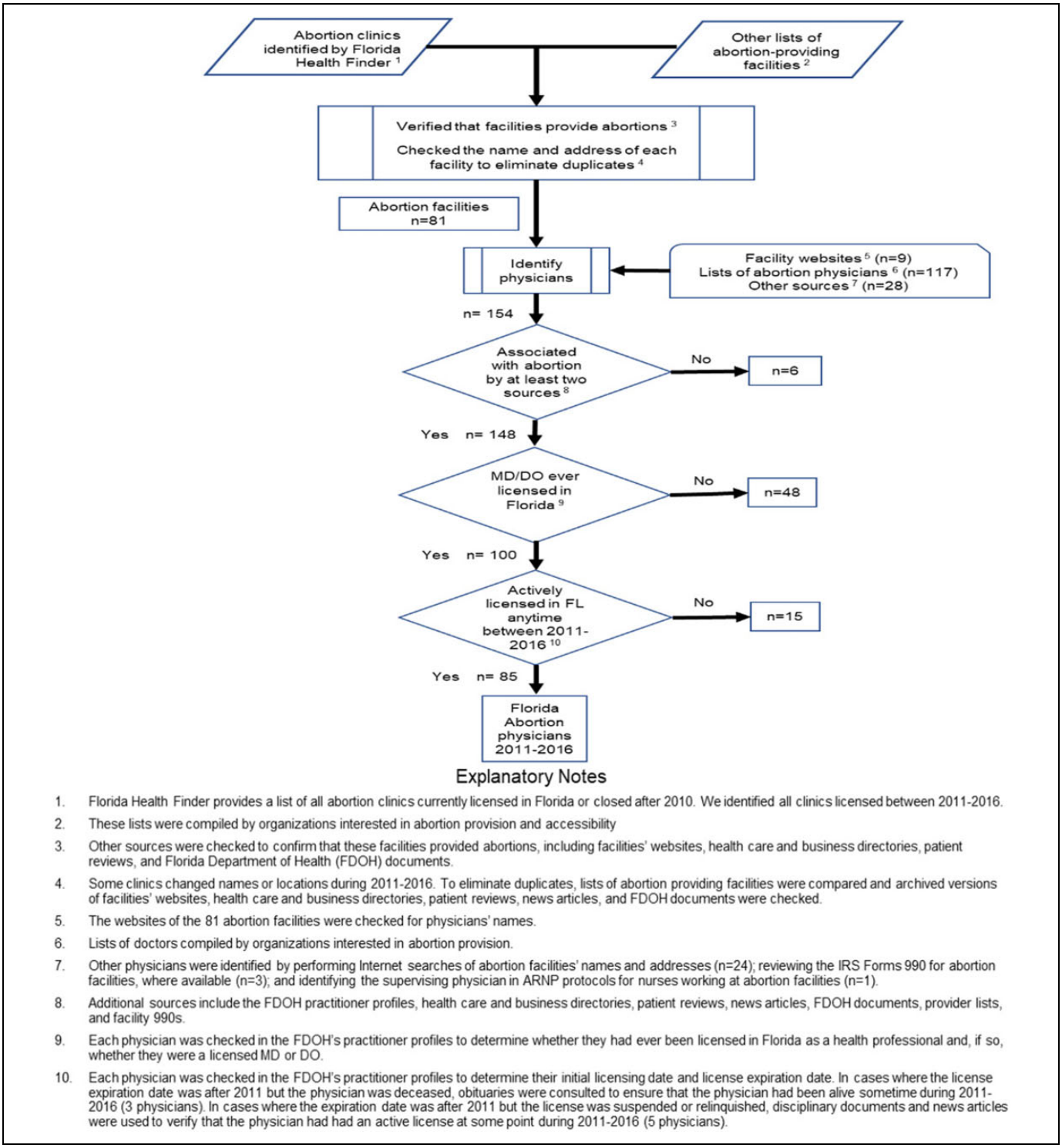

Figure 1. Identifying and validating abortionist physicians in Florida.

Florida Agency for Health Care Administration State Inpatient Database

The state inpatient database (SID) contains more than 100 clinical and nonclinical variables, such as principal and secondary diagnoses and procedures, admission and discharge status, patient demographic characteristics (eg, gender and race), expected payment sources, length of stay, and total charges. The FPP and SID are linkable via the physicians' licensure numbers.

We identified every patient discharge from Florida hospitals for women aged 15 to 44, for the years 2011 to 2016,

Table 1. Characteristics of Abortionist Physicians, n (%).

Characteristic	Total, n (%)	With Privileges	Without Privileges	*P* Value
Total, n (%)	85 (100)	43 (50.6)	42 (49.4)	
Sex				
Female	22 (25.9)	9 (20.9)	13 (31.0)	.2907
Male	63 (74.1)	34 (79.1)	29 (69.0)	
Board certification				
Yes	47 (55.3)	29 (67.4)	18 (42.9)	.0226[a]
No	38 (44.7)	14 (32.6)	24 (57.1)	
Years in practice[b,c]				
<10	2 (2.35)	0	2 (4.76)	.0552
10-19	17 (20.0)	12 (27.9)	5 (11.9)	
20-29	14 (16.5)	9 (20.9)	5 (11.9)	
30-39	31 (36.5)	15 (34.9)	16 (38.1)	
40-49	15 (17.6)	6 (14.0)	9 (21.4)	
≥50	6 (7.06)	1 (2.33)	5 (11.9)	
Medical school				
International	23 (27.1)	12 (27.9)	11 (26.2)	.8608
Domestic	62 (72.9)	31 (72.1)	31 (73.8)	
Accepts Medicaid				
Yes	36 (42.4)	26 (60.5)	10 (23.8)	.0007[a]
No	49 (57.6)	17 (39.5)	32 (76.2)	
Sanctions[d]				
None	44 (51.8)	20 (46.5)	24 (57.1)	.3310
≥1	41 (48.2)	23 (53.5)	18 (42.9)	

[a]Significant at $P < .05$.
[b]If year practice began not specified by physician, default was year issued followed by year graduated from residency.
[c]Significance tested difference between ≤29 years practice versus ≥30 years.
[d]Sanctions include malpractice, disciplinary action, public complaint, or criminal charge(s).

attributable to any of our identified physicians. For each admission, we identified the Medicare Severity Diagnosis-Related Group (MSDRG), whether the admission had occurred through the ED, and the race and pay source of the patient. Abortion doctors were also segmented into high-, medium-, and low-volume groups based upon their total number of admissions.

We used Pearson (2×2) χ^2 statistic to test the significance of differences in the characteristics of physicians with and without hospital privileges. Similarly, we used the χ^2 test of independence for assessing significant differences between the 3 admission volume determined physician groups (2×3) for the racial, pay source, ED involvement, and clinical composition of their inpatients. Significance was at the $P < .05$ level for all tests.

Findings

Physician Characteristics

Table 1 summarizes selected demographic and practice characteristics of the Florida abortionists identified in the sample. The 85 physicians are divided into those with (43, 50.6%) and without (42, 49.4%) hospital admitting privileges. Most abortionist physicians are men (63, 74.1%). Nearly 62% (n 52) of the physicians have been in practice for more than 30 years. Twenty-three (27.1%) of the abortionists are foreign medical school graduates. The foreign medical schools represented were located in the following nations and territories: Belgium, Canada, Cayman Islands, Chile, Dominica, Germany, Grenada, Italy, Iran, India, Nicaragua, Philippines, Puerto Rico, Romania, Russia, Spain, and Thailand. Physicians with hospital privileges are significantly ($P < .05$) more likely to be board certified (χ^2 5.195, P .22652) and to be approved for Medicaid payment (χ^2 11.693, P .00627). Nearly half of the physicians (n 41, 48.2%) had at least 1 malpractice claim, disciplinary action, public complaint, or criminal charge lodged against them.

Admission Volume

Between 2011 and 2016, 32 (37.6%) of the Florida abortionist physicians had at least a single inpatient hospital admission of a woman aged 15 to 44 for any reason. In total, they were involved in 21 502 admissions. The distribution of the admissions by physician volume is highly skewed, and physicians were allocated into 3 groups based on admission volume. Group 1 (high volume) was composed of 7 physicians who each accounted for 1019 to 4366 admissions over the 6-year period, representing 14 665 admissions or 68.2% of the total, averaging 349 admissions per doctor per year. Group 2 (medium volume) was composed of 8 physicians who each accounted for 430 to 881 admissions, representing 5799 admissions or 27.0% of the total, averaging 121 admissions per doctor per year. Group 3 (low volume) was composed of 17 physicians who each accounted for 1 to 288 admissions, representing 1038 admissions or 4.8% of the total, averaging 10 admissions per doctor per year.

Admissions by DRG

Admissions involving vaginal or cesarean deliveries, both with and without complicating diagnoses, account for 17 127 (79.6%) of total admissions. 1082 (5.0%) of the admissions involve surgical repair of the uterus and adnexa (fallopian tubes, ovaries) for various nonmalignant conditions both with and without complicating diagnosis. A total of 1081 (5.0%) of the admissions involve medical management of other antepartum diagnoses both with and without medical complications. Another 887 (4.1%) admissions involve abortions with and without dilation and curettage, postabortion diagnosis with and without an operating room procedure, and threatened abortion. Only 21 MSDRG categories account for nearly 97% of all admissions, with the remaining 3% of admissions distributed among nearly 300 MSDRG groups (Table 2).

Volume group differences in the composition of admissions by DRG are apparent (Table 3). Increasing volume is associated with a higher percentage of admissions associated with live births by vaginal or cesarean deliveries. Births comprise 83.5% of the high-volume doctor admissions, but only 48.2% for the low-volume group (χ^2 837.0343, P <.00001). By contrast, uterine procedures for nonmalignant conditions are more than one-fourth (27.0%) of low-volume doctor admissions, but only 3.4% for the high-volume group (χ^2 1127.7516, P <

Table 2. Total Inpatient Admissions (2011-2016) by Abortionist Physicians, by MSDRG.

MSDRG	Admissions	Description (%)	Cumulative (%)
775	8762	Vaginal delivery without complicating diagnoses (40.75)	40.75
766	4697	Cesarean delivery without CC/MCC (21.84)	62.59
765	2432	Cesarean delivery with CC/MCC (11.31)	73.90
774	1005	Vaginal delivery with complicating diagnoses (4.67)	78.58
743	864	Uterine and adnexa procedure for nonmalignancy without CC/MCC (4.02)	82.60
781	816	Other antepartum diagnoses with medical complications (3.79)	86.39
782	265	Other antepartum diagnoses without medical complications (1.23)	87.62
777	261	Ectopic pregnancy (1.21)	88.84
778	255	Threatened abortion (1.19)	90.02
767	223	Vaginal delivery with sterilization and/or D&C (1.04)	91.06
770	221	Abortion with D&C, aspiration curettage or hysterotomy (1.03)	92.09
742	218	Uterine and adnexa procedure for nonmalignancy with CC/MCC (1.01)	93.10
779	218	Abortion without D&C (1.01)	94.12
776	161	Postpartum and postabortion diagnoses without OR procedure (0.75)	94.87
812	83	Red blood cell disorders without MCC (0.39)	95.25
761	77	Menstrual and other female reproductive system disorders without CC/MCC (0.36)	95.61
759	67	Infections, female reproductive system without CC/MCC (0.31)	95.92
392	46	Esophagitis, gastroenteritis, and miscellaneous digest disorders without MCC (0.21)	96.14
745	38	D&C, conization, laparoscopy, and tubal interruption without CC/MCC (0.18)	96.31
780	32	False labor (0.15)	96.46
769	32	Postpartum and postabortion diagnoses with OR procedure (0.15)	96.61
All other	729	All other (3.39)	100.00
Grand total	21 502		

Abbreviations: CC, complication or comorbidity; D&C, dilation and curettage; MCC, major complication or comorbidity; MSDRG, Medicare Severity Diagnosis-Related Group; OR, operating room.

Table 3. Total Inpatient Admissions by Physician Volume Groups, by DRGs.

		Admissions (%)			
DRGs	Combined Description	High	Medium	Low	*P* Value
765, 766, 767, 768, 774, 775	Vaginal and cesarean section deliveries with and without complicating comorbidities or conditions	12 257 (83.6)	4369 (75.3)	501 (48.3)	<.00001[a]
742, 743	Uterine and adnexa procedures for nonmalignancy, with and without complicating comorbidities or conditions	499 (3.4)	303 (5.2)	280 (27.0)	<.00001[a]
781, 782	Other antepartum diagnoses with and without medical complications	821 (5.6)	190 (3.3)	70 (6.7)	<.00001[a]
769, 770, 776, 777, 778, 779	Abortions with and without dilation and curettage; postpartum and postabortion diagnoses with and without an OR procedure; threatened abortion; ectopic pregnancy	778 (5.3)	303 (5.2)	67 (6.4)	.25424
All other DRGs		310 (2.1)	634 (11.0)	120 (11.6)	
Total		14 665	5799	1038	

Abbreviations: DRG, Diagnosis-Related Group; OR, operating room.
[a]Significant $P < .05$.

.00001). Differences in the number of abortion-related admissions between the groups are not significant. High-volume group admissions are concentrated in a small number of DRGs compared to a dispersed pattern of a larger number of low incidence DRGs among the medium- and low-volume doctors.

Admissions Involving a Live Birth

Only 24 (28.2%) of the 85 physicians who perform abortions had 1 or more hospital admissions involving a live birth in the 6-year study period. Of the total 17 127 birth-related admissions, 2006 (11.7%) came through the ED. The top 5 doctors by birth volume accounted for 10 334 (60.3%) births. A single physician admitted nearly half (49.2%) of the births that came via ED, and only 5 doctors accounted for 1673 (83.4%) of total ED birth admissions. Ten doctors averaged 10 or more births per month, considered as a normal obstetrical case load. Five physicians averaged between 2 and 10 births per month, and 9 doctors averaged fewer than 2 births per month (Table 4).

Table 4. Birth-Related Inpatient Admissions (2011-2016) by Abortionist Physician, ED/Non-ED, Per Month.

Physician #	Non-ED	ED (%)	Total	Per Month
1	3394	162 (4.5)	3556	49.4
2	2168	67 (3.0)	2235	31.0
3	1419	78 (5.3)	1477	20.5
4	1349	128 (8.6)	1477	20.5
5	946	1 (0.001)	947	13.1
6	788	168 (17.6)	956	13.2
7	783	2 (0.002)	785	10.9
8	743	1 (0.001)	744	10.3
9	647	46 (6.6)	693	9.6
10	601	988 (62.2)	1589	22.0
11	591	227 (27.7)	818	11.4
12	460	0	460	6.4
13	446	3 (0.006)	449	6.2
14	420	0	420	5.8
15	113	73 (39.2)	186	2.6
16	72	0	72	1.0
17	51	30 (37.0)	81	1.10
18	53	32 (37.6)	85	1.20
19	40	0	40	0.50
20	14	0	14	0.19
21	10	0	10	0.14
22	5	0	5	0.07
23	4	0	4	0.05
24	4	0	4	0.05
Total	15 121	2006 (11.7)	17 127	9.91

Abbreviation: ED, emergency department.

Total Admissions by Race, Pay Source, and ED Use

Of the 21 502 total admissions, 4171 (19.4%) were admitted through the ED and 17 331 (80.6%) through the normal admitting process. The distribution of admissions by pay source was Medicaid 13 955 (64.9%), commercial 5478 (25.5%), other 1804 (8.4%), and Medicare 267 (1.2%). By race, the discharges were black 10 237 (47.6%), white 8182 (38.1%), and other 3083 (14.3%). Admissions which were both black and Medicaid numbered 7591 (35.3%), of which 1632 (21.5%) were admitted through the ED (Table 5).

Volume Group–Specific Admissions

Within-group admissions through the ED were as follows: group 1: 2703 (18.4%); group 2: 1141 (19.7%); and group 3: 327 (31.5%; χ^2 106.3229, P <.00001; Figure 2).

Within-group admissions by pay source were as follows: Medicaid—group 1: 10 089 (68.8%); group 2: 3426 (59.1%); and group 3: 440 (42.4%; χ^2 414.899, P <.00001). Commercial—group 1: 3463 (23.6%); group 2: 1602 (27.6%); and group 3: 411 (39.6%; χ^2 149.9167, P <.00001). Other—group 1: 983 (6.7%); group 2: 660 (11.4%); and group 3: 161 (15.5%; χ^2 190.2832, P <.00001). Medicare—group 1: 130 (.90%); group 2: 111 (1.9%); and group 3: 26 (2.5%; χ^2 49.9764, P <.00001).

Table 5. Total Inpatient Admissions (2011-2016) by Abortionist Physicians, by Race, Pay Source, and ED/Non-ED.

Pay Source	Black	White	Other	Total (%)
Emergency room				
Commercial	375	403	75	853 (20.4)
Medicaid	1632	702	314	2648 (63.5)
Medicare	51	41	3	95 (2.3)
Other	270	237	68	575 (13.8)
Total (%)	2328 (55.8)	1383 (33.2)	460 (11.0)	4171 (19.4)
Nonemergency room				
Commercial	1443	2512	668	4623 (26.7)
Medicaid	5959	3577	1771	11 307 (65.2)
Medicare	104	58	10	172 (<1.0)
Other	403	652	174	1229 (7.1)
Total (%)	7909 (45.6)	6799 (39.2)	2623 (15.2)	17 331 (80.6)

Abbreviation: ED, emergency department.

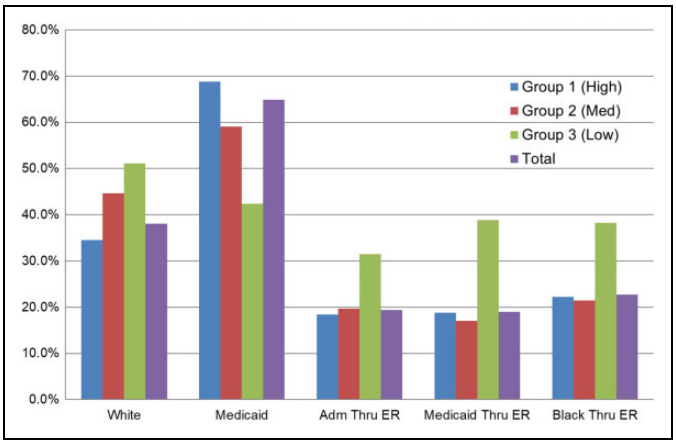

Figure 2. By volume group, white, Medicaid, and ED admissions. ED indicates emergency department.

Within-group discharges by race were as follows: black—group 1: 7449 (50.8%); group 2: 2359 (40.6%); and group 3: 429 (41.3%); white—group 1: 5061 (34.5%); group 2: 2590 (44.8%); and group 3: 531 (51.2%); other—group 1: 2155 (14.7%); group 2: 850 (14.6%); and group 3: 78 (7.5%; χ^2 295.5377, P <.00001).

Medicaid and the ED

Of the total of 13 955 Medicaid discharges, 2648 (18.9%) were admitted through the ED. At the group level, the number and percentage of Medicaid admissions through the ED were as follows: group 1: 1892 (18.7%); group 2: 585 (17.1%); and group 3: 171 (38.9%; χ^2 121.5676, P <.00001).

Black Race and the ED

Of the total of 10 237 black admissions, 2328 (22.7%) were admitted through the ED. At the group level, the number and percentage of black admissions through the ED were as

follows: group 1: 1658 (22.2%); group 2: 506 (21.4%); and group 3: 164 (38.2%; χ^2 61.7952, P <.00001).

Overall, admissions from doctors who do abortions are most likely to be Medicaid-eligible and black. Admissions of black Medicaid patients were more than one-third of the total. Admissions from the low-volume group of doctors were less likely to be black or Medicaid-eligible than the higher volume groups, but much more likely to flow through the ED.

Discussion

The profile of Florida abortionist characteristics and the findings related to their holding of hospital admitting privileges and subsequent utilization of the hospital raise questions of consequential public policy importance. This group of abortionists is relatively senior, is predominantly composed of doctors who have been in practice for more than 30 years, and is disproportionally male. Some anecdotal literature suggests that there may be barriers to abortion practice for early career doctors and that doctors who choose to do abortions often try to keep knowledge of this activity from their professional colleagues. The relatively advanced age distribution and large percentage of abortionists with some malpractice claim, disciplinary action, public complaint, or criminal charge suggest that these doctors may be a subset of practicing physicians for whom abortion practice may be a final professional expedient. A little more than half of the group is board certified, more than one-fourth are foreign trained, and less than half admit patients to the hospital. At the same time, we find a number of board-certified obstetricians with apparently high-volume delivery practices among the group. The obvious conclusion is that abortionists are heterogeneous in terms of both personal and practice characteristics.

Only 43 of the 85 abortionists held privileges and, of those with privileges, only 32 had at least a single admission during the entire 6-year study period. A few of the doctors used the hospital extensively, those being board-certified obstetricians. The overwhelming number of admissions among this small group was for deliveries. The extent to which abortion doctors are also involved in delivering babies is of considerable research interest. The typical abortionist uses the hospital infrequently. Since only a very small fraction of induced abortions occur in an inpatient setting, it seems plausible to conclude that most abortionists concentrate on outpatient abortions and practice very little medical care that is related to other illnesses and injuries, which frequently result in the need for an inpatient hospitalization.

Since volume is associated with positive outcomes across a broad array of health services, the volumes and types of induced abortions performed by each physician and their pattern of adverse outcomes (eg, complications resulting in an ED visit) are of vital interest. An analysis of physician abortion volume and inpatient admission volume, controlling for important physician characteristics (eg, board certification), would provide insight into a profile of quality determinants for abortion-related care.

Despite the relatively sparse use of the hospital, nearly one-fifth (19.9%) of the admissions come from a visit to the ED, and this percentage is nearly 40% for black and Medicaid admissions from the lowest volume doctors. Inpatient admissions through the ED are expedited if the patient is under the care of a physician who is a frequent admitter to whom the inpatient admission can be assigned. This finding also supports the conclusion that doctors who do abortions are, in fact, involved in the care of patients whose illness or condition often requires an ED visit which frequently results in an admission. Further, abortionists who use the hospital the least are proportionally more likely to use the ED as a path to admission. For hospitalizations resulting from complications of an induced abortion performed in an ambulatory setting, whether and where the abortionist holds admitting privileges is likely an important explanatory factor in the conduct and ultimate outcome of the process of care. With the ED admission as such a prominent occurrence for the Florida abortionist with hospital privileges, what is the experience of those patients who require an ED admission but whose doctor lacks privileges?

Finally, the disproportionate racial (black) and pay source (Medicaid) characteristics of abortionist inpatients confirm what is known about the large and long-standing racial disparity in abortion in the United States. In the period between 1990 and 2014, in states that reported race-specific abortion data to the Centers for Disease Control and Prevention, the black abortion rate was 3.4 times the white rate.[12] The fact that inpatient admissions from abortionist physicians are also disproportionally black and poor should stimulate further research on this understudied population.

Studies of doctors who perform abortions are absent from the peer-reviewed literature. How and why a physician becomes an abortionist are largely unexplored questions. Similarly, the extent to which these physicians are integrated with or isolated from the typical processes and communication networks of medical care, including the patient hospitalization event, is largely unknown and unexplained. A fundamental question made explicit but unanswered by this exploratory analysis is how many doctors restrict their practice exclusively to abortion. A major barrier to advancing this domain of science continues to be the lack of a universal and comprehensive reporting requirement for all induced abortions and the health-care professionals who perform them. Valid hypothesis testing analyses of these important research questions will require statistically representative samples of physicians and patients derived from such a comprehensive surveillance system.

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Author Biographies

James Studnicki is currently vice president and director of data analytics at the Charlotte Lozier Institute in Arlington, Virginia. Over a span of four decades, he held academic appointments at the Johns Hopkins University School of Hygiene and Public Health, the University of South Florida College of Public Health, and the University of North Carolina, Charlotte, where for ten years he served as the Irwin Belk Endowed Chair in Health Services Research. Studnicki holds Doctor of Science (ScD) and Master of Public Health (MPH) degrees from Johns Hopkins and a Master of Business Administration (MBA) from the George Washington University.

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Sharon J. Mackinnon, PhD, RN, FNP has over 25 years of health care experience. MacKinnon completed her doctoral work in Health Services Research at the University of North Carolina at Charlotte. Her current research focuses on the development of secure attachments and experiential relational skills training in local faith communities as they relate to the primary prevention of abortion.

EXHIBIT B

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A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015

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Abstract

Introduction: Existing research on postabortion emergency room visits is sparse and limited by methods which underestimate the incidence of adverse events following abortion. Postabortion emergency room (ER) use since Food and Drug Administration approval of chemical abortion in 2000 can identify trends in the relative morbidity burden of chemical versus surgical procedures.

Objective: To complete the first longitudinal cohort study of postabortion emergency room use following chemical and surgical abortions.

Methods: A population-based longitudinal cohort study of 423 000 confirmed induced abortions and 121,283 subsequent ER visits occurring within 30 days of the procedure, in the years 1999-2015, to Medicaid-eligible women over 13 years of age with at least one pregnancy outcome, in the 17 states which provided public funding for abortion.

Results: ER visits are at greater risk to occur following a chemical rather than a surgical abortion: all ER visits (OR 1.22, CL 1.19-1.24); miscoded spontaneous (OR 1.88, CL 1.81-1.96); and abortion-related (OR 1.53, CL 1.49-1.58). ER visit rates per 1000 abortions grew faster for chemical abortions, and by 2015, chemical versus surgical rates were 354.8 versus 357.9 for all ER visits; 31.5 versus 8.6 for miscoded spontaneous abortion visits; and 51.7 versus 22.0 for abortion-related visits. Abortion-related visits as a percent of total visits are twice as high for chemical abortions, reaching 14.6% by 2015. Miscoded spontaneous abortion visits as a percent of total visits are nearly 4 times as high for chemical abortions, reaching 8.9% of total visits and 60.9% of abortion-related visits by 2015.

Conclusion: The incidence and per-abortion rate of ER visits following any induced abortion are growing, but chemical abortion is consistently and progressively associated with more postabortion ER visit morbidity than surgical abortion. There is also a distinct trend of a growing number of women miscoded as receiving treatment for spontaneous abortion in the ER following a chemical abortion.

Keywords

induced abortion, mifepristone, medical abortion, emergency room, Medicaid

Introduction

Since its fast-track approval by the USA Food and Drug Administration (FDA) in September 2000, induced abortion by the administration of mifepristone and misoprostol (ie, chemical abortion) has grown to over 50% of all induced abortions in the United States and may, in fact, be responsible for ending a long-term decline in the number of induced abortions in the United States[1]

Research on the safety of induced abortion, and particularly those that are chemically induced, continues to be handicapped

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in the United States by the absence of a comprehensive national reporting system of pregnancy outcomes. The Centers for Disease Control and Prevention (CDC) Abortion Surveillance Reports are derived from a profoundly flawed system in which reporting by the states is voluntary, with many states reporting intermittently and some not at all. The reporting of specific data elements is similarly piecemeal and, most disappointing, no event-level data is actually available for any rigorous analytical purposes. Adverse events which may be related to an induced abortion such as a death, incomplete abortion, severe bleeding, or infection are often underreported because there is no certain way to link the adverse event to the precipitating abortion. Further, the FDA's adverse event reporting requirements for mifepristone extend only to deaths.[2] Large population-based record-linkage studies from nations with comprehensive reproductive history data linked to adverse events provide the best opportunity to overcome many of these data limitations and find a much higher overall incidence of adverse events in the chemical compared with the surgical cohort.[3,4] By contrast, USA studies of chemical abortion safety are frequently conducted on opportunity samples of women who have recently undergone an induced abortion. Already limited by the nonrandom nature of patient selection, these studies are frequently subject to design limitations such as the exclusion of an incomplete abortion as a complication, or an unacceptably high percentage of women lost to follow-up.[5,6]

The emergency room (ER) visit is a particularly insightful event by which to assess and compare the relative safety of chemical and surgical abortions for 2 reasons. First, adverse events following a mifepristone abortion are more likely to be experienced at home in the absence of a physician, increasing the likelihood of an ER visit. Second, the ER visit can be for any number of complications and is, therefore, a broad proxy indicator for abortion-related morbidity. One major concern is that ER secondary data describes treatment for a condition (eg, hemorrhage) which may be attributed to a prior event (eg, abortion), but, as we have seen, the prior event is often missed. For example, a study of abortion-related emergency room visits in the United States, using the Nationwide Emergency Department Sample, categorized whether visits were abortion related based only on information taken from the ER visit record. There was no independent confirmation from a different source that an abortion had occurred. Therefore, a woman who was experiencing excessive bleeding following a chemical abortion but did not reveal the abortion to the ER physician would not be identified as an abortion-related visit. Not surprisingly, the study found an extraordinarily low percentage (0.01%) of abortion-related visits among all ER visits to women age 15 to 49.[7] For all the reasons related to data availability and quality, as well as methodological inadequacies, evidence suggests that postabortion complications are substantially underreported.[8,9]

As we have described, research on adverse events following induced abortion varies by procedure, protocols to detect complication, length of follow-up and the sources and quality of data. The emergency room visit as a comprehensive marker for postabortion complications has been infrequently and inadequately utilized in existing research. Therefore, the objective of this research was to complete the first population based longitudinal cohort study of the trajectory of postabortion emergency room utilization following both chemical and surgical abortions in order to test the hypothesis that chemical abortion results in higher emergency room utilization. We selected a longitudinal cohort design because of its superiority to cross-sectional approaches in suggesting causation. Uniquely, our methodology includes first a confirmation of the actual provision of either a chemical or surgical abortion and, only after confirmation, identifies broadly all emergency room utilization before disaggregating abortion-related ER use. In the absence of a national abortion registry, this analysis is intended to provide the most comprehensive view of postabortion-related morbidity in the years following the FDA approval of mifepristone abortion, as well as a glimpse of what we might expect in the future.

Methods

Data were obtained from the enrollee-level Medicaid Analytic eXtract files licensed through the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse's Medicaid data. The analytic dataset is comprised of enrollees from the 17 states whose official policies applied state funds to most abortions not covered by federal Medicaid during the period 1999 through 2015. Not all states funded abortion consistently or to the same extent during the study period. Despite their official policies, Arizona and Illinois funded relatively few abortions during this period, and Alaska experienced a short interruption to its abortion coverage.[10] Not all states had provided claims data through 2015 due to differing reporting timeframes. The latest year of data relative to each state was 2013 for Arkansas, Illinois, Maryland, Montana, and New Mexico; 2014 for Arizona, Hawaii, Massachusetts, and Washington; and 2015 for California, Connecticut, Minnesota, New Jersey, New York, Oregon, Vermont, and West Virginia.

The study population was made up of enrollees over 13 years of age with at least one identifiable pregnancy outcome from 1999 through the latest year of data available for each state. For each beneficiary, all unique pregnancy outcomes were identified using International Classification of Diseases, Ninth Revision (ICD-9) codes. Additionally, Current Procedural Terminology, fourth Edition (CPT4) and Healthcare Common Procedure Coding System (HCPCS) codes were used to confirm pregnancy outcomes.

These codes were used to allocate all pregnancy outcomes into 4 categories: live birth (ICD-9V27.0, V27.2, and V27.5), natural fetal loss (ICD-9V27.1, V27.4, V27.7, 630, 631, 633, 634), induced abortion (ICD-9 635.xx, CPT4 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and HCPCS: S0199, S2260, S2265, S2266, S2267, X7724, X7726, S0190, S0191), and undetermined (ICD-9 636.xx, 637.xx, 638.xx). In order to identify each unique pregnancy, multiple diagnostic or treatment codes within 30 days of a pregnancy loss (natural, induced, or undetermined) or within 180 days of a live birth were counted as a single pregnancy outcome using the first

date associated with that series of Medicaid claims. Twins and higher order gestations that resulted in a combination of live birth and fetal loss were excluded from the analysis.

The analytic strategy was composed of 3 phases. First, we identified every confirmed surgical induced abortion (ICD/CPT codes—CPT4 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857) and every confirmed chemical induced abortion (HCPCS codes S0190, S0191) in each specific year 1999 to 2015 (index abortion). Codes S0190 and S0191 were added by CMS on January 1, 2001, so chemical abortions prior to that date could have been missed; however, because mifepristone did not receive approval from the FDA until September 28, 2000, the number of mifepristone abortions not captured here is likely minimal. Additionally, as an explanatory variable, we determined whether there was a prior induced abortion or live birth in the 12 months preceding the index abortion procedure. Second, we identified every emergency room visit occurring within thirty days of the index abortion procedure (Place of Service code 23 [emergency room]), including multiple visits for each patient. We further disaggregated ER visits into 3 categories: all-cause, abortion-related codes (ICD-9, 630-639) and spontaneous abortion code (ICD-9, 634). We mapped and adjusted the appropriate codes during the last two quarters of calendar year 2015 to reflect the transition from ICD-9 to ICD-10. The following descriptive metrics were calculated: chemical abortions as a percent of total induced abortions; ER visits following chemical abortions as a percent of total ER visits following total induced abortions; coded abortion-related visits as a percent of total ER visits following an induced abortion; miscoded spontaneous abortion ER visits as a percent of total ER visits following an induced abortion; miscoded spontaneous abortion ER visits as a percent of abortion-related ER visits following an induced abortion; and abortion ER visit rates per 1000 specified induced abortions for all-cause, coded abortion-related, and miscoded spontaneous abortion visit categories. Comparisons of the 1999 to 2015 longitudinal trajectory of these descriptive metrics are displayed in a series of 9 figures.

Third, we performed logistic regression models to identify the association of selected predictor variables with the likelihood of experiencing each of the 3 defined categories of ER visits following an induced abortion. The outcome variable in each equation was the dichotomous indication (yes/no) of the specific type of ER visit. The predictor variables were as follows: surgical abortion; chemical abortion; age at induced abortion; race; months of Medicaid eligibility at induced abortion; prior (within a calendar year of induced abortion) birth; and prior (within a calendar year of induced abortion) induced abortion. The odds ratios were calculated for the entire 17-year study period and, with the disproportional growth of chemical abortions over time, underestimate the current advantage of chemical abortion (vs surgical) in eliciting emergency room visits in the later years of the study observation period.

Summary analytic tables were created using (SAS/STAT) software, version (10) of the SAS system for (Unix). Copyright (2019) SAS Institute Inc. All comparative analyses were completed using Microsoft Excel (version 16).

The study has been exempted from Institutional Review Board (IRB) review pursuant to the USA Department of Health and Human Services Policy for Protection of Human Research Subjects at C.F.R. 46.101(b). See IRB ID: 7269, www.sterlingirb.com.

Findings

From 1999 to 2015, there was a total of 423 000 confirmed induced abortion Medicaid procedures, 361 924 surgical and 61,706 chemical. Surgical abortions increased from 4479 in 1999 to a peak of 36 204 in 2012, declined in 2013 to 2014 to 28 101, and concluded 2015 at 29 558. Chemical abortions had no Medicaid claims in the study population in 1999 to 2000 and only 15 in 2001. From 2002 when there were 352, chemical abortions increased to 8768 in 2012, followed by a 2013 to 2014 decline similar to that experienced by surgical abortion. Following inclusion of California chemical abortions in 2015, the chemical abortion number more than doubled to 15 279. As the result, mifepristone abortions grew from 4.4% of total abortions in 2002 to 34.1% in 2015 (Table 1 and Figure 1).

Similarly, emergency room visits within 30 days of an induced abortion increased during the study observation period for both surgical and chemical abortions. Emergency room visits following chemical abortions grew consistently as a percentage of all ER visits within 30 days of the procedure: 3.5% (36 ÷ [36 + 977]) in 2002; 6.9% (452 ÷ [452 + 6060]) in 2007; 22.0% (3220 ÷ [3220 + 11,401]) in 2012; and 33.9% (5421 ÷ [5421 + 10,578]) in 2015 (Table 1). The steeper growth in total and abortion-related ER visits for mifepristone abortions are apparent in the comparison of Figure 2 (surgical) and Figure 3 (chemical). Total ER visits during the study period totaled 121,283, 99,928 surgical and 21,355 chemical.

There are clear differences for surgical and chemical abortions in terms of the reason for the ER visits following the procedure. Abortion-related visits (ICD-9 630-639) remain stable at 4% to 5% of total ER visits for surgical abortions, reaching a high of 6.2% in 2015. This percentage is 8% to 9% between 2002 and 2013 for chemical abortions, with increases in 2014 to 2015 peaking at 14.6%. Abortion-related ER visits represent a higher percentage of total ER visits for chemical abortions (Figure 4).

ER visits miscoded as a spontaneous abortion following a chemical abortion range between 2% and 3% of total visits from 2003 to 2012, increasing abruptly between 2013 and 2015 reaching 8.9%. ER visits miscoded as a spontaneous abortion following a confirmed surgical abortion averaged less than 1% of all ER visits until 2008, 1.2%-1.3% from 2009 to 2014, and peaked at 2.4% in 2015. Therefore, from 2005 to 2015, visits miscoded for spontaneous abortion treatment in the ER as a percent of all visits, went from 2 to 4 times as likely following a chemical abortion as compared to a surgical abortion (Figure 5).

Table 1. Chemical and Surgical Induced Abortions and ER Visits Within 30 Days, 1999-2015.

	Chemical				Surgical			
Year	Abortions	All ER Visits	630 to 639	634	Abortions	All ER Visits	630 to 639	634
1999	0				4479	351	15	5
2000	0				7248	598	31	11
2001	15	1			9986	732	20	7
2002	352	36	3	0	7729	977	41	10
2003	803	108	6	2	13 012	1792	70	12
2004	1319	198	17	1	18 463	2871	99	14
2005	1360	316	29	9	19 226	4178	170	42
2006	1192	351	23	6	20 558	5042	218	51
2007	1521	452	37	13	21 244	6060	263	53
2008	1988	799	50	14	22 125	6954	313	66
2009	3032	1121	100	27	25 764	7879	358	91
2010	4848	1702	147	48	30 019	8820	386	114
2011	6834	2787	233	99	32 394	10 044	465	104
2012	8768	3220	277	88	36 204	11 401	536	150
2013	6856	2401	219	94	35 814	11 681	558	142
2014	6909	2442	270	117	28 101	9970	466	120
2015	15 279	5421	790	481	29 558	10 578	651	254

As a percent of abortion-related visits (ICD-9, 630-639), visits miscoded for spontaneous abortion treatments (ICD-9, 634) following a confirmed mifepristone abortion averaged approximately 30% between 2003 and 2012 and increased between 2013 and 2015, reaching 60.9%. ER visits miscoded as treatment for spontaneous abortion as a percent of abortion-related visits following a confirmed surgical abortion are a consistently lower percentage than for those following a chemical abortion, peaking at 39% in 2015 (Figure 6). Treatment in the ER miscoded as for spontaneous abortion is consistently and progressively more likely following a chemical abortion than following a surgical abortion.

All-cause ER visit rates within 30 days of an abortion have increased consistently throughout the study period for all types of induced abortion. There were 78.4 all-cause visits per 1000 surgical abortions in 1999 and 357.9 in 2015, an increase of 356% in the rate. Using 2002 as the initial year with sufficient abortion and ER visit counts to calculate a rate, the chemical

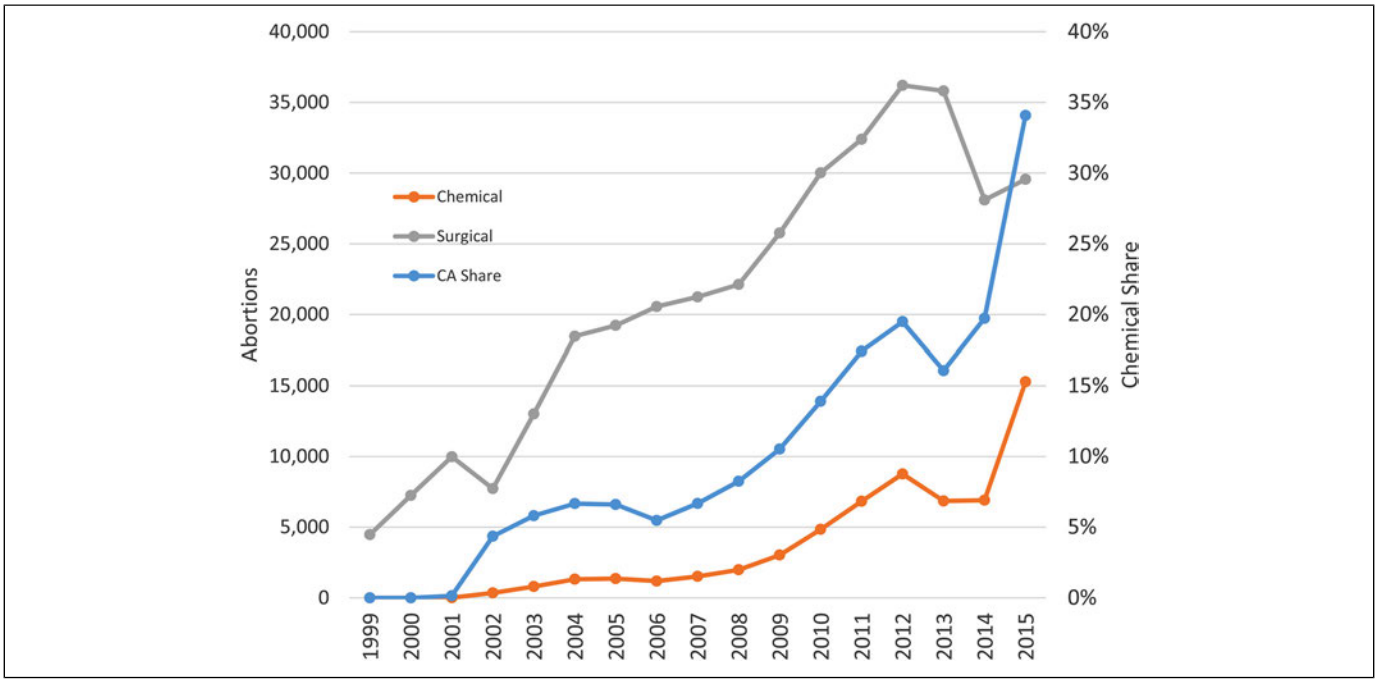

Figure 1. Medicaid abortions (surgical and chemical), 1999–2015, and chemical abortion % total.

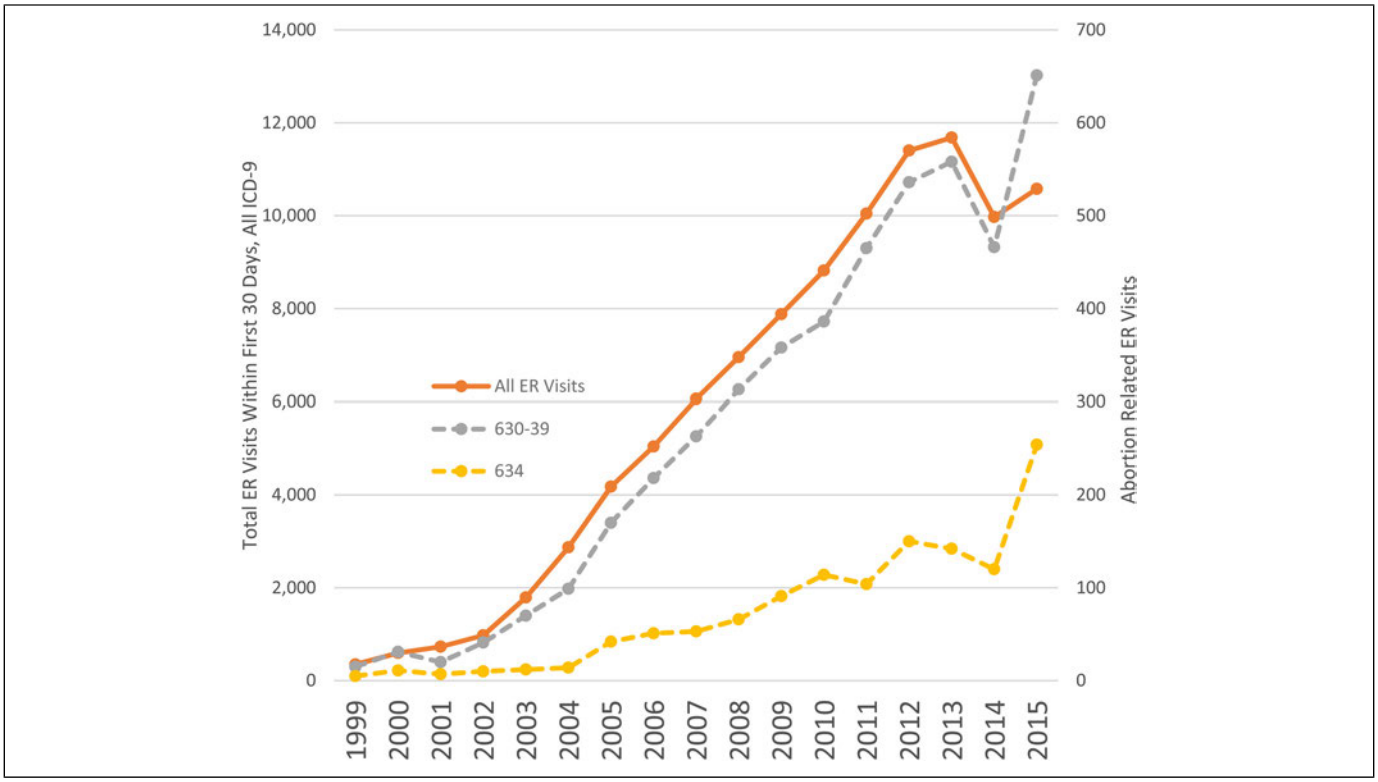

Figure 2. Emergency room (ER) use following surgical abortion, 1999-2015.

abortion rate increased from 102.3 in 2002 to 354.8, a rate increase of 247%. When the surgical rate increase is calculated from 2002 (126.4) and 2015 (357.9), the rate increase is 183%. Both the consistent increase in the rate of ER visits per abortion procedure and the higher chemical rate relative to the surgical rate after 2004 are apparent in Figure 7.

Abortion-related ER visits (ICD-9 630-639) per abortion exhibit a similar upward trend in rates for both surgical and chemical abortions, but, beginning in 2002, a growing divergence by type of abortion is evident. The surgical abortion to abortion-related visit rate increases from 5.3 in 2002 to 22.0 in 2015, an increase of 315%. Chemical abortion visit rates during the same period went from 8.5 to 51.7, an increase of 507% (Figure 9).

ER visit rates miscoded as for spontaneous abortion (ICD-9 634) within 30 days of a surgical abortion show a declining pattern from a peak of 1.5 in 2000 to a low point of 0.8 in 2004, a gradual increase between 2.2 and 4.3 from 2005 to 2014, and a doubling to 8.6 in 2015. By contrast, ER visit rates miscoded as for spontaneous abortion treatment following a chemical abortion show a consistent increase from 8.55 in 2007, the first year ER visits in this category reached double digits, to 31.5 in 2015. Between 2007 and 2015, the ER visit rate miscoded for spontaneous abortion increased 244% following surgical abortion and 268% following chemical abortion (Figure 8). Caution previously noted regarding the coding and classification of these visits is similarly warranted here.

A summary of the logistic regression analyses is in Table 2. All 3 types of ER visits during the study observation period are more likely to occur following a chemical abortion than following a surgical abortion: all-cause (OR 1.22, CL 1.19-1.24); abortion-related (OR 1.53, CL 1.49-1.58); and spontaneous abortion (OR 1.88, CL 1.81-1.96). Prior pregnancy outcomes increase the likelihood of any type of subsequent ER visit. However, an ER visit is significantly more likely to occur following a prior chemical abortion than following a prior surgical abortion: all-cause (OR 2.54, CL 2.38-2.70 vs OR 1.78, CL 1.73-1.82); abortion-related (OR 1.80, CL 1.65-1.97 vs OR 1.35, CL 1.29-1.41); and spontaneous abortion (OR 1.74, CL 1.54-1.96 vs OR 1.43, CL 1.35-1.52). A prior live birth is a lower risk factor for post abortion ER visits than is either a chemical or surgical induced abortion: all-cause (OR 1.52, CL 1.48-1.56); abortion-related (OR 1.09, CL 1.04-1.15); and spontaneous abortion (OR 1.12, CL 1.04-1.20).

Hispanics are slightly more likely than whites to experience any type of post abortion ER visit: all-cause (OR 1.07, CL 1.05-1.10); abortion-related (OR 1.03, CL 1.00-1.07); and spontaneous abortion (OR 1.03, CL 0.98-1.09). Blacks, by contrast, are consistently less likely than whites to experience any type of post abortion ER visit: all-cause (OR 0.59, CL 0.58-0.61); abortion-related (OR 0.68, CL 0.66-0.71); and spontaneous abortion (OR 0.72, CL 0.68-0.76). Age at time of the abortion and years of Medicaid eligibility are not important risk factors in predicting post abortion emergency room use.

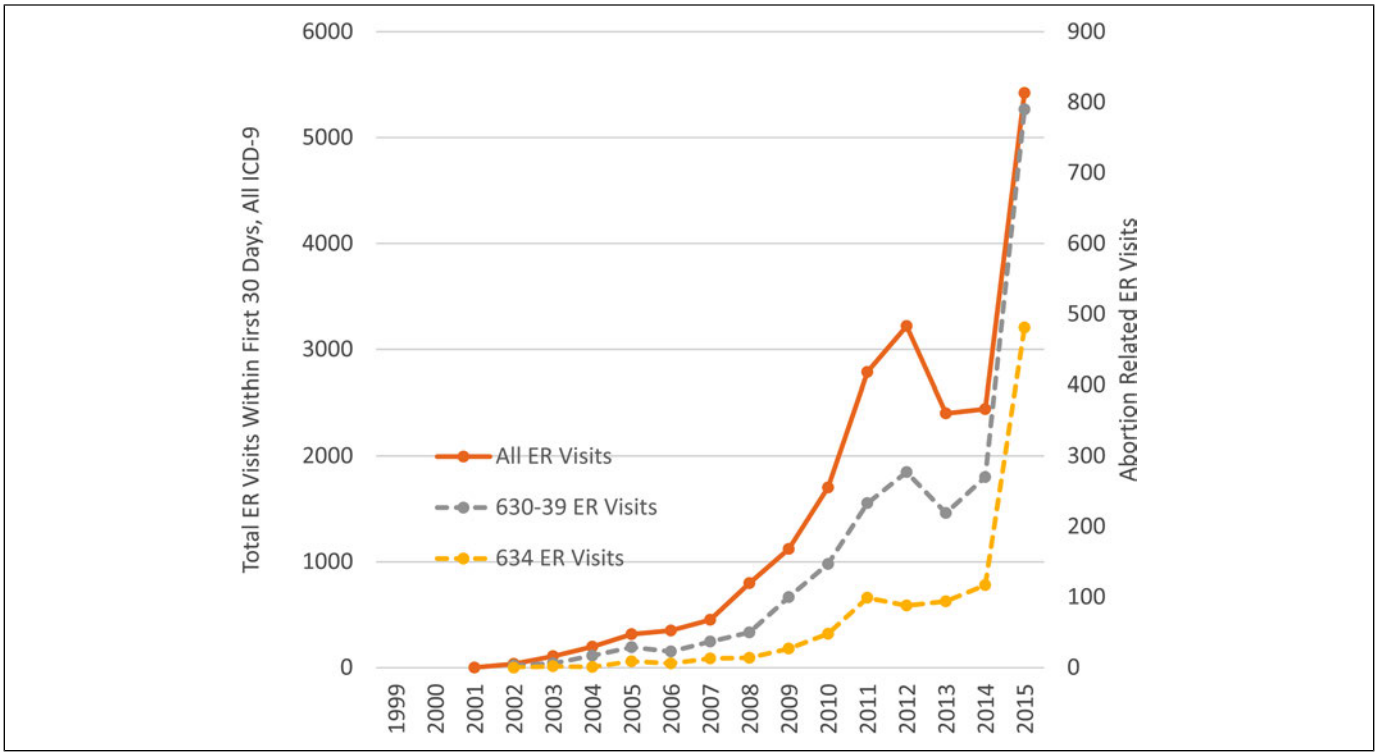

Figure 3. Emergency room (ER) use following chemical abortion, 1999–2015.

Discussion

Regression analysis definitively supports the hypothesis that chemical abortion is associated with more frequent emergency room visits of all kinds for the entire study period. In addition, we found that ER visit rates per 1000 abortion procedures increased consistently throughout the study period following both types of induced abortion, but the rates for mifepristone abortion visits grew faster, especially for abortion-related visits. By 2015, mifepristone versus surgical ER rates were: all visits (354.8 vs 357.9); miscoded spontaneous abortion

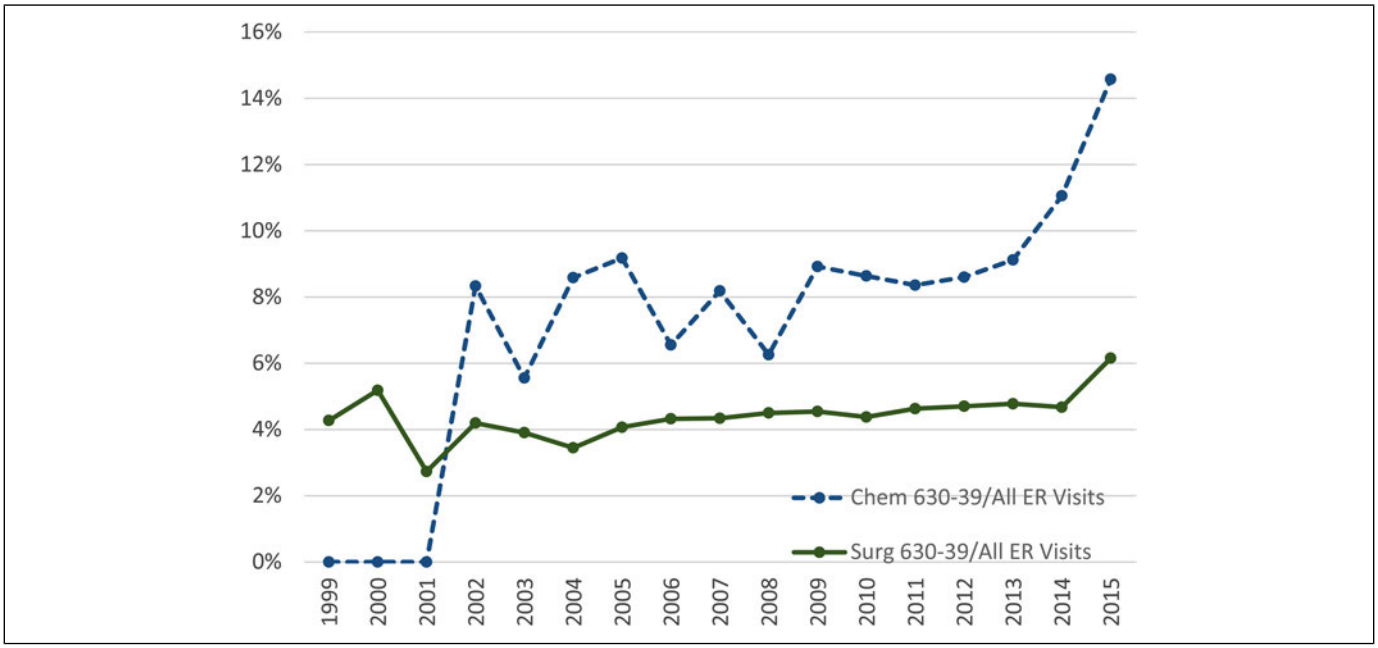

Figure 4. Abortion-related visits as a percent of all emergency room (ER) visits.

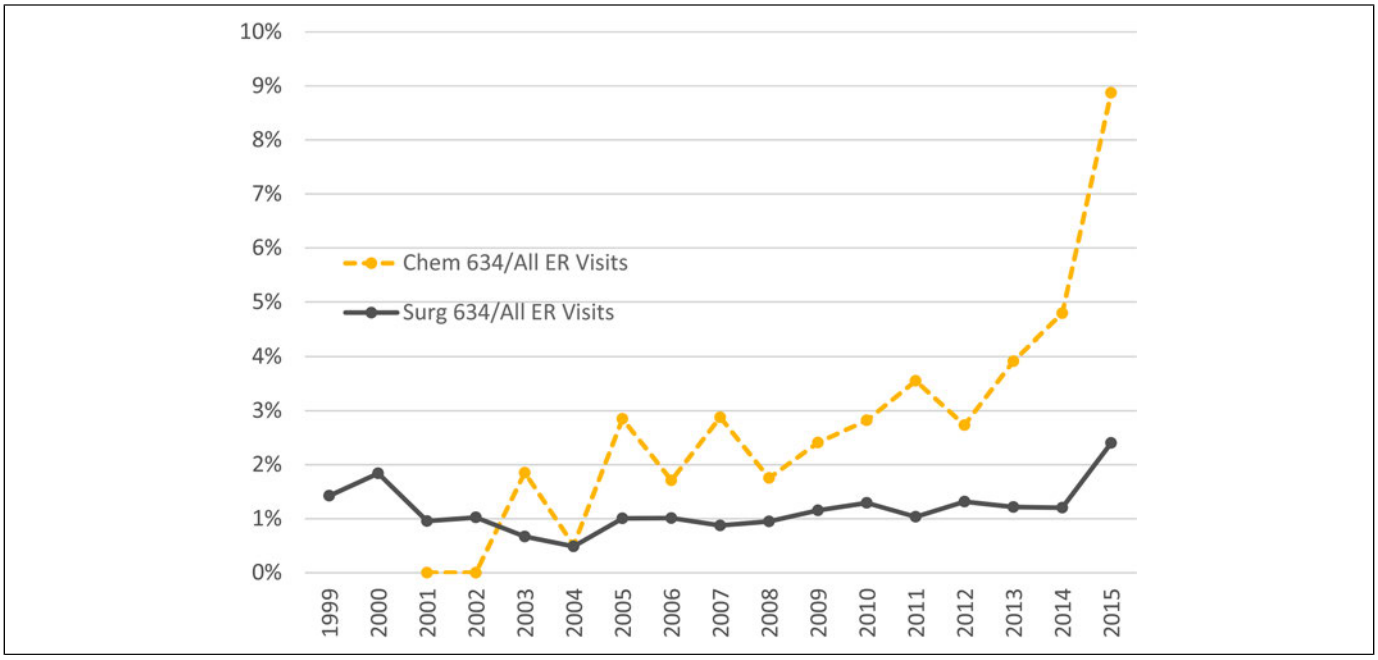

Figure 5. Miscoded spontaneous abortion visits as a percent of all emergency room (ER) visits.

(31.5 vs 8.6); and abortion-related (51.7 vs 22.0). The reasons for the increasing rate of ER visits following mifepristone abortions are not readily apparent but may be influenced by mifepristone abortion providers who are unable or unskilled to handle complications after chemical abortions. This finding would be consistent with an analysis of FDA Adverse Event Reports which showed that abortion providers only managed slightly over half of the dilation and curettage procedures (D&Cs) required for hemorrhage and retained tissue, and the remainder were handled by the emergency room.[11] Further research is needed to delineate whether there is a difference between ER visit utilization after abortions performed by those abortion providers untrained in surgical procedures (ie, midwives, advance practice clinicians, Family Medicine providers and other types of providers). This finding is also of significance when considering the implications of removing a requirement for in-person medical supervision of mifepristone abortion as is currently under consideration by the FDA.[12]

These findings are especially consequential because they are derived directly from all paid medical claims records, unlike most other studies of abortion complications which involve voluntary survey reporting and/or a more limited query of a select set of treatment codes. The more comprehensive examination of all ER codes associated with confirmed abortion events undertaken in this research requires reconsideration of previous findings which now appear to have understated the full range of risks associated with abortion. For example, previous research on only fee-for-service California Medicaid beneficiaries and using only a single code (ICD-9 635.xx) in 2009 to 2010 concluded that 6.4% of all abortions were followed by any ER visit within 6 weeks and 0.87% were followed by an abortion-related visit.[13] Results of our research summarized for the same 2 years found 4.8 times (30.7%) the number of total ER visits and 1.8 times (1.56%) the number of abortion-related visits within our shorter 30-day postabortion observation period. We were able to detect this more accurate number of complications because the women were included in our study based on a CPT code payment for mifepristone abortion, thus eliminating the need for the treating physician to recognize a complication from a chemical abortion.

The finding that many ER visits following known induced abortions are misclassified as postmiscarriage complications is particularly noteworthy. Abortion studies in the United States consistently report lower postabortion complication rates than are documented in the international scientific literature. There are likely multiple reasons for this discrepancy, but among them are the miscoding of abortion-related complications by the provider and the nondisclosure of prior abortion history by the patient. Women obtaining chemical abortions must sign a patient agreement indicating they will bring with them the mifepristone medication guide if seeking emergency care, but some abortion advocates encourage women to withhold information if seeking treatment for an adverse event.[14,15] Our study demonstrated ER visits misclassified or miscoded as spontaneous abortion grew for both types of induced abortion, reaching 39% of abortion-related visits following surgical abortion and 60.9% of visits following chemical abortion in 2015. These mifepristone abortion complications would have been invisible to previous researchers, resulting in a large underestimation of actual mifepristone abortion complications. Our more accurate estimation has significant implications for the evaluation of risks communicated

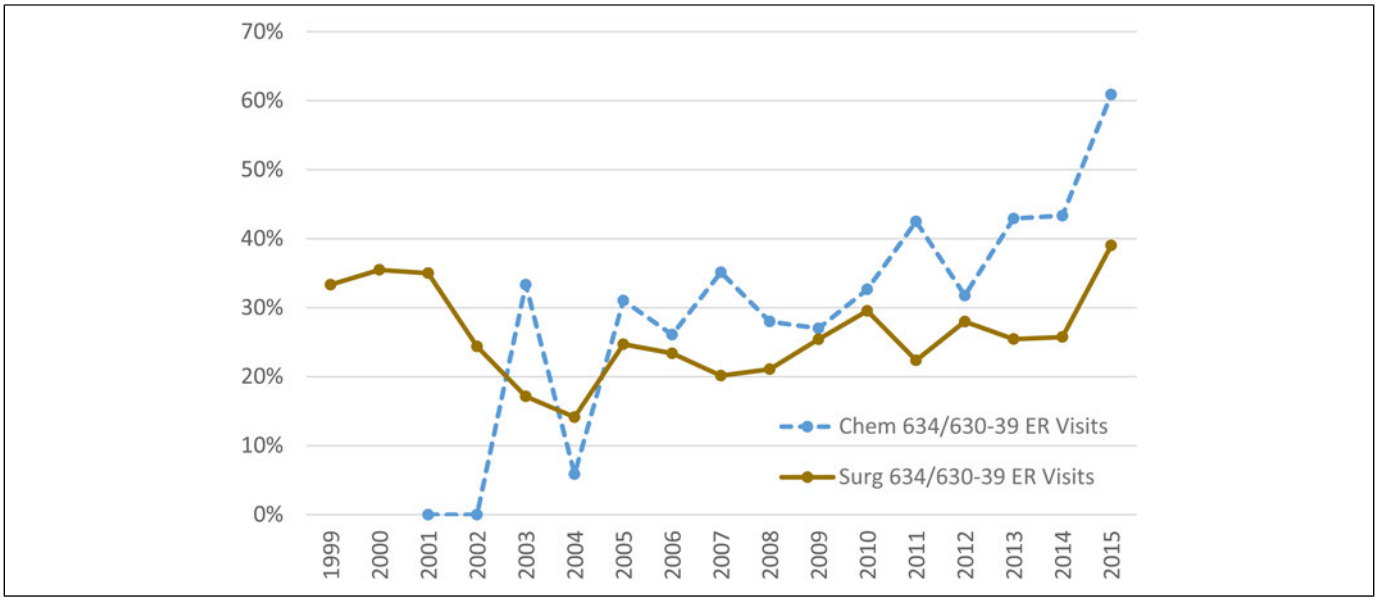

Figure 6. Miscoded spontaneous abortion visits as a percent of abortion-related emergency room (ER) visits.

to women in the process of informed consent prior to abortion, as well as in policy making regarding mifepristone abortion.

Consistent with CDC reports, we found the percentage of abortions performed by means of mifepristone and misoprostol increased from 4.4% of total abortions in 2002 to 34.1% in 2015. Similarly, ER visits following mifepristone abortion grew from 3.6% of all postabortion visits in 2002 to 33.9% of all postabortion visits in 2015. The trend toward increasing use of mifepristone abortion requires all concerned with health care utilization to carefully follow the ramifications of ER utilization.

There are limitations related to the use of Medicaid claims data. Medicaid-eligible beneficiaries are by definition financially disadvantaged and are not representative of all women experiencing abortion. Conversely, a data set composed entirely of low-income women may also be considered an advantage since results are unlikely to be explained by differences in income or other factors strongly associated with income. The lower risk of any ER visit following induced abortion among

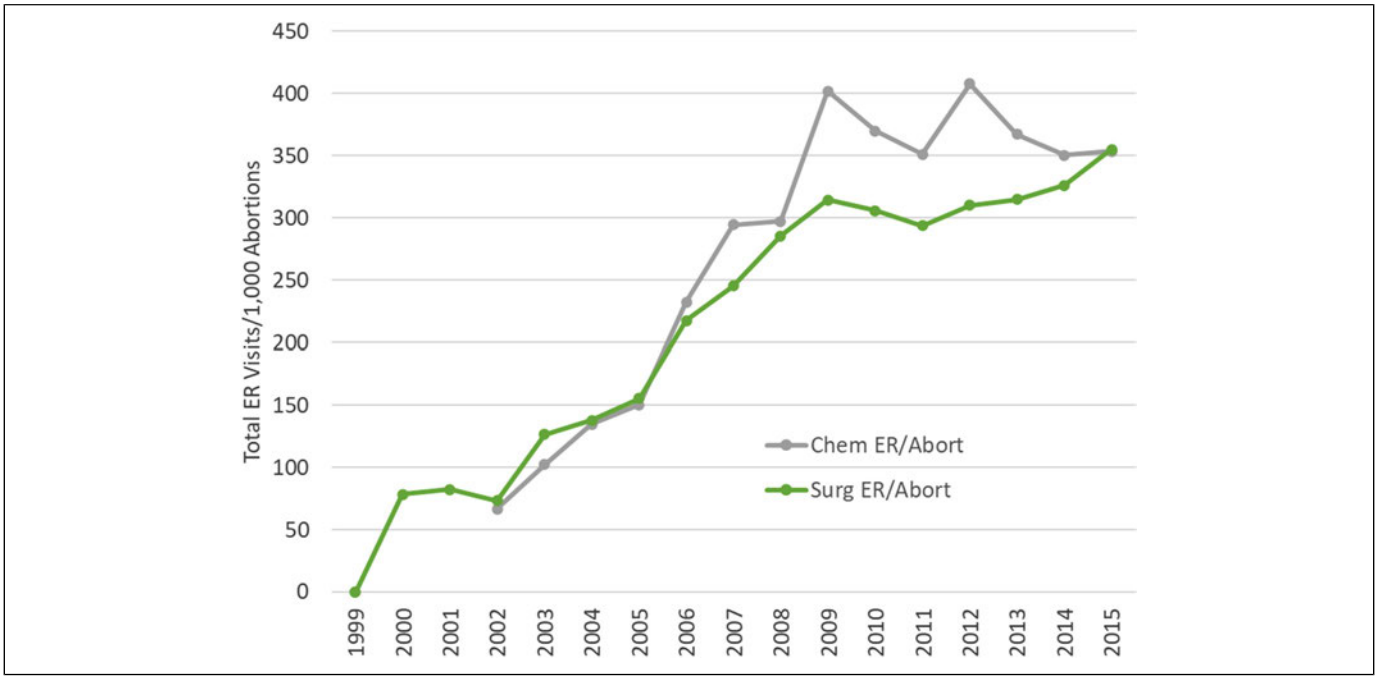

Figure 7. Total emergency room (ER) visits per 1000 abortions.

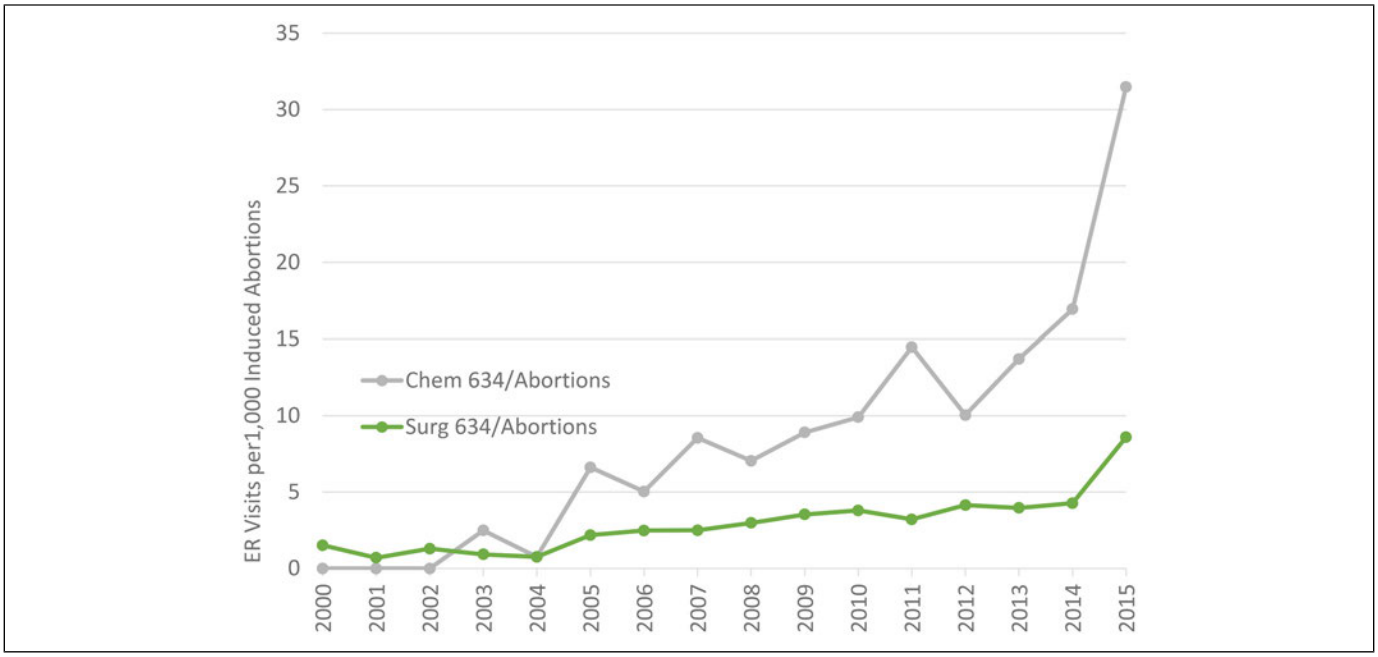

Figure 8. Miscoded spontaneous abortion emergency room (ER) visits per 1000 abortions.

Black women suggests that a more granular analysis of the influence of race is warranted. Services received by eligible women but paid by another source (eg, out of pocket) are not included in the claims data. Services received when the women were not eligible are similarly not included. Administrative data are also subject to limitations regarding coding errors, inconsistent coding, and the exclusion of codes considered nonessential for billing.[16,17] There are inconsistencies in coding which may vary state by state. Our data extraction protocol required both an ICD code and CPT code to

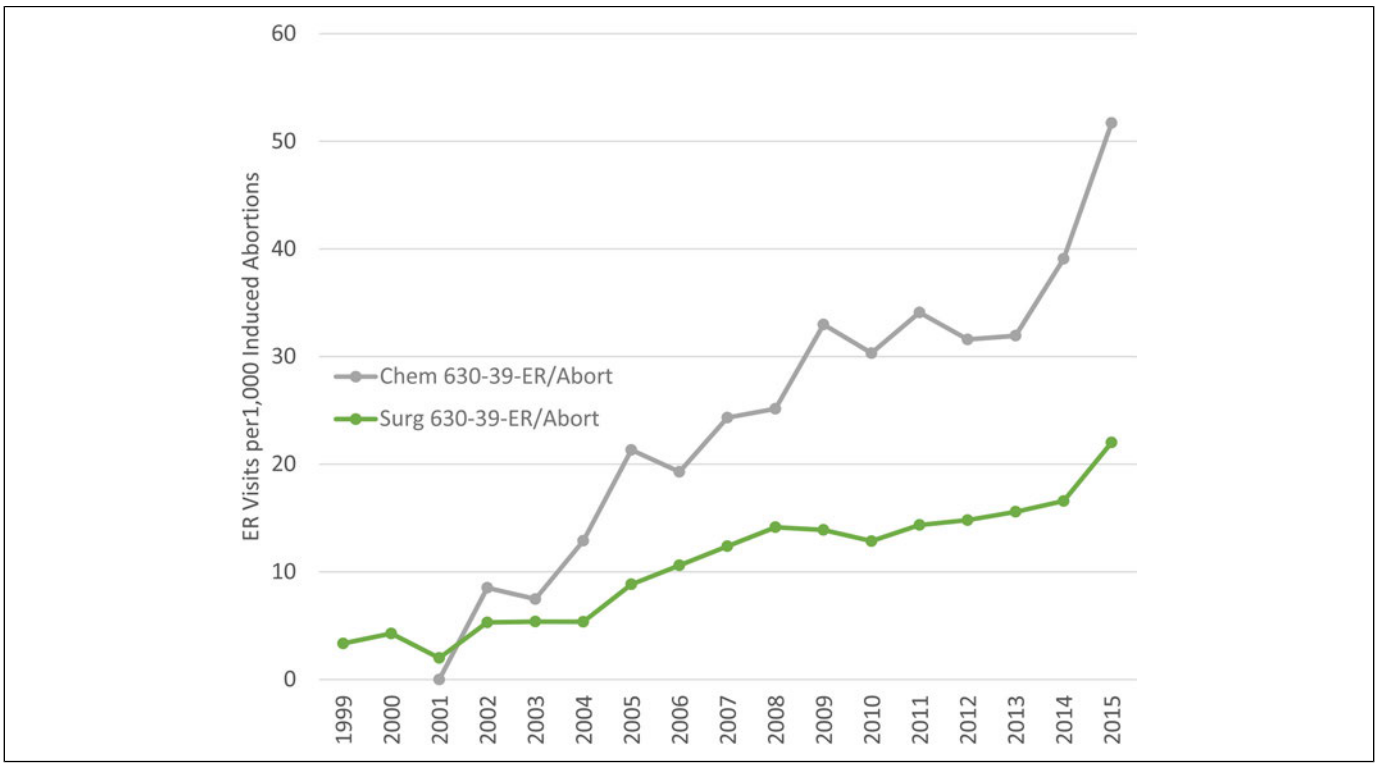

Figure 9. Abortion-related emergency room (ER) visits per 1000 abortions.

Table 2. Logistic Regression Odds Ratio Estimates (OR) and (Wald) Confidence Limits (CLs).

	Any ER Visit		Abortion-Related Visit		Spontaneous Abortion Visit	
	OR	95% CLs	OR	95% CLs	OR	95% CLs
Chemical versus Surgical Abortion	1.22	1.19 to 1.24	1.53	1.49 to 1.58	1.88	1.81 to 1.96
Race						
Black versus White	0.59	0.58 to 0.61	0.68	0.66 to 0.71	0.72	0.68 to 0.76
Hispanic versus White	1.07	1.05 to 1.10	1.03	1.00 to 1.07	1.03	0.98 to 1.09
Other versus White	0.91	0.89 to 0.93	0.88	0.85 to 0.91	0.85	0.81 to 0.89
Pregnancy 365 d prior versus no						
Prior surgical abortion	1.78	1.73 to 1.82	1.35	1.29 to 1.41	1.43	1.35 to 1.52
Prior chemical abortion	2.54	2.38 to 2.70	1.80	1.65 to 1.97	1.74	1.54 to 1.96
Prior live birth	1.52	1.48 to 1.56	1.09	1.04 to 1.15	1.12	1.04 to 1.20
Age	0.993	0.992 to 0.994	1.003	1.001 to 1.004	1.000	0.997 to 1.003
Months Medicaid Eligibility	1.008	1.007 to 1.008	1.006	1.005 to 1.007	1.006	1.006 to 1.006

identify beneficiaries who had an induced abortion. To the extent that some states or individual providers do not code an abortion with an ICD code, our study population may undercount the number of abortions. This undercount would likely be due to a random variation in coding protocols and is unlikely to affect the trends related in our findings.

In summary, mifepristone abortion is consistently and progressively associated with increased morbidity in the form of postabortion emergency room utilization among the population of women with publicly funded abortions. The determination of the causes and potential means of prevention for this burden of illness should have the highest priority of our health agencies and elected officials. Additional research is necessary to investigate the prevalence and type of effects beyond 30 days.

Declaration of Conflicting Interests

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David C. Reardon is the director of Elliot Institute, a biomedical ethicist, and a lead author on numerous studies and books examining the risk factors and effects of pregnancy loss on women and families.

John W. Fisher is currently an Associate Scholar at the Charlotte Lozier Institute. Following a 22 year career as a nuclear submarine officer, he served as the Director of Life Support and engineering at the Florida Aquarium, Chief Financial Officer of Technology Transfer Services, and 10 years as an Assistant Professor at the University of North Carolina at Charlotte College of Health and Human Services. He holds a PhD in Information Systems and Decision Sciences from the University of South Florida, a JD from Massachusetts School of Law, and Master's degrees from the Massachusetts Institute of Technology (Ocean Engineering), University of Notre Dame (Administration), Indiana University (Business Administration), and the United States Naval War College (National Security Policy). He is currently a member of the bar in New Hampshire and Massachusetts.

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EXHIBIT C

Health Services Research and Managerial Epidemiology
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A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization

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Abstract

Introduction: Previous research indicates that an increasing number of women who go to an emergency room for complications following an induced abortion are treated for a miscarriage, meaning their abortion is miscoded or concealed.

Objective: To determine if the failure to identify a prior induced abortion during an ER visit is a risk factor for higher rates of subsequent hospitalization.

Methods: Post hoc analysis of hospital admissions following an induced abortion and ER visit within 30 days: 4273 following surgical abortion and 408 following chemical abortion; abortion not miscoded versus miscoded or concealed at prior ER visit.

Results: Chemical abortion patients whose abortions are misclassified as miscarriages during an ER visit subsequently experience on average 3.2 hospital admissions within 30 days. 86% of the patients ultimately have surgical removal of retained products of conception (RPOC). Chemical abortions are more likely than surgical abortions (OR 1.80, CL 1.38-2.35) to result in an RPOC admission, and chemical abortions concealed are more likely to result (OR 2.18, CL 1.65-2.88) in a subsequent RPOC admission than abortions without miscoding. Surgical abortions miscoded/concealed are similarly twice as likely to result in hospital admission than those without miscoding.

Conclusion: Patient concealment and/or physician failure to identify a prior abortion during an ER visit is a significant risk factor for a subsequent hospital admission. Patients and ER personnel should be made aware of this risk.

Keywords

induced abortion, medical abortion, emergency room, inpatient admission, retained products of conception, medicaid

Introduction

In a previous study, we found abortion-related emergency room (ER) treatment rates from 2002–2015 increased 315% and 507% following surgical and chemical abortions respectively.[1] During this same period, we also found an increasing number of abortion patients misclassified/miscoded as having post miscarriage complications. A contributory factor to these miscodings may be the advice given to women by some abortion providers to conceal their abortion when seeking care in the ER for adverse events.[2,3] Since 60.9% of abortion-related ER visits following a chemical abortion were being miscoded as miscarriage by 2015, there is concern that this misinformation (ie, miscarriage rather than induced abortion) might result in sub-optimal care and, subsequently, an increased likelihood of hospital admission.[1] We use the risk of hospitalization following one

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or more ER treatments as a proxy for misinformed and suboptimal post abortion care.

Methods

Data were obtained from the enrollee-level Medicaid Analytic eXtract files licensed through the Centers for Medicare and Medicaid Services (CMS) Chronic Conditions Data Warehouse. The analytic dataset is comprised of enrollees from the 17 states whose official policies applied state funds to abortions not covered by federal Medicaid during the period 1999–2015. The study population was made up of enrollees over 13 years of age with at least one identifiable pregnancy outcome. For each beneficiary, all unique pregnancy outcomes were identified using International Classification of Diseases, Ninth Revision (ICD-9) codes. Additionally, Current Procedure Terminology, Fourth Edition (CPT4) and Healthcare Common Procedure Coding System (HCPCS) codes were used to confirm pregnancy outcomes. Every emergency room visit occurring within 30 days of the index abortion was identified (Place of Service code 23—emergency room). Emergency room visits within 30 days of a surgical or chemical induced abortion but treated for spontaneous abortion or miscarriage (ICD-9, primary diagnosis 634) are considered miscoded and possible concealment by the patient. Hospital admissions considered for the purpose of surgical removal of retained products of conception (RPOC) comprise ICD-9 procedure codes 690, 694, and 695.

In the original study, between 1999–2015, there were 423 000 confirmed induced abortion Medicaid procedures (361 924 surgical and 61 076 chemical), followed by 121 283 ER visits (99 928 surgical and 21 355 chemical). The exploratory post hoc analysis identified 4273 hospital admissions within 30 days of a surgical abortion and following an ER visit and 408 hospital admissions within 30 days of a chemical abortion and following an ER visit.

Summary analytic tables were created using (SAS/STAT) software, version (10) of the SAS system for (Unix). Copyright (2019) SAS Institute Inc.

The study has been exempted from Institutional Review Board (IRB) review pursuant to the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects at C.F.R. 46.101(b). See IRB ID: 7269, www.sterlingirb.com.

Results

Women experiencing chemical abortion and a subsequent emergency room (ER) visit within 30 days were less likely (OR 0.81, CL 0.70-0.95) to be hospitalized for any reason in that same time period than women who had experienced surgical abortion. This is true both for women whose prior abortion was concealed by miscoding during the ER visit and those for whom no mistaken miscarriage coding occurred (Table 1). Abortions miscoded in the ER were more likely to result in hospitalization for any reason (OR 1.06, CL 0.87-1.28) than those not miscoded. However, the subset of chemical abortion patients whose abortion was miscoded as miscarriage did exhibit a striking pattern of multiple admissions (3.2 per patient) for those women who were subsequently admitted compared to 1.8 admissions per woman whose abortion was not miscoded. Thus, the number of admissions per patient was 78% higher in women whose chemical abortion was concealed.

Further analysis determined that admissions for surgical RPOC were experienced by 86.3% of the women whose chemical abortion was subsequently miscoded in the ER, 2.5 times the rate of surgical abortion patients (34.2%) whose abortion was similarly miscoded. A very strong contrarian pattern emerges for hospital admissions involving surgical RPOC by aspiration and curettage or dilation and curettage. Chemical abortions are significantly more likely (OR 1.80, CL 1.38-2.35) than surgical abortions to result in an RPOC admission and chemical abortions miscoded in the ER are more likely (OR 2.18, CL 1.65-2.88) than abortions without miscoding to have a subsequent RPOC admission.

Chemical abortion patients whose subsequent ER visit is mistakenly coded as an adverse event related to miscarriage experience multiple hospital admissions within 30 days of the

Table 1. Hospital Admissions (for any Reason and RPOC) Following an Abortion and an Emergency Room Visit: by Type of Abortion with and without Miscoding as a Miscarriage.

	Surgical abortion			Chemical abortion		
Abortion miscoded as miscarriage (ICD 634)	Yes (%)	No (%)	Total	Yes (%)	No (%)	Total
No. patients with ER visits	567 (3.3)	16 671 (96.7)	17 238	366 (11.2)	2912 (88.8)	3278
No. ER patients admitted for any reason	114 (5.9)	1823 (94.1)	1937	22 (10.4)	190 (89.6)	212
% ER patients admitted for any reason	20.1%	10.9%	11.2%	6.0%	6.5%	6.4%
Total no. admissions for any reason	232 (5.4)	4041 (94.6)	4273	71 (17.4)	337 (82.6)	408
Admissions per patient for any reason	2.0	2.2	2.2	3.2	1.8	1.9
No. patients admitted for surgical RPOC	39 (13.0)	262 (87.0)	301	19 (21.6)	69 (78.4)	88
% admitted patients requiring surgical RPOC	34.2%	14.4%	15.5%	86.4%	36.3%	41.5%
No. surgical RPOC admissions	42 (13.3)	274 (86.7)	316	22 (23.7)	71 (76.3)	93
% surgical RPOC admissions of total admissions	18.1%	6.8%	7.4%	31.0%	21.1%	22.8%
Surgical RPOC admissions per patient	1.1	1.0	1.0	1.2	1.0	1.1

abortion and are particularly at risk to experience a hospitalization that involves RPOC.

Discussion

Our research indicates that an ER physician's misclassification of a failed induced abortion as a miscarriage correlated with higher rates of hospitalization and surgical intervention for RPOC. A patient's concealment of a chemical abortion, and/or the ER staffs' failure to identify the failed abortion attempt, are risk factors for multiple hospital admissions and delayed provision of necessary surgical treatment, compared with care for those whose abortion is not miscoded.

One possible explanation is that ER physicians may tolerate a higher level of pain, tenderness, or bleeding if they know they are dealing with an induced abortion patient rather than a spontaneous abortion patient experiencing the same symptoms. It may be that these women were considered sick enough to be admitted, yet surgical care was delayed while alternative treatment options were explored. The percent of admitted women who underwent surgical intervention for RPOC is strikingly higher for women whose induced abortions were misclassified as miscarriages.

It is important for emergency room personnel to obtain an accurate history when faced with an incomplete induced abortion. Additionally, it is inadvisable for abortion providers to tell women that if they present to an ER after the abortion, they can simply say they are having a miscarriage.[2,3]

Abortion providers should advise women that they may be at increased risk of multiple hospitalizations and surgical intervention if they do not inform medical personnel that they are experiencing an abortion complication. As required by the mifepristone Risk Evaluation and Mitigation Strategy, patients should be strongly reminded to bring the Medication Guide when seeking medical care in an emergency room.[4] Further research on adverse events associated with miscoding of induced abortion is warranted.

Declaration of Conflicting Interests

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EXHIBIT D

Reviewer's Guide

Peer review is essential for filtering out poor quality articles by assessing the validity and integrity of the research

SAGE journals

We value the work done by peer reviewers in the academic community, who facilitate the process of publication and drive research within their fields of expertise

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Types of peer review

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***Note**:The journal editor may need to approve your application to review*

1. Paper submitted

Tip: Increase your chances of being selected to review by providing an institutional email address, adding keywords to your account, or linking your account with your ORCID

2. Checked for compliance with journal guidelines

3. Fits within the journal's aims & scope?

- **Desk Reject**

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Tip: the invitation to review will include an abstract of the paper; read this before making your decision to accept or decline. If the paper is outside of your expertise, you may need to update your keywords. You may also wish to suggest alternative reviewers if you are unable to review the paper.

5. Peer reviewers selected by keywords*

*__Tip:__ make sure the keywords in your SAGE Track account are as full and accurate as possible to ensure only suitable manuscripts are sent to you to review

6. Email sent to reviewer

- **Decline:** If you don't have the time or particular knowledge to complete the review, or you have a bias or conflicts of interest that would prevent you from giving a fair review, please **decline** the invitation. If you simply ignore the email, you will be sent automatic follow-ups and it will delay the paper's review process

7. **Accept:** Please take note of the deadline set in the confirmation email and advise the editor if you encounter delays

8. Paper will appear in your 'Reviewer Centre' in SAGE Track

9. Make recommendations to Editor

Basic principles of Reviewing

- Only agree to review manuscripts within your area of expertise for which you can return your comments in a timely manner
- Respect the confidentiality of the process
- Be objective and constructive in your review
- Declare all conflicts of interest

Conflict of Interest

Personal, professional or financial relationship with any party involved in the manuscript

See the **COPE website** for full **ethical guidelines for reviewers**

So, you've agreed to review a paper... now what?

01 Initial Impression

Read the whole paper through before you start your in-depth review to get an initial impression

What to look out for and comment on

- Is this paper relevant for the journal?
- Is this research significant within the field?
- Is the work presented novel? Does it add to the subject area?

What to keep an eye on

- Does the title properly reflect the subject of the paper?
- Do the keywords reflect the content and are they up-to-date? For example, are the keywords broad enough to lure in readers with a broad interest in the topic but narrow enough to accurately reflect the contents of the paper?
- Is the paper an appropriate length?
- Are the key messages short and clear?

Note:

It is not the reviewer's job to proof-read or suggest extensive grammatical revisions to a paper. If the meaning of the paper is lost due to extensive grammatical errors, recommend the paper for language editing, via services like SAGE Language Services (https://languageservices.sagepub.com/en/).

02 Sections of the Paper

Abstract

After reading the abstract, you should already understand the aims, key data and conclusions of the manuscript. If you don't, make a note of this

Introduction

- Is it clear, short and simple?
- Does it set the scene i.e. explain the background to the study?
- Does it set out and justify the aim of the study?
- Does the literature review include the latest research?

Methods

Academic research should be rigorous and replicable – is all the relevant detail included in this section?

Consider:

- Have all necessary procedures been followed (for example, health and safety of participants in the study)?
- Have the correct guidelines been followed? (e.g. CONSORT, PRISMA)
- Are the methods used appropriate?

Ethical standards

If the paper has failed to adhere to best practice standards, for example, the paper is not properly referenced, it does not require further review and should be rejected

Results

The authors should report the results of all tests noted in the Methods section:

- Demographics – age, gender, side, site etc.
- Objective data
- Subjective data
- Complications of treatment
- Ask yourself: do the numbers make sense?
- Are the results clearly formatted and presented? Are SI units and other notation correct, and are graphs, axis heading, data labels readable?

Remember:

If a test is not stated in the Methods section then the results may not be reported in the Results

Discussion

- This should not be a repetition of the results
- It should put the results of the study in context i.e. how does it fit in with what we already know?
- Do the authors achieve their stated aim (in the Introduction)?

Look out for:

Major flaws in data, tables, figures and images

- Insufficient data
- Statistical variations
- Unclear or contradictory data

- Have they cited all relevant/ important published papers?
- Can you follow the reasoning of the paper?

The authors should compare their data with previous published studies to:

- Confirm similarities i.e. validate the study further
- Explain differences

Conclusion

Finally, the authors should describe:

- The limitations of the study
- The "take home" message as a short conclusion

Consider:

- Does the conclusion address the question/s posed? Is it consistent with the evidence and arguments presented?
- Is the conclusion contradicted by the author's evidence?

03 Your Feedback

Giving advice to authors and suggesting revisions

- Demonstrate that you have read the paper. You may wish to include an opening paragraph summarising the paper.
- Be objective, specific and constructive
- Be clear about what needs to be added or revised
- Give clear and detailed comments to the Editor
- Give constructive comments to the author/s to help them with any revisions
- If appropriate, make suggestions about additional literature that the author might read to improve their manuscript*

Some journals allow you to make two sets of comments, one of which is directed to the attention of the editor only and the other that the editor can send on to the author to allow you to direct questions or recommendations appropriately

Tip:

Number your comments – this will make it easier for the author and editor to refer back to.

Making a recommendation

Most journals will ask you to recommend whether a paper should be accepted, rejected or revised (major or minor revisions), and you may be asked to look over the changes made to a paper to ensure that improvements have been adequately made

Have an overall view of the quality of the paper and consider if it is good enough to be published in the journal

Remember to keep all activity, content and comments relating to the paper confidential

Issues to consider

- Are there major flaws i.e. factual errors?
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- Is any of the information unclear or ambiguous?
- Has similar work been published?
- Will the work be impactful?
- Are there any ethical issues?

Be as specific and detailed as you can; brief comments to an Editor will not help them make a decision

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Consider the following before undertaking a review:

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- Be careful not to make judgements about the paper based on personal, financial, intellectual biases or any other considerations than the quality of the research and written presentation of the paper.
- You may wish to involve junior researchers in the review of an article as it can be good experience for that person. However, you should ensure that you obtain permission from the journal Editor prior to accepting the invitation to review.
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- You suspect that the paper is duplicating the work of others.
- You suspect that there might be problems with the ethics of the research conducted.
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JOURNAL: Health Services Research & Managerial Epidemiology

ALL AUTHOR(S): Studnicki, James; Longbons, Tessa; Fisher, John; Harrison, Donna; Skop, Ingrid; Mackinnon, Sharon

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Journal	Health Services Research and Managerial Epidemiology
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THE PURPOSE OF RETRACTION

Retraction is a mechanism for correcting the literature and alerting readers to articles that contain such seriously flawed or erroneous content or data that their findings and conclusions cannot be relied upon. Unreliable content or data may result from honest error, naïve mistakes, or research misconduct.

The main purpose of retraction is to correct the literature and ensure its integrity rather than to punish the authors.

Retractions may be used to alert readers to cases of redundant publication, plagiarism, peer review manipulation, reuse of material or data without authorisation, copyright infringement or some other legal issue (eg, libel, privacy, illegality), unethical research, and/or a failure to disclose a major competing interest that would have unduly influenced interpretations or recommendations.

WHICH PUBLICATIONS SHOULD BE RETRACTED?

If only a small part of an article reports flawed data or content, this may be best rectified by a correction. Partial retractions are not helpful because they make it difficult to determine the status of the article and which parts may be relied upon. Similarly, if only a small section of an article (eg, a few sentences in the discussion) is plagiarised, editors should consider a correction (which could note that text was used without appropriate acknowledgement and cite the source) rather than retracting the entire article, which may contain sound, original data.

If redundant publication occurs, the journal that published first may issue a notice of redundant publication but should not retract the article unless there are other concerns, such as the reliability of the data. Any journals that subsequently publish a redundant article should retract it and state the reason for the retraction. If an article is published in more than one journal (either online or in print) around the same time, precedence may be determined by the publication dates or the dates on which a licence to publish or copyright transfer agreement was signed by the authors.

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Version 2: November 2019.

Journals that publish an article that synthesises or aggregates data from redundant publications may consider issuing a correction; duplicate counting of the same data can cause meta-analyses and systematic reviews to overestimate effect sizes and benefits of interventions.

In cases of partial overlap (ie, when authors present new findings in an article that contains a substantial amount of previously published information) editors should consider whether the entire article is retracted or whether to issue a correction clarifying which aspects had been published previously and providing appropriate attribution to the earlier work. This will depend on the amount and nature of overlap – in some cases (eg, description of a standard method), a limited degree of **Text recycling** (https://cope.onl/text-recycle) may be permissible.

Guidelines on dealing with redundant publications identified in submitted manuscripts or published articles can be found in the relevant **COPE Flowcharts** (https://cope.onl/flowcharts-1).

Posting an 'in press' or final version of an article online usually constitutes publication even if the article has not appeared (or will not appear) in print. If an article is retracted before it appears in the print or online version of a journal, or if the journal does not publish in print, the online version of the article should be retained with a clear notice of retraction and it should be included in bibliographic databases (eg, with a digital object identifier (DOI) or other permanent citation). Retaining the original work ensures transparency of the published record, as online versions may have been accessed and cited by researchers prior to retraction.

Articles that relied on subsequently retracted articles in reaching their own conclusions, such as systematic reviews or meta-analyses, may themselves need to be corrected or retracted.

Retractions may be requested by an article's author(s), by an institution, by readers, or by the editor.

WHAT FORM SHOULD A RETRACTION TAKE?

In general, a retraction notice should cover a single retracted article.

Retraction notices should mention the reasons and basis for the retraction to enable readers to understand why the article is unreliable and should also specify who is retracting the article and possibly how the matter came to the journal's attention (claimants may be named only when they have given permission).

Whenever possible, editors should negotiate with authors and attempt to agree on a form of wording that is clear and informative to readers and acceptable to all parties. However, prolonged negotiations should not unreasonably delay retraction and editors should publish retractions even if consensus cannot be reached. Retraction notices should be published in all versions of the journal (ie, print and/or online). It is helpful to include the authors and title of the retracted article in the retraction heading. A form from the **European Association of Science Editors** for checking details of the retraction is available at (http://b.link/ease).

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Retracted articles should be unmistakably identified as such in all online sources (eg, on the journal website, on the original article, and any bibliographic databases). Journals are responsible for ensuring that retractions are labelled in such a way that they are identified by bibliographic databases and should also include a link to the retracted article. The retraction should appear on all online searches for the retracted publication.

In extremely limited cases it may be necessary to remove an article from online publication, such as when the article is clearly defamatory, violates personal privacy, is the subject of a court order, or might pose a serious health risk to the general public. In these circumstances, the metadata (title and authors) should be retained and the retraction notice should clearly state why the full article has been removed.

WHO SHOULD ISSUE THE RETRACTION?

In some cases, retractions are issued jointly or on behalf of the journal's owner (eg, a learned society or publisher). However, since responsibility for the journal's content rests with the editor, they should always have the final decision about retracting material. Editors may retract publications (or issue expressions of concern) even if all or some of the authors do not agree. Who is retracting the article should be clearly identified within the retraction notice.

HOW QUICKLY SHOULD AN ARTICLE BE RETRACTED?

Publications should be retracted as soon as possible after the editor is convinced that the publication is seriously flawed, misleading, or falls into any of the categories described above. Prompt retraction should minimise the number of researchers who cite the erroneous work, act on its findings, or draw incorrect conclusions, such as from 'double counting' redundant publications in meta-analyses or similar instances. If an editor has convincing evidence that a retraction is required, they should not delay retraction simply because the authors are not cooperative. However, if an allegation of misconduct related to a potential retraction results in a disciplinary hearing or institutional investigation, it may be appropriate to wait for the outcome before issuing a retraction (but an expression of concern may be published in the interim).

If a letter or commentary that has been submitted for publication raises serious concerns about an article, an editor should not wait for a decision on publication of the letter or commentary to consider whether the article may also need to be retracted (or whether an expression of concern is needed).

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When editors or journals have credible grounds to suspect misconduct, this should be brought to the attention of the authors' institutions as early as possible, but the decision to correct or retract an article should be made by the journal and does not necessarily depend on an institutional finding of misconduct. Journals should in principle raise concerns with an author before contacting institutions, but when evidence of serious misconduct is well founded then in rare cases they may contact institutions without first informing the authors (editors should use the **COPE Guidelines,** Cooperation between research institutions and journals on research integrity cases (https://doi.org/10.24318/cope.2018.1.3) and the **CLUE Guidelines,** Cooperation and liaison between universities and editors (CLUE): Recommendations on best practice, (https://doi.org/10.1101/139170)).

If necessary, a previously corrected article may be further corrected or a previously corrected article may be retracted following the outcome of an institutional investigation. When possible, the outcome of institutional investigations should be quoted from and cited in the notice, and any findings of misconduct should be appropriately attributed to the institution who made the finding.

WHAT SHOULD EDITORS DO IN THE FACE OF INCONCLUSIVE EVIDENCE ABOUT A PUBLICATION'S RELIABILITY?

If conclusive evidence about the reliability of a publication cannot be obtained, or will not be obtained for a significant period of time, retraction may not be appropriate, but an editor could consider publishing an expression of concern.

SHOULD RETRACTION BE APPLIED IN CASES OF DISPUTED AUTHORSHIP?

Authors sometimes request that articles are retracted when authorship is disputed after publication. If there is no reason to doubt the validity of the findings or the reliability of the data, it is not appropriate to retract a publication solely on the grounds of an authorship dispute. In such cases, the editor should inform those involved in the dispute that they cannot adjudicate in such cases but will be willing to publish a correction to the author/contributor list if the authors/contributors (or their institutions) provide appropriate proof that such a change is justified. For authorship disputes occurring before publication, see the relevant **COPE Flowcharts** (https://cope.onl/flowcharts-1).

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CAN AUTHORS DISSOCIATE THEMSELVES FROM A RETRACTED PUBLICATION?

If retraction is due to the actions of some, but not all, authors of a publication, the notice of retraction should mention this when possible. However, authorship entails some degree of joint responsibility for the integrity of the reported research so it is not appropriate for authors names to be removed from a publication even if they were not directly culpable for the errors or actions that led to retraction.

ARE THERE GROUNDS FOR LEGAL PROCEEDINGS IF AN AUTHOR SUES A JOURNAL FOR RETRACTING, OR REFUSING TO RETRACT, A PUBLICATION?

Authors who disagree with a retraction (or whose request to retract a publication is refused) sometimes threaten journals and their editors with legal action. Concern over litigation can make editors reluctant to retract articles, especially in the face of opposition from authors.

Journals' instructions for authors should explain the journal's policies on publication ethics and describe the circumstances under which articles might be retracted. This information should be incorporated into author agreements and brought to the authors' attention. It is common for author agreements to contain commitments from authors confirming compliance with the journal's policies. However, even if the publishing agreement or journal instructions do not set out specific conditions for retraction, authors usually would not have grounds for taking legal action against a journal over retraction or an expression of concern if it follows a suitable investigation and proper procedures (see for example Mario Saad vs American Diabetes Association (http://b.link/ada-1)).

Legal advice may be helpful to determine appropriate wording for a retraction notice to ensure that the text is not considered defamatory. As much as possible, wording of retractions should be limited to proven facts. Retraction notices should not engage in speculation (such as about motives or elements that are unproven) and should avoid *ad hominem* or other personal attacks. Nevertheless, retraction notices should always mention the reason(s) for retraction, and a statement about misconduct findings may be included if they are properly attributed to the finding body (eg, following an institutional or funder investigation). If authors consent to the wording of a retraction statement, this may provide a defence against a libel claim.

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REPUBLISHING RETRACTED CONTENT

An author may republish some of the work if not all of the content was found to be unreliable. In order to do so transparently, authors should notify the editors of the new journal of the prior retraction and it is likely appropriate to cite the retraction, indicating why the work was flawed and what has been corrected in the new article. Permission to republish also needs to be agreed with the copyright holder of the retracted work.

In some instances, journals may wish to work with authors to concurrently retract an article that was found to be fundamentally flawed while simultaneously publishing a linked and corrected version of the work. This strategy of 'retract and republish' is not commonly used, but may provide an opportunity for journals and authors to transparently correct the literature when a simple correction cannot sufficiently address the flaws of the original article (eg, see Retraction and republication – a new tool for correcting the scientific record? *European Science Editing* (https://b.link/ese-1)). In this instance, the original article should not be completely removed or 'replaced', but should be retained and linked to.

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https://doi.org/10.24318/cope.2019.1.4

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FURTHER READING

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AUTHOR CONTRIBUTIONS

Conceptualisation:
2009 version conceptualised and written by Elizabeth Wager, Virginia Barbour, Steven Yentis and Sabine Kleinert on behalf of COPE Council.

2019 Version:
Writing – original draft preparation:
Howard Browman

Writing – review and editing:
Jessica Alexander, Catriona Fennell, Matt Hodgkinson, Heather Tierney

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PROMOTING INTEGRITY IN SCHOLARLY RESEARCH AND ITS PUBLICATION

EXHIBIT I

SUPERIOR COURT OF CALIFORNIA, COUNTY OF VENTURA

Superior Court of California, County of Ventura, Hall of Justice, Department 41

2024CUPA031167 November 21, 2024
DR JAMES STUDNICKI, et al. vs SAGE PUBLICATIONS INC 8:20 AM

Judge: Honorable Ronda McKaig
Judicial Assistant: Kim Goodman
CSR: Mary Ferreira

APPEARANCES:

Caroline P Gately, counsel, present for Respondent(s).

Philip A Sechler, counsel, present for Petitioner(s).

David Allen Shaneyfelt, counsel, present for Petitioner(s).

Patrick Strawbridge, counsel, present for Petitioner(s) telephonically.

Max Noah Wellman, counsel, present for Respondent(s).

NATURE OF PROCEEDINGS: Hearing on Petition to Compel Arbitration

8:39 a.m. Court convenes in this matter.

Pursuant to Government Code sections 68086, 70044, California Rules of Court, Rule 2.956, and the stipulation of appearing parties, Mary Ferreira, certified shorthand reporter is appointed as an official Court reporter pro tempore in these proceedings, and is ordered to comply with the terms of the Court Reporter Agreement. The Order is signed and filed this date.

Counsel have received and read the Court's written tentative ruling.

Matter submitted to the Court with argument.

The Court finds/orders:

Upon consideration of the oral argument and further review of all documents, the Court now rules in accordance with its tentative ruling modified as follows:

The Court grants Petitioners Dr. James Studnicki's, Dr. Donna Harrison's, Dr. David Reardon's, Dr. John Fisher's, Dr. Ingrid Skop's, Dr. Maka Tsulukidze's, Dr. Christina Cirucci's, Dr. Sharon Mackinnon's, Christopher Craver's, and Jessica Cox's petition for an order compelling arbitration of Petitioners' claims against Respondent Sage Publications, Inc. ("Sage") arising out of Sage's allegedly pretextual and discriminatory retraction of three articles co-authored by Petitioners in one of Sage's medical journals.

The parties shall submit Petitioners' claims to binding arbitration and the case is otherwise stayed.

Pursuant to Code of Civil Procedure §1281.6, the Court directs Respondent to provide a list of 5 potential arbitrators to the Petitioners and the Court by 11/26. By Dec. 4, the Court will publish a minute order and will serve the parties with 5 nominees for potential arbitrators from the lists provided. The parties have until Dec. 13 to agree on one of the nominees and inform the Court of the same; but if they fail to do so within that time, the Court will appoint an arbitrator from the nominees.

The Court denies all additional relief requested by Petitioners and Sage.

Status Conference re: arbitration is scheduled for 12/01/2025 at 08:35 AM in Department 41 at Hall of Justice.

The 02/26/2025 8:35 AM MANDATORY APPEARANCE CMC/Order to Show Cause Re Sanctions/Dismissal for Failure to File Proof of Service/Default in Department 41 is vacated.

Notice is waived.

EXHIBIT J

VENABLE LLP
2049 CENTURY PARK EAST, SUITE 2300
LOS ANGELES, CA 90067
310.229.9900

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF VENTURA

JAMES STUDNICKI, *et al.*,

Petitioners,

v.

SAGE PUBLICATIONS, INC.,

Respondent.

Case No. 2024CUPA031167

~~[PROPOSED]~~ ORDER ON RESPONDENT SAGE PUBLICATIONS INC.'S PETITION TO APPOINT REPLACEMENT ARBITRATOR

Judge: Hon. Mark S. Borrell
Dept.: 40

Action Filed: October 4, 2024
Trial Date: None Set

~~[PROPOSED]~~ ORDER

Having reviewed the Petition to Appoint Replacement Arbitrator for Respondent Sage Publications, Inc. (the "Petition"), and the papers associated therewith, filed on January 27, 2025, and good cause appearing therefor,

IT IS HEREBY ORDERED that

1. The Petition is DENIED ~~GRANTED~~; and

2. The Court ~~nominates~~ appoints the following ~~five~~ person to serve as the arbitrator of the parties' underlying dispute:

a. Hon. Vincent J. O'Neill

~~b. _____~~

c. _____

d. _____

e. _____; and

~~3. The parties shall have five days from notice of this order to inform the Court that they agree on a single arbitrator or that they are unable to agree; and~~

~~4. Sage is awarded its costs pursuant to Cal. Civ. Proc. Code § 1293.2.~~

3. Respondent to give notice forthwith.

IT IS SO ORDERED.

Dated: 01/29/2025

JUDGE OF THE SUPERIOR COURT

VENABLE LLP
2049 CENTURY PARK EAST, SUITE 2300
LOS ANGELES, CA 90067
310.229.9900

PROOF OF SERVICE

STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, Suite 2300, Los Angeles, CA 90067.

On **January 27, 2025**, I served a copy ☑ / original ☐ of the foregoing document(s) described as **[PROPOSED] ORDER ON RESPONDENT SAGE PUBLICATIONS, INC.'S PETITION TO APPOINT REPLACEMENT ARBITRATOR** on the interested parties in this action addressed as follows:

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☑ **BY ELECTRONIC SERVICE (CCP § 1010.6; CRC Rule 2.251(g)):** I transmitted the above-stated document(s) and an unsigned copy of this declaration from my computer (electronic notification address *KEWestcott@Venable.com*) located Venable LLP, 2049 Century Park East, Suite 2300, Los Angeles, CA 90067 to the interested parties in this action whose names and e-mail addresses are listed above. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was unsuccessful. Service by e-mail or electronic transmission was agreed upon based on a court order or an agreement of the parties to accept service.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **January 27, 2025** at Los Angeles, California.

Kenneth Westcott

VENABLE LLP
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LOS ANGELES, CA 90067
310.229.9900