RESEARCHERS' PRIVILEGE: FULL DISCLOSURE

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ABSTRACT

An ever-growing chorus of academicians report that with the expanding number of academic journals there is a concomitant increase in the number of articles based on questionable methodology. Many published studies contain improper statistical conclusions, flawed methodology, and results that cannot be replicated. The recent controversy concerning the failure of parents to vaccinate their children because of the recommendations of flawed research exemplifies this crisis. This epidemic of faulty research has been exacerbated recently by the spread of low-quality academic journals and "pay-to-publish" journals, which will publish virtually

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† The research for and writing of this article were performed in their entirety by the two authors who received no compensation from any source for this work. Furthermore, the authors did not pay any fees for having this article published, and no such fees were paid on their behalf by any source. The issue of "academic privilege" first came to our attention in a case where we (as counsel for the defendant) unsuccessfully raised it some 30 years ago. *See* Procter & Gamble Co. v. Swilley, 462 So. 2d 1188 (Fla. Dist. Ct. App. 1985). In other litigation in which we were involved, Western Virginia University raised the issue in response to our effort to seek discovery from a professor. *See* Ohio Valley Envtl. Coal. v. U.S. Army Corps of Eng'rs, No. 1:11MC35, 2012 WL 112325 (N.D. W. Va. Jan. 12, 2012). The authors thank the editors of the *Western Michigan University Thomas M. Cooley Law Review* for their helpful comments and suggestions.

anything for a fee. This Article provides an analysis of a growing crisis of reliability in scientific research and how the so-called "researchers' privilege" allows faulty research to go undetected. This Article delineates the reasons why it is difficult, if not impossible, to evaluate published research findings without access to the underlying information that researchers have in their possession. The Article then analyzes the state of the law regarding the ability of researchers to withhold records and data based on the so-called "researchers' privilege." Finally, the Article explains why courts should favor the disclosure of research data and that confidentiality concerns should be addressed by a confidentiality order.

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INTRODUCTION

In 1998, Dr. Andrew Wakefield published the results of a study in *The Lancet* that linked the administration of the mumps, measles, and rubella ("MMR") vaccine to the development of autism.[1] These

1. *See* A J Wakefield et. al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 THE LANCET 637 (Feb. 28, 1998) (subsequently retracted), *available at*

startling results shocked parents, who for almost 30 years had relied on this trusted vaccine to virtually eliminate MMR from the Western world.[2] Almost immediately, rabid movements began among parents to stop vaccinating their children.[3] Some parents feared autism more than diseases such as MMR, which they had never experienced or encountered. Even celebrities like Jenny McCarthy and Charlie Sheen launched crusades against vaccination.[4]

But there was a problem with Dr. Wakefield's research conclusions: They were false.[5] Dr. Wakefield, a paid consultant for attorneys involved in litigation against vaccine makers, based his conclusions on anecdotal evidence from an examination of only 12 children.[6] As an increasing number of studies failed to find a link

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http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/abstract; *see also What is Autism?*, AUTISM SPEAKS.ORG, http://www.autismspeaks.org/what-autism (last visited Mar. 23, 2015) (stating that autism is a complex brain disorder characterized by difficulties in social interaction, verbal and nonverbal communication, and repetitive behaviors).

2. *See* Kenneth Haller & Anthony Scalzo, "I've Heard Some Things That Scare Me": *Responding with Empathy to Parents' Fears of Vaccinations*, 109 MO. MED. 10 (2012) (arguing that Wakefield's article provides "already skeptical parents a 'scientific' excuse to indulge in popular and centuries-old misgivings about the very idea of vaccination in the public mind"); *see also Vaccines (Immunizations)*, NAT'L LIBR. MED., http://www.nlm.nih.gov/medlineplus/ency/article/002024.htm (last visited Mar. 23, 2015) (stating that the MMR vaccine contains live, but very weak, forms of the three diseases, which teaches the body to attack each virus and reduces the chance of catching any of the diseases).

3. *See* Susan Dominus, *The Crash and Burn of an Autism Guru*, N.Y. TIMES, April 24, 2011, http://www.nytimes.com/2011/04/24/magazine/mag-24Autism-t.html (noting that one supporter of Wakefield's work stated that Wakefield "is Nelson Mandela and Jesus Christ rolled up into one").

4. *See, e.g.*, Chris Mooney, *Why Does the Vaccine/Autism Controversy Live On?*, DISCOVER MAG. (May 6, 2009), http://discovermagazine.com/2009/jun/06-why-does-vaccine-autism-controversy-live-on/.

5. Steven Novella, The Lancet *Retracts Andrew Wakefield's Article*, SCI. BASED MED. (Feb. 3, 2010), http://www.sciencebasedmedicine.org/lancet-retracts-wakefield-article/ (stating that Wakefield's study could not be replicated after a decade of research and was retracted by *The Lancet*).

6. *See* Lisa A. Rickard, *The Anti-Vaccine Movement and a Trial Lawyer-Funded Climate of Fear*, FORBES (Apr. 28, 2014), http://www.forbes.com/sites/theapothecary/2014/04/28/the-anti-vaccine-movement-and-a-trial-lawyer-funded-climate-of-fear/ ("[T]he article was later retracted by the publisher for being 'utterly false,' and the author, Wakefield, was found to have been paid big bucks by plaintiff's lawyers."); *Retracted Autism Study an 'Elaborate Fraud,' British Journal Finds*, CNN (Jan. 5, 2011, 8:14 AM), http://www.cnn.com/2011/HEALTH/01/05/autism.vaccines/ ("Most of [Wakefield's] co-authors

between the administration of the MMR vaccine and the development of autism, the tide turned against the anti-vaccination activists.[7] Websites such as jennymccarthybodycount.com claimed to record the number of children who developed illnesses or died because they were not vaccinated.[8] McCarthy reportedly lost her job as a co-host on *The View*[9] partially because of her anti-vaccination activities.[10]

Because published research studies play an important role in the advancement of the world's healthcare, one might assume that the Wakefield controversy was an isolated incident of the scientific method having gone awry; however, this is not the case.[11] An ever-

withdrew their names from the study in 2004 after learning he had had (sic) been paid by a law firm that intended to sue vaccine manufacturers."); *Vaccine Study's Author Held Related Patent, Medical Journal Reports*, CNN (Jan. 12, 2011, 5:54 AM), *available at* http://www.cnn.com/2011/HEALTH/01/11/autism.vaccines/ (noting that "Wakefield received more than . . . $674,000 . . . from lawyers trying to build a case against vaccine manufacturers," one of his twelve research patients' father was involved in a joint venture with Wakefield, and he disputed holding a patent for "an alternative to the MMR vaccine"); *see also* Chris Graf et al., *Best Practice Guidelines on Publication Ethics: A Publisher's Perspective*, 61 INT'L J CLINICAL PRAC. 1, 8 (Supp. 152, 2007) (stating that conflicts of interest such as patent ownership may skew objectivity and must be disclosed); *cf.* Frank C. Woodside, III & Allison G. Davis, *The Bradford Hill Criteria: The Forgotten Predicate*, 35 T. JEFFERSON L. REV. 103, 115 (2013) (discussing research and generally accepted methodology).

7. *See* Cliff Pinckard, *Measles Outbreak in New York Brings Backlash Against Anti-Vaccine Movement (Poll)*, CLEVELAND.COM (Mar. 19, 2014, 2:43 AM), http://www.cleveland.com/nation/index.ssf/2014/03/measles_outbreak_in_new_york_b_1.html.

8. *See Anti-Vaccine Body Count*, JENNY MCCARTHY BODY COUNT, http://www.jennymccarthybodycount.com/Anti-Vaccine_Body_Count/Home.html (last visited Mar. 22, 2015).

9. *The View* (ABC broadcasts Sept. 29, 2013 – June 26, 2014).

10. Casey Balch, *Jenny McCarthy Fired from The View, Vaccinations Views to Blame*, MSTARS NEWS (June 27, 2014, 8:25 AM), http://www.mstarz.com/articles/32703/20140627/jenny-mccarthy-fired-view-vaccinations-views-blame.htm.

11. In the words of Yogi Berra, this is "déjà vu all over again." Wendy Thurm, *It's Like Deja Vu All Over Again. Sort of.*, SBNATION (June 23, 2012, 1:35 PM), http://www.sbnation.com/2012/6/23/3112502/bryce-harper-clown-question-bro-baseball-quotations. *See also, e.g.*, *Deutsch Assails Laughlin over Race Measure*, JEWISH DAILY BULL. (N.Y.C.), May 7, 1934, at 1 (referencing Dr. Harry H. Laughlin, "who is connected to the Department of Eugenics at the Carnegie Institute," and his "'purification of race theory,' [being] as dangerous and as spurious as the purified 'Aryan' race theories advanced by the Nazis, to which it bears suspicious resemblance"); *accord* BILL BRYSON, ONE SUMMER 369–70

growing chorus of academicians reports that with an expanding number of academic journals, there is a concomitant increase in the number of articles based on questionable methodology.[12] Now, an alarming number of published studies contain improper statistical conclusions, flawed methodology, and results that cannot be replicated.[13]

Importantly, judges and attorneys, like doctors, rely upon published research to make decisions.[14] For example, in medical-malpractice cases, attorneys use published research to prove and to disprove whether a defendant physician or other healthcare provider has met the standard of care in treating a patient.[15] Often, toxic-tort cases hinge upon establishing a causal chain between the chemical exposure at issue and the individual allegedly impacted—a determination that hinges upon scientific research and the science of toxicology.[16] Toxicology research relies upon technical evidence

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(2013) (noting that the Carnegie Institute hired Herbert Spencer Jennings to review Dr. Laughlin's work, and it was determined that "Laughlin had falsified data, manipulated findings to support racist conclusions, and generally perpetrated scientific fraud for over a quarter of a century").

12. *See* Francis S. Collins & Lawrence A. Tabak, *NIH Plans to Enhance Reproducibility*, 505 NATURE 612, 612 (2014); John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLOS MED. 696, 696 (2005), http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0020124&representation=PDF; John Bohannon, *Who's Afraid of Peer Review?*, SCI. MAG., Oct. 4, 2013, at 60, 64.

13. *See* Susan Haack, *Peer Review and Publication: Lessons for Lawyers*, 36 STETSON L. REV. 789, 799 (2007).

14. *See* Sean R. Tunis et al., *Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy*, 290 JAMA 1624, 1624 (2003) ("Decision makers in health care are increasingly interested in using high quality scientific evidence to support clinical and health policy choices; however, the quality of available scientific evidence is often found to be inadequate.").

15. *See* Anna C. Mastroianni, *Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy*, 16 HEALTH MATRIX 351, 379 (2006) ("[M]edical standards of care emerge through a complex interplay of professional leaders, journals, peer discussions, and meetings."); *see also* BLACK'S LAW DICTIONARY 1624 (10th ed. 2014) ("[S]tandard of care . . . [is] the degree of care that a reasonable person should exercise.").

16. *See* Anthony Z. Roisman et al., *Preserving Justice: Defending Toxic Tort Litigation*, 15 FORDHAM ENVTL. L. REV. 191, 194 (2004) ("[T]oxic tort is a wrongful injury caused by the toxic properties of a substance or product."); *see also id.* at 204 ("[T]he task of marshaling the available scientific literature and demonstrating that it is more probable than not that an exposure to a toxic

gleaned from "epidemiology, animal toxicology, in vitro testing, chemical structural analysis, and case reports" to attempt to determine causation.[17]

Litigation also relies heavily on scientific and medical literature.[18] This reliance has consequences for the judicial system because courts have admitted scientific research as evidence when that research would later be proved wrong.[19] In litigation involving the drug Bendectin, 40% of juries found for the plaintiffs—although no plaintiff should have been able to satisfy the burden of causation.[20] These verdicts, totaling over a hundred-million dollars, were based on questionable expert opinions and questionable research regarding the safety of Bendectin.[21] Later, the manufacturer of Bendectin withdrew the drug from the market because of legal and public-relations concerns.[22] Each adverse jury verdict at trial was eventually set aside as a result of post-trial motions or appeal, and thus no final judgments were entered against Bendectin's manufacturer.[23] Finally, after a 30-year absence, Bendectin returned to the U.S. market in 2013 in the form of Diclegis manufactured by Duchesnay.[24]

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substance was one of the causes of a plaintiff's illness is both daunting and expensive.").

17. MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 27 (1996).

18. *See* STEPHEN BREYER, *Introduction*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 1, 3 (3d ed. 2011) ("Scientific issues permeate the law.").

19. *See* MARGARET A. BERGER, *The Admissibility of Expert Testimony*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, *supra* note 18, at 11, 27 ("[A]nalysts of the more than 200 DNA exonerations to date claim that in more than 50% of the cases, invalid, or improperly conducted, or misleadingly interpreted forensic science contributed to the wrongful convictions.").

20. GREEN, *supra* note 17, at 328; *see also id.* at 90 (stating that Bendectin was created to treat morning sickness in pregnant women and consists of Vitamin B6 and an antihistamine, doxylamine succinate); *Doxylamine*, VICKS, http://www.vicks.com/products/safety-information/active-ingredients/doxylamine/ (last visited Mar. 25, 2015) ("Doxylamine succinate is a powerful antihistamine used in products such as nighttime cold medicines.").

21. *See* GREEN, *supra* note 17, at 301–06.

22. *Id.* at 180.

23. *Id.* at 335 ("[N]o plaintiffs have recovered money pursuant to judgment, and only a handful of trivial nuisance settlements have resulted in any transfers.").

24. *Bendectin History*, BENDECTIN, http://www.bendectin.com/en/ (last visited Mar. 3, 2015) ("Merrell Dow Pharmaceuticals ceased production of Bendectin worldwide in 1983, as their soaring legal and liability insurance costs eclipsed sales."); *id.* ("On April 8, 2013 the US Food and Drug Administration . . . approved

Yet courts continue to admit opinions based on questionable research into evidence.[25] Sometimes the authors of published studies or counsel relying on these researchers' work have attempted to place barriers in the way of academicians or counsel who wish to challenge the validity of the published studies[26] and their underlying data.[27] These barriers originate from a misunderstanding, or misuse, of the concept of academic freedom—a litigation strategy that asserts the existence of the so-called "researchers' privilege," also known as "academic privilege," "academic freedom privilege," or "the research scholar's privilege"—as well as the improper application of the Freedom of Information Act ("FOIA").[28] These challenges create a legal environment where opinions based on the published results of flawed research are admitted into evidence without providing opposing parties the opportunity to develop the facts necessary to assess the opinion's validity. This admission of uninvestigated evidence creates the potential for unjust results.

Misconceptions in academia and in society at large about the assumed ability of researchers to withhold information based on a putative ability to keep research data confidential have led to confusion. Researchers promise study participants confidentially that is not legally justified or enforceable. One example is the recent scandal involving Boston College's *Oral History Project* about the

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Diclegis . . . to treat pregnant women experiencing nausea and vomiting . . . [which] contains the same active ingredients as Bendectin.").

25. *See, e.g.*, Nathan A. Schachtman, *Misplaced Reliance on Peer Review to Separate Valid Science from Nonsense*, SCHACTMAN L. BLOG (Aug. 14, 2011, 8:11 AM), http:schachtmanlaw.com/misplaced-reliance-on-peer-review-to-separate-valid-science-from-nonsense/ (providing examples of litigation where the validity of the underlying research was at issue, such as litigation involving phenylpropanolamine, Viagra, Accutane, and silicone breast implants).

26. *See, e.g.*, Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473, 473 (2002) (concerning geneticists, "ten percent of all postpublication requests for additional information [are] denied").

27. *See, e.g.*, Dow Chem. Co. v. Allen, 672 F.2d 1262, 1276 (7th Cir. 1982) (refusing to order subpoenas of research data).

28. *See, e.g.*, United States v. Trs. of Bos. Coll., 831 F. Supp. 2d 435, 453 (D. Mass. 2011) (academic privilege); Wilkinson v. FBI, 111 F.R.D. 432, 440 (C.D. Cal. 1986) ("Academic Freedom and the Researcher's Privilege"); *In re* Grand Jury Subpoena Dated Jan. 4, 1984, 750 F.2d 223, 225 (2d Cir. 1984) (scholar's privilege); *In re* Am. Tobacco Co., 880 F.2d 1520, 1528 (2d Cir. 1989) (research scholar's privilege).

conflict in Northern Ireland.[29] In this study, researchers promised study participants that their tape-recorded interviews would be confidential without realizing that such promises were not legally enforceable.[30] Eventually, Boston College had to turn over the tape recordings to British authorities, in violation of the promises made to the study participants, and the government used the tapes to justify the arrest of Sinn Féin leader Gerry Adams.[31]

Scholars inaccurately and dangerously believe that they have a right to withhold their data by claiming that its production conflicts with their academic freedom. This Article focuses on the validity of a researcher's claim to withhold research data under the so-called "researchers' privilege." Part I delineates the reasons why it is extremely difficult to evaluate published research findings without access to the researchers' underlying information. Part II analyzes the law that governs researchers' ability to withhold records and data based on the so-called "researchers' privilege." Finally, Part III explains why courts should favor the disclosure of research data and address confidentiality concerns using a protective order.

I. THE SCIENCE OF CAUSATION

The scientific method demands that valid experimental results can be replicated by other researchers.[32] But now more than ever, few experimental results can be replicated.[33] For example, researchers from a leading pharmaceutical company attempted to reproduce the results from 53 of the most landmark cancer-research studies.[34] Although the researchers followed the same procedures used in the original research, they were only able to replicate the results in 6 of the 53 published papers.[35] In other words, scientists could confirm

29. *See, e.g.*, Peter Schworm, *BC Reflects on Missteps in Northern Ireland Project*, BOSTON GLOBE, May 18, 2014, http://www.bostonglobe.com/metro/2014/05/17/controversial-project-stumbles-end-reflects-where-things-went-wrong/Pp7b9cT3CDZ0Ltb3uuUPPI/story.html.

30. *See id.*

31. *See id.*

32. *See generally* Arturo Casadevall & Ferric C. Fang, Editorial, *Reproducible Science*, 78 INFECTION AND IMMUNITY 4972 (2010) (noting that reproducibility and replicability are not the same).

33. *See* Ioannidis, *supra* note 12, at 696.

34. C. Glenn Begley & Lee M. Ellis, Commentary, *Raise Standards for Preclinical Cancer Research*, 483 NATURE 531, 532 (2012).

35. *Id.*

the results in only 11% of these cancer-research papers.[36] This low percentage of confirmed results is concerning because "[r]esearch findings that do not replicate are worse than fairy tales; with fairy tales the reader is at least aware that the work is fictional."[37]

Reasons for this crisis in academic research include (1) researchers' inability to understand increasingly sophisticated statistics and research methods, (2) the growing *business* of research that is fueled by private-sector money and expert-witness fees, and (3) the proliferation of "vanity press" journals.[38] Finally, mounting evidence shows that certain researchers engage in questionable research practices that may constitute fraud.

A. Misunderstanding and Misuse of Statistics and Research Methods

Researchers do not necessarily have adequate training in research methods and statistics just because they possess advanced degrees. Moreover, some statistical errors in research publications transcend mere misunderstanding and instead show that researchers manipulate statistical methods to obtain the desired results.[39] Psychologist Uri Simonsohn calls this phenomena "*P*-hacking," and others refer to it as "data-dredging, snooping, fishing, significance-chasing and double-dipping."[40] Statistics defines the *P*-value as "the probability that an observed positive association could result from random error even if no association were in fact present."[41] For example, suppose that in an epidemiology study investigating the potential association between the administration of vaccines and the development of side effects, the *P*-value is 0.05. This *P*-value indicates that even if the vaccine had no effect, a positive association could be obtained in 5%

36. *Id.*

37. Eric-Jan Wagenmakers et al., *An Agenda for Purely Confirmatory Research*, 7 PERSP. ON PSYCHOL. SCI. 632, 633 (2012).

38. Dave Bricker, *Self-Publishing & Vanity Publishing: Confuse Them and Pay the Price*, THE WORLD'S GREATEST BOOK (Feb. 4, 2013), http://theworldsgreatestbook.com/self-publishing-vanity-publishing/ ("[Y]ou pay someone to be your publisher.").

39. *See* Regina Nuzzo, *Statistical Errors:* P *Values, the 'Gold Standard' of Statistical Validity, Are Not as Reliable as Many Scientists Assume*, 504 NATURE 150, 152 (2014).

40. *Id.* ("'*P*-hacking,' says Simonsohn, 'is trying multiple things until you get the desired result.'").

41. MICHAEL D. GREEN ET AL., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, *supra* note 18, at 549, 576.

of the studies due to random-sampling error.[42] Unfortunately, researchers can manipulate this relatively straightforward statistic.

Consider the following hypothetical situation. Researchers conduct an epidemiological study to determine if there is an association between exposure to substance *A* and the development of side effect *X*. Further assume that, although not actually studied, mining the underlying data reveals a statistically significant association (at a *P* value of less than 0.05) between exposure to substance *A* and the development of side effect *Y*. While a researcher may appropriately mine data to develop *hypotheses*, scientific standards would prohibit the researcher from claiming that a statistically significant association has been shown between the exposure to substance *A* and side effect *Y*. Making such a claim infers that the hypothesis was studied and confirmed, when in fact the researcher has only generated a hypothesis that requires separate study. But the pressure to engage in such behavior is great when it will result in a published paper that could help a researcher achieve tenure and gain prestige.[43]

Exacerbating the problem of the manipulation of statistical methods, academia generally exhibits a bias toward the publication of positive, as opposed to negative, results.[44] For example, a study that concludes that Drug *A* cures cancer is more likely to be published

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42. *See* Nuzzo, *supra* note 39, at 152 ("[M]any published psychology papers report *P* values that cluster suspiciously around 0.05, just as would be expected if researchers fished for significant *P* values until they found one.").

43. *See, e.g.*, Eve Heafey, Abstract, *Public Access to Science: The New Policy of the National Institutes of Health in Light of Copyright Protections in National and International Law*, 15 UCLA J.L. & TECH. 1, 6 (2011) ("[S]cientists' careers depend largely on journals, as funding is granted partly based on publications and universities often require publication in high impact journals for promotion and tenure."). "[A]uthors are under pressure to publish for career advancement and funding applications." *Id.* at 11.

44. *See Unreliable Research: Trouble at the Lab*, ECONOMIST (Oct. 19, 2013), http://www.economist.com/news/briefing/21588057-scientists-think-science-self-correcting-alarming-degree-it-not-trouble/ (discussing that funding duplicative studies is not a priority). *But see* Andrew Bissette, *Unlikely Results?*, BEHIND NMR LINES BLOG (Nov. 9, 2013), http://behindnmrlines.blogspot.com/2013/11/unlikely-results.html#links ("[A]ll scientists operate by testing well-defined hypothesis one by one and analysing the results through statistics, publishing only those with $p<0.05$. This kind of thought experiment can usefully explain the crisis of reproducibility in certain disciplines which do rely heavily upon p values for publication.").

than a study that concludes that Drug *B* does not cure cancer.[45] Thus, papers reporting negative results comprise merely 10% to 30% of published research.[46] This positive-results bias has created the tendency that "[a]uthors are more likely to submit, and editors accept, positive rather than null results."[47] Additionally, the results most likely to be published are the most surprising and counterintuitive, and thus, the most likely to be wrong.[48]

In the July 2, 2014, edition of the *Journal of the American Medical Association*, the editors introduced a new section of articles describing scientific principles that a clinician must know to understand research articles.[49] In an editorial explaining why such a section was necessary, Edward H. Livingston pointed out, "Because relatively little emphasis is placed in medical school on research methods and statistics, clinicians may have never learned enough about these topics to properly understand current research articles."[50] Livingston implied that clinicians who author articles may not have (1) received sufficient training in the procedures of properly performed research; (2) used the appropriate methodology in collecting and analyzing data from such research; or (3) correctly delineated the background methodology, results, and conclusions in the article that the clinician published.

Some commentators contend that the current culture of academic publishing rewards questionable research practices and, by its very structure, prevents the detection of such practices.[51] In a perfect

45. *See* ECONOMIST, *supra* note 44 ("[R]esearchers and the journals in which they publish are not very interested in negative results. They prefer to accentuate the positive, and thus the error-prone.").

46. *Id.*

47. David L. Sackett, *Bias in Analytic Research*, 32 J. CHRONIC DISEASES 51, 60 (1979).

48. *See, e.g.*, Freek Vermeulen, *Publication Bias (or, Why You Can't Trust Any of the Research You Read)*, FORBES (Jan. 6, 2012, 2:33 PM), http://www.forbes.com/sites/freekvermeulen/2012/01/06/publication-bias-or-why-you-cant-trust-any-of-the-research-you-read/ (declaring that "journals will only publish novel, interesting findings," which increases the likelihood that "researchers only bother to write seemingly intriguing counterintuitive findings").

49. *See* Edward H. Livingston, *Introducing the JAMA Guide to Statistics and Methods*, 312 JAMA 35 (2014).

50. *Id.*

51. *See, e.g.*, Ivan Oransky, *"The Chrysalis Effect: How Ugly Initial Results Metamorphosize into Beautiful Articles,"* RETRACTION WATCH BLOG (Mar. 25, 2014, 2:10 PM), http://retractionwatch.com/2014/03/25/the-chrysalis-effect-how-ugly-initial-results-metamorphosize-into-beautiful-articles/#more-19411

world, it should not matter who pays for research; in reality, the sources funding researchers sometimes influence the outcome of research.[52] Such funding can come from pharmaceutical companies[53] or plaintiffs' lawyers, as in the case of Dr. Wakefield.[54] Ultimately, it is impossible to discount the possible adverse consequences that outside funding may have on academic research.

B. An Ever-Growing Number of Journals and "Pay to Play"

Now, any article purportedly setting forth the results of a study can be published—even when no actual research was performed. In a recent test, computer scientist Cyril Labbé developed a program to create *faux* scientific research papers.[55] This program strung together a bunch of sophisticated-sounding words in almost incoherent sentences.[56] The pseudo-scientific papers had titles "such as 'Application and Research of Smalltalk Harnessing Based on Game-Theoretic Symmetries'; 'An Evaluation of E-Business with Fin'; and 'Simulating Flip-Flop Gates Using Peer-to-Peer Methodologies.'"[57] Although not a single one of these papers had any scientific basis, 120 of them were published.[58] The fraud was not discovered until Labbé informed the journals of the ruse.[59]

(discussing Ernest Hugh O'Boyle Jr. et al., *The Chrysalis Effect: How Ugly Initial Results Metamorphosize into Beautiful Articles*, J. MGMT., March 19, 2014, at 25 ("If we cannot self-police by establishing and enforcing best practices, then those external stakeholders that provide funding (e.g., state governments, federal grant agencies, private individuals and organizations) may reduce or withdraw their support.")).

52. *See* Bodil Als-Nielson et al., *Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events?*, 290 JAMA 921, 926–27 (2003) ("[T]he association between funding and conclusions might reflect a biased interpretation of the overall trial results. This potential bias could be due to financial conflicts of interest.").

53. *See id*.

54. *See* CNN, *Vaccine Study's Author Held Related Patent, Medical Journal Reports*, *supra* note 6.

55. James A. Foley, *Scholarly Journals Accepted 120 Fake Research Papers Generated by Computer Program*, NATURE WORLD NEWS (Mar. 1, 2014, 11:31 AM), http://www.natureworldnews.com/articles/6217/20140301/scholarly-journals-accepted-120-fake-research-papers-generated-by-computer-program.htm.

56. *Id*.

57. *Id*.

58. *Id*.

59. *Id*.

An investigation by the journal *Science* found that some seemingly respected journals will publish virtually anything for a fee.[60] At the request of *Science*, author John Bohannon created a spurious cancer-research paper that appeared legitimate but was actually replete with errors and impossible claims.[61] Bohannon then submitted the paper to journals that required the payment of a fee, some as high as $3,100, as a condition of publication.[62] Ultimately, 157 of the pay-to-publish journals accepted the *faux* article and 98 rejected it—an acceptance rate of 61% for a sham paper based on pseudo-science.[63]

C. Fraud and Questionable Research Practices

While few researchers attempt to publish gibberish, these experiments demonstrate how easy it is to publish research that is *faux*, pseudo-scientific, fraudulent, or merely flawed. Researchers today feel enormous pressure to publish.[64] Imagine the researcher's frustration when six months spent conducting research delivers results refuting the investigated hypothesis. The researcher now faces the likely consequence that no major journal will publish his or her results. In the publish-or-perish world of academic research, the honest researcher is at a distinct disadvantage.

Given the pressures of the academic and for-profit worlds, there are many significant instances where journals later withdrew published articles because someone uncovered bogus data or

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60. Bohannon, *supra* note 12, at 61.

61. *Id.* at 62.

62. *Id.* at 64–65. S*ee generally Guide for Authors, Social Science & Medicine*, ELSEVIER, http://www.elsevier.com/journals/social-science-medicine/0277-9536/guide-for-authors (last visited Mar. 6, 2015) (describing the pricing policy for open-access publication).

63. Bohannon, *supra* note 12, at 63.

64. *See, e.g.*, David Colquhoun, *Publish-or-Perish: Peer Review and the Corruption of Science*, THE GUARDIAN, Sept. 5, 2011, http://www.theguardian.com/science/2011/sep/05/publish-perish-peer-review-science.

> Not long ago, Imperial College's medicine department were told that their "productivity" target for publications was to "publish three papers per annum including one in a prestigious journal with an impact factor of at least five." The effect of instructions like that is to reduce the quality of science and to demoralise the victims of this sort of mismanagement.

Id.

problems with the underlying research,[65] generally referred to as "academic fraud" or "questionable research practices."[66] Surveys regarding the behavior of researchers found that 14% observed their colleagues engaging in "fabrication, falsification and modification" of research data.[67] Another 72% of researchers reported observing other questionable research practices.[68]

The growth of fraudulent research has led some to call for criminal charges for fraud in scientific research.[69] While fraud in other walks of life has serious consequences, academic fraud is difficult to detect and rarely results in any negative consequences for the perpetrator, even if discovered.[70] When fraud is discovered, it is often handled internally by academic institutions and is generally swept under the rug.[71]

In the rare case where research fraud is detected, the consequences can be too little, too late, as was the case with Dr. William McBride and his research concerning Bendectin.[72] McBride was heralded as a national hero in his homeland of Australia for his co-discovery of the teratogenicity of the drug thalidomide.[73] But while McBride testified in the Bendectin litigation as a plaintiff's expert witness, he was also being investigated for academic fraud for

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65. Virginia Gewin, *Retractions: A Clean Slate*, 507 NATURE 389, 389 (2014) ("[In 2013], scientific journals retracted roughly 500 papers (of more than a million published), compared with fewer than 50 per year in the early 2000's.").

66. *See generally* Richard Epstein, *Academic Fraud Today: Its Social Causes and Institutional Responses*, 21 STAN. L. & POL'Y REV. 135 (2010) (defining academic and scientific fraud, examining procedures that should be used to examine cases of suspected fraud, and discussing procedures that can be used to identify the extent of fraud after the fraud has been discovered); Leslie K. John et. al., *Measuring the Prevalence of Questionable Research Practices with Incentives for Truth Telling*, 23 PSYCHOL. SCI. 524 (2012) (discussing academic fraud and questionable research practices).

67. Daniele Fanelli, *How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data*, PLOS ONE (May 29, 2009), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0005738.

68. *Id.*

69. Helen Branswell, *Should Research Fraud Be Treated as a Crime? Toronto Expert Says Yes*, THE HAMILTON SPECTATOR, July 15, 2014, http://www.thespec.com/news-story/4633340-should-research-fraud-be-treated-as-a-crime-toronto-expert-say-yes/.

70. *See id.*

71. *See id.*

72. *See* GREEN, *supra* note 17, at 274.

73. *Id.*

falsifying data related to scopolamine.[74] Later, one of McBride's collaborators accused him of falsifying data and "cooking the books" to prove a connection between Bendectin and birth defects.[75] After years of investigation, McBride was eventually stripped of his medical license for research misconduct, but not before many years of successful work as an expert witness in drug litigation.[76]

D. Pre- and Post-Publication Peer Review Does Not Work

"Peer review" is "a process by which scholarly work (such as a paper or a research proposal) is checked by a group of experts in the same field to make sure it meets the necessary standards before it is published or accepted."[77] A common misconception is that the peer-review process required by some journals will detect poor-quality research.[78] But in a 1998 study, where peer reviewers were sent articles containing deliberate mistakes, few mistakes were found.[79] Pressure to publish has put the peer-review system under "severe strain."[80] This pressure encompasses "the explosion of scientific and medical publications; the increasing financial influence of large drug companies on the medical journals; the pressures on young scientists to get grants and to publish; the temptations to celebrity-seeking; the burgeoning expert-witness business; and so on."[81]

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74. *See id.*

75. *See* Adam Spencer, *The Insider*, AUSTRALIAN STORY (Feb. 22, 2001), http://www.abc.net.au/austory/transcripts/s248519.htm. This article refers to Bendectin as "Debonex," the name used to market the drug outside of the United States.

76. *See* GREEN, *supra* note 17, at 274.

77. *Peer Review Definition*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/peer review (last visited Mar. 19, 2015).

78. According to a recent decision by a California court, "[P]ublished academic studies are exposed to extensive peer review and public scrutiny that assure objectivity." Humane Soc'y of the U.S. v. Super. Ct., 155 Cal. Rptr. 3d 93, 122 (Ct. App. 2013).

79. Sara Schroter et al., *What Errors Do Peer Reviewers Detect, and Does Training Improve Their Ability to Detect Them?*, 101 J. ROYAL SOC'Y MED. 507, 508 (2008) (Eng.) (citing Fiona Godlee et al., *Effect on the Quality of Peer Review of Blinding Reviewers and Asking Them to Sign Their Reports: A Randomized Controlled Trial*, 280 JAMA 237, 237–40 (1998)).

80. Haack, *supra* note 13, at 799.

81. *Id.* (citing SUSAN HAACK, DEFENDING SCIENCE–WITHIN REASON: BETWEEN SCIENTISM AND CYNICISM 27–29, 107–09 (2003)).

The peer-review process can only detect the most obvious fraud and must also rely on the integrity of authors. And peer reviewers do not have the time or ability to replicate each researcher's study to check its validity.[82] The best expected result is that a peer reviewer will spot conceptual flaws in a research paper—but such flaws are not always readily apparent.[83] Further, the reader of a published article has no way to evaluate the qualifications of the peer reviewers, if any, because their identities are never disclosed.[84] Indeed, given the large number of journals, some journals will use any peer reviewer who becomes available to them, no matter how little or limited the reviewer's peer-reviewing experience may be.[85]

The mere fact that there are a large number of journals in and of itself undermines the validity of the peer-review system. Generally, authors submit their articles to the most prestigious journal they believe may publish their article, but the prestigious journals may reject up to 90% of the manuscripts submitted.[86] And many articles are rejected multiple times by a myriad of journals, each one ranking lower than the previous one, before being accepted for publication.[87] Thus, the existence of a great number of journals ensures that virtually any research paper can find a publisher—even if previously rejected by multiple prior journals because of methodological errors.[88] Between 1997 and 2012, the number of published research

82. *Id.* at 800–01.

83. *Id.* at 808 ("*[T]he fact that work has passed pre-publication peer review is no guarantee that it is not flawed or even fraudulent . . . .*").

84. *See* Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163, 163–64, (E.D.N.Y. 1988); *In re* Yasmin & Yaz (Dropspirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-md-02100-DRH-PMF, 2011 WL 5547133, at *3 (S.D. Ill. Nov. 15, 2011) (protecting the identity of peer reviewers, even from a subpoena).

85. *See* Latha Chandran & Virginia Niebuhr, *Peer Review of Manuscripts: An Online Training Module*, MEDEDPORTAL (June 14, 2013), http://www.medeportal.org/publication/9444.

86. *See* Eugenie Samuel Reich, *The Golden Club*, 502 NATURE 291, 291 (2013).

87. *See* Michael Hoenig, *"Unreliable" Articles: More on Peer Review's Frailties*, N.Y. L.J. (June 9, 2014), *available at* http://www.herzfeld-rubin.com/publ_complexlitigation_20140609.htm (according to one commentator, even when rejected by a journal with a low acceptance rate, most rejected research papers are accepted by lower-ranked publications).

88. *See* Drummond Rennie, *Guarding the Guardians: A Conference on Editorial Peer Review*, 256 JAMA 2391 (1986).

articles increased by 87%,[89] suggesting that more and more researchers are finding a place to publish.

Some argue that any possible decline in the effectiveness of the peer-review process is offset by an increase in post-publication peer review. Post-publication peer review is the evaluation of articles by readers who offer criticism in letters to the editor or other feedback. In a well-known instance of post-publication peer review, graduate student Thomas Herndon was required to replicate a prominent economic study as a project in one of his classes.[90] Herndon expected to easily replicate the study, but instead he found a number of errors that put the study's findings in question. Herndon's discovery made news and landed him an interview on *The Colbert Report*.[91]

Post-publication peer review only works well for between .01% and 1% of published research articles.[92] In the words of one commentator, "The vast majority of papers don't receive any post-publication 'review' at all, because relatively few people read them and the people who do read them mostly just read the abstract or skim."[93] Thus, only the most elite papers receive post-publication peer review because those are the only papers that are read with enough frequency for critical commentary. For the literally millions of other papers published in a given year that are not widely read, there is no meaningful post-publication peer review.[94]

II. THE SO-CALLED RESEARCHERS' PRIVILEGE

In addition to the forces challenging the integrity of the academic research community, a legal trend also enables flawed research to

89. *See id.*

90. *See* Joe Weisenthal, *Thomas Herndon's Professors Almost Didn't Let Him Start the Paper that Shook the World Austerity Movement*, BUSINESS INSIDER (Apr. 24, 2013, 7:01 PM), http://www.businessinsider.com/thomas-herndon-replication-exercise-2013-4.

91. *The Colbert Report: Austerity's Spreadsheet Error* (Comedy Central broadcast Apr. 23, 2013).

92. *See* Jeremy Fox, *Post-Publication Review Is Here To Stay—For the Scientific 1%*, DYNAMIC ECOLOGY (Mar. 20, 2014), http://dynamicecology.wordpress.com/2014/03/20/post-publication-review-comes-of-age-for-the-scientific-one-percent/.

93. *Id*. *See also* Farhad Manjoo, *You Won't Finish This Article*, SLATE (June 6, 2013), http://www.slate.com/articles/technology/technology/2013/06/how_people_read_online_why_you_won_t_finish_this_article.html (demonstrating that few people finish the articles that they begin to read online).

94. *See Unreliable Research: Trouble at the Lab*, *supra* note 44.

remain hidden, rather than making research more transparent and easier to evaluate.[95] Some assert the existence of a so-called "researchers' privilege" that protects the raw data and materials of a third-party researcher from disclosure.[96] Some consider this privilege a subcategory of the more general "academic privilege" or the "academic freedom privilege,"[97] and it is similar to other supposed privileges for academics such as the "archival" privilege.[98] The researcher—not the plaintiff or the defendant—raises the privilege when a party to a lawsuit seeks the researcher's files and data.[99] The privilege is not raised by a party to the lawsuit.[100] This request for the

95. *See* Schachtman, *supra* note 25. Major litigation that involved peer-reviewed research that did not hold up under the scrutiny of experts included Phenylpropanolamine and stroke litigation, Viagra and ophthalmic events litigation, MMR vaccine and autism litigation, Accutane and suicide litigation, and silicone and connective-tissue-disease litigation. *Id.*

96. *See generally* Robert M. O'Neil, *A Researcher's Privilege: Does Any Hope Remain?*, 59 LAW & CONTEMP. PROBS. 35 (1996) (arguing in favor of the privilege). The "researcher's" privilege is also referred to as the "scholar's" privilege, and sometimes the general term "academic privilege" is used to refer to the researcher's privilege.

97. Univ. of Pa. v. EEOC, 493 U.S. 182, 198 (1990). The case concerned access to academic tenure peer-review data in an employment-discrimination context. The Supreme Court held that there was no common-law privilege to prevent the disclosure of peer review data. Further, the Court found the university's "reliance on the so-called academic-freedom cases is somewhat misplaced." *Id.* at 183. The Court noted that other cases involving academic freedom centered on government effort to control speech and declined to define "the precise contours of any academic-freedom right against governmental attempts to influence the content of academic speech through the selection of faculty or by other means . . . ." *Id*. at 198.

98. Wilkinson v. FBI, 111 F.R.D. 432, 437–39 (C.D. Cal. 1986) (rejecting the existence of an "archival" privilege for historians).

99. *Univ. of Pa.*, 493 U.S. at 198.

100. Smith v. Dow Chem. Co., 173 F.R.D. 54, 58 (W.D.N.Y. 1997) (rejecting an attempt to claim the researcher's privilege by a party to the litigation because "plaintiff's document requests are directed at the defendants and seek only those documents pertaining to the studies that are in the possession and control of the defendants").

researcher's data may be via subpoena[101] or by a FOIA request if the researcher is a government employee.[102]

The existence of a researchers' privilege, however, violates the principle that "the public has a right to every person's evidence, absent a valid claim of constitutional, common law, or statutory privilege."[103] Currently, neither the common law nor any explicit federal or state statute protects research data.[104] Despite some ambiguity in case law, the Constitution offers no justification for withholding research data; indeed, the Supreme Court has even denied the existence of an "academic privilege."[105] Simply put, given the absence of a common law or statutory researchers' privilege, the public has a right to a researcher's data when such data is at issue in a lawsuit. Despite recent calls for the creation of such a privilege,[106] the time has come to bury the researchers' privilege once and for all.

A. There Is No Constitutional Justification for the Researchers' Privilege

Besides the North Korean government[107] and a Harvard undergraduate,[108] few seriously challenge educators' entitlement to

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101. *See In re* Grand Jury Subpoena Dated Jan. 4, 1984, 750 F.2d 223, 224 (2d Cir. 1984) (discussing a claim of privilege where the government sought research data through a subpoena).

102. *See* Burka v. U.S. Dep't of Health & Human Servs., 87 F.3d 508, 515 (D.C. Cir. 1996) (discussing research data as an agency record that was sought through a FOIA request).

103. *Wilkinson*, 111 F.R.D. at 438 (citing United States v. Nixon, 418 U.S. 683, 709 (1974); Branzburg v. Hayes, 408 U.S. 665, 688 (1972)).

104. *See* Robert H. McLaughlin, *From the Field to the Courthouse: Should Social Science Research Be Privileged?*, 24 LAW & SOC. INQUIRY 927, 960–61 (1999).

105. *See* Univ. of Pa. v. EEOC, 493 U.S. 182, 197–99 (1990) (explaining that the "academic freedom" cases applied where the government tried to control the content of speech and declining to extend the privilege to cases involving confidential peer-review materials).

106. Katherine Adams, Comment, *The Tension Between Research Ethics and Legal Ethics: Using Journalist's Privilege State Statutes as a Model for a Proposed Researcher's Privilege*, 27 GEO. J. LEGAL ETHICS 335, 351 (2014).

107. U.S. DEP'T OF STATE, DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA 2013 HUMAN RIGHTS REPORT 12 (2013) (stating that the government of North Korea restricts academic freedom, including controlling course curriculums and limiting academic travel), *available at* http://www.state.gov/documents/organization/220414.pdf.

108. One student writer in *The Harvard Crimson* does suggest replacing the

academic freedom, but the term "academic freedom" is not clearly defined.[109] On a basic level, the concept of academic freedom arises from a concern that government action against professors "inevitably tends to check the ardor and fearlessness of scholars, qualities at once so fragile and so indispensable for fruitful academic labor."[110] According to Justice Frankfurter, the "four essential academic freedoms" may be "to determine for itself on academic grounds who may teach, what may be taught, how it shall be taught, and who may be admitted to study."[111] Some would propose creating a fifth academic privilege: First Amendment protection of a researcher's information and sources.[112]

Unlike the case of a party litigant trying to obtain a researcher's records to defend against litigation, the modern jurisprudence of academic freedom responds largely to the heavy-handed McCarthy-era persecutions of leftist professors.[113] The application of academic

concept of academic freedom with "academic justice." Sandra Y.L. Korn, *The Doctrine of Academic Freedom: Let's Give Up on Academic Freedom in Favor of Academic Justice*, THE HARVARD CRIMSON, Feb. 18, 2014, http://www.thecrimson.com/column/the-red-line/article/2014/2/18/academic-freedom-justice/?page=1. According to Korn, "When an academic community observes research promoting or justifying oppression, it should ensure that this research does not continue." *Id.* Of course, Korn might have a different opinion of the value of academic freedom if "justice" and "oppression" were defined by someone other than herself.

109. *See* Walter P. Metzger, *Profession and Constitution: Two Definitions of Academic Freedom in America*, 66 TEX. L. REV. 1265, 1320 (1988) (concluding that there is a deep difference between the professional and constitutional versions of academic freedom).

110. Sweezy v. New Hampshire, 354 U.S. 234, 262 (1957) (Frankfurter, J., concurring).

111. *Id.* at 263 (quoting CONFERENCE OF REPRESENTATIVES OF THE UNIV. OF CAPE TOWN AND THE UNIV. OF THE WITWATERSRAND, THE OPEN UNIVERSITIES IN SOUTH AFRICA 11–12 (1957)).

112. Frank Murray, Note, *Boston College's Defense of the Belfast Project: A Renewed Call for a Researcher's Privilege to Protect Academia*, 39 J.C. & U.L. 659, 678–79 (2013).

113. The seminal case for the concept of academic freedom is *Sweezy v. New Hampshire*, 354 U.S. 234 (1957). The Supreme Court in *Sweezy* considered the plight of economics professor Dr. Paul M. Sweezy. In 1951, New Hampshire enacted a law designed to regulate subversive activities, particularly alleged communists. *Id.* at 236. The law made "subversive persons" ineligible for employment by the state government, including employment as a professor at a public university. *Id.* Sweezy had delivered lectures at the University of New Hampshire that were alleged to have contained pro-communist themes. *Id.* at 243–44. As a result, he became the focus of an investigation by the New Hampshire Attorney General. During the investigation, Sweezy refused to answer multiple

freedom to the researchers' privilege is less clear-cut than a law forbidding a university from hiring "subversive persons."[114] The Supreme Court of the United States noted that other cases involving academic freedom centered on government restrictions on speech when the Court refused to create an academic-freedom privilege.[115] And the United States District Court for the Eastern District of Michigan stated:

> The protection of the first amendment is designed to afford the right to write and to speak. It does not give a right to withdraw material written and published from public scrutiny, nor does it give a right to refuse to disclose facts discovered as a result of observations that are relevant in making a judgment as to the correctness of the researcher's published conclusions.[116]

Courts have had to weigh the value of privacy in conducting research against the value of the data produced by that research to the fair and accurate administration of justice. Not surprisingly, courts usually side with the administration of justice in the interest of determining the accuracy of a researcher's conclusions. Rejecting the researchers' privilege, the United States District Court for the Eastern District of Michigan expressed concern about "a person who has become a public figure as a result of a research project yet wants to remain essentially anonymous so far as the administration of justice is concerned."[117] The court perceptively noted, "The value of the

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questions about his political beliefs and his involvement with communist organizations. *See id.* The court found him in contempt and ordered him to jail. *Id.* at 244–45. Sweezy appealed to the U.S. Supreme Court after the New Hampshire Supreme Court affirmed that he was in contempt. *Id.* at 235–36. A plurality of the Supreme Court held that the contempt finding was improper. *Id.* at 255. Four justices based their reasoning on due process, *id.* at 254–55, while Justices Frankfurter and Harlan based their reasoning on First Amendment principles, specifically the new constitutional concept of "academic freedom," *id.* at 260–67 (Frankfurter, J., concurring).

114. *Id.* at 236 (plurality opinion).

115. Univ. of Pa. v. EEOC, 493 U.S. 182, 198 (3rd Cir. 1990).

116. Wright v. Jeep Corp., 547 F. Supp. 871, 875 (E.D. Mich. 1982).

117. *Id.* at 872. In this case, Jeep sought access to Dr. Richard Snyder's data. Snyder was a professor and research scientist at the Highway Safety Institute of the University of Michigan and was the principal author of the 1980, 152-page report, *On-Road Crash Experience of Utility Vehicles*, published by the institute. *Id.* at 872–73. Snyder's study concluded that the Jeep CJ-5 experienced a

conclusions [of a researcher] turns on the quality of the data and the methods used by the researcher in his analysis of that data as well as the skill and perception of the researcher."[118] Thus, "if the conclusions or end product of a research effort is to be fairly tested, the underlying data must be available to others equally skilled and perceptive."[119]

In *Dow Chemical Co. v. Allen*,[120] the United States Court of Appeals for the Seventh Circuit conflated the constitutional doctrine of academic freedom with the researchers' privilege to prevent disclosure of a university researcher's "notes, reports, working papers, and raw data relating to on-going, incomplete animal toxicity studies . . . ."[121] In this case, the EPA issued an emergency order suspending the use of two herbicides manufactured by Dow. As part of the administrative appeal process, Dow sought to subpoena the "notes, reports, working papers, and raw data relating to on-going, incomplete animal toxicity studies" of researchers from the University of Wisconsin who conducted research on the two herbicides at issue and upon which the EPA based its suspension order. [122] The Seventh Circuit upheld the district court's refusal to enforce the subpoena, partially on academic freedom grounds. According to the court:

> [E]nforcement of the subpoenas would leave the researchers with the knowledge throughout continuation of their studies that the fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party whose interests were arguably antithetical to theirs. It is not difficult to imagine that that realization might well be both unnerving and discouraging.[123]

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disproportionately high roll-over rate in accidents. *Id.* Jeep wanted access to Dr. Snyder's "research data, memoranda, drafts, correspondence, lab notes, reports, calculations" and other documents relating to his study for use in Jeep's defense of a personal injury lawsuit. *Id.*

118. *Id.* at 874.
119. *Id.*
120. 672 F.2d 1262 (7th Cir. 1982).
121. *Id.* at 1266.
122. *Id.*
123. *Id.* at 1276.

Because of this concern, the court concluded that "enforcement of the subpoenas carries the potential for chilling the exercise of First Amendment rights."[124]

In his concurrence, however, Judge Frank Pell had a different view. According to Judge Pell, the dispute was "merely a matter of recording accurately [because a] researcher's reputation perhaps deserves to be subject to some questioning if he or she cannot accurately observe and record specific factual matters."[125] Indeed, Judge Pell described the court's academic-freedom concerns more accurately as concerns about how an unfavorable critique affects a researcher's reputation. Additionally, the court and the public would benefit from permitting disclosure of errors found in research, particularly in the context of a federal safety hearing regarding herbicides.[126]

Acknowledging a "researchers' privilege" would also have the unusual effect of giving researchers greater ability to protect their sources and data than even some journalists have.[127] For instance, in *Branzburg v. Hayes*,[128] the Supreme Court rejected the First Amendment as a defense for reporters who were called to testify before a grand jury.[129] And the Court applied *Branzburg* in the civil-law context when it declined to create an academic-freedom privilege where it was unclear how the production of information would "inhibit the free flow of information."[130] Thus, while *Branzburg* is still good law, there can be no First Amendment basis for the researchers' privilege.

B. There Is No Statutory Basis for a Researchers' Privilege

Some have proposed the statutory creation of a researchers' privilege.[131] While some states have laws designed to protect journalists' sources that may be read expansively enough to protect researchers,[132] only one state, Delaware, has a "reporter's shield" law

124. *Id.*
125. *Id.* at 1279.
126. *See id.*
127. *See* Murray, *supra* note 112, at 679 (noting that it is not clear how the researcher's privilege "can thrive in the shadow of *Branzburg*").
128. 408 U.S. 665 (1972).
129. *Id.* at 667, 691–92.
130. Univ. of Pa. v. EEOC, 493 U.S. 182, 201 (1990).
131. *See* Adams, *supra* note 106.
132. *See id.* at 350.

that covers researchers.[133] The only federal law that protects the confidentiality of research subjects simply protects their identity and does not rule out the disclosure of source data with adequate redactions.[134] In the absence of specific statutory authority regarding the researchers' privilege, disputes concerning requests for a researcher's information are usually addressed with a motion to quash a subpoena under Federal Rule of Civil Procedure 45; a motion for a protective order under Federal Rule of Civil Procedure 26(a) or Federal Rule of Evidence 501; a challenge to a FOIA request; or equivalent motions under state statutes.

In *In re American Tobacco Co.*,[135] the United States Court of Appeals for the Second Circuit considered whether a researcher's interest in protecting data merited a protective order.[136] In that case, three tobacco companies sought data from a medical school and a cancer society for use in the litigation. The district court below had held that under state law, a researcher might have a cognizable interest in preventing the disclosure of research data to protect the researcher's interest in publishing unique results,[137] but the existence of such a privilege was not clear. The Second Circuit observed that while a researcher may want to prevent "preemptive or predatory publication by others" based on premature access to the researcher's data, early publication was not a concern in this case.[138]

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133. McLaughlin, *supra* note 104, at 945 ("Delaware's shield statute defines 'reporter' to mean 'any journalist, scholar, educator, polemicist' or individual engaged in producing information for public dissemination.") (citing DEL. CODE ANN. tit. 10, § 4320 (1992)).

134. *See* 42 U.S.C.A. § 241(d) (Westlaw 2015).

> The Secretary [of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health including research on the use and effects of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Id.

135. 880 F.2d 1520 (2d Cir. 1989).

136. *See id.* at 1522.

137. *Id.* at 1525–26.

138. *Id.* at 1529.

Research can be too tangential for a court to involve third-party researchers in a trial. In *United States v. Roberts*,[139] the court quashed a subpoena served by two criminal defendants who attempted to obtain discovery of data from the National Academy of Science for use in a hearing on the admissibility of DNA evidence. The defendants sought "all communications, assessments, reviews or like documents" concerning a report published by the Academy, *The Evaluation of Forensic DNA Evidence: An Update*.[140] Quashing the subpoena, the *Roberts* court expressed concern about allowing defendants to subpoena the Academy on an issue that could be relevant in any case involving DNA evidence. Clearly, there must be limits to the discovery of researchers' information.

Parties to litigation may also seek disclosure of research data under FOIA from a government agency that conducts research or from a professor at a state educational institution. Despite FOIA's strong presumption in favor of disclosure,[141] researchers have used FOIA exemptions in an attempt to prevent disclosure.[142] FOIA has played a major role in a high-profile dispute between a Virginia climate-change scientist and organizations that sought access to the scientist's email and data to investigate allegations of fraud.[143] And in the leading case on the disclosure of researcher data under FOIA, the United States Court of Appeals for the District of Columbia Circuit concluded that the Department of Health and Human Services could not refuse to produce data just "because disclosure would diminish the researchers' ability to publish their results in prestigious

139. Nos. F-771-01 and F-3986-00 (D.C. Super. Ct. Feb. 4, 2003) (order denying issuance of a subpoena).

140. *Id.*

141. *See* S. REP. NO. 89-813, at 3 (1965) (stating that the purpose of FOIA is to "establish a general philosophy of full agency disclosure . . . and to provide a court procedure by which citizens and the press may obtain information wrongfully withheld").

142. *See* Burka v. U.S. Dep't of Health and Human Servs., 87 F.3d 508, 515 (D.C. Cir. 1996); *See also* Highland Mining Co. v. W. Va. Univ. Sch. of Med., No. 12-C-275, 2014 WL 7688106, at *20 (W. Va. Cir. Ct. Mar. 19, 2014), *rev'd*, No. 14-0370, 2015 WL 3368504 (W. Va. May 21, 2015). *Highland Mining* is discussed in more detail below.

143. Bryan McKenzie, *Former UVa Climate Scientist Awarded Damages in FOIA case*, THE ROANOKE TIMES, July 13, 2014, http://www.roanoke.com/news/former-uva-climate-scientist-awarded-damages-in-foia-case/article_dbf259e4-dc70-5962-81f3-be4483cbff5f.html.

journals."[144] The court in *Highland Mining Co. v. West Virginia University School of Medicine* concluded, using a convoluted argument, that a university professor's research data was protected from disclosure under West Virginia's FOIA because of "academic freedom" and because the data was an internal memorandum prepared for a public body.[145] The West Virginia Supreme Court of Appeals disagreed, indicating that FOIA has no "academic freedom" exception to its general disclosure provision.[146]

Under the Federal Rules of Civil Procedure, courts may protect the confidentiality of study participants while allowing full disclosure with a confidentiality order.[147] In *Deitchman v. E.R. Squibb & Sons, Inc.*,[148] a drug company sought the production of every document in the Registry for Hormonal Transplacental Carcinogenesis at the University of Chicago.[149] The Registry monitored the incidence of cancers of the genital tract. On March 4, 1983, the custodian of the Registry's records and chairman of the University of Chicago's Department of Obstetrics and Gynecology, Dr. Arthur L. Herbst, filed a motion to quash Squibb's subpoenas. While Herbst cited many concerns about divulging the registry's data:

> [h]is real and deepest objection [was] that he must be allowed to divulge to the public the results of his studies only in his own time and way. His conclusions [were] still tentative, data [was] still being collected. He [had] not yet submitted his case to "peer review" as is normal in the scientific community, despite his many publications.[150]

The court, however, correctly noted that epidemiological studies, such as the registry, "may have a number of different, but inadvertent, biases present."[151] In addition, "It could easily be that

144. *Burka*, 87 F.3d at 521.

145. *Highland Mining Co.*, 2014 WL 7688106, at *11–13.

146. *Highland Mining Co.*, 2015 WL 3368504. Note that the Court remanded the case for further consideration of FOIA issues, which are not the subject matter of this Article. *See id.* at *18.

147. *See* FED. R. CIV. P. 26(c) ("A party or any person from whom discovery is sought may move for a protective order . . . .").

148. 740 F.2d 556 (7th Cir. 1984).

149. *Id.* at 558.

150. *Id.* at 560.

151. *Id.* at 563 (citing David L. Sackett, *Bias in Analytic Research*, 32 J. CHRONIC DISEASES 51 (1979)).

Squibb would be hit with large verdicts on the basis of conclusions that are avowedly only tentative. After a series of final judgments, Dr. Herbst might one day announce that new information has led him to abandon his previous conclusions."[152] Researchers cannot detect these problems and biases in the absence of access to the underlying data. At the same time, the court was concerned about the disclosure of confidential patient information. The lower court had not considered a solution, such as the use of a protective order, which could have allowed the disclosure of Registry information only to experts and attorneys involved with the litigation.[153]As a result, the court remanded the case for formulation of a solution that "allow[ed] Squibb the least necessary amount of information to avoid a miscarriage of justice without doing needless harm to Dr. Herbst or his Registry."[154]

In the absence of a statutory researchers' privilege, research data should be treated by courts as any other request for discovery directed to a third party. While courts will have to weigh the merits and the value of any discovery sought, the Constitution justifies no special treatment for academic research data. Creating a statutory researchers' privilege also poses due-process concerns if research is admitted as evidence in a trial. Unlike a news article, which is generally inadmissible as hearsay,[155] courts regularly admit research conclusions as evidence through the testimony of expert witnesses.[156] In the words of one commentator, this evidence might not be so problematic "if we could guarantee that the out-of-court writing is

152. *Id.*

153. *Id.* at 565.

154. *Id.*

155. *See* Daniel E. Field, Annotation, *Admissibility of Newspaper Article as Evidence of the Truth of the Facts Stated Therein*, 55 A.L.R. 3d 663 (1974).

156. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593 (1993), *superseded by rule of evidence*, FED. R. EVID. 702. The Supreme Court in *Daubert* recommended five factors to consider when deciding whether to admit scientific research as opposed to employing a traditional hearsay analysis. The five factors are (1) whether the evidence is "falsifiable" and has been tested, (2) "whether the theory or technique has been subjected to peer review and publication," (3) what the known or potential rate of error of the technique is, (4) whether standards exist and are maintained for controlling this technique's operation, and (5) whether the methods and reasoning are generally accepted. *Id.* at 593–94.

genuine, accurate, trustworthy, reliable, relevant and 'fits' the facts and issues in the case. But how can we know that?"[157]

C. There Is No Justification for a Common Law Researchers' Privilege

In addition to the fact that the so-called researchers' privilege is of dubious value to the academic community at large, research data does not fit the typical criteria for the creation of a common-law privilege. According to Wigmore, courts require four conditions to establish a common-law privilege that would protect communications from disclosure:

> (1) The communication must have been made with the understanding that it would not be disclosed.
> (2) The element of confidentiality must be essential to the full and satisfactory maintenance of the relationship between the parties.
> (3) The relationship must be one which in the opinion of the community ought to be sedulously fostered.
> (4) The injury that would inure to the relation by the disclosure of the communication must be greater than the benefit that would result from requiring the disclosure.[158]

Based on Wigmore's factors, a common-law researchers' privilege is unjustified. First, because a third party to the litigation typically asserts the researchers' privilege, there is no "relationship" and no "communication" to protect. Second, the "benefit" weighed in the fourth factor is the health and welfare of the public. If a court does not permit disclosure, potentially flawed research could influence legal determinations that impact public health. Third, Wigmore's factors only apply when a relationship dependent on confidentiality is at issue.[159] Thus, an academic researcher can only rely upon a common-law privilege against disclosure of research data

157. Michael Hoenig, *'Unreliable' Articles, 'Trial by Literature' Revisited*, N.Y. L.J. (May 12, 2014), *available at* http://www.herzfeld-rubin.com/publ_complexlitigation_20140512.html.

158. 8 JOHN H. WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 2285 (John T. McNaughton ed., rev. ed. 1961).

159. *See* J. Graham Matherne, Note, *Forced Disclosure of Academic Research*, 37 VAND. L. REV. 585, 608 (1984).

if the data is confidential in the first place.[160] Wigmore's factors would weight in favor of the creation of a researchers' privilege in few circumstances, and even then the court could simply protect a researcher's interest in his or her data by issuing a confidentiality order.[161] But if the research data in question is not confidential, then the researcher should produce the information, subject to requirements of Federal Rule of Civil Procedure 45 or its state-law equivalent.[162]

Indeed, the researchers' privilege would be a strange fit—if it fit at all—when compared to other privileges. This privilege is the inverse of traditional privileges because it protects the source rather than the substance of information, and it gives the ability to waive the privilege to the listener as opposed to the speaker.[163] It also begs the question: who would be entitled to assert such a privilege when the term "researcher" is used without regulation?[164] Who would be entitled to claim protection? Only college professors? Community college professors? Students doing research for a paper? Scientists employed by corporations? A common-law solution would not easily answer these questions.

Additionally, even when a researcher promises a subject confidentiality, that promise might not be of any significance to the research. The case of *In re Grand Jury Subpoena Dated January 4, 1984*, [165] involved an explosion at a restaurant.[166] A waiter at the restaurant, who was also a Ph.D. candidate, was in the process of writing his thesis, *The Sociology of the American Restaurant*, which relied heavily on his experience as a waiter at the restaurant.[167] When subpoenaed, the waiter refused to comply, claiming that he had promised many of his sources confidentiality.[168] The court noted that the waiter had provided no information as to why confidentiality was

160. See *id.*

161. *See* Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556, 564–66 (7th Cir. 1984) (noting that quashing a subpoena is inappropriate where confidentiality interests can be safeguarded by means of a protective order).

162. *See* Matherne, *supra* note 159, at 594–96.

163. *See* Adams, *supra* note 106, at 347 (citing Jeffery S. Nestler, Comment, *The Underprivileged Profession: The Case for Supreme Court Recognition of the Journalist's Privilege*, 154 U. PA. L. REV. 201, 212 (2005)).

164. *See id.*

165. 750 F.2d 223 (2d Cir. 1984).

166. *Id.* at 224.

167. *Id.*

168. *Id.*

necessary for the methodology of his study, or even what his methodology was.[169] Noting that there was not enough information to make a determination on the waiter's claim of privilege, the court stated:

> Surely the application of a scholar's privilege, if it exists, requires a threshold showing consisting of a detailed description of the nature and seriousness of the scholarly study in question, of the methodology employed, of the need for assurances of confidentiality to various sources to conduct the study, and of the fact that the disclosure requested by the subpoena will seriously impinge upon that confidentiality.[170]

III. SOLUTION: DISCLOSURE

Although research data must be available to test the reliability of published conclusions, some courts have an inflated view of the extent of the peer-review process and therefore refuse to allow discovery of third-party research data. According to the California Court of Appeals, the disclosure of research data is unnecessary because "published academic studies are exposed to extensive peer review and public scrutiny that assure objectivity."[171] This standard of review is clearly not reality. In fact, as demonstrated above, in many cases there is minimal, if any, pre-publication peer review and most publications undergo no "public scrutiny" at all.

A naïve understanding of the current state of research and an aggrandized understanding of the capabilities of the peer-review process[172] can result in rulings that are unjust and that adversely affect public health. As stated by one medical-research publication:

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169. *Id.*

170. *Id.* at 225.

171. Humane Soc'y of the U.S. v. Super. Court, 155 Cal. Rptr. 3d 93, 122 (Ct. App. 2013).

172. Indeed, there are now reports in the literature describing "fake peer-review reports" and "peer review rings." *See* Fred Barbash, *Scholarly Journal Retracts 60 Articles, Smashes 'Peer Review Ring,'* WASH. POST, July 10, 2014, http://www.washingtonpost.com/news/morning-mix/wp/2014/07/10/scholarly-journal-retracts-60-articles-smashes-peer-review-ring/; Charles Seife, *Science's Big Scandal: Even Legitimate Publishers are Faking Peer Review*, SLATE (April 1, 2015, 10:25 AM), http://www.slate.com/articles/health_and_science/science/2015/

> It has been amply documented that the current situation, with selective reporting of favorable research and biased data analyses being the norm rather than the exception, is harmful to patients and has led to the death of tens of thousands of patients that could have been avoided.[173]

If the court cannot even get a researcher to disclose data, then who can?

According to the American Association for the Advancement of Science's Committee on Scientific Freedom and Responsibility, "One of the basic responsibilities of scientists is to maintain the integrity of the work of the scientific community. Ideally, it is an open community—all findings should be publically and generally available, and open to criticism, improvement, and, if necessary, rejection."[174] Thus, the acceptance of a researchers' privilege would undermine the integrity of the scientific community by promoting secrecy and allowing researchers to insulate errors from the detection of the academic community and society at large.[175] But open access to research data promotes the integrity of science by allowing verification.[176] "Data withholding potentially limits this fundamental quality control process when authors refuse to share unique resources

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04/fake_peer_review_scientific_journals_publish_fraudulent_plagiarized_or_nonsense.html.

173. Peter C. Gotzsche, *Why We Need Easy Access to All Data from All Clinical Trials and How to Accomplish It*, TRIALS (Nov. 23, 2011), http://www.trialsjournal.com/content/12/1/249.

174. JOHN T. EDSALL, AM. ASS'N FOR THE ADVANCEMENT OF SCI., SCIENTIFIC FREEDOM AND RESPONSIBILITY 8 (1975).

175. *See* David A. Kaplan & Brian M. Cogan, *The Case Against Recognition of a General Academic Privilege*, 60 U. DET. J. URB. L. 205, 225 (1982).

> Recognition of a general privilege, on the other hand, would do no more than promote secrecy and preclude a free and open debate on the merits and conclusions of the research project. The value of academic research, whether conducted in the physical or social sciences, is diminished if the researcher can insulate errors which otherwise may be found as a result of scrutiny from either the general public or those who have a special interest in disproving the conclusions reached by the researcher.

Id.

176. *See id.*

. . . necessary to confirm scientific claims."[177] According to the Supreme Court, "It is the business of a university to provide that atmosphere which is most conducive to speculation, experiment and creation."[178] Open access to research data supports those goals.

Courts, however, have created justifications using dubious reasoning to thwart attempts to compel the disclosure of research data. These justifications include the claim that the legal system will not be able to understand the "jargon" and "midstream thinking" involved in research data.[179] And courts hypothesize that researchers would be "chilled"[180] and suffer "embarrassment and inconvenience"[181] if the "fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party whose interests were arguably antithetical to theirs."[182] In other words, some courts appear concerned that researchers will be less likely to produce research, and may even be embarrassed, if an examination of their research data by a hostile party were to find flaws in their research.[183] Contrary to the opinions of these courts, the publishers of flawed research should be embarrassed. The fear of embarrassment will result in fewer unreliable or fraudulent papers if it spurs researchers to exercise more care in their methodology, analysis, and conclusions. If researchers, authors, and peer reviewers cannot scrutinize the data, then the courts should provide a mechanism whereby it can be done.

Ultimately, the solution to this problem is simple: courts should favor the disclosure of research data by third-party researchers. If some data needs to be protected, then courts can accomplish this by

177. Eric Campbell & David Blumenthal, *The Selfish Gene: Data Sharing and Withholding in Academic Genetics*, SCIENCE (May 31, 2002), http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2002_05_31/nodoi.5822398718525511595.

178. Sweezy v. New Hampshire, 354 U.S. 234, 263 (1957) (Frankfurter, J., concurring) (quoting CONFERENCE OF REPRESENTATIVES OF THE UNIV. OF CAPE TOWN AND THE UNIV. OF THE WITWATERSRAND, THE OPEN UNIVERSITIES IN SOUTH AFRICA 11–12 (1957)).

179. *See* Humane Soc'y of the U.S. v. Super. Ct., 155 Cal. Rptr. 3d 93, 122 (Ct. App. 2013).

180. *See In re* Fosamax Prods. Liab. Litig., 74 Fed. R. Serv. 3d 190 (S.D.N.Y. 2009).

181. Apicella v. McNeil Lab., Inc., 66 F.R.D. 78, 85 (E.D.N.Y. 1975).

182. Dow Chemical Co. v. Allen, 672 F.2d 1262, 1276 (7th Cir. 1982).

183. *Id*. at 1279 (Pell, J., concurring).

issuing confidentiality orders.[184] As the Supreme Court's *Sweezy* opinion states, "It is the business of a university to provide that atmosphere which is most conducive to speculation, experiment and creation."[185] The best atmosphere for academic research is transparency, and legal precedent that prevents research data from ever seeing the light of day does not foster quality research, scientific progress, or public health.

184. *See* Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556 (7th Cir. 1984).
185. Sweezy v. New Hampshire, 354 U.S. 234, 263 (1957).