

DUQUESNE LAW REVIEW



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Jennifer Yeung

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Mountain or Molehill?

Steven Baicker-McKee*

ABSTRACT

The 2015 amendments to the Federal Rules of Civil Procedure were the latest maneuver by the conservative Supreme Court to protect big corporations, and will result in a meaningful restriction of access to justice for individuals and those with limited means. Or, perhaps, they were nothing more than minor language tinkering that leaves judges free to continue their passive bystander approach to case management—tinkering that does little to curb the abusive discovery that leads defendants to make substantial settlement payments to resolve meritless cases simply to avoid exploding litigation costs. Stakeholders reading the same text and the same Advisory Committee Notes regarding the 2015 amendments forecast these polar, antithetical outcomes. So, who was right?

Data now exist to begin to understand how parties and courts are actually applying the amended provisions: the amendments have been in effect since December 1, 2015. The early results suggest a staggering change in the frequency with which parties and courts are applying proportionality to discovery requests to eliminate or narrow discovery not because it is irrelevant, but because it is too burdensome. Of course, the data do not reveal whether this change is permanent, and leave other questions unanswered, but they certainly suggest at least a short-term seismic shift in the application of proportionality. As to the other changes, the data are more mundane. This article presents the empirical data for all of the material 2015 amendments. It also describes some of the softer gloss and themes emerging from these opinions.

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I. INTRODUCTION

In 2010, two hundred judges, practitioners, and professors attended a conference at Duke University to discuss improvements to the pretrial process. They converged on three major deficits in our civil litigation system, and summarized them as follows: “What is needed can be described in two words—cooperation and proportionality—and one phrase—sustained, active, hands-on judicial case management.”¹ To remedy these three deficits, various committees comprising the Judicial Conference of the United States drafted, and the Supreme Court ultimately proposed, extensive amendments to the Federal Rules of Civil Procedure, with a particular focus on the discovery rules.²

The proposed amendments sparked immediate and intense controversy. The committee received a torrent of comments during the public comment periods—over 2,300 written comments and

1. JUDICIAL CONFERENCE ADVISORY COMM. ON CIVIL RULES & COMM. ON RULES OF PRACTICE & PROCEDURE, REPORT TO THE CHIEF JUSTICE OF THE UNITED STATES ON THE 2010 CONFERENCE ON CIVIL LITIGATION 4 (2010).

2. Specifically, the 2015 amendments altered the text of Rules 1, 4, 16, 26, 30–34, 37, and 55, and abrogated Rule 84 of the Federal Rules of Civil Procedure.

oral testimony from more than 120 witnesses.³ Some believed the amendments were just the latest move by the Supreme Court to protect big corporate defendants and limit plaintiffs' access to justice.⁴ Others believed the amendments did not go far enough in curbing disproportionate and abusive discovery.⁵

Coming before the effective date of the amendments, those wildly disparate assessments necessarily were purely speculative, without any empirical support. The amendments have now been in effect for more than a year,⁶ however, so it is now possible to begin evaluating the actual, not predicted, effects of the 2015 amendments. In other words, we can begin to assess who was right.

In order to explore whether the amendments have fostered change (positive or negative), this article compares the courts' application of the amended rules during the first year of their effectiveness to the courts' rulings during the same one year period immediately prior to their effectiveness. The article also examines some of the trends and sometimes surprising directions the courts have taken when applying these amendments.

For example, this article compares the courts' application of proportionality during the twelve-month period from December 2014 through November 2015 with the courts' application of proportionality during the twelve-month period from December 2015 through November 2016. By using parallel timeframes, confounding factors like seasonal differences should be minimized.

It is important to note at the outset that this analysis only examines judicial opinions applying the amended provisions, and does not attempt to capture behavior that is not reflected in such opinions. Thus, for example, it is possible (although some would

3. COMM. ON RULES OF PRACTICE & PROCEDURE, SUMMARY OF THE REPORT OF THE JUDICIAL CONFERENCE COMMITTEE ON RULES OF PRACTICE AND PROCEDURE 14 (2014).

4. See, e.g., Patricia W. Hatamyar Moore, *The Anti-Plaintiff Pending Amendments to the Federal Rules of Civil Procedure and the Pro-Defendant Composition of the Federal Rulemaking Committees*, 83 U. CIN. L. REV. 1083, 1086 (2015); Hon. Craig B. Shaffer, *The "Burdens" of Applying Proportionality*, 16 SEDONA CONF. J. 55, 69–70 (2015).

5. See, e.g., Mark W. Bennett, *Essay: The Grand Poobah and Gorillas in Our Midst: Enhancing Civil Justice in the Federal Courts—Swapping Discovery Procedures in the Federal Rules of Civil and Criminal Procedure and Other Reforms Like Trial by Agreement*, 15 NEV. L.J. 1293, 1313 (2015); Edward D. Cavanagh, *The 2015 Amendments to the Federal Rules of Civil Procedure: The Path to Meaningful Containment of Discovery Costs in Antitrust Litigation?*, 13–APR ANTITRUST SOURCE 1, 7 (2014).

6. These amendments apply to cases pending on December 1, 2015, unless the court "determines that applying them in a particular action would be infeasible or work an injustice." See FED. R. CIV. P. 86(a)(2)(B). Courts adjudicating motions on or after December 1, 2015, have generally applied the amended rules, so the existing data does effectively represent a full year's experience in the courts.

say unlikely) that parties have taken to heart the amendment to Rule 1 suggesting that they construe the rules to effectuate the just, speedy, and inexpensive determination of their cases and are now voluntarily participating in the litigation process in a more cooperative manner. Likewise, parties may be asserting proportionality objections to discovery in cases where neither party sees fit to bring the issue before the court (and thus that do not result in a judicial opinion to be tallied). Indeed, those two concepts might converge if, following a proportionality objection, the parties meet and confer, then cooperatively agree to a scope of discovery that is proportional to the needs of the case. That behavior, if occurring, would be difficult for an external observer to discern, and is outside the scope of this analysis. With that caveat in mind, judicial opinions are likely a good barometer for the behavior of the bar and bench generally on these procedural issues.

A few amendments particularly caught the attention of the lawyers, scholars, and other stakeholders. This article will focus on those controversial amendments, but will include all the provisions that the courts have applied substantively. It does not address two amendments designed to speed up the litigation process: the amendments to Rules 4⁷ and 16⁸ shortening the time periods for service of a complaint and issuance of the initial case management order. These are important amendments, but are straightforward and have not resulted in any surprising or interesting judicial opinions. Similarly, amendments to Rules 16⁹ and 26(f)¹⁰ added topics for the parties and the court to address at the outset of cases, such as preservation of electronically stored information. These amendments are helpful, but likewise have not generated any noteworthy opinions, and are not discussed in this article.

The main body of this article will examine one-by-one the most controversial of the 2015 amendments. For each amendment, the article will, after describing the nature of the amendment, provide the empirical comparison of the pre-amendment and post-amendment data. The article will next describe the judicial gloss that adds nuance and understanding not reflected in the raw numbers. The article will wrap up the treatment of each rule amendment with conclusions about the effectiveness, and effects, of the amendment and how it fits into the larger picture of the three Duke Conference objectives of promoting “cooperation and

7. FED. R. CIV. P. 4(m).

8. FED. R. CIV. P. 16(b)(2).

9. FED. R. CIV. P. 16(b)(3).

10. FED. R. CIV. P. 26(f)(3).

proportionality [and] sustained, active, hands-on judicial case management.” The article will conclude with an over-arching analysis of whether the amendments are achieving these Duke Conference objectives.

II. PROPORTIONALITY—RULE 26(B)(1)

A. *The Data*

Proportionality—the balancing of the benefits and burdens of discovery—appeared to generate the most anticipatory angst¹¹ and to have since achieved the greatest traction in the courts. Proportionality is not a new concept in the Federal Rules of Civil Procedure; proportionality has been in the rules since 1983.¹² Proportionality was initially situated in Rule 26(b)(1)—the provision establishing the scope of discovery—as a limitation on otherwise discoverable information.¹³ The Advisory Committee Notes reflect a concern about the cost of discovery, the prospect that these costs were driving settlement of claims, and the need for greater judicial involvement to police this excessively expensive discovery.¹⁴

The Supreme Court and the Advisory Committees did not perceive the insertion of proportionality into the Rules to have cured the problem of excessive discovery. Accordingly, the 1993 amendments moved the limits on discovery in Rule 26(b)(1), including proportionality, into a separate section of limits in Rule 26(b)(2).¹⁵ The 1993 amendment also expanded the list of factors the courts could consider in assessing proportionality.¹⁶

11. ADVISORY COMM. ON CIVIL RULES, REPORT OF THE DUKE CONFERENCE SUBCOMMITTEE 3 (2014) [hereinafter DUKE CONFERENCE REPORT] (“This proposed change provoked a stark division in the comments.”).

12. FED. R. CIV. P. 26(b)(1)(iii) (1983).

13. The initial iteration of proportionality read, “The frequency or extent of use of the discovery methods set forth in subdivision (a) shall be limited by the court if it determines that . . . (iii) the discovery is unduly burdensome or expensive, taking into account the needs of the case, the amount in controversy, limitations on the parties’ resources, and the importance of the issues at stake in the litigation.” *Id.*

14. See FED. R. CIV. P. 26(b)(1) advisory committee’s note to 1983 amendment (“The court must apply the standards in an even-handed manner that will prevent use of discovery to wage a war of attrition or as a device to coerce a party, whether financially weak or affluent. The rule contemplates greater judicial involvement in the discovery process and thus acknowledges the reality that it cannot always operate on a self-regulating basis.”).

15. See FED. R. CIV. P. 26(b) advisory committee’s note to 1993 amendment (“Textual changes are then made in new paragraph (2) to enable the court to keep tighter rein on the extent of discovery. The information explosion of recent decades has greatly increased both the potential cost of wide-ranging discovery and the potential for discovery to be used as an instrument for delay or oppression.”).

16. See FED. R. CIV. P. 26(b) advisory committee’s note to 2015 amendment (“The 1993 amendments added two factors to the considerations that bear on limiting discovery:

Still not satisfied, in 2000, the Supreme Court and the Advisory Committees sought to strengthen the limitations on discovery in Rule 26(b)(2), including proportionality, by adding a sentence to the scope of discovery in Rule 26(b)(1) to the effect that all discovery was subject to proportionality and the other limits in Rule 26(b)(2).¹⁷ The Advisory Committee Notes recognized that this new language was superfluous, and was only added because the courts did not seem to be applying the limitations rigorously enough.¹⁸

Coming full circle, the 2015 amendments repositioned proportionality from Rule 26(b)(2) back into Rule 26(b)(1), where it started.¹⁹ The Advisory Committee's articulated purpose of this relocation was, yet again, to foster more robust application of the doctrine.²⁰ The Committee was concerned that, by moving proportionality out of the definition of the scope of discovery in 1993, the committee had inadvertently deemphasized the provision.²¹ The amendment also reordered the proportionality factors, moving "the importance of the issues at stake in the action" to the front of the list, and adding consideration of "the parties' relative access to relevant information" to the list.²²

Some commentators worried that the broad scope of federal discovery would be eroded by proportionality objections.²³ Others

whether 'the burden or expense of the proposed discovery outweighs its likely benefit,' and 'the importance of the proposed discovery in resolving the issues.'").

17. See FED. R. CIV. P. 26(b) advisory committee's note to 2000 amendment.

18. See FED. R. CIV. P. 26(b) advisory committee's note to 2015 amendment ("[T]he Committee had been told repeatedly that courts were not using these limitations as originally intended. 'This otherwise redundant cross-reference has been added to emphasize the need for active judicial use of subdivision (b)(2) to control excessive discovery.'").

19. *Id.*

20. *Id.* ("Restoring proportionality as an express component of the scope of discovery warrants repetition of parts of the 1983 and 1993 Committee Notes that must not be lost from sight. The 1983 Committee Note explained that '[t]he rule contemplates greater judicial involvement in the discovery process and thus acknowledges the reality that it cannot always operate on a self-regulating basis.'").

21. *Id.* ("The clear focus of the 1983 provisions may have been softened, although inadvertently, by the amendments made in 1993. The 1993 Committee Note explained: '[F]ormer paragraph (b)(1) [was] subdivided into two paragraphs for ease of reference and to avoid renumbering of paragraphs (3) and (4). Subdividing the paragraphs, however, was done in a way that could be read to separate the proportionality provisions as limitations, no longer an integral part of the (b)(1) scope provisions.'"); DUKE CONFERENCE REPORT, *supra* note 11, at 6 ("The purpose of moving these factors explicitly into Rule 26(b)(1) is to make them more prominent, encouraging parties and courts alike to remember them and take them into account in pursuing discovery and deciding discovery disputes. If the expressions of concern reflect widespread disregard of principles that have been in the rules for thirty years, it is time to prompt widespread respect and implementation.").

22. DUKE CONFERENCE REPORT, *supra* note 11, at 7.

23. *Id.* at 3 ("Those who wrote and testified about experience representing plaintiffs saw proportionality as a new limit designed only to favor defendants. They criticized the

believed that moving proportionality would not cause a meaningful change in behavior or instill the balance missing from the discovery process.²⁴ Although the overall impact of the proportionality amendment on the federal civil justice system is not yet known, the initial data suggest that the repositioning may have fostered real change.

Three hundred thirty-five cases have applied the new proportionality provision in the first year of amended Rule 26(b)(1).²⁵ Of those cases, in 192 (57%) the court restricted discovery in whole or in part based on proportionality.²⁶ By comparison, courts applied proportionality 79 times and restricted discovery in 46 cases (58%) during the pre-amendment comparison period. These numbers suggest that parties and courts are applying proportionality more than four times more frequently than before the amendments, and that courts are narrowing discovery on proportionality grounds more than four times more frequently post-amendment.²⁷ Moreover, the data suggest that this increase in frequency may be accelerating—the final three months of the post-amendment period contained the highest levels of the application of proportionality—almost 40% higher than the average for the year.

factors from Rule 26(b)(2)(C)(iii) as subjective and so flexible as to defy any uniform application among different courts. They asserted that ‘proportionality’ will become a new automatic and blanket objection to all discovery requests, leading to increased motion practice with attendant costs and delays. And they were particularly concerned that proportionality would routinely defeat the rather extensive discovery ordinarily needed to prove many claims that involve modest amounts of money but principles important not only to the plaintiffs but also to the public interest.”)

24. *See, e.g.*, DUKE CONFERENCE REPORT, *supra* note 11, at Tab 2B, 52 (“Moving the proportionality factors from Rule 26(b)(2)(C)(iii) to Rule 26(b)(1) ‘does not effect any substantive change in the scope of discovery.’ Rule 26(b)(1) now expressly invokes Rule 26(b)(2)(C) as a limit on all discovery.”).

25. Many cases recite the amended language in their general statement of discovery law. This analysis did not count a case as applying proportionality unless the court referenced the doctrine in its analysis or discussion of the discovery at issue.

26. The analysis for this metric started with whether the court restricted discovery in its ruling—so an opinion granting a motion to compel without limitation notwithstanding a proportionality objection would automatically be deemed one not restricting discovery based on proportionality. If the court’s ruling limited discovery, then closer analysis was necessary to determine whether proportionality (as opposed to relevance or some other consideration) was the basis for the restriction. While court opinions are not always models of clarity, and thus categorizing them often requires an exercise of judgment, this analysis attempted to use a consistent yardstick for the pre- and post-amendment periods.

27. A natural question is whether the courts’ docket size has changed over the past year. Although the U.S. Courts reports are not current enough to answer this question, the Justia Dockets and Filings website and the Judge Information Center run by Syracuse University both suggest that filings during the post-amendment year were down between three and five percent compared to the pre-amendment year, making the change, if anything, greater than the raw numbers suggest.

While it is difficult to deny the materiality of these numbers, the data leave many questions unanswered. For example, only time will tell whether this increased rate of application of proportionality will accelerate over time, persist at current levels, or return to pre-amendment levels as the amendments are less in the forefront of everyone's consciousness. Likewise, it is difficult to determine whether the courts are reaching a different *result* because of the increased application of proportionality, or whether they are reaching the same result for a different *reason*.

For example, a number of discovery rules address burdensome discovery. Rule 26(c) allows a court to issue a protective order protecting a party from "undue burden."²⁸ Similarly, Rule 26(b)(2)(C)(ii) instructs the court to limit discovery when the information can be obtained from a less burdensome source.²⁹ Thus, a court that viewed discovery as unduly burdensome prior to December 1, 2015, had the option to limit that discovery under three different provisions in Rule 26: Rule 26(c); Rule 26(b)(2)(C)(ii); or Rule 26(b)(2)(C)(iii) (where proportionality previously resided). Now, that court might reach the same decision arising out of the same concern about the burdensome nature of the discovery, but might be more likely to base its ruling on proportionality because that doctrine is in the spotlight. In other words, the outcome may not have changed and the reason for the outcome—the court's perception that the discovery is too burdensome—may not have changed, but the courts may more frequently be framing their decisions to narrow burdensome discovery under the proportionality rubric.³⁰

B. The Proportionality Judicial Gloss

In addition to the numerical increase in proportionality adjudications, the case law reveals some interesting judicial gloss on the repositioned proportionality doctrine. For example, consistent with the Advisory Committee Notes stating that the purpose of the amendment was to promote more robust application of propor-

28. FED. R. CIV. P. 26(c)(1).

29. FED. R. CIV. P. 26(b)(2)(C)(ii).

30. Indeed, case law reveals that the courts often conflate these different burdensome-oriented provisions, using the term "undue burden" in their proportionality analysis, even though that term appears only in other discovery provisions. *See, e.g.,* *Small v. Amgen, Inc.*, No. 2:12-cv-476-FtM-29MRM, 2016 WL 7228863, at *7 (M.D. Fla. Sept. 28, 2016) ("[T]he Court finds that the proposed discovery is not proportional to the needs of this case. *See* Fed. R. Civ. P. 26(b)(1). Specifically, the Court finds that requiring Defendants to produce all discovery sought irrespective of the underlying indication would potentially impose an undue and unacceptable burden on the Defendants.").

tionality, and with the manner in which the courts have apparently taken this encouragement to heart, some courts are holding that they have an independent duty to assess proportionality, *even if the parties do not raise it*.³¹ This is a marked departure from the courts' general practices, and may reflect the Supreme Court's encouragement that judges take a more active, hands-on approach to case management.

Perhaps the most significant judicial gloss involves the manner of litigating a proportionality issue. The opinions are replete with statements from the courts announcing that the relocation of proportionality did not change the parties' respective burdens.³² Thus, the party resisting the discovery has the burden of proving that the discovery should not be allowed.³³ The change comes not in an overt shifting of this burden, but in the manner in which courts are requiring parties to support their positions regarding proportionality.

Numerous courts have held that parties must submit *evidence* to support their contentions regarding the proportionality factors, not just legal *argument*.³⁴ This requirement has converted many discovery motions from contests of legal argument to evidentiary proceedings, fundamentally changing the manner in which parties must litigate proportionality. Moreover, this requirement of evidentiary support applies to both the moving party and the opposing party—regardless of which party has the initial burden, the opposing party will simply lose if it does not counter the moving party's evidence with evidence of its own. Thus, both parties now must submit evidence supporting their positions on proportionality.³⁵

31. See, e.g., *Curtis v. Metro. Life Ins. Co.*, No. 3:15-cv-2328-B, 2016 WL 687164, at *3 (N.D. Tex. Feb. 19, 2016) (holding that a court must limit disproportionate discovery even in the absence of a motion); *Arcelormittal Ind. Harbor LLC v. Amex Nooter, LLC*, No. 2:15-CV-195-PRC, 2016 WL 614144, at *6-7 (N.D. Ind. Feb. 16, 2016).

32. See *Wilmington Tr. Co. v. AEP Generating Co.*, No. 2:13-CV-01213, 2016 WL 860693 (S.D. Ohio Mar. 7, 2016); *Curtis*, 2016 WL 687164, at *3.

33. *Wilmington Tr. Co.*, 2016 WL 860693, at *2; *Curtis*, 2016 WL 687164, at *3 (holding that a party that opposes a discovery request on the basis of proportionality must come forward with specific information, to the extent that such information is available, to address the proportionality factors).

34. See, e.g., *Gregory v. Gregory*, No. 2:15-CV-0320 (WHW)(CLW), 2016 WL 6122456, at *10 (D. N.J. Oct. 18, 2016) (finding that the plaintiff failed to submit evidence of the cost of responding, much less evidence that the cost would be "excessive or unwarranted"); *VHT, Inc. v. Zillow Grp., Inc.*, No. C15-1096JLR, 2016 WL 7077235, at *1 (W.D. Wash. Sept. 8, 2016) ("[T]he dearth of evidence on the record supporting Zillow's position renders that information negligibly relevant, minimally important in resolving the issues, and unduly burdensome.").

35. See *Wilmington Tr. Co.*, 2016 WL 860693, at *2 ("Courts have, in evaluating the proportionality issue, suggested that both parties have some stake in addressing the vari-

C. *The Proportionality Assessment*

Chief Justice Roberts emphasized his belief that both parties and judges need to exercise “increased reliance on the common-sense concept of proportionality” in his 2015 Year-End Report on the Federal Judiciary.³⁶ Surprisingly, the simple movement of the existing proportionality clause from one subsection of Rule 26(b) to another, with virtually no alteration to the clause’s language, appears to be accomplishing Justice Roberts’s goal. Indeed, this repositioning—perhaps along with the encouragement of the Chief Justice—has had a greater effect than any of the other changes in the 2015 amendments. The fourfold increase in judicial opinions applying proportionality to restrict discovery is difficult to trivialize. Furthermore, the data suggest that the increased application of proportionality may be increasing over time—after a modest start immediately after the effective date of the amendments, the rate of application soared by almost 40% in the last quarter of the comparison year.

The effectiveness of the proportionality amendment is further demonstrated by the judges who concluded that they have an independent duty to assess the proportionality of discovery requests even if the parties do not raise the issue. While Rule 26 has imposed the duty on each court to limit inappropriate discovery “on motion or on its own,”³⁷ judges have rarely imposed discovery limits sua sponte in the past. Only time will tell whether these changes stick or whether proportionality gradually fades from the consciousness of the parties and the judges.

Proportionality was one of the three core needs of proportionality, cooperation, and active judicial case management to improve the civil litigation system identified at the Duke Conference, and it received the most pointedly specific mandate—amended Rule 26(b)(1) includes proportionality as a mandatory limitation on the scope of all discovery. The Supreme Court’s success at achieving greater proportionality largely hinges on the effectiveness of the amendment to Rule 26(b)(1), and at present, it appears that the

ous relevant factors.”); *Oracle Am., Inc. v. Google, Inc.*, No. 10-cv-03561-WHA (DMR), 2015 WL 7775243, at *2 (N.D. Cal. Dec. 3, 2015).

36. C.J. JOHN G. ROBERTS, JR., 2015 YEAR-END REPORT ON THE FEDERAL JUDICIARY 7 (2015) (“The amended rule states, as a fundamental principle, that lawyers must size and shape their discovery requests to the requisites of a case That assessment may, as a practical matter, require the active involvement of a neutral arbiter—the federal judge—to guide decisions respecting the scope of discovery.”).

37. FED. R. CIV. P. 26(b)(2)(C) (emphasis added).

Supreme Court has succeeded in advancing its proportionality goal.

III. SPOILIATION—RULE 37(E)

A. *The Data*

Spoilation sanctions have been a topic of much discussion over the past several years.³⁸ Prior to December 1, 2015, courts imposed sanctions for spoilation either through their general powers over cases on their dockets or, if they had entered a preservation order, through their sanctioning authority under Rule 37(b) for a violation of a discovery order.³⁹ The only provision in the Federal Rules of Civil Procedure explicitly touching on spoilation was Rule 37(e), which contained a narrow safe harbor for the destruction of electronically stored information (“ESI”) through the routine operation of a computer system.⁴⁰ As a consequence, courts were inconsistent regarding the standard for spoilation sanctions, with some courts imposing them for mere negligence⁴¹ and others requiring a heightened degree of misconduct.⁴²

New Rule 37(e) contains a national standard for spoilation of ESI. It establishes three prerequisites for any sanctions for spoilation of ESI: (1) the party failing to preserve the ESI must have had a duty to preserve it; (2) the ESI must have been “lost because the party failed to take reasonable steps to preserve” it (i.e., the ESI was lost through negligence, not a server being destroyed through flooding or a lightning strike); and (3) the ESI “cannot be restored or replaced through additional discovery.”⁴³ If all three prerequisites are satisfied, amended Rule 37(e) creates two tiers of sanctions. It only allows the most severe sanctions—dispositive sanctions (dismissal or judgment) or an adverse inference instruction to the jury—upon a finding of *intent* to deprive an opponent of the use of the lost evidence in the litigation.⁴⁴ Otherwise, sanc-

38. See, e.g., Tristan Evans-Wilent, Note, *The Electronic Document Retention System Ate My Homework: Gross Negligence and the Rebuttable Presumption of Prejudice Within the Doctrine of Spoilation in Federal Courts*, 87 ST. JOHN'S L. REV. 1193 (2013).

39. See, e.g., FED. R. CIV. P. 37(b); *Guard Ins. Grp., Inc. v. Techtronic Indus. Co.*, 80 F. Supp. 3d 497, 503 (W.D.N.Y. 2015).

40. See, e.g., *Lee v. Max Int'l, LLC*, 638 F.3d 1318, 1322 (10th Cir. 2011).

41. See, e.g., *Residential Funding Corp. v. DeGeorge Fin. Corp.*, 306 F.3d 99 (2d Cir. 2002) (authorizing the giving of adverse-inference instructions on a finding of negligence or gross negligence).

42. *Stepnes v. Ritschel*, 663 F.3d 952, 965 (8th Cir. 2011) (requiring bad faith); *Rimkus Consulting Grp., Inc. v. Cammarata*, 688 F. Supp. 2d 598, 614 (S.D. Tex. 2010) (same).

43. FED. R. CIV. P. 37(e).

44. FED. R. CIV. P. 37(e)(2).

tions are limited to those necessary to cure prejudice to opposing parties, and may not include dispositive sanctions or an adverse inference instruction.⁴⁵

With this amendment to Rule 37(e), sanctions for spoliation of ESI will, by rule, become more uniform, and case law confirms that courts across the country are now consistently applying the same standard for spoliation sanctions related to ESI.⁴⁶ The open question is whether the amendment caused the frequency of the various sanctions to change.

Courts adjudicated 54 motions for sanctions in their first year of applying amended Rule 37(e).⁴⁷ The court awarded some sanction in 26 of those, 14 of which were an adverse inference instruction. During the comparison period, courts adjudicated 54 motions for spoliation sanctions, awarding sanctions in 27, 14 of which were an adverse inference instruction. These data suggest that, while the amendment to Rule 37(e) created a uniform standard for sanctions for spoliation of ESI, the amendment has not altered the overall frequency of requests for sanctions for spoliation of ESI, imposition of sanctions for spoliation of ESI, or the severity of sanctions for spoliation of ESI that the courts have imposed.

45. FED. R. CIV. P. 37(e)(1).

46. See, e.g., *Best Payphones, Inc. v. N.Y.C.*, No. 1-CV-3924 (JG)(VMS), 2016 WL 792396, at *4 (E.D.N.Y. Feb. 26, 2016) (recognizing that negligence or even gross negligence can no longer support an adverse inference instruction as a sanction for the spoliation of ESI). There are cases where courts continue to apply case law standards instead of Rule 37(e) to the failure to preserve ESI. See, e.g., *Bordegaray v. City of Santa Barbara*, No. 2:14-cv-8610-CAS (JPRx), 2016 WL 7260920, at *5-6 (C.D. Cal. Dec. 13, 2016) (applying older case law precedent instead of Rule 37(e) to spoliation of electronic data from a police car in an excessive force case); *Estate of Romain v. City of Grosse Pointe Farms*, No. 14-12289, 2016 WL 7664226, at *3 (E.D. Mich. Nov. 22, 2016) (applying older case law precedent instead of Rule 37(e) to spoliation of Google search images).

47. As originally framed, amended Rule 37(e) would have addressed spoliation sanctions for all forms of evidence, not just ESI. DUKE CONFERENCE REPORT, *supra* note 11, at 370-71. In response to comments that spoliation sanctions were uniquely problematic with ESI and that the current regime was working appropriately for spoliation of paper documents, the Advisory Committee revised the proposed amendment and limited its scope to spoliation of ESI. Accordingly, while the articulated purpose of the amendment was to promote a nationally-consistent standard, the Advisory Committee created an odd dichotomy where failure to preserve a paper copy of a letter is potentially subject to sanctions under a court-developed standard that varies from jurisdiction to jurisdiction and failure to preserve the same letter in electronic form is subject to an entirely separate set of considerations found in Rule 37(e). See *Best Payphones, Inc.*, 2016 WL 792396, at *4 (applying two different standards to allegations of failure to preserve ESI and non-ESI in the same case). Some courts have addressed this odd result by applying Rule 37(e) to spoliation of paper documents as well, even though it does not apply on its face. See *Mcqueen v. Aramark Corp.*, No. 2:15-CV-492-DAK-PMW, 2016 WL 6988820, at *3 (D. Utah Nov. 29, 2016) (applying 37(e) when both ESI and paper were lost). Because of the limitation in amended Rule 37(e) to ESI, this article compares cases under amended Rule 37(e) to cases in the comparison period addressing allegations of ESI spoliation, to keep the comparison “apples to apples.”

Thus, the data suggest that the amendment to Rule 37(e) had precisely the effect that the Advisory Committee advanced as its goal—to establish a uniform standard without either promoting or squelching spoliation sanctions.

B. The Spoliation Judicial Gloss

Although the 2015 amendments appear to have created greater uniformity in ESI spoliation sanctions without altering the frequency of these sanctions, the amendments have also yielded some unexpected developments in the case law applying them. As with proportionality, the nature of the showing that parties need to make to support or oppose a spoliation motion is evolving.

The threshold issue in this regard is which party has the burden of proof or persuasion as to the various prerequisites and considerations under Rule 37(e). Rule 37(e) is silent on the parties' burdens, and the Advisory Committee Notes suggest that the courts have discretion to assign burdens on a case-by-case basis.⁴⁸ Some courts are assigning the burden to the moving party, as would be typical of a spoliation motion prior to the amendments.⁴⁹ However, some courts are shifting the burden onto the nonmoving party to demonstrate the absence of prejudice.⁵⁰ Furthermore, some judges are instructing the parties to develop a more complete record when they deem the parties' submissions inadequate to make the findings required under Rule 37(e).⁵¹

48. FED. R. CIV. P. 37(e) advisory committee's note to 2015 amendment ("The rule does not place a burden of proving or disproving prejudice on one party or the other. Determining the content of lost information may be a difficult task in some cases, and placing the burden of proving prejudice on the party that did not lose the information may be unfair. In other situations, however, the content of the lost information may be fairly evident, the information may appear to be unimportant, or the abundance of preserved information may appear sufficient to meet the needs of all parties. Requiring the party seeking curative measures to prove prejudice may be reasonable in such situations. The rule leaves judges with discretion to determine how best to assess prejudice in particular cases.")

49. See, e.g., *Richard v. Inland Dredging Co.*, No. 6:15-0654, 2016 WL 5477750, at *4 (W.D. La. Sept. 29, 2016); *Martinez v. City of Chi.*, 2016 WL 3538823, at *24 (N.D. Ill. June 29, 2016).

50. See *Mcqueen*, 2016 WL 6988820, at *3 (holding that where the precise nature of lost documents cannot be determined, the party failing to preserve cannot show lack of prejudice).

51. See, e.g., *Gonzalez-Bermudez v. Abbott Labs. PR Inc.*, 214 F. Supp. 3d 130, 161-63 (D. P.R. 2016) ("Having not yet shown that she is entitled to an adverse inference, Plaintiff's request is **DENIED WITHOUT PREJUDICE.**"); *Konica Minolta Bus. Sols., U.S.A. Inc. v. Lowery Corp.*, No. 15-CV-11254, 2016 WL 4537847, at *5-6 (E.D. Mich. Aug. 31, 2016) (holding that further discovery was required to determine whether reasonable steps were taken to preserve the ESI and whether the ESI can be replaced through additional discovery); *Bagley v. Yale Univ.*, No. 3:13-CV-1890 (CSH), 2016 WL 3264141, at *19 (D. Conn. June 14, 2016), *as amended* (June 15, 2016) (reserving a decision on the spoliation motion until the nonmovant defendant produced proof of its preservation efforts).

A related question is who decides whether the conditions in Rule 37(e) are satisfied—the judge or the jury? Rule 37(e) is again silent on who makes the determinations it requires, but the Advisory Committee Notes suggest that the judge has the option of sending issues like intent to the jury.⁵² Despite this implicit authority, judges have decided the vast majority of the post-2015 Rule 37(e) motions.

In *Cahill v. Dart*,⁵³ however, the judge allowed the jury to decide whether the spoliating party had the intent to affect the litigation as part of the Rule 37(e) analysis. The judge was concerned that the finding of intent to destroy the evidence was closely related to the plaintiff's claims for false arrest and malicious prosecution. Accordingly, the judge wrote that, "the best course is for the jury to decide the question of intent."⁵⁴ Although the judge did not explicitly reference the Seventh Amendment, this case highlights one important consideration in deciding whether to involve the jury in the Rule 37(e) determinations.

The courts are also divided on the extent to which any sanctioning authority outside of Rule 37(e) remains for spoliation of ESI.⁵⁵ Historically, courts used either their inherent powers over cases on their docket or, if they had issued a preservation order with which a party failed to comply, their authority under Rule 37(b) to sanction parties for failing to comply with discovery orders.⁵⁶ Thus, the question is whether either of these sources remains available following the amendment of Rule 37(e).

Regarding whether courts may continue to use their inherent authority to sanction parties for spoliation of ESI, some courts have held that Rule 37(e) forecloses the exercise of that inherent authority.⁵⁷ Other courts deem the remedy in Rule 37(e) cumula-

52. FED. R. CIV. P. 37(e) advisory committee's note to 2015 amendment ("If a court were to conclude that the intent finding should be made by a jury, the court's instruction should make clear that the jury may infer from the loss of the information that it was unfavorable to the party that lost it only if the jury first finds that the party acted with the intent to deprive another party of the information's use in the litigation. If the jury does not make this finding, it may not infer from the loss that the information was unfavorable to the party that lost it.")

53. No. 13-cv-361, 2016 WL 7034139 (N.D. Ill. Dec. 2, 2016).

54. *Id.* at *4.

55. The Advisory Committee Notes to the 2015 amendment to Rule 37(e) state that the new provision "does not affect the validity of an independent tort claim for spoliation if state law applies in a case and authorizes the claim." This article focuses on spoliation sanctions within the existing litigation, rather than such independent tort claims.

56. See *McIntosh v. United States*, No. 14-CV-7889 (KMK), 2016 WL 1274585, at *30 (S.D.N.Y. Mar. 31, 2016).

57. See *Ala. Aircraft Indus., Inc. v. Boeing Co.*, 319 F.R.D. 730, 740 (N.D. Ala. 2017) (holding that the Advisory Committee Notes foreclose reliance on the court's inherent authority); *Marshall v. Dentfirst, P.C.*, 313 F.R.D. 691, 694 (N.D. Ga. 2016) ("This amendment

tive to other sanctioning authorities.⁵⁸ Cases falling in this latter category appear to be in direct conflict with the Advisory Committee Notes,⁵⁹ and may disappear over time, but for now this remains an open issue.

Whether courts may impose the sanctions in Rule 37(b) if they have issued a preservation order remains unanswered. This is an important question. Rule 37(b) not only contains a lengthy list of approved sanctions, it also accords the courts almost complete discretion to combine the sanctions on the list or to impose any other sanctions they deem “just.”⁶⁰ Thus, the potential to use Rule 37(b) to expand the sanctions criteria and options beyond those authorized under Rule 37(e) could significantly undermine the policy objective behind the 2015 amendments to Rule 37(e) to create a uniform and predictable standard for ESI spoliation sanctions.

Case law also raises some anomalies that the Advisory Committee may not have intended to create, and may want to remedy. First, all of the other sanctioning authorities in Rule 37 provide for the award of attorney’s fees to the prevailing party in a discovery motion.⁶¹ Rule 37(e) contains no provision authorizing an award of attorney’s fees to the prevailing party in a sanctions motion, and at least one court has held that such an award would be improper.⁶² This anomalous lack of authority for an attorney’s fees in Rule 37(e) seems like an oversight, and may be corrected by the Advisory Committee or the courts over time.

‘forecloses reliance on inherent authority or state law to determine when certain measures should be used’ to address spoliation of electronically stored information.”).

58. *Cohn v. Guaranteed Rate, Inc.*, 318 F.R.D. 350, 353–54 (N.D. Ill. 2016) (“Rule 37(e) describes some of the remedies that a court may order in the event that electronically stored information is destroyed The Court also has broad, inherent power to impose sanctions for failure to produce discovery and for destruction of evidence, over and above the provisions of the Federal Rules.”); *CAT3, LLC v. Black Lineage, Inc.*, 164 F. Supp. 3d 488, 498 (S.D.N.Y. 2016) (“Where exercise of inherent power is necessary to remedy abuse of the judicial process, it matters not whether there might be another source of authority that could address the same issue.”). *See also Helget v. City of Hays, Kan.*, 844 F.3d 1216, 1225–26 (10th Cir. 2017) (discussing pre-amendment case law instead of Rule 37(e) for failure to preserve internet-usage and email history).

59. FED. R. CIV. P. 37(e) advisory committee’s note to 2015 amendment (Rule 37(e) “authorizes and specifies measures a court may employ if information that should have been preserved is lost, and specifies the findings necessary to justify these measures. It therefore forecloses reliance on inherent authority or state law to determine when certain measures should be used.”).

60. *See Valley Eng’rs Inc. v. Elec. Eng’g Co.*, 158 F.3d 1051, 1056 (9th Cir. 1998).

61. Rule 37(a)(5) provides for an award of attorney’s fees to the prevailing party on a motion to compel and Rule 37(b)(2)(B) provides for an award of attorney’s fees to the prevailing party on a motion for sanctions for failure to comply with a court order. Rules 37(c)(1)(C) and 37(d)(3) incorporate the sanctions from Rule 37(b).

62. *See Wal-Mart Stores, Inc. v. Cuker Interactive, LLC*, No. 5:14–CV–5262, 2017 WL 239341, at *2 (W.D. Ark. Jan. 19, 2017).

Second, the prerequisites in Rule 37(e) may create an unintended opening for parties to avoid the consequences of their improper conduct. In *Marquette Transportation Company Gulf Island, LLC v. Chembulk Westport M/V*, the plaintiff claimed that the defendant operated its vessel at excessive speed, causing the plaintiff's vessel to flood and capsize.⁶³ In discovery, the plaintiff sought a copy of the data from the defendant vessel's Voyage Data Recorder, or VDR.⁶⁴ The defendant produced a thumb drive that did not contain audio or radar data from the time of the incident. The defendant refused to allow the plaintiff's expert to download the vessel's VDR data, but the court ordered the download.⁶⁵ The plaintiff's expert opined that data had been deleted deliberately. During depositions, the plaintiff learned that a DVD had been created containing all the data from the VDR, and the plaintiff pursued, and eventually obtained, a copy of the DVD.⁶⁶ The plaintiff then sought sanctions for the defendant's conduct. Despite evidence potentially establishing an intent to affect the litigation, the court found that sanctions were unavailable under Rule 37(e). Before any sanctions may be awarded, the court reasoned, the moving party must demonstrate that the ESI cannot be "restored or replaced."⁶⁷ Because the plaintiff ultimately obtained a copy of the missing data, it could not satisfy this prerequisite for sanctions under Rule 37(e).⁶⁸

Judge Roby's construction of Rule 37(e) in *Marquette* seems faithful to the language of the Rule. At the same time, it creates a perverse incentive to spoliage unhelpful ESI, then to retrieve it from a backup server if sanctions appear to be forthcoming, and thereby avoid the sanctions.⁶⁹ Rule 37(e) should not excuse a party from spoliation sanctions simply because the party, upon being caught, somehow "finds" a copy of the previously lost ESI, and the Advisory Committee or the courts should close this loophole.

Finally, another open question involves the application of proportionality to spoliation sanctions. Although the Advisory Committee Notes express an intent to have proportionality factor into

63. No. 13-6216 c/w 14-2071, 2016 WL 930946 (E.D. La. Mar. 11, 2016).

64. *Id.* at *1.

65. *Id.*

66. *Id.*

67. *Id.* at *3.

68. *Id.*

69. Of course, a deliberate exercise of this strategy might trigger other forms of sanction, such as a sanction for violating the signature certification in Rule 26(g). The availability of such sanctions depends on the circumstances, but does not alter the fact that Rule 37(e) likely has an unintended loophole.

the Rule 37(e) analysis,⁷⁰ Rule 37(e) does not expressly use the term. The most likely avenue for introduction of proportionality lies in the prerequisite requiring that the spoliating party have failed to take “reasonable” steps to preserve the ESI. Courts might evaluate the reasonableness of the steps taken under the proportionality factors in Rule 26(b)(1). This concept has not yet found its way into the courts’ analysis at an explicit level.⁷¹

C. The Spoliation Assessment

Along with the proportionality amendment, the new ESI spoliation provision in Rule 37(e) has effected the greatest change in federal civil litigation among the 2015 amendments. The amendment set out to address the inconsistency among the courts in the standard for spoliation sanctions, and—with the exception of a few quirks in the case law that will likely resolve over time—Rule 37(e) accomplishes that objective. Furthermore, it appears to have done so in a manner that changed the standard for spoliation sanctions, but not the frequency with which parties sought, or the courts awarded, those sanctions.⁷²

While successful in setting a single national standard, the amendment contains some gaps and ambiguities that the Supreme Court should address by further refining the amendment. Although the amendment accomplishes uniformity of sanctions for spoliation of ESI, it makes no sense to have two different sets of

70. FED. R. CIV. P. 37(e) advisory committee’s note to 2015 amendment (“Another factor in evaluating the reasonableness of preservation efforts is proportionality. The court should be sensitive to party resources; aggressive preservation efforts can be extremely costly, and parties (including governmental parties) may have limited staff and resources to devote to those efforts. A party may act reasonably by choosing a less costly form of information preservation, if it is substantially as effective as more costly forms. It is important that counsel become familiar with their clients’ information systems and digital data—including social media—to address these issues. A party urging that preservation requests are disproportionate may need to provide specifics about these matters in order to enable meaningful discussion of the appropriate preservation regime.”).

71. In *FTC v. DirectTV Inc.*, No. 15-cv-01129-HSG (MEJ), 2016 WL 7386133, at *5 (N.D. Cal. Dec. 21, 2016), the court’s opinion might be read to suggest that matter that is not proportional need not be preserved. That approach seems misguided. The duty to preserve is determined by the applicable body of law, and may not include a proportionality component. The requirement to take reasonable steps to preserve relevant matter seems like a much more logical place to introduce proportionality considerations.

72. Of course, the question of whether the standard in Rule 37(e), requiring specific intent for the most severe sanctions and limiting other sanctions to those necessary to cure any prejudice caused by the spoliation, is open to debate. The lower threshold set by the Court of Appeals for the Second Circuit in *Residential Funding Corp. v. DeGeorge Financial Corp.*, 306 F.3d 99 (2d Cir. 2002), allowing adverse inference or case-concluding sanctions based on ordinary negligence, was a minority viewpoint that the Advisory Committee and Supreme Court explicitly rejected. Regardless of one’s view of the appropriate threshold, however, a uniform standard is appropriate across the federal courts.

spoliation rules for ESI and other types of evidence. It is frequently the case that documents exist in both paper and electronic format. Under the current framework, if a party failed to preserve both, the court might need to conduct two different sanctions analyses and might be compelled to impose two different sets of sanctions. Not only would that exercise be wasteful, it could introduce confusion to the jury as well—the jury might, for example, be instructed to presume that the paper copy contained information harmful to the spoliating party, but not to make the same presumption for the electronic copy. Additionally, Rule 37(e) should contain an attorney’s fees provision, and arguably a meet and confer requirement, like the other sanctions provisions in Rule 37. Finally, the Rule might be improved by some thoughtful language regarding the burden of proof and potential role of the jury in the factual aspects of the Rule 37(e) analysis.

The spoliation sanctions amendment does not directly address any of the three Duke Conference core needs of proportionality, cooperation, and active judicial case management (although one could argue that it tangentially advances proportionality). Thus, while the 2015 amendment to Rule 37(e) successfully accomplished the important objective of creating a uniform national standard, it did not materially advance any of the three core deficits of the civil litigation system.

IV. COOPERATION—RULE 1

A. *The Data*

Rule 1 contains the iconic, and largely aspirational, language requiring that the rules be construed to secure the “just, speedy, and inexpensive determination of every action and proceeding.”⁷³ The amendment expressly extends that duty to the parties, whereas the prior language could be read to apply only to the courts. The amendment to Rule 1 was the Advisory Committee’s primary attempt to foster greater cooperation, and scholars have criticized this amendment as unlikely to have any material effect.⁷⁴

In the first year following the 2015 amendments’ effectiveness, courts discussed amended Rule 1 in 432 cases. In the majority, the court either mentioned the rule in general background (e.g.,

73. FED. R. CIV. P. 1.

74. See Bennett, *supra* note 5, at 1313.

“Summary judgment is not a disfavored remedy, See Rule 1”⁷⁵ or admonished the parties to be mindful of Rule 1’s strictures going forward.⁷⁶ In 177 cases (41%), however, the court included Rule 1 among the grounds supporting its ruling on issues like whether to grant requests for extensions of time.⁷⁷ By comparison, courts discussed Rule 1 389 times in the comparison year prior to the amendments’ effective date, and based their rulings on Rule 1 in 161 (41%) of those cases. Thus, courts invoked Rule 1 more frequently post-amendment than they did before the amendment, but the difference is small enough as to be likely meaningless.

B. The Cooperation Judicial Gloss

The Advisory Committee Note accompanying the 2015 amendment to Rule 1 is quite short—consisting of two spare paragraphs—and does not illuminate much about the Committee’s thought processes. The Note does suggest that the amendment, by adding an express reference to the parties’ obligations to construe the rules to achieve the just, speedy, and inexpensive resolution of matters, was designed to foster greater cooperation.⁷⁸ As discussed above, the data do not show any significant numerical increase in the application of Rule 1. Moreover, it is difficult to discern any evidence of increased cooperation in the reported opinions discussing Rule 1.⁷⁹

75. See, e.g., *Krajsnik v. Ramsey*, No. MJG–15–3708, 2017 WL 3868560, at *2 (D. Md. Sept. 5, 2017) (“When evaluating a motion for summary judgment, the Court must bear in mind that the ‘summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy and inexpensive determination of every action.’” (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (quoting Rule 1 of the Federal Rules of Civil Procedure))).

76. See, e.g., *United States ex rel. Feaster v. Dopps Chiropractic Clinic, LLC*, No. 13–cv–1453–EFM–KGG, 2016 WL 6462041, at *6 (D. Kan. Nov. 1, 2016); *Scranton Products, Inc. v. Bobrick Washroom Equip., Inc.*, 190 F. Supp. 3d 419, 427 (M.D. Pa. 2016).

77. See, e.g., *Vanderklok v. United States*, No. 15–00370, 2016 WL 1720449, at *2 (E.D. Pa. Apr. 29, 2016).

78. FED. R. CIV. P. 1 advisory committee’s note to 2015 amendment (“Most lawyers and parties cooperate to achieve these ends. But discussions of ways to improve the administration of civil justice regularly include pleas to discourage over-use, misuse, and abuse of procedural tools that increase cost and result in delay. Effective advocacy is consistent with—and indeed depends upon—cooperative and proportional use of procedure.”).

79. Obviously, issues tend to come before the court when the parties are not cooperating and the process is not running smoothly—that is when parties tend to file motions and the courts tend to issue opinions. Thus, it is not surprising that the vast majority of opinions that discuss whether the parties are complying with Rule 1 criticize one of the parties—or both parties—for failing to uphold the spirit of Rule 1. The lack of any meaningful change in the number of these cases is strong evidence that the parties have not, as a result of the 2015 amendment to Rule 1, suddenly started “playing well together.” The research

Although the Rule 1 opinions do not demonstrate increased cooperation, they do contain some noteworthy jurisprudence. The Advisory Committee Notes explicitly state that the amendment to Rule 1 does not create a new basis for sanctions; a party cannot file a successful motion asking the court to sanction an opposing party because the opposing party is applying the rules in a manner that causes delay or unnecessary costs in violation of Rule 1.⁸⁰

The natural question, then, is not whether parties have started seeking sanctions under Rule 1—in direct contravention of the Committee Note—but whether they are using violations of Rule 1 to support motions for sanctions under other sanctioning authority.⁸¹ The case law reflects that both parties and the courts are citing violations of Rule 1 as support for sanctions under another rule. For example, courts are regularly citing conduct inconsistent with Rule 1—such as discovery conduct that causes delay or drives up the cost of litigation—as part of the basis for their decisions to impose sanctions under Rule 37.⁸² Likewise, the failure to uphold the goals of Rule 1 has been cited as part of the basis for an award of sanctions under the court's contempt power in 18 U.S.C. § 401,⁸³

for this article did not uncover any instances of the court praising the parties for their newfound cooperative spirit.

80. FED. R. CIV. P. 1 advisory committee's note to 2015 amendment (“This amendment does not create a new or independent source of sanctions.”).

81. The Advisory Committee Note suggests that such a tactic is not improper. FED. R. CIV. P. 1 advisory committee's note to 2015 amendment (explaining that while the amendment does not create a new sanctioning authority, “neither does it abridge the scope of any other of these rules.”).

82. *See, e.g.*, *Sec. & Exch. Comm'n v. Wu*, No. 11-cv-04988-JSW, 2016 WL 4943000, at *2 (N.D. Cal. Sept. 16, 2016) (citing Rule 1 violations as supporting “termination sanctions” under Rule 37). *See also* *Century Sur. Co. v. Nafel*, No. 3:14-CV-00101-JWD-EWD, 2016 WL 4059678, at *9 (M.D. La. July 28, 2016) (holding that with Rule 1's objectives “so firmly embedded in the Rules . . . this Court must find that [the defendant] contravened his discovery obligations, triggering Rule 37.”); *Hardy v. GlobalOptions Servs., Inc.*, No. 2:14-cv-00513-APG-CWH, 2016 WL 4154943, at *2 (D. Nev. July 15, 2016) (listing Rule 1 as a basis for sanctions under Rules 16 and 37); *Thomas v. FTS USA, LLC*, No. 3:13cv825, 2016 WL 3566657, at *12 (E.D. Va. June 24, 2016) (listing Rule 1 violations as a basis for sanctions under Rule 37); *Greene v. Wal-Mart Stores, Inc.*, No. 2:15-cv-00677-JAD-NJK, 2016 WL 829981, at *5 (D. Nev. Jan. 26, 2016) (“As the text of Rule 1 now makes explicit, the duty to strive toward that goal is shared by the Court and the parties. It is with that charge as a guide that courts construe and administer the Rules. There are several mechanisms by which this goal can be accomplished, including entering case-dispositive sanctions against a party who fails to comply with the Rules or unnecessarily multiplies the proceedings.”) (citations omitted).

83. *N. States Power Co. agent of Xcel Energy v. TriVis, Inc.*, No. 16-51 (DSD/BRT), 2016 WL 2621953, at *5 (D. Min. May 6, 2016).

an award of attorney's fees,⁸⁴ involuntary dismissal under Rule 41(b),⁸⁵ and the court's decision to award Rule 11 sanctions.⁸⁶

Conversely, courts also use Rule 1 regularly to excuse minor transgressions of other rules. So, for example, in *AK Steel Corporation v. PAC Operating Limited Partnership*, the court based its decision to overlook a party's failure to seek leave to amend a pleading on Rule 1 considerations.⁸⁷ Likewise, in *In re: Ex Parte Application of Pro-Sys Consultants and Neil Godfrey*, the court allowed an alternate form of service of a subpoena to advance the Rule 1 interests.⁸⁸

Finally, the indicia that proportionality has gained traction in the courts as a result of the 2015 amendments extends to Rule 1. The Advisory Committee Note to Rule 1 suggests its tie to proportionality,⁸⁹ and the courts are starting to pair the two concepts. For example, in *Hyatt v. Rock*, the court described the standard in Rule 1 as "enveloping the interpretation of Rule 26."⁹⁰

C. The Cooperation Assessment

Chief Justice Roberts described the amendment to Rule 1 as expanding the scope of the rule by "a mere eight words" but characterized those as "words that judges and practitioners must take to heart."⁹¹ Whereas the proportionality and spoliation amendments seem to have achieved meaningful change, there is not yet any evidence that either judges or practitioners have "taken to heart" the new obligations in Rule 1. The courts pay some lip service to the amendment in their opinions, but the data does not suggest that the parties or the courts are invoking or applying Rule 1 in a meaningfully different manner.

84. *Joe Hand Promotions, Inc. v. Tickle*, No. 4:12-cv-01874, 2016 WL 393797, at *10 (M.D. Pa. Feb. 2, 2016).

85. *Kost v. Hunt*, No. 13-cv-583 (JNE/TNL), 2016 WL 5539768, at *4 (D. Min. Aug. 11, 2016).

86. *Keister v. PPL Corp.*, 318 F.R.D. 247, 258 (M.D. Pa. 2015).

87. No. 15-9260-CM-GEB, 2016 WL 6163832, at *5 (D. Kan. Oct. 24, 2016) ("In direct contravention of Rule 1's directive to 'secure the just, speedy, and inexpensive determination' of this proceeding, a motion for leave would frankly only add to the cost and delay of the case.").

88. No. 16-mc-80118-JSC, 2016 WL 6025155, at *2 (N.D. Cal. Oct. 14, 2016).

89. FED. R. CIV. P. 1 advisory committee's note to 2015 amendment ("Effective advocacy is consistent with—and indeed depends upon—cooperative and proportional use of procedure.").

90. No. 9:15-CV-0089 (DNH/DJS), 2016 WL 6820378, at *2 (N.D.N.Y. Nov. 18, 2016). See also *Waters v. Drake*, No. 2:14-cv-1704, 2016 WL 4264350, at *17 (S.D. Ohio Aug. 12, 2016) (discussing the interplay between Rules 1 and 26(b)(1) in a "Prefatory Statement").

91. C.J. ROBERTS, JR., *supra* note 36, at 5-6.

With regard to the Duke Conference core needs of proportionality, cooperation, and active judicial case management, the amendment to Rule 1 is the closest the amendments come to promoting greater cooperation. Although this section uses the term “cooperation” in its title and discussion, however, Rule 1 does not even use the word “cooperation,” much less attempt to mandate cooperation. Rather, Rule 1 as amended and applied appears to impose an obligation on each party separately and independently to employ the rules to obtain the just, speedy, and inexpensive determination of each action. Thus far, there is no evidence that the amendment to Rule 1 has created a greater spirit of cooperation, although that might admittedly be difficult to tease out of reported opinions.

V. DISCOVERY COST-SHIFTING—RULE 26(C)(1)(B)

Another concern regarding the 2015 amendments pertained to the authorization to shift the costs of responding to discovery from the responding party to the requesting party. Although the default has always been that the responding party bears the cost of responding to discovery requests, the courts have long had the inherent authority to shift those costs to the requesting party,⁹² and the 2015 amendment simply codified that judge-made rule. Scholars and other stakeholders worried that this new express authority would result in cost-shifting becoming the norm, limiting access to information for parties with limited resources.⁹³

A. *The Data*

Cost-shifting certainly has not become the norm in the first year of explicit authority in Rule 26(c)(1)(B). Only three decisions have adjudicated a motion seeking a protective order shifting discovery costs under the amended rule, with one court granting the motion.⁹⁴ At the same time, that is three more motions than were filed in the year prior to the 2015 amendments; not a single case adjudicated a fee-shifting protective order request in 2015.

92. See *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978).

93. Judge Shira A. Scheindlin from the Southern District of New York submitted a comment stating that the new rule, in combination with Rule 26(b)(2)(B), “may encourage courts to adopt a practice of requiring parties to pay for the discovery they request or to do without.” She opined that fee shifting “should not become our default position.” DUKE CONFERENCE REPORT, *supra* note 11, Tab 2B, at 121.

94. See *Knapp v. Evgeros, Inc.*, No. 15 C 754, 2016 WL 2755452, at *2 (N.D. Ill. May 12, 2016).

B. The Cost-Shifting Assessment

The amendment to Rule 26(c) was billed as simply bringing the rules into alignment with the practice without changing the default condition that the responding party incurs the cost of responding to discovery, and the results so far are consistent with that objective. While it is potentially significant that the amendment prompted three requests for fee-shifting protective orders in the first year post-amendment as compared to none in the prior year, the overall effect on civil litigation thus far is minimal.

With regard to the Duke Conference core needs of proportionality, cooperation, and active judicial case management, the Supreme Court did not intend for the amendment to Rule 26(c) to address any of those core needs, and it does not in practice seem to have had any effect on any of those deficits.

VI. OFFICIAL FORMS—RULE 84

A. The Forms Judicial Gloss

Prior to December 1, 2015, Rule 84 established the official forms of the Federal Rules of Civil Procedure in one simple sentence: “The forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate.”⁹⁵ This one sentence accomplished two important purposes: alerting judges and lawyers that the forms provided guidance as to the level of detail and complexity required in federal court papers (very low); and establishing that a court paper that followed one of the forms was deemed sufficient (and thus could not be challenged as insufficient) under the rules.⁹⁶

The 2015 amendments abrogated Rule 84 and eliminated the federal forms. Scholars have bemoaned this amendment.⁹⁷ Their criticism stems back to the Supreme Court’s revised pleading

95. FED. R. CIV. P. 84 (repealed 2015).

96. See, e.g., *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1360 (Fed. Cir. 2007).

97. See, e.g., Brooke D. Coleman, *Abrogating Magic: The Rules Enabling Act Process, Civil Rule 84, and the Forms*, 15 NEV. L.J. 1093 (2015). Professor Coleman argues that the abrogation of Rule 84 and the forms was essentially an amendment to each of the Rules that the forms illustrate, yet without publication and public comment. Professor Coleman uses Rule 8 and Form 11 as an example. Form 11 was, arguably, the impetus for abrogating Rule 84 and the forms. Form 11 contains a very simple negligence complaint, which most scholars would agree falls short of the plausibility standard established by the Supreme Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Eliminating Form 11, Coleman argues, was effectively amending the pleading standard in Rule 8, but without following the procedures under the Rules Enabling Act. Coleman, *supra*.

standard announced in *Twombly*⁹⁸ and confirmed in *Iqbal*.⁹⁹ Those cases, the argument runs, altered the pleading standard in Rule 8 without subjecting the revisions to the amendment process, in violation of the Rules Enabling Act.¹⁰⁰ That new pleading standard requires that pleadings contain enough factual allegations to establish that each element of each claim is “plausible.”¹⁰¹ Form 11 contains an extremely bare bones negligence complaint, lacking virtually any factual content, and most commentators agree that Form 11 would not satisfy the plausibility standard.¹⁰² Rather than attempt to fix Form 11, the Supreme Court opted to do away with the official forms altogether.¹⁰³

Accordingly, since Rule 84 has been abrogated, there are no longer any opinions applying Rule 84 post amendments (and thus no comparison data). Even while Rule 84 was in effect, however, courts did not frequently apply the Rule—indeed, if anything they discuss it slightly more in absentia. Courts have referenced the abrogation of Rule 84 fourteen times in the first year post-amendment, whereas they cited Rule 84 in the comparison period thirteen times.

The most frequently cited form, both in the year before the abrogation of Rule 84 and in the year following, is Form 18 for patent complaints.¹⁰⁴ Prior to the abrogation of Rule 84, many courts held that a direct infringement patent complaint was sufficient if it complied with Form 18, without subjecting it to a rigorous *Twombly/Iqbal* analysis.¹⁰⁵ After the abrogation, many courts have held that Form 18 no longer figures into the analysis.¹⁰⁶ However, at least one court has held that the abrogation of Rule 84 should not change the standard for evaluating a direct patent

98. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

99. *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009).

100. 28 U.S.C. § 2072. See Nathan R. Sellers, Note, *Defending the Formal Federal Civil Rulemaking Process: Why the Court Should Not Amend Procedural Rules Through Judicial Interpretation*, 42 LOY. U. CHI. L.J. 327, 330 (2011).

101. *Iqbal*, 556 U.S. 662.

102. See, e.g., Sellers, *supra* note 100, at 372.

103. *Id.* at 373.

104. See, e.g., *Robern, Inc. v. Glasscrafters, Inc.*, 206 F. Supp. 3d 1005, 1008–09 (D.N.J. 2016).

105. See, e.g., *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1334 (Fed. Cir. 2012) (holding that, to the extent “*Twombly* and its progeny conflict with the Forms and create differing pleading requirements, the Forms control.”); *Arthrex, Inc. v. W. Coast Med. Res., LLC*, No. 8:15-cv-910-EAK-MAP, 2015 WL 12844946, at *2–3 (M.D. Fla. Nov. 25, 2015); *Rosetta-Wireless Corp. v. Apple Inc.*, No. 15 C 799, 2015 WL 6955492, at *3 (N.D. Ill. Nov. 10, 2015).

106. See, e.g., *Disc Disease Sols., Inc. v. VGH Sols., Inc.*, No. 1:15-cv-188 (LJA), 2016 WL 6561566, at *1 (M.D. Ga. 2016); *e.Digital Corp. v. iBaby Labs, Inc.*, No. 15-cv-05790-JST, 2016 WL 4427209, at *2–3 (N.D. Cal. Aug. 22, 2016).

infringement complaint because the Advisory Committee Notes specifically state that the abrogation was not intended to change the pleading standards.¹⁰⁷

B. The Forms Assessment

Chief Justice Roberts did not particularly elucidate the objectives of Rule 84's abrogation. He opined that many of the forms have become "antiquated or obsolete," but did not offer any reason as to why the Court opted to eliminate the forms rather than modernize them.¹⁰⁸ Leaving aside the wisdom, and even legality, of abrogating the forms, the amendment abrogating Rule 84 certainly accomplished the stated objective of eliminating the forms. As the split in authority illustrates, however, the possibility exists that the effects of the forms live on.

With regard to the Duke Conference core needs of proportionality, cooperation, and active judicial case management, as with the amendment to Rule 26(c), the Supreme Court did not intend for the abrogation of Rule 84 to cause any substantive changes, and it does not in practice seem to have had any effect on any of those deficits.

VII. PRODUCTION REQUESTS—RULE 34

Some of the revisions to Rule 34 are among the most profound changes in the 2015 amendments, but they have received far less attention from scholars and the other stakeholders. Because the amended provisions are entirely new, there is no empirical basis for a "before and after" comparison. The opinions applying amended Rule 34, however, do raise some interesting issues.

A. The Document Requests Judicial Gloss

The Rule 34 amendment with the greatest potential impact is the new requirement that parties who interpose objections to a production request state whether they are withholding any documents on the basis of the objection.¹⁰⁹ The purpose of the provision is to allow the requesting party to make a more informed decision regarding whether to challenge the objection—the request-

107. See *Hologram USA, Inc. v. Pulse Evolution Corp.*, No. 14-cv-0772-GMN-NJK, 2016 WL 199417, at *2 n.1 (D. Nev. Jan. 15, 2016).

108. C.J. ROBERTS, JR., *supra* note 36, at 8–9.

109. FED. R. CIV. P. 34(b)(2)(c) ("An objection must state whether any responsive materials are being withheld on the basis of that objection.").

ing party would be more likely to forgo a challenge if the responding party did not withhold any documents based on the objection (conserving the parties' and the courts' resources).¹¹⁰

The new provision makes eminent sense, but compliance could prove problematic in some circumstances. For example, if a term in a document request is vague or ambiguous, a responding party might have great difficulty in determining whether it has any documents meeting the various alternative meanings of the term that it is not producing.

The courts have yet to wrestle with this particular problem in a reported opinion, but they have repeatedly addressed motions asserting that a party has failed to comply with the requirement to disclose whether documents have been withheld. In the first year of the amendment's effectiveness, courts issued sixteen opinions discussing the requirement. Initially, the courts were lenient—likely because of the newness of the provision—and simply ordered the responding party to supplement its response to comply with the new Rule with no other sanction.¹¹¹ More recently, however, courts have started to sanction parties who fail to comply.¹¹²

The manner in which parties must describe the documents they are withholding on the basis of their objections is not explicitly articulated in Rule 34(b)(2)(C). The Advisory Committee Note suggests that a log, akin to a privilege log, is not required, and that a statement describing limitations in the search used to collect responsive documents is adequate.¹¹³ Thus far, courts seem to be adhering to the Committee's suggested construction of the Rule.¹¹⁴

110. FED. R. CIV. P. 34 advisory committee's note to 2015 amendment ("This amendment should end the confusion that frequently arises when a producing party states several objections and still produces information, leaving the requesting party uncertain whether any relevant and responsive information has been withheld on the basis of the objections.").

111. See, e.g., *Scranton Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 190 F. Supp. 3d 419, 437–38 (M.D. Pa. 2016); *Douglas v. Kohl's Dep't Stores, Inc.*, No. 6:15-cv-1185-Orl-22TBS, 2016 WL 1637277, at *3–4 (M.D. Fla. Apr. 25, 2016).

112. See *Asphalt Paving Sys., Inc. v. Gen. Combustion Corp.*, No. 6:15-cv-49-Orl-41TBS, 2016 WL 3167712, at *2 (M.D. Fla. June 7, 2016) (awarding attorney's fees against the party failing to specify whether it withheld documents in its response).

113. FED. R. CIV. P. 34 advisory committee's note to 2015 amendment ("The producing party does not need to provide a detailed description or log of all documents withheld, but does need to alert other parties to the fact that documents have been withheld and thereby facilitate an informed discussion of the objection. An objection that states the limits that have controlled the search for responsive and relevant materials qualifies as a statement that the materials have been 'withheld.'").

114. See *Rowan v. Sunflower Elec. Power Corp.*, No. 15-cv-9227-JWL-TJJ, 2016 WL 3743102, at *5 (D. Kan. July 13, 2016) ("An objection that states the limits that have controlled the search for responsive and relevant materials qualifies as a statement that the materials have been 'withheld.'").

The 2015 amendment to Rule 34 also introduced language requiring parties to state objections with specificity, eliminating an unintended incongruity with the requirement in Rule 33 that objections to interrogatories be stated with specificity.¹¹⁵ Opinions applying this new requirement for specificity in objections have cast doubt about the continued viability of “general objections.”

A common practice in responding to written discovery is to include a set of “general objections” at the beginning of the response, in addition to the objections to specific discovery requests.¹¹⁶ In the general objections, the responding party might object to any improper instructions or definitions in the discovery request, and might object to any broad, thematic aspects of the requests.¹¹⁷

Following the enactment of the 2015 amendments, parties have challenged general objections. These challenges assail the generic concept of general objections, not the particular general objections raised in their opponents’ discovery responses.¹¹⁸ These movants have argued that a general objection fails, by its nature, to comply with the specificity requirement in Rule 34(b)(2)(B), which requires that a responding party state with specificity the objections for “each item or category.”¹¹⁹ Some courts have been persuaded, holding general objections categorically insufficient.¹²⁰ Other courts have stopped short of a categorical prohibition on general

115. FED. R. CIV. P. 34 advisory committee’s note to 2015 amendment (“Rule 34(b)(2)(B) is amended to require that objections to Rule 34 requests be stated with specificity. This provision adopts the language of Rule 33(b)(4), eliminating any doubt that less specific objections might be suitable under Rule 34.”).

116. *See Johnson v. Kraft Foods N. Am., Inc.*, 236 F.R.D. 535, 538–39 (D. Kan. 2016).

117. *See id.*

118. *See Meredith v. United Collection Bureau, Inc.*, No. 1:16 CV 1102, 2016 WL 6649279, at *2 (N.D. Ohio Nov. 10, 2016) (noting that the plaintiff had requested that the court deem all general objections waived).

119. *See id.*

120. *See, e.g., Nkansah v. Martinez*, No. 15–646–JWD–RLB, 2016 WL 6595921, at *3 n.1 (M.D. La. Nov. 7, 2016) (“Pursuant to Rule 34(b)(2)(B) of the Federal Rules of Civil Procedure, any objection must ‘state with specificity the grounds for objecting to the request, including the reasons.’ Any general objection presumably applicable to all discovery requests, that fails to comply with Rule 34, is insufficient and will not be considered by the Court.”); *Auburn Sales, Inc. v. Cypros Trading & Shipping, Inc.*, No. 14–cv–10922, 2016 WL 3418554, at *3 (E.D. Mich. June 22, 2016) (holding that general objections do not satisfy the requirement that, “[f]or each item or category” the response state objections with specificity; with general objections it is unclear as to which requests the defendants objected and as to which they produced documents); *Asphalt Paving Sys., Inc. v. Gen. Combustion Corp.*, No. 6:15–cv–49–Orl–41TBS, 2016 WL 3167712, at *2 (M.D. Fla. June 7, 2016) (“Federal Rule of Civil Procedure 34(b)(2)(B) provides that objections to requests for production shall ‘state with specificity the grounds for objection to the request, including the reasons.’ The Court does not consider frivolous, conclusory, general, or boilerplate objections.”).

objections, and analyze the objections individually under the new specificity requirement.¹²¹

Further doubt regarding the continuing viability of general objections arises when the requirement to state whether documents are being withheld on the basis of the objections is considered. Because general objections speak to problems with the set of requests as a whole, rather than problems with an individual request, the obligation to state whether the responding party is withholding documents on the basis of the general objections is awkward. For example, general objections are often where a responding party might object to any general definitions in the requests. Determining whether the responding party is withholding any documents on the basis of an objection to a vague definition would entail not only considering the wording of the definition, but also every individual request that uses the vaguely defined term, then conducting a search for documents that might be responsive to any of the alternative meanings of the vague term.

Another typical general objection states that the responding party objects to the instructions in the request to the extent that they purport to impose greater obligations than those set forth in the Federal Rules of Civil Procedure. Similarly, parties often interpose a general objection “to the extent that the requests seek documents outside the scope of discovery in Rule 26(b)(1).” It is not readily apparent how parties are to assess whether they are withholding documents as a result of general objections like these. Thus far, the courts have not directly confronted this issue, and the Advisory Committee Notes do not address it either.

While the 2015 amendment brought objections to Rule 34 document requests into alignment with objections to Rule 33 interrogatories in terms of the specificity requirement, the amendment left a related inconsistency in place. Rule 33 expressly provides that “[a]ny ground not stated in a timely objection is waived unless the court, for good cause, excuses the failure.”¹²² Amended Rule 34, curiously, does not contain a parallel waiver provision. So far, the courts disagree as to whether this difference means that parties do not waive objections to document requests if they fail to assert them timely.¹²³

121. See *Meredith*, 2016 WL 6649279, at *2 (declining to deem general objections waived).

122. FED. R. CIV. P. 33(b)(4).

123. *Compare* 17 Outlets, LLC Healthy Food Corp. v. ThurKen III, LLC, No. 15-cv-101-JD, 2016 WL 6781217, at *2 (D.N.H. Nov. 16, 2016) (“Unlike Federal Rule of Civil Procedure 33, which governs interrogatories, Rule 34 does not include a waiver provision . . . [T]he sanction of waiver is reserved for cases ‘where the offending party committed unjusti-

The 2015 amendments also changed Rule 34 to allow for early service of document requests (in advance of the Rule 26(f) discovery conference)¹²⁴ and to allow the responding party to simply produce responsive documents instead of making them available for inspection.¹²⁵ These changes are appearing in the reported opinions, but not in a way that is surprising or controversial.

B. The Document Requests Assessment

Curiously, Chief Justice Roberts did not even reference the amendments to the document request provisions in Rule 34 in his annual update. While the amendments to Rule 34 may not be as controversial as some of the other amendments, they have the potential to improve the litigation process meaningfully.

The process in which parties can serve document requests before they conduct their Rule 26(f) discovery conference and interact with the court regarding the initial case management order, if implemented in good faith and in the spirit embodied in Rule 1, should make the litigation process flow more efficiently and proportionally. Likewise, the requirement to disclose whether the responding party is withholding documents on the basis of any objections, now stated with specificity, should result in better decisions by the requesting party regarding challenging the objections. As the judicial gloss section above illustrates, however, the amended language leaves some uncertainty that has caused the courts to struggle and, at times, to reach inconsistent decisions. Accordingly, these provisions should be more and more successful as the courts or further amendments refine the Rule.

With regard to the Duke Conference core needs of proportionality, cooperation, and active judicial case management, the amendments to Rule 34 do not directly address any of these needs. They primarily promote greater transparency in the objection process, leading to a more informed decision regarding whether to challenge objections. That is a sensible objective, and should lead to more cost-effective discovery, but does not really promote proportionality in discovery. The new opportunity to serve early document requests might foster greater cooperation if it leads parties to work together to solve document production issues, rather than merely enabling them to bring their disputes to the judge sooner.

fied delay in responding to discovery.”), *with* *Sheets v. Villas*, No. 8:15-cv-1674-T-30JSS, 2016 WL 6584877, at *2 (M.D. Fla. Nov. 7, 2016) (finding waiver).

124. FED. R. CIV. P. 26(d)(2) & 34(b)(2)(A).

125. FED. R. CIV. P. 34(b)(2)(B).

In any event, the amendments to Rule 34 do not directly advance any of the core needs.

VIII. CONCLUSION

The sections above measure individual rule amendments against their stated objectives. With the exception of the amendment to Rule 1, the other amendments seem to be achieving their goals. Parties and courts are injecting proportionality into the discovery mix more vigorously. Courts are generally using a uniform standard when considering sanctions for spoliation of ESI. Courts are requiring parties to assert their objections to document requests with specificity, and are requiring them to declare whether they are withholding documents on the basis of their objections. These individual amendments are the trees, and they seem to be growing as envisioned when they were planted, save for a branch here and there sprouting in an unanticipated direction.

But what about the forest? Are the 2015 amendments achieving their “big picture” objectives, as articulated at the Duke Conference? Are they promoting “cooperation and proportionality [and] sustained, active, hands-on judicial case management?” At the forest level, the success of the 2015 amendments is less clear.

The collective data and the individual opinions suggest that, at least over the first year, the 2015 amendments have quite successfully fertilized the growth of proportionality. It is unlikely that even the most rabid supporter of these amendments would have predicted that the courts would be applying Rule 26(b)(1) to limit discovery they viewed as disproportional more than four times more frequently in this first year post-amendments. The Advisory Committee and the Supreme Court can certainly check the proportionality box.

To cultivate more cooperation, the Committee added an advisory phrase to Rule 1 that does not use the word “cooperation,” specifying explicitly that those who resist this advisement may not be sanctioned as a result. Professor Mark Bennett’s reaction to this impotent measure was to quote tennis legend John McEnroe: “YOU CANNOT BE SERIOUS.”¹²⁶ Although cooperation is difficult to quantify, and may be extremely difficult to mandate and monitor, neither the collective data nor the individual opinions reflect any change in the level of cooperation. Perhaps an attitude

126. See Bennett, *supra* note 5, at 1313.

adjustment of this nature takes more than one year to manifest, but based on the evidence currently available, the 2015 amendments have thus far failed to foster an observable spirit of greater cooperation.

To compel more active judicial case management, the Committee did . . . virtually nothing. While greater judicial management is easy to legislate (in contrast to greater cooperation between adversaries), the Advisory Committee and the Supreme Court opted to encourage, rather than require, judges to actively manage their cases. For example, Rule 16 makes it optional for a judge to meet with the parties prior to issuing the initial case management order.¹²⁷ Judges only conduct such conferences 45% of the time.¹²⁸ Thus, in over half the cases, the judge sets the time periods, limits, and other parameters for discovery without even meeting with the parties. Rule 16 could easily be amended to mandate such conferences, but the Supreme Court has thus far resisted such a mandate. Reported opinions yield no hint that judges are heeding the Supreme Court's encouragement to actively manage cases. For those who believe that "sustained, active, hands-on judicial case management" is the one true *sine qua non* for material improvement in the federal civil litigation system, this was an opportunity lost.¹²⁹

Meaningful change takes time, and often requires more than one attempt. While the Advisory Committee and the Supreme Court may eventually succeed in promoting greater cooperation

127. FED. R. CIV. P. 16(b)(1).

128. EMERY G. LEE III & THOMAS E. WILLGING, FED. JUDICIAL CTR., NATIONAL, CASE-BASED CIVIL RULES SURVEY: PRELIMINARY REPORT TO THE JUDICIAL CONFERENCE ADVISORY COMMITTEE ON CIVIL RULES 13 (2009).

129. The Committee has been encouraging active case management since at least 1983, but the data suggest that judges have resisted changing their traditional roles. See Richard L. Marcus, *Slouching Towards Discretion*, 78 NOTRE DAME L. REV. 1561, 1588 (2003) ("Beginning in 1983, Rule 16 was amended to require case management activity by all judges in most cases, and to encourage more managerial activity than was required."); David L. Shapiro, *Federal Rule 16: A Look at the Theory and Practice of Rulemaking*, 137 U. PA. L. REV. 1969, 1984–87 (1989) (describing the history of Rule 16 and the purposes of the 1983 amendment). Amending the rules to mandate a more active role for judges may be the only way to change most judges' behavior, and the present litigation climate makes the need for managerial judges more compelling. Not only is there a rare consensus among parties on "both sides of the v" that the process benefits from such active judges, the current decline in jury trials has diminished the historic primary role of judges. See Jonathan T. Molot, *An Old Judicial Role for a New Litigation Era*, 113 YALE L.J. 27, 34–36 (2003); Victor Eugene Flango, *Judicial Roles for Modern Courts*, NAT'L CTR. FOR STATE COURTS, <http://www.ncsc.org/sitecore/content/microsites/future-trends-2013/home/Monthly-Trends-Articles/Judicial-Roles-for-Modern-Courts.aspx> (last visited Sept. 7, 2017) ("Yet we all have a conception of what a judge should be—a distinguished person presiding over a trial.").

and active judicial case management, the early returns suggest that they have more work to do.

Why did the amendments appear to have succeeded in fostering more robust application of the proportionality doctrine but not in promoting cooperation or active judicial case management? One factor may be the Supreme Court's willingness to be more directive in its amendments regarding proportionality; the Supreme Court may be reluctant to direct the lower court judges as to how to manage their dockets. Another less obvious one, though, might be marketing. Because Chief Justice Roberts emphasized and urged proportionality in his annual report discussing the 2015 amendments, district court judges were primed to consider the issue, as evidenced by numerous lower court opinions quoting his report in their discussions of proportionality.¹³⁰

The amendment process is designed such that the Advisory Committee prepares draft amendments, publishes them for public comment, responds to the public comments, and then submits them to the Supreme Court along with Advisory Committee Notes.¹³¹ Judges and lawyers then rely on that record, and in particular the Advisory Committee Notes, to construe the amendments. In the case of the 2015 amendments, however, lower court judges have relied heavily on Justice Roberts's annual report—a document external to the “legislative history” of the amendments. Whether this degree and type of influence by one individual is appropriate warrants careful consideration.

130. See, e.g., *United States v. Talmage*, No. 1:16-cv-19-DN-PMW, 2017 WL 1047315, at * 2 (D. Utah Mar. 17, 2017); *Mcswain v. United States*, No. 2:15-cv-01321-GMN-GWF, 2016 WL 4530461, at *3 (D. Nev. Aug. 30, 2016); *Grober v. Mako Prod. Inc.*, No. 2:04 CV 8604 JZ (DTBx), 2016 WL 7429139, at *1 (C.D. Cal. Aug. 9, 2016).

131. See STEVEN BAICKER-MCKEE, WILLIAM M. JANSSEN & JOHN B. CORR, *FEDERAL CIVIL RULES HANDBOOK*, Pt. I, 2–5 (2017 ed.).

INSURING BIAS: DOES EVIDENCE OF COMMON INSURANCE DEMONSTRATE RELEVANT EXPERT WITNESS BIAS IN MEDICAL NEGLIGENCE LITIGATION?

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I. INTRODUCTION

The objectivity of the expert witness . . . is one of the more valued qualities that an expert hopes to bring to the legal system, despite the latter's necessarily partisan adversarial structure. Despite this ideal, dealing with bias constitutes one of the central challenges for expert witnesses in the legal system. The issue has been considered throughout the history of forensic work.¹

When the medical profession sets a moral standard that demands that a physician, testifying under oath in court, must state his opinion fairly and fully without bias and without regard to the side that calls him, neither suppressing nor over-emphasizing any aspect of the case, then, and only then, you will have real medical expert testimony.²

Consider the following scenario: plaintiff, a former patient, sues defendant-physician for medical negligence. An expert witness-physician³ is engaged by defense counsel to testify at trial that the care and treatment rendered by the defendant-physician complied with the applicable standard of care.⁴ Fortuitously, the defendant-physician and the defendant-physician's expert witness maintain professional liability insurance with the same liability insurer. Does this "common insurance"—insurance shared by the defendant

1. Michael Lamport Commons, Patrice Marie Miller & Thomas G. Gutheil, *Expert Witness Perceptions of Bias in Experts*, 32 J. AM. ACAD. PSYCHIATRY & L. 70, 70 (2004).

2. Lee M. Friedman, *Expert Testimony, Its Abuse and Reformation*, 19 YALE L.J. 247, 254 (1910).

3. For an explanation of the function of the medical expert witness, see Fred L. Cohen, *The Expert Medical Witness in Legal Perspective*, 25 J. LEGAL MED. 185, 191–92 (2004).

4. See Joseph H. King, Jr., *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1236 (1975); Charles Markowitz, *Medical Standard of Care Jurisprudence as Evolutionary Process: Implications Under Managed Care*, 2 YALE J. HEALTH, POL'Y L. & ETHICS 59, 59 (2002); Larry W. Myers, "The Battle of the Experts:" *A New Approach to an Old Problem in Medical Testimony*, 44 NEB. L. REV. 539, 539 (1965).

and defense expert—establish expert witness bias, constituting ammunition for cross-examination at trial?⁵

It is well understood that “evidence” of the presence or absence of liability insurance is simply inadmissible to prove fault, pursuant to Federal Rule of Evidence 411⁶ (and similar state evidentiary rules), which provides:

Rule 411—Liability Insurance

Evidence that a person was or was not insured against liability is not admissible to prove whether the person acted negligently or otherwise wrongfully. But the court may admit this evidence for another purpose such as proving a witness’s bias or prejudice or proving agency, ownership, or control.⁷

But Rule 411 is not a complete bar to admissibility and allows the trial court to admit evidence of liability insurance to prove “a witness’s bias or prejudice.”⁸ Is a medical expert witness more likely to testify in support of the defendant-physician simply because of common insurance? On the periphery, this argument for admissibility appears rather tenuous, but, beneath the surface, it may have some traction. In the past ten to fifteen years, the common insurance question has received attention by state courts.⁹ A comprehensive examination of the topic is appropriate at this time.¹⁰

Essentially, the common insurance concern is as follows: an expert witness insured by the same professional liability insurer as the defendant-physician has a financial interest in a jury verdict in favor of defendant. A verdict in favor of the plaintiff would cause

5. See Steven Feola & Richard A. Alcorn, *Expert Witness Advocacy: Changing Its Culture*, ARIZ. ATT’Y, Mar. 2009, at 24, 25 (urging that commonality of insurance is one of the “[n]umerous factors [which] appear to cause or contribute to the problem of expert witness advocacy”).

6. FED. R. EVID. 411.

7. *Id.*

8. *Id.*

9. See *Hawes v. Chua*, 769 A.2d 797 (D.C. 2001); *Bonser v. Shainholtz*, 3 P.3d 422 (Colo. 2000); *Vasquez v. Rocco*, 836 A.2d 1158 (Conn. 2003); *Chambers v. Gwinnett Cmty. Hosp., Inc.*, 557 S.E.2d 412 (Ga. Ct. App. 2001); *Cetera v. DiFilippo*, 934 N.E.2d 506 (Ill. App. Ct. 2010); *Kan. Med. Mut. Ins. Co. v. Svaty*, 244 P.3d 642 (Kan. 2010); *Woolum v. Hillman*, 329 S.W.3d 283 (Ky. 2010); *Anderson v. O’Rourke*, 942 A.2d 680 (Me. 2008); *Wells v. Tucker*, 997 So. 2d 908 (Miss. 2008); *Reimer v. Surgical Servs. of the Great Plains, P.C.*, 605 N.W.2d 777 (Neb. 2000); *Cobb v. Shipman*, 35 N.E.3d 560 (Ohio Ct. App. 2015); *Schultz v. Mayfield Neurological Inst.*, No. C-120764, 2013 WL 5432103 (Ohio Ct. App. Sept. 25, 2013), *appeal denied*, 3 N.E.3d 1218 (Ohio 2014); *Givens v. Sorrels*, No. M2012-01712-COA-R3-CV, 2013 WL 4507946 (Tenn. Ct. App. Aug. 21, 2013).

10. For a prior examination of this topic by a law student, see Maggie C. Bednar, *Medical Expert Witness Bias Due to Commonality of Insurance*, 23 J. LEGAL MED. 403 (2002).

the professional liability insurer to pay a potentially sizeable sum to the plaintiff and this payment (and other similar payments in other litigation) would cause professional liability insurance premiums to increase to cover losses. Therefore, the defendant-physician's expert would be financially motivated to testify in favor of the defendant-physician. Of course, the concept of impeaching an expert witness by demonstrating financial interest in the litigation is nothing new. A physician's income derived from medico-legal consultation and testimony, the frequency of consultation, and the party for whom the expert consults (plaintiff or defendant-physician) have always been proper subjects for cross-examination.¹¹ Common insurance is different, and likely does not evidence more than a theoretical, indirect financial interest of the medical defense expert.

II. PURCHASING PROFESSIONAL MEDICAL LIABILITY INSURANCE AND PHYSICIAN NEGLIGENCE

As far back as 1954, a professor of legal medicine noted “[t]he likelihood of being sued for malpractice is now so great that the practicing physician must recognize that it constitutes a definite occupational hazard.”¹² Medical literature has reported efforts to predict the risk of such claims.¹³ Therefore, a physician does not purchase professional liability insurance because the physician is planning to provide negligent care to patients. Professional liability insurance, much like other liability insurance, is purchased consistent with the “[virtue] of spreading the risk of loss among many to make it possible for the individual to bear the economic burden of adversity.”¹⁴

Purchasing (or not purchasing) liability insurance does not evidence negligent conduct and, therefore, is not admissible to prove fault pursuant to Federal Rule of Evidence 411.¹⁵ McCormick's evidence treatise explains the policy supporting this exclusion:

11. See *Trower v. Jones*, 520 N.E.2d 297 (Ill. 1988) (annual income from services related to expert testimony; frequency with which expert testifies for plaintiffs/defendants); see also Julie A. Correll, *Trower v. Jones: Expanding the Scope of Permissible Cross-Examination of Expert Witness*, 20 LOY. U. CHI. L.J. 1071 (1989); Michael H. Graham, *Impeaching the Professional Risk Expert Witness by a Showing of Financial Interest*, 53 IND. L.J. 35, 38 (1977).

12. Louis J. Regan, *Malpractice, An Occupational Hazard*, 156 JAMA 1317, 1317 (1954).

13. See, e.g., Sara C. Charles et al., *Predicting Risk for Medical Malpractice Claims Using Quality-of-Care Characteristics*, 157 W.J. MED. 433 (1992); Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 NEW ENG. J. MED. 629 (2011).

14. Melvin M. Belli, *The Social Value of Liability Insurance*, 13 HASTINGS L.J. 169, 169 (1961).

15. FED. R. EVID. 411.

This rule rests on two premises. The first is the belief that insurance coverage reveals little about the likelihood that one will act carelessly. Subject to a few pathological exceptions, financial protection will not diminish the normal incentive to be careful, especially when life and limb are at stake. Similarly, the argument that insured individuals or firms are more prudent and careful, as a group, than those who are self-insurers seems tenuous and also serves to counteract any force that the first argument might have. Thus, the relevance of the evidence of coverage is doubtful.¹⁶

As previously mentioned, Federal Rule of Evidence 411 provides for evidence of insurance to prove witness bias or prejudice. How might a medical negligence plaintiff develop this evidence?

Illinois is an excellent example of a state in which common professional liability insurance may be anticipated. As of 2012, Best's Statistical Study of U.S. Professional Liability—2012 Direct Premiums Written¹⁷ listed ISMIE Mutual Group (ISMIE) as the tenth largest writer of medical professional liability insurance in the United States.¹⁸ In its 2013 report, the Illinois Department of Insurance reported that, in 2011, ISMIE was the largest medical malpractice insurer in Illinois, covering 62.9% of the state's market.¹⁹ ISMIE had an even larger market share, 72.3%, in medical/surgical coverage and a 77.8% market share in other/not classified coverage.²⁰ Therefore, it is predictable that an Illinois physician-defendant will be insured by ISMIE. If that physician retains an expert witness-physician who practices medicine in Illinois, it is also likely that the expert will have ISMIE coverage.

The Illinois Rules of Evidence (IRE) include IRE 411, which provides:

Rule 411—Liability Insurance

Evidence that a person was or was not insured against liability is not admissible upon the issue whether the person acted negligently or otherwise wrongfully. This rule does

16. KENNETH BROUN ET AL., MCCORMICK ON EVIDENCE 427 (7th ed. 2013).

17. BESTLINK, BEST'S STATISTICAL STUDY, U.S. MEDICAL PROFESSIONAL LIABILITY—2012 DIRECT PREMIUMS WRITTEN 1 (2013).

18. *Id.*

19. ILL. DEP'T OF INS., 2013 COST CONTAINMENT ANNUAL REPORT TO THE ILLINOIS GENERAL ASSEMBLY 21 (2013).

20. *Id.* at 22.

not require the exclusion of evidence of insurance against liability when offered for another purpose, such as proof of agency, ownership, or control, or bias or prejudice of a witness.²¹

Thus, IRE 411 contemplates the admissibility of evidence of insurance to demonstrate witness bias, as does FRE 411. Is it, therefore, reasonable to conclude that, in Illinois, a state in which common insurance between a physician-defendant and the expert-physician is predictable, evidence of common insurance should be admissible to provide expert witness bias? Of course, if the plaintiff retains an Illinois physician as an expert witness and that physician shares common insurance with the defendant-physician, is that expert more credible due to a willingness to provide testimony that may support a verdict to be paid by a common insurance provider? That position is no more logical than the rationale “suggesting” common insurance bias when focusing on the defense expert.

In order to explore potential common insurance and expert witness bias, it is helpful to examine an important model of professional liability insurance. Professor Tom Baker at the University of Connecticut School of Law noted that “physician-controlled mutual insurance companies have a very significant market share in many states.”²² As reported in 1991, “[o]ver half of the total dollar volume of physicians’ malpractice insurance is now written by physician-owned mutual companies.”²³ Furthermore, “[m]utual insurance companies by definition are owned entirely by their policyholders. Any profits earned are returned to policyholders in the form of dividend distributions or reduced future premiums.”²⁴ The argument, then, is that physicians insured by mutual professional liability insurers directly benefit in profitable years by receiving dividend payments from their insurers. The expert witness-physician, therefore, gains a direct financial benefit if the common insurer is not required to pay jury verdicts in favor of plaintiffs.

21. ILL. R. EVID. 411

22. Tom Baker, *Medical Malpractice and the Insurance Underwriting Cycle*, 54 DEPAUL L. REV. 393, 428 (2005).

23. Patricia M. Danzon, *Liability for Medical Malpractice*, 5 J. ECON. PERSP. 51, 59 (1991).

24. NAT’L ASS’N OF INS. COMM’RS, CAPITAL MARKETS SPECIAL REPORT (2015), http://www.naic.org/capital_markets_archive/150428.htm. See also J.A.C. Hetherington, *Fact v. Fiction: Who Owns Mutual Insurance Companies*, 1969 WIS. L. REV. 1068 (1969); Gary Kreider, *Who Owns the Mutuals? Proposals for Reform of Membership Rights in Mutual Insurance and Banking Companies*, 41 CIN. L. REV. 275 (1972); Joan Lamm-Tennant & Laura T. Starks, *Stock Versus Mutual Ownership Structures: The Risk Implications*, 66 J. BUS. 29 (1993).

This argument is, presumably, the Rule 411²⁵ argument in favor of admissibility. The basic weakness of this argument is that the defendant's expert witness-physician is more likely to testify in support of the defendant-physician because the expert actually believes that malpractice did *not* occur and that the medical care and treatment provided by the defendant complied with the applicable standard of care. A more cynical view of medical expert witnesses and testimonial bias is that medical experts are very intelligent and understand that litigation is adversarial. Perhaps expert X, retained by plaintiff, would have been comfortable testifying for the defendant-physician, if only defense counsel would have contacted expert X before plaintiff's counsel did. This scenario simply suggests that medical experts are intelligent mercenaries, capable of convincing juries of either a plaintiff's or defendant's position in any given medical negligence case. That is a problem, which, I suggest, overwhelms the likelihood that common insurance influences a medical expert's testimony.

A corollary to the common insurance "bias" is that common professional liability insurers are directly or indirectly compensating the defendant-physician's expert for consulting, testifying at a deposition, and testifying at trial. Arguably, compensation of expert witness fees by a common professional liability insurer and administrative involvement of the expert witness with the common insurer further complicates the issue.

III. SURVEYING THE STATES

The common insurance basis for medical expert witness bias is due for comprehensive analysis and comment. To do so requires an examination of various jurisdictions that have addressed this issue.

A. Ohio—The Per Se Rule of Admissibility

The 1994 seminal case in Ohio is *Ede v. Atrium South OB-GYN*,²⁶ in which the Supreme Court of Ohio pronounced that evidence of common insurance between a physician-defendant and the physician-defendant's medical expert "is sufficiently probative of the expert's bias as to clearly outweigh any potential prejudice evidence of insurance might cause."²⁷ In *Ede*, the Supreme Court was confronted with common professional liability coverage provided by a

25. FED. R. EVID. 411.

26. *Ede v. Atrium S. OB-GYN*, 642 N.E.2d 365 (Ohio 1994).

27. *Id.* at 368.

mutual professional liability insurer.²⁸ Plaintiff urged that “each insured’s policy is evidence of some fractional part ownership in [the insurer],”²⁹ creating a “built-in-bias—fewer successful malpractice claims means lower premiums charged for malpractice insurance.”³⁰ The Supreme Court was quite critical of the trial court’s refusal to consider any potential bias that might result from fractional ownership in a mutual professional liability insurer³¹ and pronounced the aforementioned rigid rule of admissibility.³²

Remarkably, in 2015, the Court of Appeals of Ohio, in *Cobb v. Shipman*,³³ applied the *Ede* rule of common insurance admissibility³⁴ even when the defendant-physician’s expert was unaware of the existence of common insurance. Apparently, the expert’s unawareness of common insurance simply constitutes a credibility consideration.³⁵ It is difficult to explain this implicit or subliminal bias.

The *Ede* dissent³⁶ aptly pointed out that the majority opinion stated: “[t]he scope of cross-examination of a medical expert on the questions of the expert’s bias and pecuniary interest and the admissibility of evidence relating thereto are matters that rest in the sound discretion of the trial court,”³⁷ and that a per se rule of admissibility removes the trial court’s discretion.³⁸ The dissent further suggested that the majority created a new Ohio rule of evidence and, “in doing so, has circumvented the proper rulemaking procedures required by the Ohio Constitution.”³⁹

Worthy of note is the 2013 opinion of the Court of Appeals of Ohio in *Schultz v. Mayfield Neurological Institute*.⁴⁰ Here, the Court of Appeals reviewed a defense verdict following a bench trial. The trial judge precluded the plaintiff from cross-examining the defendant’s medical expert regarding common professional liability insurance.⁴¹

In affirming the trial court, the Court of Appeals stated:

28. *Id.* at 366.

29. *Id.*

30. *Id.*

31. *Id.* at 368.

32. *Id.*

33. *Cobb v. Shipman*, 35 N.E.3d 560 (Ohio Ct. App. 2015).

34. *Ede*, 642 N.E.2d at 368.

35. *Cobb*, 35 N.E.3d at 574.

36. *Ede*, 642 N.E.2d at 369 (Wright, J., dissenting).

37. *Id.* at 369 (citation omitted).

38. *Id.* at 369–70.

39. *Id.*

40. *Schultz v. Mayfield Neurological Inst.*, No. C–120764, 2013 WL 5432103 (Ohio Ct. App. Sept. 25, 2013).

41. *Id.* at *2.

On the facts of this case, even if the trial court erred by excluding the testimony, we cannot say that the Schultzes' substantial rights were prejudiced as a result. The concerns expressed by the *Ede* court with respect to jury determinations were not present here—this was a bench trial where both parties had ample opportunity to argue their positions on the commonality-of-insurance matter directly to the trier of fact. So the Schultzes cannot demonstrate that the outcome of the trial would have been otherwise had the testimony not been excluded. Accordingly, we overrule the second assignment of error.⁴²

On the periphery, this statement seems harmless. The problem is “the ample opportunity to argue their positions on the commonality-of-insurance matter directly to the trier of fact.”⁴³ The Court of Appeals does not explain this opportunity. How could the trial court consider this issue in the absence of *evidence*? Without the evidence, how does the *Schultz* opinion⁴⁴ conform to the *Ede* rule,⁴⁵ even in the absence of a jury trial? I am not advocating *Ede*⁴⁶ as the sensible approach to evidence of common insurance. I am simply suggesting that the effort of the Court of Appeals in *Schultz*⁴⁷ to explain away the trial court's departure from *Ede*⁴⁸ is dubious.

The rigid, per se Ohio rule of admissibility does not address a very real evidentiary problem: What type of evidence will be necessary to prove or disprove bias allegedly resulting from common insurance? Representatives of the common insurer will need to testify about the structure of the insurer, the calculation of premiums, the determination of whether dividends may be payable to various member insureds in a given year, how jury verdicts affect the actual premium paid by a specific physician-insured, financial statements and, perhaps, other topics. These items are, of course, collateral to the issues of the alleged medical negligence. Accordingly, the Ohio rule applied to simple common insurance, without more, will likely create jury distraction and confusion, and will not yield relevant evidence probative of expert witness bias.

42. *Id.* at *3.

43. *Id.*

44. *See generally id.*

45. *Ede*, 642 N.E.2d at 368.

46. *Id.*

47. *Schultz*, 2013 WL 5432103, at *2–3.

48. *Ede*, 642 N.E.2d at 368.

B. Kansas—Strict Exclusion or Not Quite So Strict?

As recently as 2010, the Supreme Court of Kansas suggested that evidence of common insurance should not be admissible to demonstrate expert witness bias. In *Kansas Medical Mutual Insurance Co. v. Svaty*,⁴⁹ the Kansas Supreme Court considered the propriety of an order requiring a mutual professional liability insurer, which insured a defense expert but *not* the defendant, to disclose insurance information regarding the defense expert. In its lengthy opinion, the Supreme Court noted that this was not a case of common insurance since “the defense expert[] is insured by a company that is the servicing carrier for [the defendant physician’s] insurance plan.”⁵⁰ However, the Supreme Court also noted that “[plaintiff] would have a stronger argument [for expert witness bias] if, as initially believed, [defendant] and [defendant’s expert] were both insured by the same member-owned insurance company.”⁵¹

Despite this comment, suggesting that the Supreme Court might be receptive to an argument alleging expert witness bias due to common insurance, the Court reviewed the common insurance jurisprudence of other jurisdictions. The Court acknowledged Ohio’s *per se* rule of admissibility but then referred to “Kansas’ long-standing position that insurance should not be interjected [at] trial.”⁵² The Court also reflected on Kansas jurisprudence “in which attorneys sought to determine juror bias by asking jurors during voir dire whether they were members of or stockholders in insurance companies,”⁵³ a practice uniformly condemned by the Supreme Court.⁵⁴ Significantly, the Supreme Court stated that its prior opinions “reject arguments that the financial connection of buying insurance in the same market or even having a joint ownership interest in an insurance company is a bias that would disqualify a potential juror or is of the nature that warrants interjection of insurance into a liability trial.”⁵⁵

If the *Kansas Medical Mutual Insurance Co.*⁵⁶ opinion appeared to embrace the exclusion of evidence of common insurance, the Court of Appeals of Kansas more recently may have retreated from this stance in *Hamrick v. Huebner*,⁵⁷ an unpublished opinion in

49. Kan. Med. Mut. Ins. Co. v. Svaty, 244 P.3d 642 (Kan. 2010).

50. *Id.* at 661.

51. *Id.*

52. *Id.* at 663.

53. *Id.*

54. *Id.*

55. *Id.* at 663–64.

56. *See generally id.*

57. *Hamrick v. Huebner*, No. 106,215, 2012 WL 2785930 (Kan. Ct. App. July 6, 2012).

2012. In *Hamrick*, the trial court excluded evidence that the defendant and his expert witnesses were insured by the same mutual professional liability insurer.⁵⁸ Plaintiff argued that “a judgment against [the defendant] could adversely affect [his experts’] medical liability insurance premiums.”⁵⁹ The defense experts “testified that they were unaware of their common insurance carrier until it was pointed out by [plaintiff].”⁶⁰ The Court of Appeals cited *Kansas Medical Mutual Insurance Co.* as reflecting Kansas’ policy of excluding evidence of insurance at trial,⁶¹ but then stated:

[W]e conclude that given the fact that the experts did not know they shared a common insurer with [defendant] until after they had formulated and disclosed their opinions in the case, the proffered evidence did not have any tendency in reason to prove bias on the part of the witnesses. Further, if the evidence did have any probative value, it was so slight that it was clearly outweighed by its prejudicial effect. The district court did not err in excluding this testimony.⁶²

The *Hamrick* opinion may have retreated from a policy of complete exclusion of common insurance evidence, due to the reference to the timing of the experts’ knowledge of common insurance.⁶³ If so, until the Supreme Court of Kansas again speaks to this issue, the state of the law in Kansas seems unclear.

C. Mississippi—Strict Exclusion

The Supreme Court of Mississippi has taken a tough stance against the admission of common insurance evidence. In *Wells v. Tucker*,⁶⁴ the Mississippi Supreme Court characterized the gist of the controversy as follows:

The central issue on appeal involves the fact that Dr. Tucker and some, if not all of his experts were members of, and had their medical malpractice liability policies through, the same insurer—Medical Assurance Company

58. *Id.* at *2.

59. *Id.*

60. *Id.* at *3.

61. *Id.* at *2 (citing *Kan. Med. Mut. Ins. Co.*, 244 P.3d 642).

62. *Id.* at *3 (relying on *Kan. Med. Mut. Ins. Co.*, 244 P.3d at 663–64).

63. *Id.* at *2.

64. 997 So. 2d 908 (Miss. 2008).

of Mississippi (MACM). A nonprofit corporation, MACM is a limited pool of Mississippi physicians who are self-insured for protection against medical negligence suits.⁶⁵

The trial court refused to allow the common insurance-based cross-examination of the expert witnesses.⁶⁶ The Court of Appeals reversed this ruling based on calculations of insurance equity accounts in the event of an adverse verdict and on the calculations of premiums in the event of settlements or plaintiffs' verdicts.⁶⁷

The Supreme Court favorably referred to the dissent in the Court of Appeals, which highlighted the experts' testimony "of economic or financial bias."⁶⁸ The jury heard testimony of the hourly rates paid to plaintiff's and defendant's experts for their work.⁶⁹ The experts could have been, but were not, asked to testify about the total sums they received for their work as experts in the case and the number of times and for whom they have testified.⁷⁰ A verdict against the defendant might have affected the equity accounts of member physicians by \$136.⁷¹ Interestingly, the Court of Appeals dissent noted that the majority opinion, supporting the admissibility of common insurance, would yield "the practical impact"⁷² of limiting the medical expert witness pool (presumably for defendants) in Mississippi cases to non-Mississippi physicians.⁷³

Adopting the reasoning of the Court of Appeals dissent, the Supreme Court reversed the judgment of the Court of Appeals, holding, common insurance, alone, is not sufficient to evidence medical defense expert witness bias in Mississippi.⁷⁴

D. *Common Insurance—"Plus"*

Ohio appears to be the only jurisdiction adopting a per se rule of admissibility for common insurance alone—professional liability insurance carried by the defendant-physician and the defendant-physician's expert provided by the same insurer, typically a mutual,

65. *Id.* at 909.

66. *Id.* at 910–11.

67. *Id.* at 913–14.

68. *Id.* at 916 (citing *Wells v. Tucker*, 997 So. 2d 925, 940 (Miss. Ct. App. 2007) (Griffins, J., dissenting)).

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at 917.

73. *Id.*

74. *Id.* at 917.

“physician-owned” company.⁷⁵ This per se rule ignores the evidentiary problem associated with it: What type of evidence is necessary to show bias arising from common insurance? How many insurance company executives must testify to the intricacies of the mutual insurance business? Is it possible to prove that a plaintiff’s verdict in a single case could cause an insurance premium to increase such that a defense expert witness would be biased to testify for the defendant-physician simply due to common insurance? The Ohio approach seems unrealistic and unfair. It would yield much collateral evidence which could distract the jury from the central issue in the litigation—whether the care and treatment rendered by the defendant-physician complied with the applicable standard of care.

Fortunately, the Ohio rule has not tempted other jurisdictions, which have adopted a common insurance “plus” analysis. This more reasonable approach, consistent with classic cross-examination of medical expert witnesses, actually consists of multiple variants, now to be explored by this paper.

1. More Than a Cursory Interest—Significant Economic Services Test (Illinois)

Illinois has rejected the admissibility of common insurance alone through two Appellate Court opinions,⁷⁶ the latest of which was delivered in 2010. In *Golden v. Kiswaukee Community Health Services Center*,⁷⁷ a case of first impression, the Appellate Court focused on a commonly insured expert who “performed significant economic services for [the insurer] in reviewing claims made against the [insurer’s] doctor members to determine if those suits should have any impact on the insurance premiums they pay.”⁷⁸ Furthermore, the Appellate Court noted that “[t]he possibility of some significant question of bias exceeding potential prejudice should have been recognized by the court in this instance. The benefit to the [insurer] in premium adjustments that take place is ineluctable.”⁷⁹

More recently, in *Cetera v. Difilippo* the Appellate Court rejected evidence of common insurance, alone, to demonstrate expert witness bias.⁸⁰ The Appellate Court favorably referred to the *Golden*

75. *Ede v. Atrium S. OB-GYN*, 642 N.E.2d 365, 368 (Ohio 1994).

76. *Cetera v. DiFilippo*, 934 N.E.2d 506, 524–25 (Ill. App. Ct. 2010); *Golden v. Kiswaukee Cmty. Health Servs. Ctr., Inc.*, 645 N.E.2d 319 (Ill. App. Ct. 1994).

77. *Golden*, 645 N.E.2d 319.

78. *Id.* at 325.

79. *Id.*

80. *Cetera*, 934 N.E.2d at 524–25.

Court's adoption of the significant economic services analysis, which focuses on the actual services performed by the medical expert for the common insurer.⁸¹

2. The "Exceptional Case" Test (Arizona)

In 1988, the Supreme Court of Arizona recognized that evidence beyond common insurance was necessary to establish the potential bias of a defendant-physician's medical expert witness. In *Barsema v. Susong*⁸² the Supreme Court considered a medical negligence claim against a physician insured by an insurance company organized as a mutual insurer. "One of defendant's expert witnesses was . . . allegedly a MICA [Mutual Insurance Company of Arizona] shareholder and insured."⁸³ The expert "was a vice president and member of MICA's board of directors."⁸⁴ He "was compensated for the duties he performed"⁸⁵ for the common insurer and "his duties as a board member included trying to keep premiums low."⁸⁶ Pursuant to an Arizona statute prohibiting the introduction of insurance-related evidence at a medical negligence trial,⁸⁷ the trial court granted a motion in limine designed to exclude the evidence of the relationship of the expert witness with the common insurer.⁸⁸

The Arizona Supreme Court held that the aforementioned statute was unconstitutional as it was contrary to the Arizona Rules of Evidence, particularly Rules 401, 403, and 411.⁸⁹ The Supreme Court pronounced that "[i]n all but the exceptional case, a trial judge applying Rule 403 should hold that the danger of prejudice resulting from the interjection of insurance evidence substantially outweighs the probative value of evidence that the witness and a party have a common insurer."⁹⁰ The Supreme Court held that the trial court "erred in precluding the introduction of evidence that [the expert witness] was [the common insurer's] vice president and a member of its board of directors."⁹¹

81. *Id.* (citing *Golden* 465 N.E.2d 319).

82. *Barsema v. Susong*, 751 P.2d 969, 971 (Ariz. 1988).

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.* at 971-72 (citing Non-admissibility of Certain Types of Evidence Relating to Professional Liability Insurance, ARIZ. REV. STAT. ANN. § 12-569 (2016)).

88. *Id.* at 971-72.

89. *Id.* at 971-74 (citing ARIZ. R. EVID. 401, 403 & 411).

90. *Id.* at 973.

91. *Id.* at 974.

3. *The Direct Interest Test (Nebraska)*

The Supreme Court of Nebraska, in *Reimer v. Surgical Services of the Great Plains*,⁹² recognized that evidence of common insurance between the defendant-physician and defendant's medical expert "indicate[s] only a remote possibility of bias."⁹³ Citing Texas authority,⁹⁴ the Supreme Court stated that "absent evidence that a witness has a direct interest in the outcome of the litigation, such as an agent, owner, or employee of the defendant's insurer, the potential for bias is too remote and is outweighed by the prejudice its admission would cause."⁹⁵ No such evidence existed in *Reimer* beyond common insurance.⁹⁶

4. *The Strong Connection Test (Kentucky)*

In 2010, in *Woolum v. Hillman* the Supreme Court of Kentucky adopted a strong connection test for the admissibility of common insurance and related evidence to demonstrate expert witness bias.⁹⁷ Unfortunately, a close examination of *Woolum* reveals a troubling analysis by the Court.⁹⁸

Woolum involved a defendant-physician and expert with a common liability insurer.⁹⁹ To be sure, the defense expert was concerned about the impact an adverse verdict would have on the cost of his insurance premiums.¹⁰⁰ Moreover, at his deposition, the defense expert "described how several malpractice claims against his former liability insurer had driven up his premiums and eventually drove the insurer into bankruptcy, effectively forcing him out of practice in Mississippi."¹⁰¹ The trial court denied the defendant-physician's motion to exclude this evidence and "then permitted evidence of the common insurance coverage to be introduced at trial."¹⁰²

92. *Reimer v. Surgical Servs. of the Great Plains, P.C.*, 605 N.W.2d 777 (Neb. 2000).

93. *Id.* at 781.

94. *Id.* (citing *Mendoza v. Varon*, 563 S.W.2d 646 (Tex. Civ. App. 1978)).

95. *Id.*

96. *Id.*

97. *Woolum v. Hillman*, 329 S.W.3d 283 (Ky. 2010).

98. *Id.*

99. *Id.* at 286–87.

100. *Id.* at 287.

101. *Id.*

102. *Id.*

The Kentucky Supreme Court rejected the Ohio per se admissibility rule pronounced in *Ede*¹⁰³ and then focused on the factors supporting the trial court's decision to admit common insurance evidence at trial:

- The defense expert's "belief and opinion that malpractice cases result in, and have a direct link to, rate increases."¹⁰⁴
- The defense expert's belief of "collusion between judges and lawyers in malpractice cases."¹⁰⁵
- The defense expert's severe comments during his deposition.¹⁰⁶
- The defense expert's "general hostility to medical negligence cases."¹⁰⁷
- The defense expert and the defendant-physician "had worked side by side for twenty years in the same community hospital."¹⁰⁸

These "factors" are curious because, other than the first listed, the remaining factors are likely appropriate ammunition for cross-examination, without any reference to common insurance. The Supreme Court actually recognized this.¹⁰⁹ Nevertheless, the Court concluded "these factors also develop a link between the shared insurance and [the expert's] bias against this malpractice claim. They demonstrate [the expert] is no average, passive policyholder, but instead a practitioner very concerned with the affairs of his insurer."¹¹⁰ Finally, the Supreme Court stated, "[a]s a result of the strong connection between common insurance and witness bias, it was not an abuse of discretion to admit this evidence."¹¹¹

Kentucky's strong connection test, five years earlier referred to as "a more compelling degree of connection" test,¹¹² may be reasonable. However, the requisite connection must be between the common insurance and expert witness bias. The *Woolum* opinion misses the mark.¹¹³ It may be fair to suggest that any physician is concerned about potential increases to insurance premiums. The

103. *Id.* at 288 (citing *Ede v. Atrium S. OB-GYN*, 642 N.E.2d 365, 368 (Ohio 1994)).

104. *Id.* at 289.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.* at 290.

112. *Bayless v. Boyer*, 180 S.W.3d 439, 447 (Ky. 2005).

113. *Woolum*, 329 S.W.3d at 289-90.

other “factors” emphasized in *Woolum* are unrelated to common insurance and would have been proper topics for cross-examination of the defense expert in any event.¹¹⁴

5. *The Substantial Connection Test*

After surveying jurisdictions that have considered the admissibility of common insurance to establish expert witness bias, it is apparent that the substantial connection test is the most often utilized. The substantial connection test operates to exclude evidence of common insurance, alone. Instead, it focuses on specific links of the defense expert to the common professional liability insurer, typically a mutual company. Substantial connection examples may be distilled from reviewing the jurisprudence of Colorado,¹¹⁵ Connecticut,¹¹⁶ Georgia,¹¹⁷ Maine¹¹⁸ and Oklahoma,¹¹⁹ as follows:

- Co-founded the insurance trust¹²⁰
- Sat on the original board of directors¹²¹
- Founded the insurer to provide good quality dentists with affordable insurance and to benefit the public¹²²
- Testified that an adverse judgment could impact the expert financially¹²³
- Had an employment relationship with the insurer¹²⁴
- Received an annual salary from the insurer¹²⁵
- Set the compensation paid by the insurer for expert testimony¹²⁶
- Reviewed claims for the insurer¹²⁷

Certainly, any of these examples in combination, and possibly alone, in addition to evidence of common insurance, should satisfy the substantial connection test for admissibility.

114. *Id.*

115. *Bonser v. Shainholtz*, 3 P.3d 422 (Colo. 2000).

116. *Vasquez v. Rocco*, 836 A.2d 1158 (Conn. 2003).

117. *Chambers v. Gwinnett Cmty. Hosp., Inc.*, 557 S.E.2d 412 (Ga. Ct. App. 2001).

118. *Anderson v. O'Rourke*, 942 A.2d 680 (Me. 2008).

119. *Mills v. Grotheer*, 957 P.2d 540 (Okla. 1998).

120. *Vasquez*, 836 A.2d at 1165; *Bonser*, 3 P.3d at 426; *Chambers*, 557 S.E.2d at 416.

121. *Vasquez*, 836 A.2d at 1165; *Bonser*, 3 P.3d at 426; *Chambers*, 557 S.E.2d at 416.

122. *Bonser*, 3 P.3d at 426.

123. *Id.*

124. *Chambers*, 557 S.E.2d at 416; *Mills*, 957 P.2d at 543.

125. *Anderson v. O'Rourke*, 942 A.2d 680, 684 (Me. 2008).

126. *Id.*

127. *Id.*; *Mills*, 957 P.2d at 543.

E. The Indiana Patient Compensation Fund

The State of Indiana maintains a statutorily-created Patient Compensation Fund¹²⁸ which assists in paying medical malpractice damages:

The [Patient Compensation Fund] is administered by the Indiana Department of Insurance . . . and overseen by the insurance commissioner The [Patient Compensation Fund] is used to pay out large medical malpractice claims levied against an eligible provider The [Patient Compensation Fund] takes effect when a claim exceeds \$250,000. The health care professional's primary insurer is required to pay up to \$250,000 either by judgment of more than \$250,000 or by agreeing to settle for \$250,000 and then the court orders a remedy in excess of that amount After a settlement or judgment is reached, the defendant hospital or physician is removed from the process and the [Patient Compensation Fund] comes into play [T]his provision . . . positions the State as the insurer for a large portion of a medical malpractice claim if the judgment grants the maximum recovery to the claimant.¹²⁹

In 2012, the Court of Appeals of Indiana discussed the Indiana Patient Compensation Fund in *Tucker v. Harrison*.¹³⁰ Here, the patient sought to introduce evidence that every Indiana physician is biased as they all participate in the Fund, "which acts as a sort of supplemental mutual insurance provider for all qualified healthcare providers licensed in Indiana, and therefore have a financial interest in whether payouts are made from the Fund."¹³¹ By state statute, all Indiana-licensed physicians must be available to serve as members of a review panel and each panel member must take an oath to render a non-biased opinion.¹³² Under Indiana law, all medical negligence complaints are reviewed by a panel consisting of an attorney and three health care providers.¹³³ The Court of

128. IND. CODE ANN. § 34-18-6-1 (LexisNexis 2017).

129. Bruce D. Jones, *Unfair and Harsh Results of Contributory Negligence Lives in Indiana: The Indiana Medical Malpractice System and the Indiana Comparative Fault Act*, 6 IND. HEALTH L. REV. 107, 115-16 (2009). See also Frank A. Sloan et al., *Public Medical Malpractice Insurance: An Analysis of State-Operated Patient Compensation Funds*, 54 DEPAUL. L. REV. 247 (2005).

130. 973 N.E.2d 46 (Ind. Ct. App. 2012).

131. *Id.* at 54.

132. IND. CODE ANN. § 34-18-10-17(e) (LexisNexis 2017).

133. *Id.* § 34-18-10-3.

Appeals rejected the notion that any physician's participation in the Fund's required process evidenced any more than a remote potential for bias.¹³⁴

IV. WHAT EXACTLY IS THE (THEORETICAL) COMMON INSURANCE BIAS?

Presumably, the common insurance "plus" bias suggests that the physician-defendant's medical expert, who "shares" a liability insurer with the defendant, will be inclined to support the defendant at trial due to a financial interest in a verdict favorable to the defendant. Of course, the common insurance "plus" bias is not disqualifying—it is simply ammunition for cross-examination of the defense expert as "bias" is relevant to the weight of testimony, not admissibility. Cross-examination of the defense expert does not occur until the expert, on direct examination, has testified to standard of care opinions that support the defendant-physician. Therefore, logic dictates that expert witness bias is revealed in the substance of the expert's testimony, which favors the defendant-physician because of the bias.

Of course, I am mindful of another position, attractive to plaintiffs, which urges the admissibility of common insurance "plus" to demonstrate bias. This position is, essentially, analogous to Federal Rule of Evidence 609,¹³⁵ which provides for witness impeachment by evidence of a criminal conviction. Rule 609 "[m]odern practice rests upon the assumption that certain convictions of a witness are probative of lack of credibility, or as courts have suggested, that a witness's demonstrated willingness to engage in antisocial conduct in one instance is probative of willingness to give false testimony."¹³⁶ Rule 609 does not require any causative link to particular testimony. The party successfully impeaching a witness with a prior conviction can argue to the jury that the witness is simply not honest and not credible, due to the prior conviction. It is unlikely that such a deep-rooted policy supports the Rule 411¹³⁷ admissibility of insurance to demonstrate witness bias. It seems a stretch to urge that a commonly-insured defense expert witness will testify in support of the defendant purely as a result of the common insurance. If a plaintiff urges that a defense expert is biased only due to common insurance and any other link to the common insurer, the

134. *Tucker*, 973 N.E.2d at 55.

135. FED. R. EVID. 609.

136. GLEN WEISSENBERGER & JAMES J. DUANE, FEDERAL RULES OF EVIDENCE: RULES, LEGISLATIVE HISTORY, COMMENTARY AND AUTHORITY 377 (7th ed. 2011).

137. FED. R. EVID. 411.

defendant must interpose a Rule 403¹³⁸ objection, urging that the resulting distraction and trial of collateral matters outweighs any conceivable probative value of common insurance.

Would a medical expert witness, testifying on behalf of a defendant-physician, give false testimony as a result of a supposed common insurance “plus” bias? It is possible but, I suspect, unlikely due to the extraordinarily weak link between the financial interest of an expert witness and the outcome of the trial. In states such as Illinois, in which one professional liability insurer dominates the market, many highly-qualified, objective experts share an insurer with defendant-physicians. They are willing to testify on behalf of defendant-physicians, not because they share a professional liability insurer, but because they believe that the medical care provided was appropriate. This, in my opinion, is why the Ohio per se rule of admissibility and, perhaps, the common insurance “plus” rule of admissibility,¹³⁹ are flawed. To borrow a concept from tort law, neither model embraces a “causation” component—neither model requires a showing that the alleged bias produces specific false testimony.

There is another issue worthy of mention at this point. This paper has not focused on the question of whether jurors are influenced by hearing evidence of insurance because it is distinct from the question of witness bias. Will testimony at trial about the defendant-physician’s and defense expert’s common insurer cause the jury to enter a verdict for the plaintiff, and, perhaps, inflate a verdict because the jury is aware of the existence of professional liability insurance to cover the loss? This topic has received significant attention in the literature over a lengthy period of time.¹⁴⁰ This issue, of course, relates to the primary function of Federal Rule of Evidence 411¹⁴¹—to exclude evidence of the presence or absence of insurance to prove negligence. Expert witness bias due to common insurance relates to witness credibility, not liability. FRE 411 clearly distinguishes these concerns and so does this paper.

138. FED. R. EVID. 403.

139. *Ede v. Atrium S. OB-GYN*, 642 N.E.2d 365, 366, 368 (Ohio 1994).

140. See, e.g., Alan Calnan, *The Insurance Exclusionary Rule Revisited: Are Reports of its Demise Exaggerated?*, 52 OHIO ST. L.J. 1177 (1991); Samuel R. Gross, *Make-Believe: The Rules Excluding Evidence of Character and Liability Insurance*, 49 HASTINGS L.J. 843 (1998); J.E. Lyerly, *Evidence: Revealing the Existence of Defendant’s Liability Insurance to the Jury*, 6 CUMB. L. REV. 123 (1975); R. Pettigrew, *Another Look at That Forbidden Word—Insurance*, 10 FLA. L. REV. 68 (1957).

141. FED. R. EVID. 411.

V. THE RISK ASSUMED BY THE DEFENDANT'S BIASED MEDICAL EXPERT WITNESS

The problem created by the biased defendant's medical expert witness (or the biased plaintiff's medical expert witness) is inherent in expert witness testimony. Expert medical witnesses are intelligent, influential, and believable. These "qualities" yield the potential for false testimony, incapable of recognition by the jury. The medical expert who falsifies testimony in order to support a litigant is, at trial, subject to cross-examination on matters of testimonial substance and credibility.¹⁴² But expert witnesses who falsify their testimony will know more about the subject matter of their testimony than the cross-examining attorney,¹⁴³ may be believable, and their testimony may cause the entry of verdicts based on purposefully erroneous testimony.

Returning to the focus of this paper—common insurance—does the defendant's medical expert bear any professional risk if the expert's bias results in false trial testimony? If so, is the risk so great that it likely outweighs the reward—a verdict in favor of the defendant-physician?

A. The Risk That the Expert's Medical License Will Be Disciplined

The licensure of physicians is governed by state law.¹⁴⁴ The practice of medicine is defined by state law (including state court decisions)¹⁴⁵ and state law provides the vehicle by which physicians' licenses may be disciplined.¹⁴⁶ "[M]ost states authorize discipline under a broad category of 'unprofessional conduct,' which may include violations of codes of medical ethics, conduct that brings the medical profession into disrepute, or other unspecified forms of 'dishonorable conduct,' including criminal acts (typically felonies or crimes of 'moral turpitude')." ¹⁴⁷ Medical literature suggests that physician

142. FED. R. EVID. 611(b) ("Cross-examination should not go beyond the subject matter of the direct examination and matters affecting the witness's credibility. The court may allow inquiry into additional matters as if on direct examination.")

143. Jennifer A. Turner, *Going After the 'Hired Guns': Is Improper Expert Witness Testimony Unprofessional Conduct or the Negligent Practice of Medicine?*, 33 PEPP. L. REV. 275, 288 (2006).

144. See BARRY FURROW ET AL., LAW AND HEALTH CARE QUALITY, PATIENT SAFETY, AND MEDICAL LIABILITY 65 (7th ed. 2013); Nadia N. Sawicki, *Character, Competence, and the Principles of Medical Discipline*, 13 J. HEALTH CARE L. & POLY 285, 286 (2010); Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 434 (2015).

145. Sawicki, *supra* note 144, at 290; Zettler, *supra* note 144, at 435–36.

146. See James Morrison & Peter Wickersham, *Physicians Disciplined by a State Medical Board*, 279 JAMA 1889 (1998); Sawicki, *supra* note 144, at 290.

147. Sawicki, *supra* note 144, at 293.

license discipline occurs largely for the following reasons: substance abuse, criminal conduct, sexual contact with patients, prescribing violations, financial improprieties, negligence, incompetence, and unprofessional conduct.¹⁴⁸ The Federation of State Medical Boards has published a lengthy list of examples of unprofessional conduct,¹⁴⁹ but false medical expert testimony is absent from this list. Even with these various categories of physician conduct which could lead to license discipline, it has been reported that “medical boards only take disciplinary action against less than one-half of one percent of physicians annually”¹⁵⁰

There is very little reported judicial precedent relating to the question of whether false medical expert witness testimony is a proper subject for license discipline. In *Joseph v. D.C. Board of Medicine*,¹⁵¹ a physician’s license was disciplined in Maryland for “false testimony and misrepresentations made by him in his capacity as an expert witness in a medical malpractice case, [which] constituted a false report in the practice of medicine”¹⁵² The District of Columbia licensing board then instituted a disciplinary proceeding against the physician and determined that giving testimony as a non-treating expert witness “is in the nature of giving a second opinion”¹⁵³ and arises from the practice of medicine.¹⁵⁴ The Court of Appeals found that the physician, as an expert witness, was involved in the diagnostic process.¹⁵⁵ The decision of the District of Columbia Board of Medicine was affirmed.¹⁵⁶

In the same year *Joseph*¹⁵⁷ was decided, the Missouri Court of Appeals decided *Missouri Board of Registration for the Healing Arts v. Levine* (“*Missouri Board*”),¹⁵⁸ holding that “acting as a non-treat-

148. See Neal D. Kohatsu, *Characteristics Associated with Physician Discipline*, 164 ARCH. INTERN. MED. 653, 655 (2004); Morrison & Wickersham, *supra* note 146, at 1890.

149. FEDERATION OF STATE MED. BDS., U.S. MEDICAL REGULATORY TRENDS AND ACTIONS 7 (May 2014).

150. Sawicki, *supra* note 144, at 287.

151. *Joseph v. D.C. Bd. of Med.*, 587 A.2d 1085, 1086 (D.C. 1991).

152. *Id.* at 1086.

153. *Id.* at 1087.

154. *Id.*

155. *Id.* at 1089, 1091.

156. *Id.* at 1091.

157. *Id.* at 1085.

158. *Mo. Bd. of Registration for Healing Arts v. Levine*, 808 S.W.2d 440 (Mo. Ct. App. 1991).

ing expert medical witness does not constitute the practice of medicine or the function or duty of a licensee”¹⁵⁹ Dr. Levine’s alleged transgression had been false testimony regarding the number of attempts necessary to pass a board certification exam.¹⁶⁰

More recently, the Court of Appeals of Mississippi, in *Mississippi State Board of Medical Licensure v. Harron*,¹⁶¹ considered an interesting medical licensure matter involving expert testimony. Unlike in *Joseph*¹⁶² and *Missouri Board*,¹⁶³ Dr. Harron was a physician involved in “producing diagnostic reports on 6,700 of the claimants in the Texas [silicosis]¹⁶⁴ litigation,”¹⁶⁵ and “was listed as the diagnosing physician on 2,600 of these claims.”¹⁶⁶ He “testified about his practices of letting medically untrained secretaries and typists interpret his reports, insert a diagnosis, stamp his signature on the reports, and sent them out with no review by him.”¹⁶⁷ Dr. Harron’s medical license was disciplined as a result of this conduct but, on review, the Chancery Court “ruled that the Board had no jurisdiction to discipline Dr. Harron because his actions were as an expert witness and he was not engaged in the practice of medicine.”¹⁶⁸

In reversing the decision of the Chancery Court, the Court of Appeals used quite broad language in pronouncing that “the [licensing] Board’s jurisdiction to discipline doctors is not limited to situations where the doctor is actually practicing medicine on a particular patient.”¹⁶⁹ Typically, expert medical testimony of the type discussed in this paper does not involve patient treatment by the expert. Standard of care and causation opinions are most often derived from the expert’s review of medical and hospital records, deposition testimony, literature, and the expert’s education, training, and experience. Yet, the Court of Appeals did note that Dr. Harron was, in fact, a diagnosing physician for many patients when he testified as an expert witness.¹⁷⁰ Therefore, despite the specific facts

159. *Id.* at 443.

160. *Id.* at 441.

161. *Miss. State Bd. of Med. Licensure v. Harron*, 163 So.3d 945 (Miss. App. 2014).

162. *Joseph*, 587 A.2d 1085.

163. *Levine*, 808 S.W.2d 440.

164. Brooke T. Mossman & Andrew Churg, *Mechanisms in the Pathogenesis of Asbestosis and Silicosis*, 157 AM. J. RESPIRATORY & CRITICAL CARE MED. 1666, 1667 (1998) (“Silicosis is disease produced by inhalation of one of the forms of crystalline silica, most commonly quartz.”).

165. *Harron*, 163 So.3d at 945.

166. *Id.*

167. *Id.*

168. *Id.* at 951.

169. *Id.* at 952.

170. *Id.* at 953–54.

in *Harron*,¹⁷¹ the opinion may very well support the position that classic medical expert witness testimony constitutes the practice of medicine.

Medical and legal scholarship has reported that the American Medical Association (AMA) considers expert witness testimony to be the practice of medicine.¹⁷² These reports derive from an AMA resolution¹⁷³ reflecting “current AMA policy . . . that expert witness testimony is the practice of medicine subject to peer review.”¹⁷⁴ Although a 1998 AMA Report of the Board of Trustees on expert witness testimony¹⁷⁵ does not define “peer review,” the report does state: “Several medical and specialty organizations are working to deter false testimony. For example, the Florida Medical Association (FMA) has developed a program by which physicians who falsely testify are reported to the state licensing board for discipline. The AMA is currently is [sic] studying programs like the FMA’s.”¹⁷⁶

Therefore, the AMA policy, which considers expert witness testimony to be the practice of medicine, appears to contemplate licensure discipline for false testimony. Additional evidence for this stance is the AMA’s Code of Medical Ethics.¹⁷⁷ Opinion 9.07, Medical Testimony, provides, in relevant part: “Organized medicine, including state and specialty societies, and medical licensing boards can help maintain high standards for medical witnesses by assessing claims of false or misleading testimony and issuing disciplinary sanctions as appropriate.”¹⁷⁸

I do not know how well publicized the risk of medical license discipline is to potential medical expert witnesses (and physicians generally) as a sanction for false testimony. To the extent that license discipline is a realistic sanction for false expert witness testimony, the sanction is not worth the risk of the supposed common insur-

171. *Id.* at 946.

172. See B. Sonny Bal, *The Expert Witness in Medical Malpractice Litigation*, 467 CLINICAL ORTHOPAEDICS & RELATED RES. 383, 384–85 (2009); Juan Carlos B. Gomez, *Silencing The Hired Guns—Ensuring Honesty in Medical Expert Testimony Through State Legislation*, 26 J. LEGAL MED. 385, 393 (2005); Robert S. Peck & John Vail, *Blame it on the Bee Gees: The Attack on Trial Lawyers and Civil Justice*, 51 N.Y. L. SCH. L. REV. 324, 334 (2006); Russell M. Pelton, *Medical Societies’ Self-Policing of Unprofessional Expert Testimony*, 13 ANNALS HEALTH L. 549, 550, 552 (2004).

173. AM. MED. ASS’N HOUSE OF DELEGATES, RESOLUTION 211 (1998).

174. THOMAS R. REARDON, REPORT OF THE BD. OF TRUSTEES: B OF T REPORT 5–A–98 1 (1998), <http://truthinjustice.org/amareport.htm>.

175. *Id.*

176. *Id.* at 4.

177. AM. MED. ASS’N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS (2014–2015 ed.).

178. *Id.* at 365 (emphasis added).

ance “plus” expert witness bias. The risk of discipline, in my estimation, makes less likely that the existence of common insurance would influence expert testimony in favor of the defendant-physician.

B. The Risk That The Expert Will Be Disciplined By A Professional Medical Society

The risk that an expert witness’ false testimony may lead to discipline by a professional medical society is not theoretical. At least one author has suggested that professional medical societies play a prominent role in the discipline of medical expert witnesses.¹⁷⁹ Many professional medical societies, which are voluntary associations of physicians, and neither grant degrees nor board certification, have guidelines, policies, statements, and ethical opinions relating to expert witness testimony.¹⁸⁰

179. See Pelton, *supra* note 172, at 552.

180. See, e.g., AM. ACAD. OF NEUROLOGY, QUALIFICATIONS AND GUIDELINES FOR THE PHYSICIAN EXPERT WITNESS (June 25, 2005), [https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/8.Membership/5.Ethics/1.Code_of_Conduct/Membership-Ethics-American%20Academy%20of%20Neurology%20Qualifications%20and%20Guidelines%20for%20the%20Physician%20Expert%20Witness%20\(2\).pdf](https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/8.Membership/5.Ethics/1.Code_of_Conduct/Membership-Ethics-American%20Academy%20of%20Neurology%20Qualifications%20and%20Guidelines%20for%20the%20Physician%20Expert%20Witness%20(2).pdf); AM. ACAD. OF OPHTHALMOLOGY, ADVISORY OPINION OF THE CODE OF ETHICS: EXPERT WITNESS TESTIMONY (Feb. 27, 2017), <https://www.aao.org/ethics-detail/advisory-opinion--expert-witness-testimony>; AM. ACAD. OF PAIN MED., GUIDELINES FOR EXPERT WITNESS QUALIFICATIONS AND TESTIMONY (June 12, 2012), <http://www.painmed.org/files/aapm-expert-witness-guidelines.pdf>; AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, ACOG COMMITTEE OPINION NO. 374: EXPERT TESTIMONY (2016), <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Expert-Testimony>; AM. COLL. OF RADIOLOGY, ACR PRACTICE PARAMETER ON THE PHYSICIAN EXPERT WITNESS IN RADIOLOGY AND RADIATION ONCOLOGY: RESOLUTION 9 (2017); AM. COLL. OF RHEUMATOLOGY, POLICY AND GUIDELINES FOR EXPERT WITNESS TESTIMONY IN MEDICAL MALPRACTICE LITIGATION (June 22, 2015), <http://www.rheumatology.org/Portals/0/Files/ACR%20Policy%20and%20Guidelines%20for%20Expert%20Witness%20Testimony.pdf>; AM. SOC’Y OF ANESTHESIOLOGISTS, GUIDELINES FOR EXPERT WITNESS QUALIFICATIONS AND TESTIMONY (Oct. 16, 2013), <https://www.asahq.org/about-asa/office-of-general-counsel/expert-witness-testimony-review-program>; Am. Acad. of Pediatrics, *Policy Statement, Guidelines for Expert Witness Testimony in Medical Malpractice Litigation*, 109 PEDIATRICS 974 (2002); Am. Coll. of Med. Genetics, *Guidelines for Expert Witness Testimony for Specialty of Medical Genetics*, 2 GENETICS IN MED. 367 (2000); Ramsey M. Dallal et al., *American Society of Metabolic and Bariatric Surgery Patient Safety Committee Policy Statement on the Qualifications of Expert Witnesses in Bariatric Surgery Medicolegal Matters*, 8 SURGERY OBESITY & RELATED DISEASES. e9 (2012); *Expert Witness Guidelines for the Specialty of Emergency Medicine*, AM. COLL. OF EMERGENCY PHYSICIANS (June 2015), <https://www.acep.org/Clinical---Practice-Management/Expert-Witness-Guidelines-for-the-Specialty-of-Emergency-Medicine>; *Statement on the Physician Acting as an Expert Witness*, AM. COLL. OF SURGEONS (Apr. 1, 2011), <https://www.facs.org/about-acfs/statements/8-expert-witness>; *Expert Witness Testimony in Medical Liability Cases*, AM. UROLOGICAL ASS’N, <https://www.avanet.org/education/policy-statements/testimony> (last visited June 3, 2016).

*Austin v. American Association of Neurological Surgeons*¹⁸¹ involved a medical society membership suspension of a neurosurgeon as a result of his “irresponsible” expert testimony against another neurosurgeon.¹⁸² Dr. Austin sued the AANS “claiming that he had been suspended in ‘revenge’ for having testified as an expert witness for the plaintiff in a medical malpractice suit brought against another member of the [AANS].”¹⁸³ Procedurally, the suspension occurred following a verdict for the defendant neurosurgeon and the defendant’s complaint to the AANS, triggering the AANS disciplinary process.¹⁸⁴ Dr. Austin’s lawsuit was resolved by summary judgment in favor of the AANS.¹⁸⁵ The Seventh Circuit Court of Appeals affirmed, and after commenting on medical literature and Dr. Austin’s related trial testimony, stated:

There is little doubt that his testimony was irresponsible and that it violated a number of sensible-seeming provisions of the Association’s ethical code. These include provisions requiring that a member appearing as an expert witness should testify “prudently,” must “identify as such, personal opinions not generally accepted by other neurosurgeons,” and should “provide the court with accurate and documentable opinions on the matters at hand.”¹⁸⁶

The Seventh Circuit’s opinion in *Austin*¹⁸⁷ certainly reveals and supports the ability of a voluntary professional medical society to discipline a member based upon that member’s “irresponsible” expert testimony.¹⁸⁸ It was referred to more recently in the disposition of another claim by a suspended member of a voluntary professional medical society in *Brandner v. American Academy of Orthopaedic Surgeons*.¹⁸⁹

In *Brandner*,¹⁹⁰ a member of the “American Academy of Orthopaedic Surgeons . . . and its interrelated and parallel organization, the American Association of Orthopaedic Surgeons [collectively, the

181. *Austin v. Am. Ass’n of Neurological Surgeons*, 253 F.3d 967 (7th Cir. 2001).

182. *Id.* at 971.

183. *Id.* at 968.

184. *Id.* at 970.

185. *Austin v. Am. Ass’n of Neurological Surgeons*, 120 F. Supp. 2d 1151 (N.D. Ill. 2000).

186. *Austin*, 253 F.3d at 971.

187. *Id.* at 967.

188. *Id.* at 971.

189. *Brandner v. Am. Acad. of Orthopaedic Surgeons*, No. 10 C 8161, 2012 WL 4483820 (N.D. Ill. 2012), *aff’d*, 760 F.3d 627 (7th Cir. 2014).

190. *Brandner*, 2012 WL 4483820.

‘AAOS’],”¹⁹¹ was “suspended . . . from membership based on certain expert testimony he provided during a medical malpractice case.”¹⁹² Dr. Brandner filed suit against these professional societies, contending “that the AAOS’s sole intent was to punish and make an example of him for offering expert testimony against another orthopedic surgeon who was a fellow member of the AAOS,”¹⁹³ and the failure “to follow their own bylaws, acting in bad faith and violating his due process rights.”¹⁹⁴ The trial court granted the AAOS motion for summary judgment.¹⁹⁵

After the resolution of the underlying case, the medical malpractice defendant, against whom Dr. Brandner testified, filed “a grievance report with the AAOS against Brandner.”¹⁹⁶ The District Court, in discussing the grievance procedure, noted that the AAOS Committee on Professionalism recommended “that Brandner be suspended from the AAOS for one year based on ‘unprofessional conduct in the performance of expert witness testimony.’”¹⁹⁷ After action by the AAOS Board of Directors, and a rehearing of the matter, the Board voted to suspend Dr. Brandner for one year.¹⁹⁸

Significantly, the District Court commented on the discretion of voluntary associations in Illinois while conducting internal affairs, stating:

In Illinois, voluntary associations have great discretion in conducting their internal affairs, and their conduct is subject to judicial review only when they fail to exercise power consistently with their own internal rules or when their conduct violates the fundamental right of a member to a fair hearing.¹⁹⁹

Adding to its pronouncement of the great deference to be given to the decisions of Illinois voluntary associations, the District Court further stated that:

191. *Id.* at *1.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.* at *4.

197. *Id.* at *6.

198. *Id.*

199. *Id.* at *8 (citing *Austin v. Am. Ass’n of Neurological Surgeons*, 120 F. Supp. 2d 1151, 1152 (N.D. Ill. 2000)).

This Court's limited review of an association's actions regarding its members does not permit it to review whether the decision was right or wrong, but simply whether it was made without bias, prejudice or bad faith, by following proper association procedures and in the absence of a due process violation.²⁰⁰

The District Court opined that Dr. Brandner was not denied his due process rights.²⁰¹

Dr. Brandner appealed the District Court's opinion to the Seventh Circuit Court of Appeals, which, in 2014, affirmed the opinion, noting a scant record on appeal.²⁰² Dr. Brandner's claim against the AAOS reveals that disciplinary action by a professional medical society, although not as drastic as that by a medical licensing board, is realistic following false testimony by a medical expert witness.

VI. CONCLUSION

The supposed bias of the defendant's expert witness resulting from sharing a professional liability insurer with the defendant-physician is misplaced. The expert's financial interest in a defense verdict is, at best, weak. The proof necessary to demonstrate this theoretical bias would require the introduction into evidence of the operation of a mutual insurance company and financial information which would be unrelated to the issues at trial, likely incapable of being understood by the jury, and, in my estimation, violate Federal Rule of Evidence 403.²⁰³ The *per se* rule of admissibility adopted in Ohio²⁰⁴ is excessively rigid, should be revisited by Ohio courts, and eliminated.

The common insurance "plus" jurisdictions allow evidence of common insurance with additional evidence linking the defense expert to the common insurer. Even in these jurisdictions, it is difficult to establish how common insurance "plus" actually influences a defense expert's testimony. In these jurisdictions, it is necessary to discover the existence of common insurance, make this existence known to the defendant's expert witness before trial (likely during a deposition) and overcome a motion in limine, pursuant to the

200. *Id.* at *12.

201. *Id.*

202. *Brandner v. Am. Academy of Orthopedic Surgeons*, 760 F.3d 627 (7th Cir. 2014).

203. FED. R. EVID. 403.

204. *Ede v. Atrium S. OB-GYN*, 642 N.E.2d 365, 368 (Ohio 1994).

state's version of Federal Rule of Evidence 403,²⁰⁵ to bar this evidence. Plaintiff, in opposition to the motion in limine, must assert that evidence of common insurance "plus" is itself evidence of expert witness bias, much like the evidentiary rule allowing impeachment of a witness with a prior conviction.²⁰⁶ The weakness of this position, I submit, is the lack of a policy which underscores impeachment by prior conviction, requiring no causative link to specific false testimony.²⁰⁷

Does common insurance, shared by the defendant-physician and the defendant-physician's expert witness actually *cause* false testimony in favor of the defendant-physician? This is a difficult question to answer but what appears certain is that the answer cannot be discerned during the trial of a medical negligence case. These cases are tried before lay juries, not blue ribbon juries.²⁰⁸ Neither lawyers nor judges have the wherewithal to know if a medical expert witness is falsifying testimony, due to common insurance or any other reason.²⁰⁹ What is known is that false expert testimony is forbidden by numerous professional medical associations, is subject to discipline by them, and may constitute the practice of medicine, subjecting it to review and discipline by state medical licensing boards. Therefore, false expert witness testimony carries a potentially substantial professional risk.

The common insurance "plus" expert witness bias, not requiring any causative link to identifiable false testimony, unfortunately will likely remain part of the jurisprudence in those states which have recognized it. Courts should understand, however, that the claim of bias is tenuous and the evidence necessary to "prove" bias will be time-consuming, distracting, and collateral to the issues central to the trial.

205. FED. R. EVID. 403.

206. FED. R. EVID. 609.

207. See WEISSENBERGER & DUANE, *supra* note 136.

208. A blue ribbon jury would be comprised of more highly educated jurors or jurors from the defendant's profession. See Grant P. Du Bois, Jr., *Desirability of Blue Ribbon Juries*, 13 HASTINGS L.J. 479 (1962); Valerie P. Hans, *Judges, Juries, and Scientific Evidence*, 16 J. L. & POL'Y 19 (2007); Deborah R. Hensler, *Science in the Court: Is There a Role for Alternative Dispute Resolution?*, 54 L. & CONTEMP. PROBS. 171 (1991); Harry H. Root, *Medical Malpractice Litigation: Some Suggested Improvements and a Possible Alternative*, 18 U. FLA. L. REV. 623 (1966).

209. For an opinion referring to "[t]he discomfort of the legal profession, including the judiciary, with science and technology . . . [.] see Jackson v. Pollion, 733 F.3d 786, 788 (7th Cir. 2013) (commenting on the mistaken view of two judges regarding plaintiff's medical condition). See also Root, *supra* note 208, at 631.

A Law and Economics Critique of the Law Review System

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ABSTRACT

The law review system prizes placement of articles in highly-ranked journals, and the optimum method to ensure the best placement, which many scholars have intuited, is a saturation submission strategy of submitting articles to as many journals as possible. However, there has neither been an explanation as to what incentivizes this submission strategy nor any analysis as to what happens to scholars who cannot afford this strategy. This article uses a law and economics approach to study the incentive structures of the law review system, and identifies two features of the system that encourage saturation submission and punishes the poorly-resourced: (a) journals have no availability to accept all articles of equal quality; and (b) there is an insufficient match between acceptance and journal ranking. It demonstrates that the law review system behaves as a market, and is meritocratic only for those scholars who can afford to practice saturation submission. This article concludes with some thoughts about reforming the system.

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I. INTRODUCTION

The law review system is central to the enterprise of legal scholarship. Faculty hiring,¹ tenure decisions,² and even salaries³ are dependent on the number of publications placed in highly-ranked journals. To that end, the quality of law faculties and, by extension,

1. See, e.g., anonprof, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Mar. 3, 2017, 8:49 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/14/#comments> (“I have chaired my school’s appointments committee several times, and I talk quite a bit with chairs at other schools. Here’s my opinion—we are impressed by publications that we immediately know are ‘good.’ What determines good can be the prestige of the journal, but more often, it’s the perceived prestige of the school. Thus, a publication in the flagship journal in any school in the T30 of U.S. News will get our attention—probably true of the T50 as well (although the closer you get to 50, the less that’s the case).”).

2. See, e.g., AnonProf, *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 2, 2016 10:11 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/4/#comments> (“Look, the sad truth is rarely will people read your work, but many in your career will read your CV. They’ll look over your publications and they will absolutely use your placements as a proxy for how good a scholar you are. When it’s tenure time, you’re [sic] faculty (whether they admit it or not) will be considering your placements . . . Thus, nobody is saying any journals are unworthy, but it’s foolish to not try and get the highest placement you can—especially if you’re a relatively new prof[essor] with unfulfilled career aspirations.”).

3. See, e.g., Anonymouse, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 28, 2017, 9:57 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/11/#comments> (“for many of us our annual compensation is impacted by article placement.”); Furball, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Mar. 8, 2017, 11:17 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/17/#comments> (“I am curious. For how many of you does summer research funding depend on publishing above a certain point, e.g., top 50[?] I will go first. Mine does.”); Westie, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Mar. 12, 2017, 10:51 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/19/#comments> (“at my school (and a number of others) our summer compensation and merit based pay raises turn on prestige of journal placement—low enough placement and you essentially forfeit a month of salary.”).

the research they produce, rely on the integrity of the system. It is therefore of critical importance to identify elements of the system that are not meritocratic or unfair so that the system can be remedied to properly reward the best scholarship.

Although the system has been characterized as a black box,⁴ participants within it have by experience converged upon certain strategies to deal with its peculiarities. For example, it is generally agreed that the best way to guarantee the best placement of an article is to submit to as many journals as possible, that is, saturation submission.⁵ But what makes saturation submission the best strategy? And what happens to those who cannot afford to execute saturation submission?

The law review system is actually quite amenable to analysis. The rules, such as how the submission system operates, are clear, and it is therefore possible to examine the incentive structure that results. And although data is hard to come by, there are some statistics and clues about demonstrated preferences, for example, on PrawfsBlawg, which serves in part as a gossip site for legal scholars.⁶

This article utilizes the law and economics approach to study the law review system itself. It begins by outlining the “law” that governs the system, namely, the peculiarities of articles submission as well as the ranking of the journals. It then analyzes the strategies and outcomes using an idealized system, and, by adding realistic constraints to the system, shows how the system creates a market structure that encourages saturation submission and disadvantages the scholars who cannot afford to do so. It concludes with some proposals about reforming the system.

From a broader perspective, the ills of the law review system are simply too deep and too numerous to be addressed in any single article.⁷ To that end, the reader is highly encouraged to refer to the

4. See Brian Galle, *The Law Review Submission Process: A Guide for (and by) The Perplexed 1* (Aug. 12, 2016) (Georgetown University Law Center), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2822501 (“No one really understands the law review publication process. I certainly don’t.”).

5. *Id.* at 5 (“The game is that one first submits to a very large number of journals.”).

6. For example, PrawfsBlawg has an “angsting” thread for every submission season, where legal scholars discuss which journals have accepted their articles and how journal acceptances should be weighed. See, e.g., *Law Review Submission Angsting Thread: Fall 2017*, PRAWFSBLAWG (Aug. 4, 2017), <http://prawfsblawg.blogs.com/prawfsblawg/2017/08/law-review-submission-angsting-thread-fall-2017.html>. The information posted on these threads provide a glimpse into the behavior of actual legal scholars.

7. For other problems with the law review system that have been noted by scholars, see Leah M. Christensen & Julie A. Oseid, *Navigating the Law Review Article Selection Process: An Empirical Study of Those With All the Power—Student Editors*, 59 S.C. L. REV. 175 (2007) (analyzing some of the problematic factors, such as a reviewer’s ability to recognize the school

forthcoming essay, “Law Review Publishing: Thoughts on Mass Submissions, Expedited Reviews, and Potential Reforms,” by Michael Cicchini.⁸ Unlike this article, which examines the law review system from a systematic point of view, Cicchini’s essay takes a more granular look at the morally questionable practices used by individual legal scholars to enhance their article placement. This article and Cicchini’s article are independently written; however, the reader may consider the two articles as companion pieces in their criticisms of the entire law review system.

II. HOW THE LAW REVIEW SYSTEM OPERATES

In order to analyze the law review system using the law and economics approach, it is important to first identify the underlying “laws.” Readers who are regular users of the system will be well familiar with these “laws,” but it is useful to briefly set forth the essentials as a basis for discussion.

A. Peculiarities of Law Journal Submissions

As in all fields of academia, authors submit their research articles to journals, which decide whether or not to publish the articles. However, there are a few distinguishing features with regard to law journals, as compared to, for example, scientific journals.⁹

First, legal scholars generally do not submit articles to journals on an exclusive basis. Authors may submit to any number of journals and pick the most desirable among the offers. Desirability will be addressed in a subsequent discussion; for now, it is sufficient to note that it is not unheard of for authors to simultaneously submit a single article to 100 journals.¹⁰

at which the author teaches, used in article publication decisions), Richard A. Posner, *Against the Law Reviews*, LEGAL AFFAIRS (2004), https://www.legalaffairs.org/issues/November-December-2004/review_posner_novdec04.msp (noting that the background of law review editors may not equip them to review papers on interdisciplinary work), and Richard A. Wise et al., *Do Law Reviews Need Reform? A Survey of Law Professors, Student Editors, Attorneys, and Judges*, 59 LOY. L. REV. 1, 8–24 (2013) (summarizing common criticisms of the law review system).

8. Michael D. Cicchini, *Law Review Publishing: Thoughts on Mass Submissions, Expedited Reviews, and Potential Reforms*, 16 U. N.H. L. REV. (forthcoming 2017).

9. For a brief description of the typical journal submission process in an area of study outside of law, see Posner, *supra* note 7. For an example of the policy of a scientific journal, see Science: *Editorial Policies*, SCIENCE, <http://www.sciencemag.org/authors/science-editorial-policies> (last visited Sept. 1, 2017).

10. See, e.g., Anotheranon, *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 29, 2016, 11:11 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/7/#comments> (“My suggestion would be to submit much more broadly (think at least 100 journals, not 30).”).

Second, authors are generally required to pay a submission fee. While some journals have allowed submission through emails for free,¹¹ as of this writing, a large number of law journals accept articles exclusively through Scholastica, which charges authors a \$5 “management charge” for each submission to each journal.¹² This can easily lead to expenditures of hundreds of dollars to have an article published.¹³ It should be noted that Scholastica increased the price for submissions to \$6.50 in early 2017, a 30% price hike.¹⁴

Third, law articles are generally selected by student editors of journals, not by peer review.¹⁵ Some of the most prestigious journals may incorporate some element of review by scholars into their review process,¹⁶ but the ultimate decisions about publishing reside with student editors. Purely peer-reviewed journals, such as the *Journal of Legal Education*, are rare.

Fourth, because authors may submit to multiple journals at once, the expedite mechanism exists so that an author can alert more desirable journals about acceptance from a less desirable journal.¹⁷ That way, the more desirable journals can be prompted to decide whether to accept the article before the offer for acceptance from the less desirable journal expires.

B. Ranking of Law Journals

To understand how journals are ranked, it is important to note that each school generally produces a “flagship” journal, such as *Stanford Law Review*. Some may have “niche” journals focused on

11. For a summary of the submission policies of 203 law journals, see Allen Rostron & Nancy Levit, Information for Submitting Articles to Law Reviews & Journals (July 2017) (University of Missouri at Kansas City School of Law), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1019029.

12. *The Top Choice Among Law Reviews for Article Selection*, SCHOLASTICA, <https://scholasticahq.com/law-reviews> (last visited Oct. 17, 2016).

13. See, e.g., Anonymous, *Submission Angsting Fall 2016*, PRAWFSBLAWG (Aug. 7, 2016, 6:17 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/07/submission-angsting-fall-2016/comments/page/2/#comments> (“I have spent about \$300 for my current submission.”); Anonymouse, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 28, 2017, 9:57 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/11/#comments> (“I think I have racked up about \$650 in submission fees which fortunately my school pays for.”).

14. *January 2017 Law Review Submission Price Update*, SCHOLASTICA, <http://blog.scholasticahq.com/post/law-review-submission-price-update/> (last visited Oct. 17, 2016).

15. Posner, *supra* note 7.

16. Galle, *supra* note 4, at 13.

17. A complete description of the expedite practice is beyond the scope of this article. For more, see Cicchini, *supra* note 8, at 7.

specific topics, such as *Stanford Technology Law Review*. Publication in the “flagship” journal commands more respect than publication in a “niche” journal of the same school.

What is more complicated is how scholars compare journals published by different schools. The consensus is that legal academics rank journals by the *U.S. News & World Report* ranking of the law school publishing the law review.¹⁸ That is, if William & Mary ranks as 33 according to the magazine, then *William & Mary Law Review* ranks as 33 among the “flagship” journals.

There exists a seemingly never-ending dispute among legal scholars about how the “niche” journals published by higher-ranked schools should be ranked against the “flagship” journals of lower-ranked schools. Brian Galle, a tax scholar, provides this perspective:

I have heard international law scholars say that placing with Harvard's international-law journal [i.e., *Harvard International Law Journal*] is almost as good as placing in the *Harvard Law Review*. Let me be blunt. That is absurd. For most purposes, specialty placements are not as valuable as general-interest journal placements, and a 40- or 50-place discount seems closer to my sense of the difference than 20. Certainly, I would never take a [*Virginia Tax Review*] placement over, say, the *Emory Law Journal*. But this can vary by field and by journal. . . .

There is probably a premium for the very top specialty journals. I might put outlets such as the *Yale Journal on Regulation* in or close to the top 20, while some Columbia or Virginia journals, say, are probably best measured by adding 50 or more.¹⁹

18. *Id.* at 4. It should be noted that, for purposes of ranking journals, some scholars prefer the use of the peer assessment score, one of the factors used by the *U.S. News & World Report* to determine its overall rankings, instead of the overall rankings themselves. See, e.g., anon, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Mar. 8, 2017, 11:11 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/7/#comments> (“[T]he general USNWS rankings are unhelpf [sic] for gauging the quality of law reviews. Use the peer assessment scores instead, they are typically consistent year-to-year: http://taxprof.typepad.com/taxprof_blog/2016/03/2017-us-news-peer-reputation-rankings-v-overall-rankings.html.”). The peer assessment score is determined by surveys of “law school deans, deans of academic affairs, chairs of faculty appointments and the most recently tenured faculty members,” who are asked to “rate programs [of peer schools] on a scale from marginal (1) to outstanding (5).” Robert Morse, *Methodology: 2017 Best Law Schools Rankings*, U.S. NEWS & WORLD REPORT (Mar. 16, 2016, 9:30 PM), <http://www.us-news.com/education/best-graduate-schools/articles/law-schools-methodology>.

19. Galle, *supra* note 4, at 9.

Here is a slightly different take, from an exchange between scholars on PrawfsBlawg:

I received two offers in the past day. One from a T50–60 general law review, and one from one of the top 3 specialty law journals. Thoughts on which is better?²⁰

Posted by: Anon

There are different ways to think about it. For me, the most important is to decide who I hope will read the article. If I am really hoping to reach colleagues in my field, and not much beyond, then I would take the offer from the top 5 specialty journal, which has a good chance of being read regularly by lots of scholars in the field (who might not see the piece if published in a main-line law rev[iew])[.] If the piece contains important themes that transcend the specialty categories, then I might go for the main-line law journal.

Another way to look at it is from the perspective of the Dean's/faculty's review criteria at your school. Will one type of publication "count" more than another in terms of future research grants etc.?

Posted by: crimprof²¹

Some scholars treat publication in a specialty journal as a mark of failure:

Generally, I think placing in a specialty journal is a bad idea. Unless it's a super well-regarded specialty, I view such placements as a signal that the author failed to get a decent offer from a general journal.

20. Anon, *Submission Angsting Fall 2016*, PRAWFSBLAWG (Aug. 2, 2016, 8:02 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/07/submission-angsting-fall-2016/comments/page/1/#comments>.

21. crimprof, *Submission Angsting Fall 2016*, PRAWFSBLAWG (Aug. 2, 2016, 8:55 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/07/submission-angsting-fall-2016/comments/page/1/#comments>.

Posted by: AnonHiringChair²²

There are a number of practical problems with using the *U.S. News & World Report* rankings of law schools to rank the journals they publish.²³ First, the method simply cannot account for journals that are not affiliated with a law school. Examples of such journals include the *Journal of Legal Education*, a publication of the Association of American Law Schools, and the *Federal Courts Law Review*, a publication of the Federal Magistrate Judges Association.

Second, the law school rankings of *U.S. News & World Report* do not take into account the quality of the journals that the law schools publish. Rather, the magazine ranks law schools based on factors such as peer assessments, selectivity, and success in job placement of graduating students.²⁴ That the *U.S. News & World Report* ranks schools without a consideration of journal quality is well understandable; after all, the magazine is publishing the rankings for prospective students to decide which school to attend.²⁵ However, by using the *U.S. News & World Report* rankings of law schools to rank journals, legal academics are taking the rankings far beyond their intended use and essentially are ranking journals based on factors that have little to do with the journals themselves.

Legal scholars are virtually unique in ranking journals in such a way. Scientists, for example, have their own disagreements about how to rank journals; the predominant method of using journal impact factors published by Thomson Reuters is particularly controversial.²⁶ Nonetheless, journal impact factors are still based on counts of citations to articles within the journals.²⁷ Whether or not

22. AnonHiringChair, *Submission Angsting Fall 2016*, PRAWFSBLAWG (Aug. 23, 2016, 9:39 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/07/submission-angsting-fall-2016/comments/page/4/#comments>.

23. *Best Law Schools Ranked in 2017*, U.S. NEWS & WORLD REPORT, <https://www.usnews.com/best-graduate-schools/top-law-schools/law-rankings> (last visited Sept. 6, 2017).

24. Morse, *supra* note 18.

25. U.S. NEWS & WORLD REPORT, *supra* note 23 (introducing the rankings with these two sentences: "A career in law starts with finding the school that fits you best. With the U.S. News rankings of the top law schools, narrow your search by location, tuition, school size and test scores.")

26. Ewen Callaway, *Beat It, Impact Factor! Publishing Elite Turns Against Controversial Metric*, NATURE (July 12, 2016), <http://www.nature.com/news/beat-it-impact-factor-publishing-elite-turns-against-controversial-metric-1.20224>. The journal impact factors are made available at present by Thomson Reuters through a service called the Journal Citation Reports. While the reader would not be able to access the rankings without a subscription, the reader can get a sense of what the service is about by browsing through its website at <http://about.jcr.incites.thomsonreuters.com/>.

27. Eugene Garfield, *The Clarivate Analytics Impact Factor*, CLARIVATE ANALYTICS, <http://wokinfo.com/essays/impact-factor/> (last visited Sept. 6, 2017) ("The impact factor is one

citation count is a fair reflection of the journal's quality is certainly debatable, but the count is undoubtedly an attribute of the journals themselves. The same could not be said of ranking law journals based on the *U.S. News & World Report* law school rankings.

There do exist journal ranking systems within the law review system that take into account the attributes of the journals. For example, the law library of Washington and Lee University School of Law maintains a system that ranks law journals by citation counts and impact factor.²⁸ Likewise, Google Scholar produces a ranking of journals based on the number of citations.²⁹ However, these systems have not gained the popularity of the method of using the *U.S. News & World Report* rankings of law schools to rank the journals they publish.³⁰

The best and most convincing explanation for this behavior of legal scholars is laziness. As a scholar noted on PrawfsBlawg:

Here's my thoughts—always go with U.S. News. The reason is that people reviewing your CV tend to have an idea of where that journal's school is ranked; nobody walks around with encyclopedic knowledge of W&L rankings, nor will most take the time to look it up. For instance, W&L ranks Lewis and Clark as #40 (USNEWS ranking = 92) and Alabama as #41 (USNEWS ranking = 28). NOBODY would consider a L&C placement as even comparable to an Alabama placement, much less superior.³¹

If you're someone who is publishing in hopes of getting hired into a tenure track position, please don't fool yourself into thinking that those who will be evaluating your candidacy will spend the time asking themselves, of the journals you've published in, how widely read they are and whether

of these; it is a measure of the frequency with which the 'average article' in a journal has been cited in a particular year or period.”)

28. *Law Journals: Submissions and Ranking Explained*, WASHINGTON AND LEE UNIV. LAW SCH. OF LAW LAW LIBRARY, <http://lawlib.wlu.edu/LJ/method.asp> (last visited Dec. 7, 2016).

29. Robert Anderson, *Google Law Review Rankings 2015*, WITNESSETH: LAW, DEALS, & DATA (Feb. 15, 2016), <http://witnesseth.typepad.com/blog/2016/02/google-law-review-rankings-2015.html>.

30. Galle, *supra* note 4, at 8 (“Q: U.S. News rankings or Washington & Lee rankings? A: U.S. News peer reputation score. Q: Really? People don't care about Washington & Lee? A: I mean, W&L itself has several different rankings systems. Who could possibly keep track of which journal is ranked where in which ranking?”).

31. AnonProf, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 18, 2017, 1:55 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/6/#comments>.

that journal typically publishes “good” articles. Instead, it’ll be a relatively snap judgement of 1) have I heard of this journal before and 2) how well regarded is the school to which it is attached.³²

Legal scholars are already well-versed in the law school rankings of the *U.S. News & World Report*. To use alternative rankings to judge the quality of the journals, they would need to take the actual effort to look up these alternative rankings. In contrast, it is a trivial exercise to discern from the name of a law journal which law school published the journal and then to apply the *U.S. News & World Report* ranking of the law school to rank the journal.

C. *Player Strategy within the Law Review System*

Legal scholars have converged on a strategy to deal with the law review system: submission by saturation, and then work up the rankings using the expedite system. Here is a description provided by Galle:

The game is that one first submits to a very large number of journals. After receiving an initial offer, one then send[s] requests for expedited review to journals that you prefer to the offering journal, but which are not far, far, higher ranked than the offering journal. A typical heuristic is to expedite to the next 50 or so higher-ranked journals. One then hopes for another offer from that grouping, and then sends news of the two offers to the next 50. And so on, potentially.³³

As far as this author can tell, players have arrived at this strategy by experience and not by actual analysis. It is one aim of this article to explain why saturation submission exists.

That each submission costs \$5 or \$6.50 means that saturation submission can be costly to implement, particularly for junior scholars unaffiliated with an institution who cannot rely on an institutional account and have to pay out of their own pockets. Some authors simply cannot afford this strategy at all. It is another aim of

32. AnonProf, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 18, 2017, 2:36 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/6/#comments>.

33. Galle, *supra* note 4, at 5.

this article to broadly explain the negative impact of authors' financial constraints on their article placements.

III. THE IDEALIZED LAW REVIEW SYSTEM

To understand which part of the real-world law review system results in the strategies and outcomes we empirically observe, we begin by analyzing an idealized law review system.

A. *Properties of the Idealized System*

To simplify our analysis, we will assume a universe of 100 journals. All will be assumed to be “flagship” journals; we will ignore the complexity of “niche” journals. Of these 100, we will assume that the *U.S. News & World Report* rankings govern preferences for publication offers. To make the numbers easier to interpret, we will assume that the submission fee is the old, round figure of \$5 instead of the new, increased cost of \$6.50.

As in real life, the top 3 journals will be assumed not to charge a submission fee.³⁴ Of the other 97, 10 others will be assumed to be willing to accept articles by email; that is, they have an avenue for submission without fees. These 13 journals will be collectively referred to as the “free journals” and their ranks are assumed to be evenly distributed throughout the ranking spectrum.³⁵ All others are assumed to accept articles exclusively through Scholastica.

We will further assume that there actually exists an objective grading of articles as deserving of a journal of a particular rank. In other words, we will assume that it is possible to say, “this article is worthy of *The University of Chicago Law Review*.” In the real world, it is difficult to assign such grades or even to ascertain what factors should govern the grading. But we intuitively do know that some articles deserve to be placed in journals of higher rank than others, so this assumption is not overly unrealistic. We will also

34. *Yale Law Journal*, *Harvard Law Review*, and *Stanford Law Review* have their proprietary submissions systems that do not require a charge.

35. We make the assumption that the free journals are evenly distributed throughout the ranking spectrum because it preserves a translational symmetry. In other words, the handicap to an article resulting from the author's financial constraints is the same whether the article merits to be published in the journal ranked 34 or the journal ranked 72. But in reality, as of spring of 2017, there are 40 journals that accept articles exclusively through Scholastica. Of these, 35 are in the top 50, based on the *U.S. News & World Report* rankings. This concentration of journals that demand submission fees on the higher end of the ranking scale implies that, the better an article, the greater the disadvantage resulting from financial constraints.

assume that authors will accept the highest-ranked journal that accepts their articles.³⁶

Finally, we will assume that journals have perfect judgment about article merit relative to their ranks and have an infinite capacity to accept articles worthy of their ranks. We will return to these last two assumptions in a subsequent discussion.

B. Scholars with Infinite Resources

At one extreme are the scholars with an infinite amount of resources. These could include, for example, well-entrenched professors who can call upon secretaries to manage article submissions and cover letter preparations as well as charge the Scholastica fees to research accounts. They would also include law firm partners who can impose the drudge work on associates and bill the costs to “business development.”

For these individuals, the marginal cost of an article submission is basically zero.³⁷ However, for them, there is always a positive marginal benefit to article submission because they stand a better chance at a higher journal placement with another submission.³⁸

These incentives govern their submission strategy. Because the marginal benefits to an article submission always exceed the marginal costs, in practical terms, these individuals will submit their articles to every journal in existence. When they receive offers for publication, they will use the offers to expedite review at higher-ranked journals.

In our idealized system, the net amount these individuals spend would be \$5 for each of the 87 journals that requires a submission fee, totaling \$435. In real life, these individuals would hardly bother themselves with the more troublesome avenue of submitting to the free journals by emails rather than through Scholastica, which would result in a net amount spent closer to \$500.³⁹

36. This assumption may not hold true in real-life. For more, see *infra* note 58 and accompanying text and Cicchini, *supra* note 8.

37. In layman’s terms, the marginal cost is the value of what one would have to give up in order to obtain an additional unit. Because the law firm partners and professors have some other entity to pay for their submissions, they do not really give up any value in submitting one more article and so the marginal cost of an article submission for them is basically zero. Of course, the marginal cost to the entity actually paying for the submission is not zero.

38. The marginal benefit is the value of what one would give up to acquire an additional unit. The point at which people would stop acquiring units would be the point at which marginal cost is equal to the marginal benefit.

39. Scholastica essentially allows authors to select a number of journals into a “shopping cart” and mass submit one article to all the journals in the cart at once. This is, obviously, more convenient than submitting articles to journals one-by-one. The interactive system of

These individuals can be assured that their articles will receive the placement they deserve. Situations may arise where, by overplaying their hand, they spoil their article placement. For example, an author can face the problem where a higher-ranked journal refuses to consider her article before the deadline of a publication offer extended by a lower-ranked journal, and the author, being overconfident, turns down the lower-ranked journal only to find the work rejected by the higher-ranked journal. But in general, no one is in a better position to claim the rightful placement for his or her work than these well-resourced scholars.

C. Scholars with Very Limited Resources

At the other extreme are the scholars with very few resources. Examples of such individuals include those who are in the faculty job market or in government employment who have to pay the submission fees out of their own pockets.

As a simplification, we will first consider those who are completely cash-strapped. The strategy of these poorly-resourced scholars is easy enough to predict. They will submit their articles to all the free journals.⁴⁰ Because they have no money to spend, they will stop at this step and accept the best offer they have.

The placement of the articles these individuals produce relative to the intrinsic merit of the articles is heavily dependent on the distribution of free journals in the journal hierarchy. Let us assume, for example, that a completely cash-strapped individual has an article worthy of placement in the journal ranked 34. In an even distribution of free journals across the hierarchy, say, the journals ranked 30 and 40 are free, the individual may be able to place her article in a journal ranked 40. It is a slight dent, not entirely damaging, to the placement. However, if there is a big gap in the rankings between the free journals, say, the journals ranked 30 and 60 are the two free journals closest in rank, then this author would be

Scholastica is best appreciated by directly testing it out, but a written description can be found at <https://blog.scholasticahq.com/post/announcing-improved-law-review-article-submission-on-scholastica/>.

40. This analysis ignores the transaction costs associated with free submissions which further complicate the problem for poorly-resourced scholars. First, submission by email relative to Scholastica entails a much larger investment of time. Second, the journals that accept submissions by email often openly state their preference for submissions through Scholastica. See, e.g., *Submissions*, PEPPERDINE LAW REVIEW, <http://pepperdinelawreview.com/submit/> (last visited Feb. 6, 2017) (“Although submission via email or U.S. mail to the addresses below is acceptable, we strongly prefer submissions via Scholastica.”). All of the uncertainty and effort associated with free submissions constitute transaction costs. Still, we would have to imagine that most poorly-resourced scholars would not opt for Scholastica over email; after all, a \$5 submission fee per journal adds up very, very quickly.

forced to publish in the journal ranked 60. That is a massive drop in placement.

D. Scholars in Between the Two Extremes

Most scholars, we would think, will likely fall somewhere in between the two extremes of the infinitely-resourced and the completely cash-strapped. For example, these authors may have a \$100 budget to spend as opposed to \$435 at one extreme and \$0 at the other. And this is where the considerations for article placement become most complex and interesting.

A simple analysis would suggest that these authors would adopt a strategy between those used by persons at the two extremes. That is, these authors should try to use the \$100 to submit to 20 journals, which, added to the 13 free journals, tallies to submissions to 33 journals within the entire pool of 100. They would attempt to evenly spread out the distribution of these 33 submissions, that is, one submission for every 3 ranks, so as to best approximate the spectrum of the 100 journals.

To that end, with \$100, they can cover roughly one-third of the journals considered in the idealized system. That would seem like a fair amount of coverage and will seem to guarantee that the article will not be published in a journal significantly lower than where it deserves to be.⁴¹

As we can see, even this idealized system rewards the saturation submission strategy, although the benefits are not significant. The situation changes completely when we consider other realities of the law review system.

IV. ADDING REALISTIC CONSTRAINTS TO THE IDEALIZED SYSTEM

A. No Journal Accepts All Articles Deserving of Its Rank

In reality, no journal accepts all articles that deserve to be published in it. A large number of reasons, many of which are legitimate, govern these considerations. For example, a journal may not be interested in the subject matter of a well-deserving article at a particular time. A journal may also have already accepted all of the articles it could accept for a particular submission season.

41. Because they submit to one journal in every three ranks, these authors would place their articles in journals at most two ranks below where their articles deserve to be.

The key effect of this resource constraint is to turn the idealized system from deterministic to probabilistic.⁴² An author has some chance of being published in a higher-ranked journal than his article merits, for example, if there were not enough better articles to fill the higher-ranked journal. Alternatively, in the more likely case, the abundance of higher-quality articles may create an overflow of articles in higher-ranked journals and push his article to a lower placement than where it actually deserves to be placed.

The precise effect of the resource constraint is dependent on the number of articles in the system, the distribution in the quality of these articles, and the specific submission strategies of each author. But still, even with the resource constraint, the probability of having an article accepted in a lower-ranked journal is never lower than that of having an article accepted in a higher-ranked journal. In other words:

$$Probability_{acceptance}(lower-ranked) \geq Probability_{acceptance}(higher-ranked)$$

This insight allows us to construct a simple test. Let us assume there were multiple authors who produced articles worthy of placement in the journal ranked 34. Let us assume also that all the journals ranked in the 30's are full, but one journal ranked in the 40's, two journals ranked in the 50's, three journals ranked in the 60's, etc., will accept these articles.

In this situation, the author who could submit to all 100 journals may not be able to place her article in the journal ranked 34, even though that is where her article deserves to be published. However, because she submits her article to all the journals, she will be able to publish in that one journal ranked in the 40's that would accept her article.

As stated above, the author with a \$100 budget can submit to only one-third of the available journals. This essentially means that he can submit to every third journal according to the rankings. As a simplification, this author can submit to three journals in each decile. To be published in the journal ranked in the 40's that will accept his article, it becomes a question of probability whether he picked the correct journal with his three submissions within that decile.

Without a full explanation of the mathematics, we have tabulated the probabilities of acceptance at every decile for authors who can

42. A deterministic system, unlike a probabilistic system, is one in which there is no randomness involved in determining the outcome.

only afford: (A) three submissions for every decile; (B) two submissions for every decile; and (C) one submission for every decile. Example calculations are provided in the footnotes.

Journal Rank	Number of Journals Accepting Article	3 Submissions Every Decile			2 Submissions Every Decile			1 Submission Every Decile		
		Probability of Not Getting Any Acceptance at This Decile	Probability of Getting an Acceptance at This Decile	Probability of Article Acceptance at This Decile and Above	Probability of Not Getting Any Acceptance at This Decile	Probability of Getting an Acceptance at This Decile	Probability of Article Acceptance at This Decile and Above	Probability of Not Getting Any Acceptance at This Decile	Probability of Getting an Acceptance at This Decile	Probability of Article Acceptance at This Decile and Above
41-50	1	0.70	0.30	0.30	0.80	0.20	0.20	0.90	0.10	0.10
51-60	2	0.47	0.53	0.67	0.62	0.38	0.50	0.80	0.20	0.28
61-70	3	0.29 ⁴³	0.71 ⁴⁴	0.90 ⁴⁵	0.47	0.53	0.77	0.70	0.30	0.50
71-80	4	0.17	0.83	0.98	0.33	0.67	0.92	0.60	0.40	0.70
81-90	5	0.08	0.92	1.00	0.22	0.78	0.98	0.50	0.50	0.85
91-100	6	0.03	0.97	1.00	0.13	0.87	1.00	0.40	0.60	0.94

Table 1: Probabilities of Acceptances for Different Submission Frequencies

The expected rank of the placement is a probability-weighted average,⁴⁶ which we can tabulate as follows:

43. There are three journals in this decile willing to accept the article, and the author has three submissions within this decile. There are seven journals within this decile which will not accept the article, so the probability of the first of these three submissions not being accepted is 7/10. For the second of these three submissions, there are only six out of nine journals which will not accept the article. Accordingly, the probability of rejection decreases to 6/9. The overall probability of no journal within this decile accepting the article is: $\frac{7}{10} \times \frac{6}{9} \times \frac{5}{8} = 0.29$.

44. This is simply 1 minus the probability of no journal accepting the article in this decile, so: $1 - 0.29 = 0.71$.

45. The probability of the article being accepted in the 60's without being accepted in any journal ranked above is: $0.70 \times 0.47 \times 0.71 = 0.23$. The probability of the article being accepted in any journal ranked in the 60's and above is therefore: $0.23 + 0.67 = 0.90$.

46. The precise formula is:

$$Expected Rank = 100 - \sum (Probability_{placement}(rank) \times (100 - rank))$$

	Saturation Submission	3 Submissions Every Decile	2 Submissions Every Decile	1 Submission Every Decile
Expected Journal Rank of Article	45	56 ⁴⁷	61	71

Table 2: Expected Placement for Different Submission Frequencies

Even in this simple system, the penalty in journal rank is steep for those who cannot afford saturation submission. The author who spends \$100 versus \$435 places 11 ranks lower. If the acceptance statistics are more stringent, say, 0.5 acceptances in the 40's, 1 in the 50's, 1.5 in the 60's, etc., the penalty would be even harsher.⁴⁸

However, there is a bigger problem still for the poorly-resourced authors.

B. Acceptance Statistics Lack a Good Match with Journal Rank

As stated, even with the resource constraint:

$$Probability_{acceptance}(lower-ranked) \geq Probability_{acceptance}(higher-ranked)$$

Intuitively, we would think that it should be easier to place in a lower-ranked journal than in a higher-ranked journal and that the probabilities should so reflect. But is that true?

Available data on how articles placed in high-ranked journals fared in lower-ranked journals is rare,⁴⁹ but some can be found on the "Submission Angsting Spring 2016" thread of PrawfsBlawg.⁵⁰ A small number of scholars have reported acceptance and rejection

It is necessary to subtract the rank from 100 and then subtract the ultimate sum from 100 because the ranking system is inverted from actual preference. For example, it is more preferable to be published in a journal ranked 40 rather than a journal ranked 90. The subtraction corrects for this artificial inversion.

47. This figure is tabulated using the formula stated in footnote 46 and using the numbers in Table 1 as follows: $100 - (45 \times 0.30 + 55 \times (0.67 - 0.30) + 65 \times (0.90 - 0.67) + 75 \times (0.98 - 0.90) + 85 \times (1.00 - 0.98) + 95 \times (1.00 - 1.00)) = 56.34 \cong 56$.

48. The reader can calculate the penalty using the example calculations provided in Table 1 and Table 2. Under this new distribution, the expected journal rank for the author who spends \$100 versus \$435 is 65, that is, 20 ranks lower.

49. Authors generally withdraw submissions to lower-ranked journals after receiving offers for publication from higher-ranked journals. Accordingly, there will always be little data on whether lower-ranked journals would have accepted articles placed in higher-ranked journals.

50. *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 2, 2016), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016.html>.

statistics, which, although probably incomplete, is sufficient for our analysis here.

The data from four of the most prolific reporters is presented below:

Journal Rank	"Taking Care of Business"		"Magnolia"		"Bartok"		"Abominable Snowman in the Market"	
	Acceptances	Rejections	Acceptances	Rejections	Acceptances	Rejections	Acceptances	Rejections
1-10		****		*****		*****		*****
11-20		**		*****	*	***		*****
21-30		***		****	*		*	
31-40		*****		***		***		***
41-50		***	*			*		*
51-60		**		*				
61-70	*	**		**				
71-80	*	*	*					
81-90		*						
91-100		**		*				

Table 3: Statistics from "Submission Angsting Spring 2016" Thread of PrawfsBlawg

There appears to be very little correlation between journal ranking and acceptance. The highest-ranked journal that accepted "Taking Care of Business"'s article was ranked 65. The same article was also accepted by the journal ranked 74. However, the article was also rejected by journals ranked 65 (x2),⁵¹ 72, 82, 97, and 100.

51. There were 7 law schools ranked 65. Michael Spivey, *USNWR Schools Ranked 1-100*, SPIVEY CONSULTING (Mar. 9, 2016), <http://blog.spiveyconsulting.com/usnwr-schools-ranked-1-50-now-with-from-last-year/>. "Taking Care of Business" reported submitting to 3 journals from these 7 schools.

“Magnolia” had his or her article accepted at the journal ranked 45. The article was also accepted at the journal ranked 72. However, the article was rejected at journals ranked 55, 65 (x2), and 100.

“Bartok” and “Abominable Snowman in the Market” are particularly worth comparing. Both reported acceptance at the same journal ranked 22. “Bartok” also reported acceptance at the journal ranked 20; however, he or she reported rejections at journals ranked 33 (x2), 37, and 55 and no other acceptances from journals ranked below 22. “Abominable Snowman in the Market” apparently only had one acceptance; his or her article was rejected at journals ranked 33, 38, 48, and 55.

Accordingly, these data, incomplete though they are, suggest that this equation may not hold true in the real world:

$$Probability_{acceptance}(lower-ranked) \geq Probability_{acceptance}(higher-ranked)$$

There are two possible causes. First, journals may not be very good at judging the merit of articles relative to their ranks, or they simply may not judge articles based on their ranks at all. Second, journal acceptances may be clustered around particular deciles or, in other words, journals ranked below where the articles deserve to be published have a tendency to reject the articles. For example, we can observe that “Taking Care of Business” received acceptances from journals ranked in the 61–80 range but found rejections in the journals ranked below 80.

There are simply not enough data to support either one conclusion or the other, although we have reason to be skeptical of the second. For lower-ranked journals to reject articles that are, for all intents and purposes, “too good” for them to publish essentially requires journals to have an extremely good grasp of the quality of articles they can realistically hope to publish. However, law journals have a yearly turnover of staff, so it is difficult for them to retain an institutional knowledge about which of their offers to publish will be accepted.⁵² Also, while we are not privy to the discussion in the editorial offices of lower-ranked journals, it seems implausible that student editors would vote to reject articles on the ground

52. The policy of *Duquesne Law Review* about how the journal takes on members every year can be found at <http://www.duqlawblogs.org/lawreview/membership/>. The process utilized by *Duquesne Law Review* is typical.

that articles were “too good.”⁵³ Moreover, lower-ranked journals can always count on higher-ranked journals not to accept all of the best articles; rejecting articles “too good” for them would mean publishing inferior articles overall.

Regardless, either possibility is bad news for poorly-resourced authors. If journals do not accept articles in accordance with their ranks, then the system approaches randomness. The best strategy for obtaining a good placement for any particular article will be complete and total saturation submission.

The best strategy for dealing with clustered acceptances is also saturation submission. After all, authors do not know which journals their articles would qualify for.⁵⁴ It is only after they have received acceptances that they know generally where their articles could place. Because of this lack of knowledge, the authors have to treat the law review system as completely random even if it is not.

Without more data allowing for some characterization of the distribution of acceptances across the journal hierarchy, it is not possible to estimate the harm to the poorly-resourced. What can be said is that the harm from the lack of correlation between article merit and acceptance is even greater than the harm from the inability of journals to publish all meritorious articles.⁵⁵

C. Implications of the Real-World Law Review System

The definition of marketization is the exposure of a system to market forces.⁵⁶ The above discussion demonstrates that the addition of the two realistic constraints results in the marketization of the idealized law review system because they magnify the reward in article placement for those who can pay more.

To that end, it must be noted that the idealized law review system, even with the two realistic constraints, is still not fully marketized. The system naturally imposes a ceiling in spending; there are only 100 journals in the system. There is therefore a maximum number of submissions and a maximum amount of submission fees.

53. It should be noted that there is some indication that lower-ranked law journals do reject articles from authors affiliated with higher-ranked schools. The question of how author credentials and article quality relate to one another is a controversy that is beyond the scope of this article.

54. If authors knew how their articles would place ahead of time, they would be able to work to improve their articles to achieve a higher placement.

55. The reader is invited to try the tabulation of Table 1 and Table 2 using the example calculations but with different probability assumptions, for example, one acceptance in the 40's, zero in the 50's, two in the 60's, etc.

56. *Marketization*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/marketization> (last visited Sept. 6, 2017).

Once a particular legal scholar pays for saturation submission, he or she joins an elite group that is immune from market forces. This upper limit preserves a meritocracy, but only for scholars who participate in saturation submission.

Do these market dynamics apply in the real-world law review system? In the real-world, there are far more than 100 journals. In theory, given the many hundreds of journals to submit to, there is complete and total marketization. Nonetheless, from a practical point of view, there is a limited number of journals that “matter” to legal scholars. It is worthwhile to consider this dialogue on PrawfsBlawg:

I’ve got an offer that expires today from a journal which is just . . . ok. . . . I can’t decide whether it is madness at this point in the cycle to turn down the only firm offer I have in favor of hopefully placing somewhere better. As background, I’m in a good—but temporary—teaching job now, and plan to go on the market this fall. I’m already published, but nowhere particularly impressive. Any thoughts or advice would be greatly appreciated. (And any more insight into AnonProf’s list of journals that are “going to hurt you,” would be welcome, too!)

Posted by: ALurkerNoLonger⁵⁷

What will “hurt you” is entirely relative. If you are already published, the question I would ask is whether the current offer is from a journal appreciably higher ranked than your previous placement(s). If no, I would let the offer lapse (after attempting to negotiate an extension, of course). Adding yet another publication at a similar rank will not add much to your candidacy (in part because the expected placement of a listed “work in progress” will be roughly that).

Posted by: anon⁵⁸

57. ALurkerNoLonger, *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 25, 2016, 9:26 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/5/#comments>. For more on this subject, see Cicchini, *supra* note 8.

58. anon, *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 25, 2016, 9:35 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/5/#comments>. For more on this subject, see Cicchini, *supra* note 8.

In terms of what will “hurt you,” I would stay away from any journal whose school is unaccredited or ranked in the fourth tier. I also wouldn’t publish in a specialty at any school not in the top 10 (unless that journal just happens to have a particularly great reputation . . .), and I also wouldn’t publish in a specialty [sic] journal that’s less than five years in existence. In short, I would aim for at least a top 100 general placement.

Posted by: AnonProf⁵⁹

At the outset, it is a horrendous distortion of academic values that publication in lowly-ranked journals is considered *harmful* to scholarly careers. It also runs contrary to any pedagogic principle to have lowly-ranked journals discussed as if they were pornographic publications, to have real-world, good faith student editors at lowly-ranked schools treated as the *dalit* of law students. There are many reasons why students end up in law schools ranked below 100 on the *U.S. News & World Report*, but their inability to pick good articles for publication and to “*Bluebook*” and cite-check law review articles are unlikely to be among the top reasons.

But however distasteful it is, the dialogue reflects the belief and practice within the legal academia, which we must accept in any empirical discussion about the matter. And we can infer that, in practice, there is a limited number of journals that scholars want to publish in; the total number of journals in the entire real-life law review system may be irrelevant. The assumption of 100 journals in the idealized system may be a bit restrictive, but, based on the above-cited comments from PrawfsBlawg, the number is not an unreasonable estimate of the number of journals that “matter.”

Accordingly, we can conclude that the dual-track market dynamics predicted in the idealized system may exist in real-life. And, to that end, legal scholars must wrestle with the idea that, unlike any other academic discipline, their publication system is a market which rewards the maximum payment of submission fees. In the United States, we generally accept the idea that those with more money can buy and get more. But when is this advantage too much? Perhaps we may find it acceptable that authors with only \$100 to spend on submissions be published in journals 10 ranks below where they could have published had they \$300 to spend. But what

59. AnonProf, *Submission Angsting Spring 2016*, PRAWFSBLAWG (Feb. 25, 2016, 9:44 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/02/submission-angsting-spring-2016/comments/page/5/#comments>. For more on this subject, see Cicchini, *supra* note 8.

if the disadvantage results in a 50 rank drop? At what point does the correlation between the size of budgets for article submission and the resulting placement of articles interfere with the overall aims of the academic community, which, presumably, are not related to the amount of money an author can spend?

It is also important to consider the identity of the players in the real-world law review system. As stated above, those who can best afford saturation submission are professors or law firm partners who can expense the submission fees. These are, for lack of a better word, the “insiders” among the legal scholars.⁶⁰ Those who are least likely to afford saturation submission, in contrast, are those who are on the faculty job market or in government employment and have to pay the fees out of their own pockets. These “outsiders” are the ones subjected to the marketization of the law review system while the “insiders” are not.

The disparate impact of marketization on “outsiders” and “insiders” has very serious practical implications for legal scholarship. First, the quality of the population of “insiders” relies on the success of “outsiders” in the law review system. After all, it is the “outsiders” who join the “insiders” through the faculty job market. To the extent that the “outsiders” who succeed in the job market are those who have more publications in the higher-ranked journals, we must be troubled by the idea that success in the law review system is at least in part a factor of the ability and willingness to spend on submission fees.

We must also note that purchasing success in the law journals is not cheap. The recent tightening of the faculty job market has resulted in the need for applicants to have longer publication records to succeed in their job search. It is difficult to ascertain exactly how

60. As extensively documented by Cicchini, some of these “insiders” have the practice of submitting to lower-ranked journals even when they have no intention of ever accepting any offer of publication from these journals. Cicchini, *supra* note 8. These scholars merely use acceptances by lower-ranked journals as a basis for expedites to higher-ranked journals or as a way to experiment with placement. If they end up with a placement they do not like, they revise and submit the article again the next submission season. See, e.g., Magnolia, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 26, 2017, 4:12 AM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/10/#comments> (“If you hope to go on the market soon, do not chop off 1–39. I would actually recommend chopping off dozens at the lower end of things, and if the article isnt picked up thats [sic] a sign you should get more comments and revise the piece. . . . In terms of timing, I submitted 3/1 last year and received two offers in top 60 and top 35 range. I decided to revise the piece, and I resubmitted 8/29 and received a top 20 offer 6 days later with no other offers, thus no expedites.”). It is obvious that this submission practice can easily multiply the costs of submissions. It is unclear how widespread and successful this practice of resubmission is, but, if such methods were broadly and successfully used by those whose submissions are subsidized, the impact of article placement would be even more highly affected by the size of the budgets for submissions.

many articles are needed to secure a job, but it is not too difficult to imagine that applicants may need to risk several thousand dollars on submission fees to have a chance at success in their job search. What kind of person can risk this type of money in such a manner? And what would happen to legal scholarship as a whole if such persons predominate in the faculty job market?

Second, that the law review system would punish “outsiders” is effectively a statement that “outsiders” do not provide valuable contributions to legal scholarship. But that certainly cannot be true with respect to the applicants for faculty jobs.⁶¹ After all, these “outsiders” are specifically evaluated based on their potential for contribution to legal scholarship, which is judged from their existing contribution. It would be a contradiction of the premise of the faculty job market to treat these “outsiders” as incapable of good legal scholarship.

But even outside of the subset of legal scholars who are in academia or who seek to be in academia, judges as well as lawyers working in government, in public interest organizations, and in law firms can benefit and advance the state of legal scholarship.⁶² By being in practice, they are best placed to comment about the practice. It should be a matter of concern that the real-life law review system is systematically biased against the better placement of articles from practitioners by the imposition of significant, personal financial barriers to article submission.⁶³

61. The phenomenon known as “letterhead bias” further disadvantages the “outsiders.” Letterhead bias is the preference among student editors for articles written by law professors, who are, of course, among the “insiders.” It is unclear how widespread and how strong this bias is among the editors of the various law reviews. It certainly exists to the extent that some law journals make their bias explicit within their submissions policy. See, e.g., *Submissions*, U. LOUISVILLE L. REV., <http://www.louisvillelawreview.org/submissions> (last visited Feb. 6, 2017) (“Except under unusual circumstances, it also is the policy of the [*University of Louisville*] *Law Review* not to publish articles . . . that have been authored by someone other than a full-time law faculty member at an American Bar Association accredited law school.”).

62. Presumably, those who work in law firms are better paid and can better afford the fees required for saturation submission, even if they were not law firm partners who could expense the fees altogether.

63. See YesterdayIKilledAMammoth, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Feb. 17, 2017, 12:27 PM), <http://prawfsblawg.blogspot.com/2017/02/submission-angsting-spring-2017/comments/page/5/#comments> (“I think that the Scholastica price hike is a pretty good indicator that law reviews subs are becoming a closed game. Pretty soon, practitioners, clerks and profs from lower-ranked schools that don’t have much institutional support won’t be able to afford to submit as widely as they need to. This at the time when the academy is wringing its hands over being too far removed from the actual practice of law.”).

V. SOME CONCLUDING THOUGHTS AND PROPOSALS

Legal scholars have basically intuited that they should resort to saturation submission to deal with the law review system. This article explains that this is indeed the correct strategy because more submissions help ensure a higher placement.

However, this article goes further and identifies two realities that result in harm for poorly-resourced authors. First, not all journals accept all articles that deserve to be accepted. Second, journal rankings do not seem to be strongly correlated to the merit of the articles.

The first is a simple fact of life. No journal can accept all articles of any given merit level commensurate to its rank. The second observation, however, suggests that the existing system may be unfair. Moreover, it does potentially suggest that the negative impact of the peculiarities of the system on poorly-resourced authors can be rectified by changing how articles are reviewed. There have been numerous proposals, such as the institution of peer review, which have been thoroughly discussed elsewhere.⁶⁴ This article does not intend to add to that discussion.

But to the extent that these two problems cannot be fixed, the fairness of the system can be improved by democratizing the availability of saturation submission tactics. For example, instead of charging authors for each article submitted to each journal, the system could be changed to charge authors upon publication.⁶⁵ Charging authors upon publication allows them to submit to as many journals as they wish, so long as they can afford the publication fees, and opens up the availability of saturation submission to all authors.

Opening saturation submission to all authors, however, means that all journals have to review more articles. From personal experience as an articles editor, this author can say with certainty that journals are already overburdened with article submissions. The deficiencies of the system cannot be practically remedied by making reviewing articles more difficult than it already is.

Alternatively, the system can be structured to punish saturation submission. One way to do so is to increase the fees for additional submissions. *Scholastica* at present charges \$6.50 for every article

64. See, e.g., Posner, *supra* note 7 (“Ideally, one would like to see the law schools ‘take back’ their law reviews, assigning editorial responsibilities to members of the faculty.”).

65. This is a common practice in physics journals. See, e.g., *Publication Charges and Reprints for Physical Review Letters*, AM. PHYSICAL SOC’Y (Jan. 2017), <http://journals.aps.org/authors/publication-charges-physical-review-letters>.

submitted to a journal. The formula can be changed so that it costs \$4 per submission for the first 10 submissions, \$5 for the next 10, \$6 for the next 10, etc., until the 100th submission costs \$13. Punishing saturation submission would not solve the fundamental arbitrariness inherent to journal acceptance, but, to the extent it would stop authors from submitting to any and all journals in existence, it would mean that negative effects of such arbitrariness are borne by all authors and not just those who are poorly-resourced.

An interesting and particularly welcome development to that end is the increase in the number of journals offering an exclusive submission track, under which authors agree to exclusively submit their articles for a set period of time in exchange for an expedited, but binding, decision on publication.⁶⁶ The exact motivation for this trend is not clear,⁶⁷ but it is of significance that these journals accept articles through free avenues. These exclusive submission tracks help restore some sense of balance between the poorly-resourced scholars and the infinitely-resourced because they allow free and open access to all scholars and they impose some costs on scholars who engage in saturation submission.

One other beneficial fix to the system would be to strengthen the relationship between journal acceptance and journal rank:

$$Probability_{acceptance}(lower-ranked) \geq Probability_{acceptance}(higher-ranked)$$

A way to do so is to implement a system, within Scholastica, that allows lower-ranked journals to reject articles for higher-ranked

66. Journals offering an exclusive submission track this season include *Northwestern University Law Review*, *Buffalo Law Review*, and this law journal. *Print Submissions*, NW. U. L. REV., <http://www.northwesternlawreview.org/submissions> (last visited Feb. 6, 2017); Ari Goldberg, *Buffalo Law Review—Volume 65 Exclusive Submission Track*, SCHOLASTICA (Jan. 30, 2017), <https://submissions.scholasticahq.com/conversation/questions/buffalo-law-review-volume-65-exclusive-submission-track>; Alfred Brophy, *Duquesne Law Review: Exclusive Submission Window*, THE FACULTY LOUNGE (Jan. 10, 2017, 4:18 PM), <http://www.thefacultyounge.org/2017/01/duquesne-law-review-exclusive-submission-window.html>.

67. It has been speculated that this change is a result of journals becoming “tired of being screeners for [higher-ranked journals],” who “[use] this to lock down a few top authors who either don’t want to play the game or need something published fast.” YesterdayIKilledAMammoth, *Northwestern Law Review Exclusive Submissions*, PRAWFSBLAWG (Dec. 29, 2016, 11:12 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2016/12/northwestern-law-review-exclusive-submissions.html#comments>. The problem with higher-ranked law journals using lower-ranked ones as a screen is a well-recognized evil within the law review system. Galle, *supra* note 4, at 5. A full discussion of this subject matter is beyond the scope of this article.

journals.⁶⁸ Journal editors can be presented with these options when rejecting an article: (1) the article is unacceptable at this journal and at a journal of higher rank; (2) this article is acceptable but not of interest to this journal at this time; or (3) no opinion. When there is more than one rejection on ground (1), an article can be automatically rejected by Scholastica at all journals ranked higher than the highest-ranked journal which has rejected an article on ground (1). For example, if the journal ranked 34 and 18 rejected an article on ground (1), then that article is automatically rejected at all journals ranked 18 and higher.⁶⁹ Such a system would help ensure that the probability of acceptance at higher-ranked journals would always be lower than that at lower-ranked journals, reduce the element of randomness within journal acceptances, and help cut down on the benefits of saturation submission.

At any rate, the existing incentives of the law review system create a market system for the placement of articles in law journals, which preserves a meritocracy only for those who can afford saturation submission strategies but punishes those who cannot. The negative effects may be ameliorated, but not fully remedied, without a complete change in these incentives. There sadly appears to be very little inclination within legal scholarship to alter the structure of the law review system.

Nonetheless, if we legal scholars do nothing about eliminating these existing incentives, then we must also concede that legal scholarship is a game of “pay to play.” And if we lazily insist on the *U.S. News & World Report* rankings of the schools publishing the journals publishing a scholar’s papers as a proxy of his or her scholarship, rather than judge the scholar based on a critical reading of the actual works, then we have no ground to complain when other

68. Such a proposal would require institutionalizing journal rankings within the fabric of Scholastica itself. This would be a tragic outcome that rightly would be considered a surrender by editors of lower-ranked journals. However, as documented by Cicchini, the lower-ranked journals are already suffering from extensive abuse and humiliation from legal scholars who incorporate the *U.S. News & World Report* rankings in their submission practices. Cicchini, *supra* note 8. This proposal at the least restores some sense of balance by giving the editors of lower-ranked journals some formal input into the publication decisions of higher-ranked journals. Higher-ranked journals would also appreciate this proposal because it allows them to leverage on the editorial input of lower-ranked journals to filter out unmeritorious articles. Indeed, given the widespread reliance in the higher-ranked journals on expedites from lower-ranked journals to guide their article review process, it is clear that many higher-ranked journals are comfortable with outsourcing some of their own editorial discretion to the editors of lower-ranked journals.

69. It is possible to adjust the threshold for automatic rejections to require, say, five journals to reject an article on ground (1) before automatic rejection is applied at the highest-ranked journal rejecting the article on ground (1). The threshold is arbitrary and an appropriate setting can be found to balance the interests of journals and authors.

disciplines judge ours as unmeritocratic and look upon our work with contempt. Indeed, as of now, not even our own field thinks well of our system:

In regard to summer money being dependent on article placement, think of how utterly absurd it is that at some schools the salaries of tenured law professors are to a significant extent set by 2Ls, making publishing decisions about subjects they almost always know next to nothing about. I'm assuming that people actually read the articles in tenure files, and make judgments independent of placement, when voting on their colleagues' professional futures. Oh who am I kidding? What a mess.

Posted by: Another Tenured Prof ⁷⁰

70. Another Tenured Prof, *Submission Angsting Spring 2017*, PRAWFSBLAWG (Mar. 12, 2016, 7:31 PM), <http://prawfsblawg.blogs.com/prawfsblawg/2017/02/submission-angsting-spring-2017/comments/page/19/>.

Patients Battle the FDA

*Robert D. Clark, Jr.**

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I. INTRODUCTION

Patients diagnosed with terminal illnesses often struggle to obtain medication that provides safe and effective treatment of their illnesses. One story illustrates this struggle. In 2011, two brothers, Austin and Max LeClaire, respectively 12 and 9 years old at the time, were diagnosed with a form of muscular dystrophy.¹ Duchenne muscular dystrophy causes muscular degeneration, and, ultimately, death.² After learning of an investigational drug, the boys' mother tried to enroll them in the clinical trial for the drug.³

In the summer of 2011, Max was admitted to the drug's clinical trial.⁴ Austin, however, was not accepted, because his symptoms had progressed too far for the study.⁵ After sixteen weeks on the drug, Max's health improved drastically, and he was able to walk and play like other children his age.⁶ Austin's health continued to

1. Bonnie Rochman, *'Both my Sons Deserve to Live': A Mother's Plea for Quicker Action from the FDA*, TIME (Feb. 7, 2013), <http://healthland.time.com/2013/02/07/both-my-sons-deserve-to-live-a-mothers-plea-for-quicker-action-from-the-fda/>.

2. *Duchenne Muscular Dystrophy (DMD)*, MUSCULAR DYSTROPHY ASS'N, <https://www.mda.org/disease/duchenne-muscular-dystrophy> (last visited Jan. 30, 2016).

3. GoldwaterInstitute, *Goldwater Institute CEO Darcy Olsen Discusses Right to Try with Stossel (3/27/2014)*, YOUTUBE (Apr. 1, 2014), <https://www.youtube.com/watch?v=0pjOJmYA16A> (showing John Stossel's "Government Bullies," which was broadcast on Fox Business television on March 27, 2014).

4. Rochman, *supra* note 1.

5. *Id.*

6. *Id.*

worsen, as he was unable to gain access to the drug.⁷ Max, and the eleven other fortunate patients accepted for the trial, stabilized, with most of them regaining muscular strength they had lost.⁸ The patients in the trial suffered no serious side effects.⁹ Despite the positive results of the testing and the inevitability of death for other patients with this illness, no patients outside the clinical trial could access the drug, because the Food and Drug Administration (FDA) believes that only it can properly assess the safety and efficacy of drugs.¹⁰ The FDA's clinical trial process for the approval of investigational drugs prohibits other patients from gaining access to new drugs, with the stated goal of protecting patients from unsafe or ineffective drugs.¹¹ Due to this lack of access to the experimental drug, other patients may only use the less successful, approved drugs, leaving them likely to die from the illness. As Max improved in health, Austin continued to worsen.¹² Should Austin be denied access to the drug that saved his brother's life just because the FDA's arbitrary rules claim to protect patients from the possible harm of ineffective or unsafe new drugs? This article argues that, even assuming that the FDA rules protect patients from harm, terminally ill patients who have no other treatment options should be able to make their own medical choices concerning use of new drugs, rather than being subject to the hegemony of the FDA.

This article addresses the topic of terminally ill patients accessing investigational new drugs, when those patients have no other remaining treatment options. This article discusses the history of the FDA and the drug approval process, and then examines the current regulations imposed on investigational drugs. Part II explains the history of drug regulation in the United States, as well as the current drug regulation and new drug approval process under the

7. *Id.* While, obviously, admission to a clinical trial or investigational drug does not guarantee a cure, that access at least gives the patient a chance of a cure, when the FDA rules would instead result in access merely to drugs that have provided only marginal treatment for the illness. *See, e.g., id.* It is possible that the new drug would not help Austin at all, but this article argues that, regardless of efficacy, the use of new drugs should be decided by the patient in consultation with the physician, rather than a government bureaucrat.

8. GoldwaterInstitute, *supra* note 3.

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.* Austin LeClaire eventually gained access to the new drug through a different clinical trial, which he believes has helped to slow the progression of the disease. Alex Hogan, Hyacinth Empinado & Jeffery DelViscio, *For Two Brothers with Duchenne, an FDA Drug Approval Brings Joy and Relief*, FOX NEWS (Sept. 20, 2016), <http://www.foxnews.com/health/2016/09/20/for-two-brothers-with-duchenne-fda-drug-approval-brings-joy-and-relief.html>. After the initial writing of this article, the FDA approved the drug in September 2016. *Id.*

FDA. Part III covers the various problems with the current new drug approval process, such as the arbitrariness and delays involved in the approval process, and the lack of new drug access for terminally ill patients.

Part IV analyzes the groups that have formed to advocate for expanded drug access for terminally ill patients, such as the Abigail Alliance for Better Access to Developmental Drugs,¹³ and the efforts they have undertaken to achieve their goals. This section also analyzes Abigail Alliance's federal lawsuit against the FDA, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,¹⁴ which was the Abigail Alliance's initial effort to expand drug access for terminally ill patients. Part V argues that the Alliance's asserted right of terminally ill patients to access new drugs was fundamental and should have been protected.

Part VI explores the crux of this article: more recent efforts undertaken by advocates for new drug access for terminally ill patients, including states' so-called Right to Try laws.¹⁵ This section also discusses other efforts to expand new drug access that have made less headway but actually provide more realistic opportunities for reform, such as changes in federal law or regulation. The section concludes by noting the possibility that the recent efforts to expand new drug access for terminally ill patients may still provide a political solution to the problem, though the state Right to Try laws will ultimately fail due to the supremacy of federal law. Part VII then concludes by finding that the state Right to Try laws will fail to directly expand access to new drugs, but may succeed in bringing about a political solution to expanding access by pressuring the FDA to modify its regulations.

II. A SHORT HISTORY OF DRUG REGULATION IN THE UNITED STATES TO THE PRESENT DAY

Early federal drug regulation was minor, not widespread, and only began in the United States in the mid-nineteenth century in

13. Abigail Alliance, founded in 2001, advocates for expanded new drug access for terminally ill patients. *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> (last visited Jan. 18, 2016). The group began after Abigail Burroughs was diagnosed with cancer and unable to access experimental drugs, ultimately dying. *Id.*

14. 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

15. See GOLDWATER INST., RIGHT TO TRY MODEL LEGISLATION (Jan. 28, 2015), http://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2016/1/5/GoldwaterInstituteRighttoTryModel.pdf.

response to rampant drug “misbranding” and “adulteration.”¹⁶ Since that time, however, the United States Government created the Food and Drug Administration, which now implements a vast regulatory regime concerning the approval of drugs for sale to patients.¹⁷ The history of the development of drug regulation is important for understanding how the current regime has developed and also in determining whether drug regulation has been part of the nation’s traditions, which is relevant for analyzing any fundamental rights in relation to drug access.¹⁸

A. *The Development of Drug Regulation in the United States*

To resolve the problem of drug adulteration and misbranding, Congress passed the Import Drugs Act of 1848,¹⁹ which was the first federal law regulating drugs, and applied only to drugs imported into the United States.²⁰ Fifty years later, Congress passed the first drug law that directly regulated the entire United States drug market: the Pure Food and Drug Act of 1906.²¹ The 1906 Act applied the prohibitions on adulteration and misbranding to drugs manufactured in the United States and traded in interstate commerce.²² Although the law mandated that any label on the drug be true and that certain ingredients be listed if they were included in the drug,²³ the Pure Food and Drug Act implemented no real safety or effectiveness requirements.²⁴

Congress expanded the drug regulation regime in 1938 with the Federal Food, Drug, and Cosmetic Act,²⁵ which, among other things, required drug manufacturers to provide scientific evidence regard-

16. Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 422 (1981).

17. See 21 U.S.C. § 301–399 (2015).

18. See *Abigail Alliance I*, 445 F.3d at 482.

19. Import Drugs Act, ch. 70, 9 Stat. 237 (1848).

20. Janssen, *supra* note 16, at 423.

21. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906); see also *Abigail Alliance II*, 495 F.3d at 705.

22. Pure Food and Drug Act of 1906, 34 Stat. at 768. A drug is adulterated, under the Act, when it differs in “strength, quality, or purity” from the stated professional standard. *Id.* at 769–70. A drug is mislabeled when the label of the drug falsely or misleadingly states the ingredients of the drug, fails to note any narcotics included in the drug, or labels an imitation drug under the name of another drug. *Id.* at 770.

23. *Id.* at 769–70.

24. PHILIP J. HILTS, PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 53–54 (2003).

25. 21 U.S.C. §§ 301–399 (2015).

ing the safety of their drugs before introducing them to the market.²⁶ The addition of the safety-testing element gained support after elixir sulfanilamide—a liquid form of an otherwise safe drug—caused approximately 107 deaths, showing that safety testing was necessary before any new drug could be sold.²⁷ Prior to the Act, drug producers could even sell their drugs over-the-counter without meeting any safety standards.²⁸ The Federal Food, Drug, and Cosmetic Act finally addressed this lack of safety standards.²⁹

By 1945, Congress determined that these regulations and standards should be expanded and created the category of prescription drugs, requiring a physician's prescription for use.³⁰ The Humphrey-Durham Amendment,³¹ enacted in 1951, finally defined the types of drugs that would be considered prescription drugs,³² and effectively codified professional pharmaceutical standards into federal law.³³ Congress then amended the Food, Drug, and Cosmetic Act in 1962, requiring drug manufacturers to provide evidence of effectiveness of the drugs before the FDA would approve the drug for public use.³⁴ This amendment, called the Kefauver-Harris Amendment, created the basic clinical testing framework now in place and required a showing that the new drug was both safe and effective.³⁵

The 1945 and 1962 amendments to the Food, Drug, and Cosmetic Act created the framework for the present-day drug approval process:³⁶ the FDA must review all new drugs to determine their safety and effectiveness and use clinical trials for testing before approval.³⁷ Through these amendments, the FDA was given full law-making power with respect to drug regulations,³⁸ something that

26. Janssen, *supra* note 16, at 429. See 21 U.S.C. § 355 (2015).

27. HILTS, *supra* note 24, at 92–93.

28. See Janssen, *supra* note 16, at 430.

29. See *id.* at 429–30.

30. Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 9 Fed. Reg. 12,255 (Oct. 10, 1944). See also Janssen, *supra* note 16, at 433.

31. Humphrey-Durham Amendment, ch. 578, 65 Stat. 648 (1951) (amending the Federal Food, Drug, and Cosmetic Act).

32. See *id.* at 649.

33. Janssen, *supra* note 16, at 435. See also 21 U.S.C. § 353 (2015).

34. See Kefauver-Harris Amendment, Pub. L. No. 87–781, 76 Stat. 780 (1962). Congress enacted these amendments, known as the Kefauver-Harris Amendments, after Thalidomide, a drug for morning sickness, resulted in severe birth defects in some children whose mothers took the drug. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 725 (D.C. Cir. 2007) [*Abigail Alliance II*].

35. See § 102, 76 Stat. at 781.

36. See *id.* at 782–84.

37. *Id.* at 781–82.

38. See *id.* at 782–83.

has allowed the FDA to implement arbitrary regulations that ultimately prohibit terminally ill patients from accessing investigational new drugs to attempt to save their lives.³⁹

B. *The Current Scheme for New Drug Approval*

Congress requires FDA approval before any new drugs may enter interstate commerce, giving the FDA massive control over the marketing and sale of prescription drugs.⁴⁰ Congress has defined “drug” under the Food, Drug, and Cosmetic Act, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” among other things.⁴¹ A “new drug,” which requires approval for use, is a drug that “is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested,” or which medical experts recognize as safe and effective “but which has not . . . been used to a material extent or for a material time under such conditions.”⁴² However, critics of the Food, Drug, and Cosmetic Act have decried the law for its complexity and length, which is symbolic of much of the FDA’s regulation in the area of new drugs.⁴³

The FDA’s rules, which control the Investigational New Drug application (“IND”)⁴⁴ and the testing and approval of new drugs, lay out the approval process for new drugs.⁴⁵ The manufacturer often must undertake animal testing of the new drug before submission of the IND to test the toxicological effects of the drug.⁴⁶ After sufficient animal testing concerning the drug’s toxicity, the drug’s manufacturer may submit an IND to the FDA to formally begin the approval process.⁴⁷ Within the IND, the manufacturer must include information regarding its plan for clinical testing, as well as the results of animal testing to show that the drug is safe enough to begin human testing.⁴⁸ The FDA then reviews the application, along with

39. See Janssen, *supra* note 16, at 439.

40. See 21 U.S.C.A. § 355(a) (West 2015).

41. *Id.* § 321(g)(1).

42. *Id.* § 321(p)(1)–(2).

43. See, e.g., Kimiya Sarayloo, *A Poor Man’s Tale of Patented Medicine: The 1962 Amendments, Hatch-Waxman, and the Lost Admonition to Promote Progress*, 18 QUINNIPIAC HEALTH L.J. 1, 25 (2015) (quoting Judge Roger W. Titus as stating that, “[t]here’s a special place in Hell where they torture people who write things like this”).

44. The IND is the application form that declares a drug manufacturer’s desire to start human clinical trials in an attempt to bring the new drug to market. HILTS, *supra* note 24, at 168.

45. See Investigational New Drug Application, 21 C.F.R. § 312.1 (West 2015).

46. See *id.* § 312.23(a)(8). The animal testing varies widely in extent and type based on other FDA requirements not discussed in this article. See *id.*

47. *Id.* § 312.20.

48. *Id.* § 312.23(a)(3)(iv).

an Institutional Review Board (“IRB”) made up of faculty from hospitals and drug research groups.⁴⁹ Once the FDA and IRB review the animal testing results, the FDA and IRB must approve the drug for clinical testing on humans in order for the new drug to continue on the approval process.⁵⁰

C. *The FDA’s Three Phase Approval Process*

The FDA’s new drug approval process consists of three phases of human clinical testing,⁵¹ involving studies in which physicians give human subjects the new drug or, often in the second and third phase, a placebo or a previously-approved drug created for the same purpose as the new drug being tested.⁵² The physicians and other health care experts then monitor the subjects to examine the new drug’s effects on the subjects.⁵³ The first phase of clinical trials “[is] designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.”⁵⁴ This phase usually involves between twenty and eighty healthy volunteers, not patients, with a focus on understanding the basic reaction of the drug in the body and determining basic levels of safety.⁵⁵ After the drug passes the first stage of testing, meeting basic safety standards and showing a lack of toxicity, the manufacturer may begin phase two testing.⁵⁶

The drug manufacturer’s phase two testing consists of a controlled, highly monitored study, with an increased number of patients and a different focus.⁵⁷ The second phase’s purpose is to determine the effectiveness of the drug, as well as discovering any side

49. *Id.* § 312.23(a)(1)(iv); see also *The FDA’s Drug Review Process: Ensuring Drugs are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2014), <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> [hereinafter *FDA’s Drug Review Process*].

50. 21 C.F.R. § 312.23(a)(1)(iv); see also *FDA’s Drug Review Process*, *supra* note 49.

51. See 21 C.F.R. § 312.21.

52. *FDA’s Drug Review Process*, *supra* note 49.

53. *Id.*

54. 21 C.F.R. § 312.21(a)(1).

55. *Id.* See *FDA’s Drug Review Process*, *supra* note 49. The FDA’s requirement of basic safety levels means that the testing does not show “unacceptable toxicity,” as determined by the FDA. *Id.*

56. *FDA’s Drug Review Process*, *supra* note 49.

57. 21 C.F.R. § 312.21(b). Whereas the phase one testing focuses on toxicity and is not a highly controlled study, phase two studies focus on effectiveness and consist of controlled testing, with some patients receiving the new drug and others receiving a placebo or other drug designed to treat the illness. *FDA’s Drug Review Process*, *supra* note 49.

effects or risks of using the drug.⁵⁸ The second stage of testing usually involves “no more than several hundred subjects.”⁵⁹

Once the clinical testing in phase two has shown the drug is effective,⁶⁰ phase three begins with both controlled and uncontrolled testing.⁶¹ The third phase provides the final testing of the drug’s safety and effectiveness in order to provide a fuller understanding of the risks and benefits of the drug to aid physicians in properly labeling the drug before prescribing it to a patient.⁶² As many as several thousand patients may take part in phase three testing.⁶³ Once the FDA determines the drug has shown sufficient levels of safety and effectiveness,⁶⁴ the drug passes the third and final phase of clinical testing, moving the new drug to the next step of the total approval process.⁶⁵

The data collected from the clinical trials must be included in the drug manufacturer’s New Drug Application (“NDA”) to the FDA.⁶⁶ The NDA is the final, formal request that the FDA approve the new drug for marketing and sale,⁶⁷ and must include all the data collected from the drug’s human and animal testing.⁶⁸ The FDA has sixty days to decide whether to even consider the application, as the FDA may decide that the manufacturer must carry out further testing or include more information and thus refuse to consider the

58. 21 C.F.R. § 312.21(b).

59. *Id.*

60. The FDA’s effectiveness standards require that the new drug “have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in its labeling.” Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.125(b)(5) (West 2016). For the FDA to consider the drug to be effective, the drug must result in a “statistically significant effect on a clinically meaningful endpoint.” EILEEN NAVARRO, EVIDENCE OF CLINICAL EFFECTIVENESS AND DATA REQUIREMENTS 11 (2015), <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm466488.pdf>. In other words, the FDA requires that the drug show a positive impact in accordance with its labelling in at least two independent, controlled studies, when compared to the placebo or the other drugs used as a control in the study. *Id.* at 11.

61. 21 C.F.R. § 312.21(b)–(c). The third phase normally consists of both controlled and uncontrolled tests. The controlled tests involve giving one group of patients the new drug and another group being given a placebo or other drug that treats the illness, in order to eliminate bias in examining the test’s results. The uncontrolled tests merely give all the patients the new drug. *See id.*; *FDA’s Drug Review Process*, *supra* note 49.

62. *See* 21 C.F.R. § 312.21(c).

63. *Id.*

64. *See supra* note 60 and accompanying text. Concerning its safety standards, the FDA requires that the new drug undergo “adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.” 21 C.F.R. § 314.125(b)(2).

65. *See FDA’s Drug Review Process*, *supra* note 49.

66. *See* 21 C.F.R. § 314.50(f).

67. *See* HILTS, *supra* note 24, at 168.

68. *See* 21 C.F.R. § 314.50(d), (f).

NDA.⁶⁹ The FDA's consideration of the NDA takes several months, with the FDA making a determination on 90% of applications within ten months.⁷⁰ The FDA's decision concerning the NDA concludes the required application process. Accepted drugs proceed to market, with continued post-market monitoring of the drug's safety and effectiveness.⁷¹ After drug development, animal testing, the IND application, at least three phases of human clinical testing, and submission, review, and approval of the NDA application, the drug manufacturer may finally label and market the drug for sale, though the drug manufacturer must receive approval from the FDA throughout the entire approval process.⁷²

III. PROBLEMS WITH THE CURRENT FDA APPROVAL PROCESS

While the FDA claims that its entire drug approval process is necessary for all drugs, the approval process includes many inefficiencies and delays that make the process more harmful than helpful, particularly in relation to terminally ill patients. The IND process is complicated, time-consuming, and expensive. In the 1970s, the approval process took an average of eight years, from a drug manufacturer's initial research to the FDA's approval of the NDA, costing an average of \$50 million.⁷³ Since then, the process has only increased in length and cost.⁷⁴

While proponents of the FDA's approval process may argue that the length and cost of the process are essential, even if the process restricts patients from accessing new drugs,⁷⁵ this article contends that the many requirements create an unnecessarily long approval process for new drugs. Due to the time-consuming nature of new-drug approval, there is a drug lag in the United States compared to Europe, where many drugs attain approval more quickly.⁷⁶ The drug lag between Europe and the United States means that many

69. *FDA's Drug Review Process*, *supra* note 49.

70. *Id.*

71. *Id.*

72. *See FDA Drug Approval Process Infographic*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2014), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm295473.htm>.

73. Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y, 295, 306 (2000).

74. *Id.*

75. *See, e.g.*, Ed Silverman, *'Right to Try' Laws Wrong to Skirt FDA*, BOSTON GLOBE (Oct. 12, 2015), <https://www.bostonglobe.com/business/2015/10/12/right-try-laws-are-wrong-usurp-fda/54t1CnBEQ4DHMkYd1ZIdJ/story.html>.

76. *See* Greenberg, *supra* note 73, at 306. The existence of the drug lag is significant because it calls into question the necessity of the American new drug approval process's complexity and length in comparison to that of other developed nations, such as those in Europe that approve new drugs under a faster process. *See id.*

drugs that have been approved for use in Europe are unavailable to American patients, despite the determination under European nations' standards that the drugs are safe and effective.⁷⁷ The drug lag resulted because the United States has historically maintained the highest standards of any nation with respect to drug effectiveness requirements.⁷⁸

The FDA's high standard may be desirable in many cases, but with respect to terminally ill patients, the FDA's standard is unnecessarily high. Terminally ill patients possess a right to life, and that right should include a right to try to preserve their lives by taking non-FDA-approved medication in an effort to live.⁷⁹ Terminally ill patients have nothing or little to lose if the new drug proves ineffective; death is inevitable for terminally ill patients, who often have no other treatment options.⁸⁰ The fact that many other European nations have a lower standard for efficacy shows that it may not be particularly dangerous to loosen the FDA's requirements, at least with respect to terminally ill patients.

A. *The Excessive Delays of the New Drug Approval Process*

While the FDA has shortened the time required for most drugs to obtain FDA approval, the length of time it takes a new drug to get from development to market is still several years, which raises serious problems for terminally ill patients awaiting approval of new drugs.⁸¹ The FDA approval process takes approximately seven and a half years, on average, from phase one testing to marketing of the drug.⁸² That time period includes an average of eighteen months of wait time after completion of testing in order for the FDA to consider approving the NDA,⁸³ though it can take the FDA up to two

77. Daniel Henninger, *Drug Lag*, LIBR. OF ECON. & LIBERTY (2002), <http://www.econlib.org/library/Enc1/DrugLag.html> (last visited Jan. 21, 2016).

78. STEPHEN J. CECCOLI, PILL POLITICS: DRUGS AND THE FDA 81 (2004). While high standards may seem desirable, the standards may be unnecessarily high. One may understand the possibility of unnecessarily high standards by considering a hypothetical drug standard requiring 100% effectiveness and no side effects for the FDA to approve any drug. At some point, the detriments of heightened safety and effectiveness standards outweigh the benefits. *See id.*

79. *See generally* Kurt Altman & Christina Sandefur, *Right-To-Try Laws Fulfill the Constitution's Promise of Individual Liberty*, HEALTH AFF. BLOG (July 14, 2015), <http://healthaffairs.org/blog/2015/07/14/right-to-try-laws-fulfill-the-constitutions-promise-of-individual-liberty/>.

80. *See id.*

81. *See* Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 164 (2003).

82. *Id.*

83. *Id.* at 165.

and a half years to approve the NDA.⁸⁴ For a terminally ill patient who has no treatment option besides a new drug that has just passed the first phase of clinical trials, this wait time ensures a death sentence.

While the length of the FDA's approval process may be necessary in many cases, the process's wait time makes new drugs that are currently in phase two testing practically inaccessible within the lives of terminally ill patients. Due to the lengthy delays in the new drug approval process, the FDA created a certain process by which a terminally ill patient may apply for access to non-approved new drugs.⁸⁵ This expanded access provision allows terminally ill patients with no other treatment options to apply for access to an investigational drug that has passed phase one of clinical trials, based on a physician's recommendation.⁸⁶ These provisions require a lengthy application process and case-by-case determination by the FDA, however, before a patient may access the new drug.⁸⁷

B. The Lack of Investigational New Drug Access for Terminally Ill Patients

Despite the expanded access process created by the FDA, that process provides little aid to terminally ill patients, because few patients use the expanded access program due to the complexity and length of the applications.⁸⁸ The patient's doctor must file an IND application, patient history, treatment plan, and an assurance that the doctor will receive informed consent from the patient.⁸⁹ The doctor must also receive approval from the Institutional Review Board.⁹⁰ The expanded access application process requires complex filings that take an average of 100 hours to complete, which must be done by the physician at the patient's expense.⁹¹ Few patients are able to have a physician complete such a task, or at best can

84. *New Drug Approval Process*, DRUGS.COM, <http://www.drugs.com/fda-approval-process.html> (last visited Jan. 21, 2016).

85. *See* Investigational New Drug Application, 21 C.F.R. §§ 312.300–312.320 (West 2015).

86. *See* Thomas A. Hemphill, *Is State 'Right to Try' Legislation Misguided Policy?*, REGULATION, Fall 2014, at 2.

87. *See id.*

88. Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment*, 266 GOLDWATER INST. POL'Y REP. 1, 10–11 (Feb. 11, 2014) (noting that despite the millions of terminally ill patients, fewer than 1,000 were able to gain expanded access in 2012).

89. *Id.* at 9.

90. *Id.*

91. *Id.* at 9–10.

only do so at great expense.⁹² Doctors often ignore expanded access as a possibility because of the time required to file an application with the FDA, with smaller hospitals often unable to gain expanded access at all due to their lack of resources for applying and obtaining that access.⁹³ While the FDA regularly accepts the applications that it does receive, after a 30-day review, the administration reserves the right to reject the application.⁹⁴ The expanded access process has resulted in minimal new drug access for terminally ill patients though, due to the complexity of the application, as only 940 patients gained expanded access in 2012.⁹⁵ The complexity and difficulty of obtaining investigational drug access for terminally ill patients led to the formation of groups advocating for further expanded access and changes to the law,⁹⁶ including by a federal lawsuit⁹⁷ and passage of state laws.⁹⁸

IV. ATTEMPTS TO EXPAND NEW DRUG ACCESS FOR THE TERMINALLY ILL

Historically, many terminally ill patients sought to gain access to non-FDA-approved drugs in an attempt to save their lives, such as AIDS patients in the 1980s.⁹⁹ Similarly-situated individuals have more recently coalesced into groups advocating for drug access for terminally ill patients, with the Abigail Alliance for Better Access to Developmental Drugs (“the Alliance”) being one of the most well-known examples.¹⁰⁰ The Abigail Alliance formed after Abigail Burroughs, a cancer patient, was unable to gain access to a promising cancer drug that her doctor had suggested.¹⁰¹ Abigail lobbied the drug companies and engaged in television and newspaper interviews to gain popular support for her cause, but ultimately never

92. *Id.* at 10.

93. *Id.* at 11.

94. *Id.*

95. *Id.* Even in 2015, the FDA only received 1,262 IND applications for expanded access to investigational drugs. FOOD & DRUG ADMIN. EXPANDED ACCESS SUBMISSIONS, FY 2010–2015 GRAPH, at 6 (Jan. 27, 2017), <http://www.fda.gov/downloads/NewsEvents/PublicHealth-Focus/ExpandedAccessCompassionateUse/UCM471305.pdf>.

96. *See, e.g., The Abigail Alliance Mission*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/mission.php> (last visited Jan. 22, 2016).

97. *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

98. *See* GOLDWATER INST., *supra* note 15.

99. *See* Editorial Staff, *The Right-to-Try Revolt*, WALL ST. J. (Feb. 9, 2015, 7:16 PM), <https://www.wsj.com/articles/the-right-to-try-revolt-1423527365>.

100. *See* ABIGAIL ALLIANCE, *supra* note 96.

101. ABIGAIL ALLIANCE, *supra* note 13.

gained access to the drug and died in 2001.¹⁰² Her father, Frank Burroughs, continued the mission of the Alliance, attempting to broaden new drug access for terminally ill patients.¹⁰³

The Alliance and similar groups fought to change the FDA rules in the past and continue to do so in the present.¹⁰⁴ The possible paths for change include challenging the FDA rules in court, enacting state or federal statutes, and affecting regulatory change by the FDA itself. Advocates for change may also effect a change in the rules by using state and federal statutes as a source of persuasion to obtain a political solution.¹⁰⁵ State “Right to Try” laws are the most recent form of attempted change to the FDA rules.¹⁰⁶

A. *The First Attempt for Change: A Federal Lawsuit*

The Alliance brought a federal lawsuit against the FDA in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*.¹⁰⁷ The Alliance sought to gain access for terminally ill patients to investigational drugs that had passed the first phase of clinical trials.¹⁰⁸ The Alliance argued that the FDA rules violated the substantive due process rights of terminally ill patients by infringing patients’ fundamental rights to life, privacy, and liberty.¹⁰⁹ The district court dismissed the Alliance’s claim after finding that the Alliance failed to assert a fundamental right and the FDA rules satisfied a rational basis test.¹¹⁰ A panel of the court of appeals reversed the district court decision, determining that terminally ill patients have a fundamental right to access investigational drugs that passed the first phase of clinical trials.¹¹¹ Ultimately, on rehearing before the court of appeals, the court held that terminally

102. *Id.*

103. *See id.*

104. *See, e.g., Compassionate Use Programs*, ALS ASS’N, <http://www.alsa.org/als-care/resources/publications-videos/factsheets/compassionate-use.html> (last visited Dec. 16, 2015); *Mission Statement*, TREATMENT ACTION GRP., <http://www.treatmentactiongroup.org/mission> (last visited Feb. 5, 2016).

105. AIDS patients obtained expanded access in this manner. *See Corieri, supra* note 88.

106. *See GOLDWATER INST., supra* note 15.

107. 495 F.3d 695 (D.C. Cir. 2007).

108. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 471–72 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev’d en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

109. *Id.* at 472.

110. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340, at *11–12 (D.D.C. Aug. 30, 2004).

111. *Abigail Alliance I*, 445 F.3d at 486.

ill patients do not have a fundamental right to access investigational drugs, denying the Alliance's claim and ending their lawsuit.¹¹²

1. *Background of the Case*

The Alliance's federal lawsuit against the FDA, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,¹¹³ constituted the first organized attempt to change the current FDA regulations and approval process. The Alliance sought to enjoin the FDA from banning the sale of phase two investigational drugs to terminally ill patients who were not enrolled in the clinical trials.¹¹⁴ Beginning in 2003, the Alliance made a proposal to the FDA requesting access to post-phase one investigational drugs for terminally ill patients.¹¹⁵ The FDA denied the request three months later.¹¹⁶ The Alliance filed a Citizen's Petition¹¹⁷ in June 2003, making the same request as in the initial proposal.¹¹⁸ When the FDA did not respond to the Petition within the allotted time, the Alliance brought suit, challenging the constitutionality of the FDA's rules regarding the approval process for investigational drugs when applied to terminally ill patients.¹¹⁹ The Alliance asserted that the FDA's rules violated terminally ill patients' "substantive due process rights to privacy, liberty, and life."¹²⁰

2. *Overview of Substantive Due Process Analysis*

The characterization of the substantive due process right asserted by the Alliance represented the crucial decision for the court, as the existence of that right determines the applicable standard of review for the court's analysis of the law at issue.¹²¹ Standard of review is crucial in constitutional law cases.¹²² In this case, the Alliance's claim turned on whether the alleged right—"the right to

112. *Abigail Alliance II*, 495 F.3d at 712.

113. *Id.*

114. *Abigail Alliance I*, 445 F.3d at 471–72.

115. *Id.* at 473.

116. *Id.*

117. A Citizen's Petition consists of a formal petition to the FDA to remove or alter a regulation or cease an administrative action. Initiation of Administrative Proceedings, 21 C.F.R. § 10.25 (West 2015).

118. *See Abigail Alliance I*, 445 F.3d at 473.

119. *Id.* at 473–74.

120. *Id.* at 472.

121. *See Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997).

122. The standard of review means the level of scrutiny the court applies in considering whether the government's law infringes on the claimant's rights. Strict scrutiny is the highest standard of review, requiring the court to overturn the law unless the law's "infringement

access potentially life-sustaining medication where there are no alternative government-approved treatment options”¹²³—was fundamental.¹²⁴ The court of appeals initially determined that the Alliance’s claim implicated a fundamental right and analyzed the FDA rules under the heightened level of strict scrutiny, requiring that the law be narrowly tailored to a compelling state interest to survive review.¹²⁵ Based on the characterization of the right and application of the heightened standard of review, the court recognized the Alliance’s claim and held that the FDA rules violated the Alliance’s due process rights.¹²⁶ When the court of appeals later reheard the case, however, the court determined that the Alliance failed to assert a fundamental right and applied a mere rational basis test to the FDA rules, analyzing whether the rule was rationally related to a legitimate government interest.¹²⁷ The court held that the FDA rules did not violate the Alliance’s due process rights.¹²⁸ The court’s characterization of the asserted right ultimately played a crucial role in deciding whether the FDA rules violated the Alliance’s due process rights to life and liberty.

3. *District Court Rules Against Expanding New Drug Access*

When the Alliance’s case initially came before the District Court, the Alliance argued that the FDA’s new drug approval scheme vio-

is narrowly tailored to serve a compelling state interest.” *Id.* at 721 (citing *Reno v. Flores*, 507 U.S. 292, 302 (1993)). The lowest level of scrutiny that the court applies in substantive due process cases is rational basis review, requiring that the law “be rationally related to legitimate government interests” to survive review. *Id.* at 728.

123. *Abigail Alliance I*, 445 F.3d at 472.

124. Fundamental rights “are, objectively, ‘deeply rooted in this Nation’s history and tradition,’ and ‘implicit in the concept of ordered liberty,’ such that ‘neither liberty nor justice would exist if they were sacrificed.’” *Glucksberg*, 521 U.S. at 720–21 (citing *Moore v. City of E. Cleveland, Ohio*, 431 U.S. 494, 503 and *Palko v. Connecticut*, 302 U.S. 319, 325–26 (1937)). The claimants of the right must also provide a “‘careful description’ of the asserted fundamental liberty interest.” *Id.* at 721. If a law implicates a claimant’s fundamental rights, then the court applies the strict scrutiny standard of review in determining whether the law violates the substantive due process rights of the claimant. *See id.* at 720; *supra* note 122 and accompanying text. If a law does not implicate a fundamental right, then the court merely applies the rational basis standard of review in determining whether the law violates the claimant’s rights. *See id.* at 728; *supra* note 122 and accompanying text.

125. *Abigail Alliance I*, 445 F.3d at 486.

126. *Id.* *See also* U.S. CONST. AMEND. V. (“No person shall . . . be deprived of life, liberty, or property, without due process of law.”); *supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

127. *Abigail Alliance II*, 495 F.3d at 712.

128. *Id.* *See supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

lated the Fifth Amendment's Due Process Clause by denying fundamental rights to terminally ill patients.¹²⁹ Specifically, the Alliance alleged that the FDA rules infringed upon the privacy and liberty rights of the terminally ill by improperly interfering with the patients' medical treatment decisions and their fundamental "right to life" by prohibiting the sale of new drugs, effectively giving these patients "a death sentence."¹³⁰

The trial court found that the Alliance's alleged fundamental right was more analogous to the right to physician-assisted suicide—which the U.S. Supreme Court has not yet recognized—than the right to refuse life-saving medical treatment, as the Alliance had argued.¹³¹ The court characterized the alleged "right to life" as an affirmative right to drug access, rather than a right to be free from government interference in medical treatment decisions.¹³² The court held that this affirmative right was not fundamental, because no protection of it existed in American history and traditions.¹³³ Therefore, the FDA rule was not subject to strict scrutiny and the court instead applied rational basis review, which the court found that the FDA rules satisfied based on the importance of protecting patient and public health.¹³⁴ The court dismissed the Alliance's complaint for failure to state a claim.¹³⁵

4. *Court of Appeals Panel Recognizes a Fundamental Right*

On appeal to the D.C. Circuit Court of Appeals, a panel of three judges reversed the district court, finding in favor of the Alliance.¹³⁶ The court considered the Alliance's claim as "the right of a mentally competent, terminally ill adult patient to access potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, even where that medication carries risks for the patient."¹³⁷ The

129. See Complaint at 10–11, *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340 (D.D.C. Aug. 30, 2004) (No. 1:03CV1601).

130. *Id.* at 10–11.

131. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, 2004 WL 3777340 at *10 (D.D.C. Aug. 30, 2004) (noting the Supreme Court's decisions recognizing a fundamental right to refuse life-saving medical treatment and denying a fundamental right to physician-assisted suicide).

132. *Id.* at 11.

133. *Id.* at 10.

134. *Id.* at 12.

135. *Id.*

136. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

137. *Abigail Alliance I* at 472.

court of appeals panel found that this was a fundamental right because it was both “carefully described” and the United States government had not historically interfered with the right.¹³⁸ In fact, the panel noted that the common law held individuals liable for interfering with a third party’s efforts to save the life of another.¹³⁹ Likewise, the court decided that the practice of regulating drugs based on their efficacy was a relatively recent development in American drug regulation and the traditions of the United States, meaning that the FDA’s rules were not rooted in the nation’s traditions.¹⁴⁰ The court determined that “the right to access potentially life-sustaining medication where there are no alternative government-approved treatment options” more closely resembled the right to refuse life-saving treatment, rather than that of physician-assisted suicide.¹⁴¹ The court ultimately held that “a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause.”¹⁴²

5. *Court of Appeals Reverses on Rehearing En Banc*

On rehearing en banc,¹⁴³ the D.C. Circuit Court of Appeals reversed itself in *Abigail Alliance II*, finding that the Alliance’s claimed right was not a fundamental right.¹⁴⁴ In making this determination, the court focused on the history of safety-based drug regulation, rather than simply efficacy-based regulations, beginning in the colonial era.¹⁴⁵ Therefore, the majority found that “our Nation has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both drug safety and efficacy.”¹⁴⁶ The court approached the claimed right as one of assuming “enormous risks’ in pursuit of *potentially* life-saving drugs,” which was not based in the nation’s traditions.¹⁴⁷ Applying rational basis review, the majority

138. *Id.*

139. *See id.* at 480–81.

140. *See id.* at 482.

141. *Abigail Alliance I*, 445 F.3d. at 472.

142. *Id.* at 486. *See* U.S. CONST. amend. V.

143. A rehearing en banc means that all the judges for that court, the entire bench, rehear the case, rather than merely the panel that initially heard the case. FED. R. APP. P. 35.

144. *See Abigail Alliance II*, 495 F.3d at 712. *See also supra* note 122 and accompanying text; *supra* note 124 and accompanying text.

145. *See Abigail Alliance II*, 495 F.3d at 703–04.

146. *Id.* at 703.

147. *Id.* at 710.

held that “the Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug.”¹⁴⁸ The court recognized that “the FDA’s policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill.”¹⁴⁹ Therefore, the FDA rules passed a rational basis test and the Alliance’s claim failed.¹⁵⁰

However, the court did note that the Alliance could challenge the FDA’s new drug approval process through the “democratic process,” which is “better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so.”¹⁵¹ While the Alliance’s fundamental right arguments ultimately failed, they possessed strong persuasive power and may result in a different holding if the federal courts take up the issue again.

V. THE RIGHT TO ACCESS INVESTIGATIONAL DRUGS: A FUNDAMENTAL RIGHT

In light of *Abigail Alliance II*, this article sets forth the relevant arguments to combat the en banc panel’s decision. While the en banc court rejected the Alliance’s claim that the right of terminally ill patients to access investigational new drugs was fundamental, this section argues that the en banc court was incorrect because the fundamental rights to autonomy, privacy, and life suggest that terminally ill patients should have access to new drugs in limited circumstances. The autonomy and privacy rights are interconnected and have both been recognized by the Supreme Court in a medical context,¹⁵² though not in the particular context of accessing unapproved, experimental drugs. The autonomy and privacy rights suggest that the government should not interfere with the private and autonomous medical decision-making of patients, unless the interference passes strict scrutiny review.¹⁵³ Terminally ill patients

148. *Id.* at 713.

149. *Id.*

150. *See Abigail Alliance II*, 495 F.3d at 712.

151. *Id.* at 713.

152. *See, e.g., Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261, 269 (1990) (noting the individual’s right of possession and control over one’s own person and the importance of bodily integrity); *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965) (recognizing the right of privacy’s protection against government interference in the context of accessing contraceptives).

153. *See B. Jessie Hill, The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 306–07 (2007).

have a fundamental right to life that protects them against any government interference that puts their lives at risk, or prevents them from preserving their lives.¹⁵⁴ Government interference with terminally ill patients' lives occurs, however, when the FDA's rules prevent terminally ill patients from obtaining potentially life-saving drugs when those drugs are the only remaining option. The right to life also arguably relates to the right of an individual to self-defense, applied in the medical context, as a right to defend one's self from death by taking experimental medication.¹⁵⁵

A. *The Rights to Autonomy and Privacy*

The Supreme Court recognized the right to autonomy in making medical decisions, based on an individual form of autonomy and dignity.¹⁵⁶ The idea of autonomy in medical decision-making particularly played a role in the Court's decisions regarding contraceptives in *Griswold v. Connecticut* and *Eisenstadt v. Baird*.¹⁵⁷ The Court recognized the right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹⁵⁸ Along with the fundamental importance of the decision to bear a child, "[t]he choice between life and death is a deeply personal decision of obvious and overwhelming finality."¹⁵⁹ The decision to attempt to preserve one's life may be equivalently fundamental to that of bearing a child, and the state should recognize that an individual's autonomy extends to this area as well. Personal medical decisions are essential "to personal dignity and autonomy, [and] are central to the liberty protected by the Fourteenth Amendment" under the Due Process Clause's substantive protection.¹⁶⁰ The substantive due process protection of autonomy should extend to an individual's decision to try new drugs that are currently in the midst of the FDA approval

154. See THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776); *Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).

155. See Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1818 (2007). While the Supreme Court has never recognized the right to life in this context, the Alliance argued, and some courts of appeal judges agreed, that the right to life is applicable in the context of terminally ill patients' access to new drugs. See *Abigail Alliance II*, 495 F.3d at 722 (Rogers, J., dissenting).

156. See Hill, *supra* note 153, at 305–06.

157. See *id.* at 306–07 (describing the theme of individual autonomy, developed by these cases, in the context of making individual medical treatment decisions without interference from the government); see also *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Griswold*, 381 U.S. 479.

158. *Eisenstadt*, 405 U.S. at 453.

159. *Cruzan*, 497 U.S. at 281.

160. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

process, particularly when the individual is terminally ill and has no other treatment options.

The right to individual privacy is related to that of autonomy and similarly presents a strong argument for protecting a terminally ill patient's ability to use experimental drugs.¹⁶¹ The autonomy arguments discussed in *Griswold* and *Eisenstadt* eventually evolved into right to privacy arguments in which two landmark decisions were grounded, *Roe v. Wade*¹⁶² and *Doe v. Bolton*,¹⁶³ the initial abortion cases.¹⁶⁴ The privacy arguments generally involve an element of privacy in the patient-doctor relationship and in making certain medical decisions.¹⁶⁵ The *Roe* Court noted that the absolute denial of the choice to have an abortion would impose a great harm on the woman.¹⁶⁶ In contrast to the government absolutely making the decision for the woman, as the state abortion ban had intended, the Court stated that only the woman, with her physician's consultation, could properly consider all the factors and make the appropriate decision.¹⁶⁷

The Court's analysis in *Roe* focused on the fact that only the woman could properly weigh the many factors inherent in the abortion decision,¹⁶⁸ which applies similarly to the decisions of terminally ill patients who have exhausted all other medical treatment options and seek to obtain experimental drugs to treat the illness. Only the patient, in consultation with the physician, can properly consider the risk of harm if the drug is unsafe, the results if it is not effective, the price of the drug, and the results of not taking the

161. See Hill, *supra* note 153, at 310.

162. 410 U.S. 113 (1973).

163. 410 U.S. 179 (1973). The abortion ban at issue in *Doe* differed from that in *Roe* because it included exceptions for the health of the mother, particular mental or physical defects in the child, and when the pregnancy resulted from rape. *Id.* at 183. The Court held that the abortion law must defer to the medical decision-making of the patient and physician, rather than giving only limited circumstances when abortion was lawful. *Id.* at 192. The abortion law also required that any abortions be performed at hospitals that held particular accreditation, which the Court overturned. *Id.* at 193–94. The Court similarly found that a requirement that a hospital abortion committee review all abortions before allowing the procedure was unconstitutional. *Id.* at 198. The abortion law required that two physicians give their confirmation before the performance of any abortions, which the Court held was an unconstitutional interference with the decision of the patient and the physician's own best medical judgment. *Id.* at 199. Finally, the Court determined that the law's requirement that the patient be a Georgia resident to receive an abortion in Georgia was unconstitutional. *Id.* at 200.

164. Hill, *supra* note 153, at 309.

165. See *id.* at 309–10.

166. See *Roe*, 410 U.S. at 153.

167. See *id.* (discussing the ability of the woman alone to consider the relevant factors, including the harms of pregnancy, the stress of being a mother, the difficulties of raising a child, and the current family environment the child would live in if born).

168. *Id.*

experimental drug. The privacy right of *Roe* is not absolute though, as the government may limit the right to protect other government interests, such as public health.¹⁶⁹ Similarly, any privacy argument in the context of the FDA's new drug approval process could be limited based on the government's interest in protecting public health. However, the *Roe* decision made clear that the government could not interfere with the privacy right when the woman's life was at stake.¹⁷⁰ The limitation on government interference with the privacy right when the individual's life is at stake analogizes to the case of terminally ill patients because the interest of the woman and the patient in their own lives should overcome the government's interests in interfering with their privacy. While the FDA rules may serve compelling state interests, the privacy right of the individual to make medical decisions "to preserve the life or health of the [patient]" may override the state's interest in implementing the FDA rules on new drugs.¹⁷¹

B. *The Right to Life*

Terminally ill patients have a fundamental right to life that similarly supports recognition of the right asserted in *Abigail Alliance*.¹⁷² The right to life includes, as a corollary, a right "to attempt to preserve life," which must exist for the right to life to provide the fullest protection to the individual against the state.¹⁷³ Historically, many legal commentators believed that the right to life includes a right to self-preservation, meaning that one has a right not to be murdered as well as a right to live.¹⁷⁴ The Supreme Court's jurisprudence on the right to life has largely focused on the right only in the contexts of abortion¹⁷⁵ and the death penalty.¹⁷⁶

The right to life found in the Fifth Amendment cannot possibly exist fully, however, if terminally ill patients are prohibited from a

169. See *id.* at 154. The privacy right eventually falls when the government's interests, such as protecting health or medical standards, become dominant. When a fundamental right is implicated, then the privacy right only yields to a compelling government interest and a law narrowly tailored to that interest. *Id.* at 155.

170. See *id.* at 163–64.

171. Hill, *supra* note 153, at 310 (quoting *Roe*, 410 U.S. at 164).

172. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695, 715 (D.C. Cir. 2007) [*Abigail Alliance II*] (Rogers, J., dissenting).

173. *Id.* at 722.

174. See Valerie L. Myers, *Vacco v. Quill and the Inalienable Right to Life*, 11 REGENT U. L. REV. 373, 387 (1999) (citing John Locke, William Blackstone, and other legal commentators and discussing their beliefs that individuals have a "right of self-preservation").

175. See *Roe*, 410 U.S. at 156–57.

176. See *Furman v. Georgia*, 408 U.S. 238, n.141 (1972) (Marshall, J., concurring).

final attempt to save their lives by taking non-FDA-approved new drugs. The right does not involve special treatment by the government, but merely requires that the government not interfere with a dying patient's attempts to obtain potentially life-saving medication.¹⁷⁷ The FDA rules violate the right to life of terminally ill patients by removing the only possible means of preserving life those patients have remaining, even if that possibility of life may be highly speculative. While the FDA rules may protect the lives of some patients, the rules also sacrifice the lives of terminally ill patients who are awaiting potentially life-saving drugs that are stuck in the new drug approval process. The government exists to secure the right to life of its citizens;¹⁷⁸ it should seek to protect the ability of terminally ill patients to fight for their lives, as they attempt to obtain the last possible chance for life by way of investigational drugs.

C. *The Right to Medical Self-Defense*

Related to the patients' right to life, the right to access potentially life-saving medication may be analogized to the right to self-defense.¹⁷⁹ The doctrine of self-defense allows a person to use force when the life or health of that person or another is placed at risk.¹⁸⁰ The doctrine of self-defense has been long-recognized as a defense against a criminal conviction or tort claim, allowing a person to "use force against another to protect himself from bodily harm or offensive contact."¹⁸¹ The doctrine of self-defense even allows the use of lethal force in some cases: lethal force against an attacker is justified when the attacker places another individual at risk of death or serious injury, even if the attacker does not have the moral culpability necessary for a crime.¹⁸²

Applying the doctrine of self-defense in a medical context, if an individual may even kill an attacker to preserve one's life, then it follows that an individual may use experimental drugs in order to preserve one's life.¹⁸³ The state may limit the right to self-defense as well as the medical self-defense right. The individual may only use lethal self-defense against the source of harm if the source

177. See *Abigail Alliance II*, 495 F.3d at 727–28 [*Abigail Alliance II*] (Rogers, J., dissenting).

178. See THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

179. See Volokh, *supra* note 155, at 1816.

180. *Id.* at 1817.

181. 33 AM. JUR. 2D *Proof of Facts* § 211 (1983).

182. See Volokh, *supra* note 155, at 1817.

183. See *id.* at 1818.

threatens the life of the defender, or at least serious harm to the defender.¹⁸⁴ Thus, again, if the self-defense doctrine was applied in a medical context, only terminally ill patients could use the doctrine as a theory for accessing investigational drugs.¹⁸⁵

The doctrine of medical self-defense has already been used in the context of abortion.¹⁸⁶ A pregnant woman always has the right to obtain an abortion when her life or health is at risk.¹⁸⁷ In other words, medical self-defense applies in the abortion context because the mother always has the right to self-defense against the fetus when her life is at stake. The mother's interest in her own life prevails against that of the unborn child because the child threatens her life and the mother has a right to defend herself against that threat, based on her own right to life.¹⁸⁸

As another limitation on the right to self-defense, the individual engaging in self-defense may not use force against a person who is not creating the threat, meaning that the ill patient may not steal medication or harm others to obtain it.¹⁸⁹ The limitation does not affect the ability of the patient to obtain voluntarily exchanged medication, though.¹⁹⁰ Similarly, as the defender may not interfere with others' rights, the patient has no affirmative right to receive access to drugs, but does have a right to not be interfered with in attempts to obtain access.¹⁹¹ Just as the right of self-defense is limited to situations involving imminent harm, the medical self-defense right similarly requires that the medical harm be sufficiently imminent, meaning that this right only applies for terminally ill patients who have no other medical treatment options.¹⁹² The right to self-defense may be applied to terminally ill patients, as this right has already been applied in the medical context in other situations.¹⁹³

184. *See id.* at 1821.

185. *See id.*

186. *Id.* at 1824.

187. *See* Petition for a Writ of Certiorari at 2, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 2007 WL 2846053 (U.S. Sep. 28, 2007) (No. 07-444). "If the State is interested in protecting fetal life after viability, it may go so far as to proscribe abortion during that period, except when it is necessary to preserve the life or health of the mother." *Roe v. Wade*, 410 U.S. 113, 163-64 (1973). Therefore, the states must always allow for an abortion to protect the mother's life and health, placing the interest in the mother's life above that of the unborn child. *See* Volokh, *supra* note 155, at 1824.

188. *See* Volokh, *supra* note 155, at 1824.

189. *See id.* at 1821-22.

190. *See id.* at 1822.

191. *See id.* at 1827.

192. *Id.* at 1823-24.

193. *Id.* at 1824.

While the right to an abortion is highly controversial, the medical self-defense portion of the abortion right is widely accepted, likely due to the grounding in self-defense itself.¹⁹⁴ While the Supreme Court has only implicitly recognized the right to medical self-defense in the abortion context,¹⁹⁵ the right logically applies to the context of investigational drugs. If a woman has the right to abort a potential life to protect her own life without government interference,¹⁹⁶ then it follows that the woman has a right to attempt to obtain investigational drugs to save her life without government interference.¹⁹⁷ Post-viability, the woman's right to an abortion derives from her right to medical self-defense, not her reproductive right to choose an abortion, and this cannot be distinguished from the context of investigational drugs.¹⁹⁸ The right to medical self-defense, as used in abortion cases, applies equally as a justification for expanding investigational drug access for the terminally ill and supports the argument that the terminally ill have a fundamental right to access these drugs in limited situations.

D. Substantive Due Process Analysis if Recognized as a Fundamental Right

If the right to privacy, autonomy, life, and medical self-defense arguments were to prevail, resulting in recognition of the fundamental right to access investigational drugs, then the strict scrutiny standard would apply when reviewing the FDA's rules. While the state's interests in the FDA rules may overcome the rights of most patients, terminally ill patients are in a life-threatening situation and the FDA rules are not narrowly tailored to protect the state's interests when applied in these situations.¹⁹⁹ The state has an interest in protecting patients from drugs that are either unsafe or

194. *Id.* at 1825 (noting the acceptance of the medical self-defense abortion by the dissenting justices in *Roe*, the many restrictive state abortion laws prior to *Roe*, and the subsequent public recognition of the right to an abortion when the mother's life is at stake); *see also* *Roe v. Wade*, 410 U.S. 113, 173 (1973) (Rehnquist, J., dissenting).

195. *See Roe*, 410 U.S. at 164–65.

196. *See id.*

197. Volokh, *supra* note 155, at 1826.

198. *Id.*

199. For example, the state's interest in protecting the health of patients from unsafe drugs does not fully apply for terminally ill patients because their lives are at risk already from their illness and they are likely willing to take the risk of harm from the drugs in order to attempt to find a cure for their deadly illnesses. Similarly, the state's interest in protecting patients from ineffective medication that would waste their time and resources does not fully apply for terminally ill patients who have no effective treatment options and are likely willing to try a potentially ineffective medication as a last resort when no other options are available. *See generally* Corieri, *supra* note 88.

ineffective, but neither of those interests fully apply in the case of terminally ill patients.

The state's interest in protecting patients from harm from unsafe drugs is drastically mitigated for terminally ill patients because the greatest risk for those patients is to die from the illness. The drug may hasten the inevitable, but may also prevent the patient's death. Furthermore, the fact that the drug has already passed animal testing and phase one basic safety testing means that the drug has been shown to be reasonably safe for patients in clinical testing, meaning most harm would be irrelevant due to the patient's inevitable death regardless.²⁰⁰ When the terminally ill patient is certain to die without access to an unproven, but potentially life-saving medication, the FDA rules are not narrowly tailored to protecting the health and safety of those patients, because the rules actually rob the patients of the only possible option to protect them. This analysis holds true even if the medication ultimately fails to save the patient or if it hastens death.²⁰¹ Therefore, the FDA fails to narrowly tailor its rules on investigational drugs to its compelling interest in protecting the health and safety of patients, in the context of terminally ill patients.

The FDA fails to narrowly tailor its rules to protect terminally ill patients from ineffective drugs as well.²⁰² The state's protection against ineffective drugs provides little aid to terminally ill patients, as they have no other options but to die without any medication.²⁰³ Because of the situation in which terminally ill patients are placed, the state has a much less compelling interest in protecting them from ineffective drugs, considering they have no other options and the drugs have at least passed basic testing that analyzes effectiveness.²⁰⁴ The state interests that justify the FDA's rules on investigational new drugs fail under strict scrutiny review when applied in the context of terminally ill patients. While these arguments have failed in the federal courts, the ever-changing medical world and momentum of public support for expanded access may require the law to change and recognize these arguments as compelling.

200. See Brief of Appellants at 43–44, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006) (No. 04–5350).

201. See *id.* at 44–45.

202. See *id.* at 46.

203. See *id.*

204. See *id.* at 46–47.

VI. OTHER OPTIONS FOR EXPANDING NEW DRUG ACCESS: RIGHT TO TRY LAWS AND BEYOND

After the court rejected the Alliance's claim on rehearing, advocates for expanded new drug access sought other avenues for reform. The primary method for reform consisted of state "Right to Try" laws.²⁰⁵ The state laws allegedly give terminally ill patients access to new drugs in a manner similar to that sought by the Alliance in its lawsuit.²⁰⁶ A similar federal statute provides an alternative and more legally solid method for reform, with the Senate having passed such a bill, though the House bill is currently sitting in committee with minimal support.²⁰⁷ Advocates for reform may achieve success by directly appealing to the FDA to change its regulations and expand access to terminally ill patients, which has succeeded in the past.²⁰⁸ Even if these methods for reform fail to directly achieve expanded access, the pressure on the FDA from state governments, some members of Congress, and the popular support of the people may force the FDA to alter its rules and expand access to terminally ill patients.

A. *State Right to Try Laws*

Despite the failure of the D.C. Circuit Court of Appeals to recognize the Alliance's right asserted as fundamental, advocates for post-phase one investigational drug access for terminally ill patients began to push for a change in the law using Right to Try laws passed by individual states, while also lobbying the United States Congress and the FDA directly.²⁰⁹ Right to Try laws attempt to resolve the issue of terminally ill patients' access to new drugs by allowing a terminally ill patient, who has exhausted all FDA-approved options for treating the disease, to gain expanded access to investigational drugs.²¹⁰ The Right to Try laws are tailored to assert that individuals have a right to try to save their lives by taking not fully approved drugs, based on the recommendation of a

205. See, e.g., GOLDWATER INST., *supra* note 15.

206. See *id.*

207. See Right to Try Act of 2017, S. 204, 115th Cong. (2017); H.R. 878, 115th Cong. (2017).

208. See Corieri, *supra* note 88, at 7–8.

209. See Shari Rudavsky, *Legislation Would Allow 'Right to Try' Trial Drugs*, USA TODAY (Feb. 3, 2015), <http://www.usatoday.com/story/news/nation/2015/02/03/legislation-would-allow-right-to-try-experimental-drugs/22821457/>.

210. See, e.g., GOLDWATER INST., *supra* note 15 (providing the model legislation on which many states based their own Right to Try laws).

physician.²¹¹ This was essentially the same relief sought in *Abigail Alliance*.²¹²

Similar to the Alliance's arguments in its Circuit case, advocates for the Right to Try argue that the right is based on the fundamental right to life.²¹³ The advocates insist that the FDA's investigational process improperly interferes with the fundamental right to life with respect to terminally ill patients.²¹⁴ Right to Try advocates argue that a terminally ill patient who meets the requirements of the Right to Try laws, including having no other treatment options, receiving a physician's recommendation, and giving informed consent, should have the right to at least *negotiate with* drug manufacturers to gain access to the investigational drug.²¹⁵

1. State Right to Try Laws Gain Wide Support

Many state legislatures have agreed with the arguments of Right to Try advocates, as thirty-three states have passed Right to Try laws and another sixteen have recently considered Right to Try bills.²¹⁶ The laws have reportedly not been used by any terminally ill patients yet, as there are concerns about how the FDA and federal government will react and how the laws would actually work in reality.²¹⁷

The Right to Try laws are generally based on model legislation published by the Goldwater Institute.²¹⁸ The Right to Try law's investigational drug access for terminally ill patients applies only to

211. See *id.* at 1.

212. Compare *id.* with *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 471–72 (D.C. Cir. 2006) [*Abigail Alliance I*], *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) [*Abigail Alliance II*].

213. See Corieri, *supra* note 88, at 20.

214. See *id.*

215. See *id.* at 20–21.

216. See *Right to Try*, TENTH AMENDMENT CTR., <http://tracking.tenthamentendmentcenter.com/issues/right-to-try/> (last visited Jan. 5, 2017). The following states have passed Right to Try legislation: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, Wyoming. *Right to Try in Your State*, RIGHT TO TRY, <http://righttotry.org/in-your-state/> (last visited Feb. 2, 2017). The following states have recently considered Right to Try bills: Alaska, Delaware, Hawaii (vetoed), Iowa, Kansas, Kentucky, Massachusetts, Maryland, Nebraska, New Jersey, New York, Pennsylvania, Rhode Island, Washington, Wisconsin, Vermont. *Id.*

217. See Trevor Brown, "Right to Try" Laws in 24 States Not Working, *Medical Experts Say*, WYO. TRIBUNE EAGLE (Aug. 28, 2015), http://www.wyomingnews.com/articles/2015/08/28/news/19local_08-28-15.txt#_ViD_TfVikp.

218. See GOLDWATER INST., *supra* note 15.

drugs that have passed the first phase of FDA clinical testing.²¹⁹ The model legislation notes that a drug manufacturer is not required to provide the drug, and if the manufacturer does then it may do so either without compensation, or by charging the patient at cost.²²⁰ Further, the patient's health insurance company does not have to pay for the drug, but it may do so.²²¹ The law provides that there is no cause of action against a manufacturer who has complied with the law in good faith and exercised reasonable care.²²² The law places no obligation on any party involved; it merely prohibits state officials from blocking the patient's access to the investigational drug. The model legislation prohibits the state's medical licensing or disciplinary board from punishing the patient's physician merely for recommending the drug to the patient.²²³

2. *The Failure of Nullification and States' Rights to Support State Right to Try Laws*

Advocates of the Right to Try laws argue that these state laws provide access to investigational drugs for terminally ill patients, despite the FDA rules.²²⁴ These arguments rely on theories of states' rights related to the Tenth Amendment and nullification of federal law by states.²²⁵ Advocates of the Right to Try laws insist that the FDA rules unconstitutionally interfere with the privacy and right to life of terminally ill patients, meaning that the state laws could nullify the unconstitutional federal rules.²²⁶ For these arguments to prevail, however, the advocates must show that the FDA rules are unconstitutional in one of two possible ways, either:

219. *See id.* at 1.

220. *See id.* at 2–3.

221. *See id.* at 3.

222. *See id.* at 4.

223. *See id.* at 3.

224. *See* T.J. Martinell, *Right to Try: States Take on the FDA*, TENTH AMENDMENT CENTER (Nov. 30, 2014), <http://tenthamendmentcenter.com/2014/11/30/right-to-try-states-take-on-the-fda/>.

225. *See id.* *See also* U.S. CONST. amend. X (“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”).

226. *See* Martinell, *supra* note 224. According to advocates for the use of nullification to obtain expanded new drug access for terminally ill patients, nullification has two possible meanings. In its legal form, opponents of the FDA rules may nullify the rules legally by passing other laws that would make the FDA rules null and void. In its practical form, opponents of the FDA rules may nullify the rules by rendering the rules ineffective, in any manner possible. *See* TENTH AMENDMENT CTR., 2015 STATE OF THE NULLIFICATION MOVEMENT: REPORT ON THE GROWTH OF STATE-LEVEL RESISTANCE TO FEDERAL POWER 1, 4 (2015), <https://s3.amazonaws.com/TACHandbooks/2015-state-of-the-nullification-movement-report.pdf>.

(1) the FDA rules improperly interfere with the rights of the terminally ill; or (2) the United States Constitution did not delegate the power to the federal government to create the FDA rules regulating new drugs.²²⁷ The first argument failed in the *Abigail Alliance* cases,²²⁸ meaning that the state laws cannot nullify the FDA rules on that ground unless the Supreme Court were to hear a case on the issue and overrule the *Abigail Alliance II* ruling. The second argument will also fail because the United States Constitution gave the federal government broad powers to regulate interstate commerce, which would include prescription drugs sold in interstate commerce.²²⁹

If advocates for the Right to Try laws argued that the United States Constitution never delegated the power to the federal government to make rules regarding new drugs, this argument would fail as well. Congress gave the FDA the power to make regulations regarding the sale, marketing, and testing of new drugs sold in interstate commerce.²³⁰ Congress' power to make a law regulating new drugs sold in interstate commerce clearly derives from the Commerce Power, granted to Congress by the United States Constitution, because it regulates prescription drugs in interstate commerce.²³¹ Therefore, Congress acted in a constitutional manner, in passing the Food, Drugs, and Cosmetic Act that allowed the FDA rules,²³² under the Commerce Clause.²³³ Thus, the FDA rules are

227. See U.S. CONST. art. VI, cl. 2. The Supremacy Clause of the United States Constitution states that any constitutional federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *Id.* Therefore, the FDA rules, as long as they are constitutional, are supreme and defeat any contrary state laws. See *id.*

228. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007) [*Abigail Alliance II*].

229. See U.S. CONST. art. I, § 8, cl. 3.

230. See 21 U.S.C. § 355 (2015).

231. See U.S. CONST. art. I, § 8, cl. 3. The Commerce Power gives Congress the constitutional authority to regulate commerce between the states. See *id.* Because the FDA's rules on new drugs are limited to regulating drugs "introduc[ed] . . . into interstate commerce," the rules remain within the powers granted to Congress by the Constitution. 21 U.S.C. § 355(a). When Congress determines that an activity affects interstate commerce, then it may regulate that activity under the Commerce Power, as long as Congress' determination is rational. See *Hodel v. Va. Surface Mining and Reclamation Ass'n, Inc.*, 452 U.S. 264, 277 (1981). Under the Commerce Power, Congress may regulate the production of "goods shipped in interstate commerce," even when produced intrastate, as long as the goods have an effect on interstate commerce. *Id.* at 281. The regulation of the production of prescription drugs (which are goods) that are shipped in interstate commerce clearly falls within this power of Congress, making the FDA's new drug rules constitutional under the Commerce Power.

232. 21 U.S.C. §§ 301–399 (2015).

233. See U.S. CONST. art. I, § 8, cl. 3 (giving Congress the power "[t]o regulate Commerce . . . among the several States").

constitutional and any Tenth Amendment or nullification arguments challenging the rules would fail.

Because the FDA rules are constitutional exercises of federal power, the rules prevail against any state laws that contradict them, preempting the state laws under the Supremacy Clause.²³⁴ Therefore, the state laws provide no direct access for terminally ill patients, nor do they protect physicians or drug manufacturers from liability for violating the FDA rules. State Right to Try laws are powerless as far as providing a direct solution to the issue of expanding new drug access for terminally ill patients, though they may provide an indirect solution. Other avenues for change still exist as well, such as a change in the federal law or regulations, or use of the state and federal law initiatives as pressure to effect a political solution, as discussed in the following sections.

B. Federal Right to Try Law

While the Right to Try laws fail to directly provide access to terminally ill patients, the state laws may instigate a change in the law on the federal level. A change in the federal law would directly alter the FDA rules by congressional legislation. For example, recently introduced before the House of Representatives, H.R. 3012²³⁵ attempted to alter federal law to give Right to Try laws effective power in expanding new drug access to terminally ill patients.²³⁶ The bill prohibited the federal government from restricting the sale and manufacture of investigational new drugs for terminally ill patients when authorized by a state law, such as the Right to Try laws.²³⁷ In another federal attempt to expand new drug access, H.R. 790²³⁸ sought to directly enact the Right to Try laws in federal form, which would apply to the entire nation, rather than merely recognizing Right to Try laws in the states that passed the law.²³⁹ The law involved essentially the same elements that are present in the

234. See U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

235. H.R. 3012, 114th Cong. (2015).

236. See *id.*

237. See *id.* The bill died in the most recent Congress. See *H.R. 3012 (114th): Right to Try Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

238. H.R. 790, 114th Cong. (2015).

239. See *id.*

state laws and model legislation.²⁴⁰ Despite the success of state legislatures in passing Right to Try laws, H.R. 3012 gathered sixty-one cosponsors and failed to even come up for a vote.²⁴¹ Similarly, only four congressmen cosponsored H.R. 790, which also failed to come up for a vote.²⁴² In the Senate, Senator Ron Johnson had introduced S. 2912, which sought to enable terminally-ill patients to access unapproved drugs when authorized by state law.²⁴³ Despite gaining forty-three cosponsors, S. 2912 did not come up for a vote.²⁴⁴ However, Senator Johnson reintroduced the bill as S. 204, on January 24, 2017, which has since been passed by unanimous consent of the Senate, on August 3, 2017.²⁴⁵ A change to the federal law or regulations presents the most definitive method for change, which seems to have become significantly more possible under the presidency of Donald Trump.²⁴⁶

In January 2017, President Donald Trump met with several pharmaceutical CEOs and told them that he planned to “[cut] regulations at a level no one has ever seen before.”²⁴⁷ President Trump specifically focused on cutting regulations regarding the new drug approval process, in order to shorten the time required to obtain FDA approval.²⁴⁸ He also explicitly noted the problem that Right to Try laws attempt to address, stating that “one thing that’s always

240. See *id.* The bill died in the most recent Congress. *H.R. 790 (114th): Compassionate Freedom of Choice Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr790> (last visited Feb. 2, 2017).

241. See *H.R. 3012: Right to Try Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

242. See *H.R. 790: Compassionate Freedom of Choice Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/hr3012> (last visited Feb. 2, 2017).

243. S. 2912, 114th Cong. (2016). See *S. 2912 (114th): Trickett Wendler Right to Try Act of 2016*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/s2912> (last visited Feb. 2, 2017).

244. See GOVTRACK, *supra* note 243.

245. S. 204, 115th Cong. (2017). See *S. 204: A Bill to Authorize the Use of Unapproved Medical Products by Patients Diagnosed with a Terminal Illness in Accordance with State Law, and for Other Purposes*, GOVTRACK, <https://www.govtrack.us/congress/bills/115/s204> (last visited Nov. 12, 2017). A parallel bill currently exists in the House of Representatives, but it is still in committee and has 45 co-sponsors. See *H.R. 878: Right to Try Act of 2017*, GOVTRACK, <https://www.govtrack.us/congress/bills/115/hr878> (last visited Nov. 12, 2017).

246. See, e.g., Carolyn Y. Johnson, *Trump Calls for Lower Drug Prices, Fewer Regulations in Meeting with Pharmaceutical Executives*, WASH. POST (Jan. 31, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/01/31/trump-calls-for-lower-drug-prices-fewer-regulations-in-meeting-with-pharmaceutical-executives/?utm_term=.6b83c12bd7bd; Patrick Cox, *Trump’s FDA Chief May Implement Progressive Approval For Drugs*, FORBES (Dec. 14, 2016, 5:36 PM), <http://www.forbes.com/sites/patrickcox/2016/12/14/trumps-fda-chief-may-implement-progressive-approval-for-drugs/#449846b71c34>.

247. Zachary Brennan, *Trump to Pharma CEOs: 75% to 80% of FDA Regulations Will be Eliminated*, REGULATORY AFFAIRS PROF’LS SOC’Y (Jan. 31, 2017), <http://raps.org/regulatoryDetail.aspx?id=26745>.

248. *Id.*

disturbed me, they come up with a new drug for a patient who is terminal and the FDA says ‘we can’t have this drug used on the patient’ . . . but the patient is not going to live for more than 4 weeks.”²⁴⁹ On the campaign trail, Vice President Mike Pence specifically addressed the Right to Try laws, one of which he signed into law as Indiana Governor,²⁵⁰ and “promise[d]” to “open the doors to treatment” at the federal level.²⁵¹ The Trump White House seems to support patients’ right to try, though it is unclear whether President Trump will push for change through a federal law or regulatory change.²⁵²

C. *Regulatory Change: Lobbying and Pressuring the FDA for Change*

Advocates for expanded new drug access could also lobby the FDA to change its own regulations in order to effect change. Similar efforts to alter the FDA rules and obtain expanded access have succeeded in the past. In the 1980s, the FDA made major changes to its rules in order to give terminally ill patients greater access to new drugs after AIDS patients demanded access.²⁵³ Though the FDA proved reluctant to alter its rules, the dire situation of AIDS patients—who had no approved treatment options and would likely die before any became available—eventually brought about a change to the rules.²⁵⁴

In 1987, the FDA altered its rules to create Expanded Access Programs (EAPs), also known as “‘compassionate use’ programs.”²⁵⁵ The primary EAP, called the treatment investigational new drug (IND) program, allows a company to apply to allow a new drug in phase three clinical testing to be accessible to certain groups of terminally ill patients.²⁵⁶ Approval of the EAP makes the drug available “to a pre-defined patient group.”²⁵⁷ The clinical testing of the drug must be nearly complete, however, for the FDA to approve the

249. NBC Nightly News with Lester Holt, FACEBOOK (Jan. 31, 2017), <https://www.facebook.com/nbcnightlynews/videos/10155090457778689/>. See also Brennan, *supra* note 247.

250. See Starlee Coleman, *Indiana Governor Mike Pence Signs Right to Try Legislation into Law*, GOLDWATER INST. (Mar. 24, 2015), <http://www.goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/indiana-governor-mike-pence-signs-right-to-try-leg/>.

251. Goldwater, *Boy Pleads for “Right to Try” at Mike Pence Rally*, RIGHT TO TRY (Aug. 9, 2016), <http://righttotry.org/boy-pleads-for-right-to-try-at-mike-pence-rally/>.

252. See Cox, *supra* note 246; Johnson, *supra* note 246; NBC Nightly News with Lester Holt, *supra* note 249.

253. See Corieri, *supra* note 88, at 7–8.

254. See *id.* at 7–8.

255. *Id.* at 8.

256. See *id.*

257. *Id.*

treatment IND.²⁵⁸ The treatment INDs provided significantly less aid to terminally ill patients than had initially been anticipated, with fewer than three being approved each year for any type of illness.²⁵⁹

Because of the failure of the treatment IND program to provide the necessary aid to terminally ill patients, the FDA created an individual IND program in 1997.²⁶⁰ Individual INDs allowed a drug sponsor or a patient's physician to apply for access to a new drug for an individual patient who failed to gain access to the clinical trials.²⁶¹ The FDA approves individual INDs only if the application includes sufficient information to show that no other treatment options exist, the drug is sufficiently safe and effective, and giving access to the drug will not interfere with ongoing clinical trials or drug marketing.²⁶² Due to the time and effort required from physicians in completing applications, the individual INDs have failed in providing much greater access for terminally ill patients.²⁶³ The advocates for expanded access may successfully lobby the FDA to change its rules and allow the access sought by the Right to Try laws, as that strategy has achieved expanded access in a limited manner in the past.

D. Right to Try Laws as a Political Solution

Despite the failure of direct appeals to the FDA and Right to Try laws to bring a significant improvement in expanded access, the Right to Try laws may provide a political solution by instigating the FDA to alter its rules. With many states enacting Right to Try laws and pressure growing from advocates of expanded access, the FDA attempted to simplify and expand the EAPs in order to give better access to terminally ill patients and weaken the opposition against its rules.²⁶⁴ While the requirements for gaining access through an EAP remain similar to its initial requirements, the primary

258. *See id.*

259. *Id.* at 9.

260. *See id.*

261. *See id.*

262. *See id.*

263. *See id.* at 10.

264. *See* Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies its Compassionate Use Process*, REGULATORY AFFAIRS PROF'LS SOC'Y (Feb. 4, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/>. *See also* Investigational New Drug Application, 21 C.F.R. § 312.310 (2015).

changes since 1997 have consisted of simplification of the application and the creation of two new EAP processes.²⁶⁵

Released on February 4, 2015, the new application provides a much shorter and more streamlined version of the old EAP, while also requiring less complex information that a physician could more easily provide.²⁶⁶ In limited circumstances, patients' physicians may even apply online or by telephone.²⁶⁷ The two new EAPs consist of a single patient emergency program and an intermediate size program.²⁶⁸ The intermediate size program presents an option similar to the treatment IND, but for smaller patient groups.²⁶⁹ The single patient emergency program allows an individual patient to apply for access, similar to the individual IND, but does so with faster access due to an emergency that limits the time that patient has to obtain access.²⁷⁰ While these changes have made it much easier for terminally ill patients to access experimental drugs, the access is severely limited compared to that sought by Right to Try laws and their advocates.

By creating the new EAPs, the FDA granted greater access to drugs for terminally ill patients, attempting to relieve the pressure placed on the FDA by the Right to Try laws.²⁷¹ For the desires of Right to Try advocates to be satisfied, the FDA must undertake significant further change. The EAPs provide no access to new drugs that have passed phase one, with access only allowed during or after phase three testing or, under seriously limited circumstances, after phase two.²⁷² Further, the FDA still maintains full power to deny any EAP application at its discretion.²⁷³

Ultimately, because the FDA's EAPs only aid patients after a tedious application process and allow access merely to drugs that are nearly approved already, the EAPs provide little help to patients, particularly compared to the potential access that would exist under the Right to Try laws. The EAPs fail to provide the fuller access to terminally ill patients that Right to Try laws seek. These patients may need a new drug currently in earlier phases of testing,

265. See Gaffney, *supra* note 264.

266. *Id.*

267. *Id.* The physician may file an EAP application by phone or online when the drug is required for an emergency situation, which means that the patient needs the drug before the required written application can be filed. See 21 C.F.R. § 312.310(d).

268. See Gaffney, *supra* note 264.

269. See *id.*

270. See *id.*

271. See *id.*

272. See Corieri, *supra* note 88, at 8.

273. See *Expanded Access: Information for Patients*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2015), <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>.

which would have several years still before its approval. If Right to Try laws continue to grow in popularity among the states, or even in Congress, then they may pressure the FDA into loosening its rules with respect to investigational new drug access for terminally ill patients. By this process, the Right to Try laws may ultimately provide a political solution to the issue of investigational new drug access for terminally ill patients.

VII. CONCLUSION

While the FDA's rules regulating investigational new drugs may provide protection for many patients against unsafe or ineffective drugs, the rules also prevent many terminally ill patients from obtaining their last potentially life-saving treatment option. The FDA clinical testing rules result in inefficient delays in the approval of new drugs, as well as restrict access for patients who have no other treatment options. Advocate groups challenged the FDA rules by bringing a federal lawsuit against the FDA, arguing that the FDA approval process infringed terminally ill patients' rights to privacy, autonomy, and life. This attempt failed, however, as the D.C. Circuit Court of Appeals rejected the argument that access to investigational new drugs constituted a fundamental right, and finding the FDA rules did not infringe the patients' due process rights.²⁷⁴ Strong arguments support the belief that investigational new drug access for terminally ill patients does, in fact, constitute a fundamental right, considering the circumstances of these patients who have no other treatment options and will inevitably die without the new drug, even if the probability of the new drug's success is low.

Since their federal lawsuit failed, advocates for expanded new drug access for terminally ill patients have supported state Right to Try laws as the most recent source for change in the law.²⁷⁵ These state laws provide no direct aid to patients, however, due to the supremacy of the federal law and regulations enacted by the FDA. An advocate for expanded access could successfully use the state laws to pressure the FDA into changing its regulations to expand access, as has been done in the past by advocates for expanded access to AIDS patients.

The state Right to Try laws have already succeeded in instigating a simplification and expansion of access programs for terminally ill

274. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712 (D.C. Cir. 2007) [*Abigail Alliance II*].

275. See, e.g., GOLDWATER INST., *supra* note 15. See also TENTH AMENDMENT CTR., *supra* note 216 (displaying a map that shows each state's current position on the Right to Try laws and providing information on each state's proposed or enacted Right to Try law).

patients and may continue to push the FDA to expand access. Therefore, the advocates for expanded access have gained limited success with Right to Try laws and could reach further success as the laws continue to gain political support, particularly under the Trump presidency. The Right to Try laws may ultimately provide a political solution to the issue of investigational new drug access for terminally ill patients who have no other treatment options. The state Right to Try laws may eventually bring about the long-sought-after expanded access for terminally ill patients and will surely aid in continuing the decades-long struggle of the Abigail Alliance and similar advocates for expanded access.

SB-277 Calls the Shots: How California Can Mend the Divide Between Proponents and Opponents of Mandatory Vaccination Laws

Jennifer Yeung

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I. INTRODUCTION

Since the world’s eradication of smallpox in 1979,¹ vaccination has been touted as one of the greatest tools in the public health arsenal.² In fact, its near elimination of diphtheria, rubella, and measles are such outstanding feats³ that in 2011, the Centers for Disease Control and Prevention (CDC) declared vaccination as one of

1. Scott Barrett, *The Smallpox Eradication Game*, 130 PUB. CHOICE 179, 179 (2006); accord Natalia A. Escobar, Note, *Leaving the Herd*, 80 BROOK. L. REV. 255, 261 (2014).

2. INST. OF MED., ADVERSE EFFECT OF VACCINES: EVIDENCE AND CAUSALITY 1, 4 (2011), <http://www.nationalacademies.org/hmd/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>.

3. *Vaccines and Immunizations—What Would Happen If We Stopped Vaccinations?*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 19, 2014), <http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm>.

the twentieth century's top ten public health achievements.⁴ Without vaccinations, rates of infection would soar, claiming thousands of lives and costing millions of dollars each year.⁵ This explains why governments are so interested in regulating the practice—so they can better control the spread of disease.⁶

When it comes to children, one of society's most vulnerable groups, all fifty states presently require proof of immunization as a prerequisite for admission to school.⁷ Legislation is left to each state's government, as no federal laws compel the practice.⁸ However, federal funding supports most of the costs therein.⁹

Between parents' interest in making autonomous decisions regarding their children's health and states' interest in protecting public welfare, few areas within the public health arena are as highly contentious as compulsory vaccination.¹⁰ In fact, debates between those who fervently oppose it and those who staunchly defend it have become so emotional and polarized in recent times¹¹

4. See Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—Worldwide, 2001–2010*, 60 MORBIDITY & MORTALITY WKLY. REP. 805, 814–15 (2011).

5. Michael Poreda, Comment, *Reforming New Jersey's Vaccination Policy: The Case for the Conscientious Exemption Bill*, 41 SETON HALL L. REV. 765, 775 (2011).

6. Kimberly J. Garde, *This Will Only Hurt For . . . Ever: Compulsory Vaccine Laws, Injured Children, and No Redress*, 3 PHOENIX L. REV. 509, 519 (2010).

7. Poreda, *supra* note 5, at 771; Ctrs. for Disease Control & Prevention, *Public Health Law: State School Immunization Requirements and Vaccine Exemption Laws* (Mar. 27, 2015), <http://www.cdc.gov/phlp/docs/school-vaccinations.pdf> (summarizing state vaccination laws as of March 2015); *State Mandates on Immunization and Vaccine-Preventable Diseases*, IMMUNIZATION ACTION COALITION (Sept. 26, 2017), <http://www.immunize.org/laws/>.

8. Escobar, *supra* note 1, at 268.

9. Poreda, *supra* note 5, at 777.

10. See JAMES K. COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 2 (2006) (stating that “[o]ne of the most fundamental and enduring tensions in the enterprise of public health is the balance between the rights of the individual and the claims of the collective, and nowhere is this dynamic more salient than in policies and practices surrounding immunization”).

11. Escobar, *supra* note 1, at 265.

that a middle ground seems nearly impossible.¹² For a prime example, look no further than the heated discussions surrounding California's Senate Bill 277 (SB-277).¹³

Taking into consideration both sides' interests, this comment will attempt to: (1) narrow the divide between SB-277's proponents and opponents, and (2) strengthen the bill's constitutionality by suggesting amendments where it may be susceptible to constitutional attack. Together, Sections II and III will set the stage for which to analyze SB-277. Section II includes an overview of the evolution of vaccination jurisprudence, while Section III highlights some of vaccination's advantages and disadvantages. Section IV contains an analysis of SB-277 and delves into aspects of the bill that the California Legislature should consider amending.

II. THE EVOLUTION OF VACCINATION JURISPRUDENCE IN THE CONTEXT OF SCHOOLS AND CHILDREN

A. *The Pivotal Role of Increasingly Serious Outbreaks of Smallpox*

In the 1830s, two events were responsible for bringing vaccination jurisprudence into existence¹⁴: the first was the passing of laws mandating public school attendance, which brought large groups of children together; the second was increasingly serious outbreaks of smallpox as a result of these children not having been vaccinated.¹⁵ Massachusetts was the first state to enact a mandatory vaccine program, and by the mid-nineteenth century, other states followed suit.¹⁶ Collectively, efforts by all participating states yielded such success that in 1949, the United States deemed smallpox officially

12. Compare Jimmy Kimmel Live, *Jimmy Kimmel's Update on the Anti-Vaccination Discussion*, YOUTUBE (Mar. 3, 2015), <https://youtu.be/i2mdwmpLYLY> (taking a pro-vaccine end-of-conversation stance), with TheHealthRanger, *VAXXED: The ABC News Interview That Big Pharma Didn't Want You to See*, YOUTUBE (Mar. 27, 2016), <https://www.youtube.com/watch?v=tvcdh7KlgPI> (revisiting the causal link between the Measles-Mumps-Rubella (MMR) vaccine and autism and taking a more open-the-conversation stance). Note that *Vaxxed* is a documentary that was pulled from the 2016 Tribeca Film Festival's official list by Robert De Niro, one of the festival's founders, amid criticism and backlash. Robert De Niro later went on the Today Show regretting his decision and stating, "There's something to that movie I wanna know the truth The thing is, to shut it down—there's no reason to. If you're a scientist, let's see. Let's hear. Everybody doesn't seem to want to hear much about it." Robert De Niro's interview can be accessed here: <https://www.youtube.com/watch?v=FJ7iPn39i08&t=223s>.

13. S.B. 277, 2015–2016 Reg. Sess. (Cal. 2015).

14. See Escobar, *supra* note 1, at 262.

15. *Id.*

16. Poreda, *supra* note 5, at 770.

eradicated.¹⁷ Fourteen years later, with the advent of the measles vaccine, the federal government went down a warpath to make it the nation's second vaccine-eliminated disease.¹⁸ For those states not yet convinced to jump on board, studies revealing a forty to fifty percent reduction in infection rates where compulsory vaccination programs were in place provided just the right impetus.¹⁹ By 1981, every state had enacted mandates, not just for smallpox and measles, but for a plethora of other diseases as well, including diphtheria, polio, pertussis, mumps, and rubella.²⁰

Today, no state is without some kind of mandatory vaccination program.²¹ Parents wishing to exclude their children from such programs may do so only if an exemption—medical or non-medical—applies.²² As of July 2016, all fifty states and the District of Columbia allow for medical exemptions; forty-seven states and the District of Columbia allow for non-medical, religious-based, exemptions; and seventeen states and the District of Columbia allow for non-medical, personal belief-based, exemptions.²³ To minimize threats to public health, many states' statutes include quarantine clauses prohibiting school attendance of unvaccinated children during the event of an outbreak or the imminent risk of one.²⁴

17. *Id.* at 771.

18. *Id.* at 770.

19. *Id.* at 771. *But see* John B. McKinlay & Sonja M. McKinlay, *The Questionable Contribution of Medical Measures to the Decline of Mortality in the United States in the Twentieth Century*, 55 MILBANK MEMORIAL FUND Q.: HEALTH & SOC'Y 405, 425 (1977) (questioning the true efficacy of medical intervention techniques like vaccinations and estimating that, at most, such techniques could have only accounted for 3.5 percent of the total decline in mortality since 1900). *See also* U.S. DEP'T OF HEALTH, EDUC., & WELFARE, VITAL STATISTICS OF THE UNITED STATES: VOLUME II—MORTALITY PART A, at 1–18 to 1–19 (1963), https://www.cdc.gov/nchs/data/vsus/mort63_2a.pdf (reporting that by the time the measles vaccine was available to the American public in 1963, the number of people dying from the disease—only 364 that year—was already at an all-time low); Roman Bystryanyk & Suzanne Humphries, *Vaccines: A Peek Underneath the Hood*, INT'L MED. COUNCIL ON VACCINATION (Nov. 12, 2013), <http://www.vaccinationcouncil.org/2013/11/12/vaccines-a-peek-beneath-the-hood-by-roman-bystryanyk-and-suzanne-humphries-md/> (suggesting that the decline in mortality could have been due, not to vaccinations, but to improved hygiene, sanitation, nutrition, labor laws, electricity, chlorination, refrigeration, and pasteurization instead).

20. Poreda, *supra* note 5, at 771.

21. *See supra* note 7 and accompanying text.

22. *See* Poreda, *supra* note 5, at 781.

23. *See State Vaccination Exemptions for Children Entering Public Schools*, PROCON.ORG (July 8, 2016), <http://vaccines.procon.org/view.resource.php?resourceID=003597>.

24. Poreda, *supra* note 5, at 786 n.151. For example, ARIZ. REV. STAT. ANN. § 15–873(C) (2015) provides that “[p]upils who lack documentary proof of immunization shall not attend school during outbreak periods of communicable immunization-preventable diseases,” while LA. STAT. ANN. § 17:170(F) (2015) provides that “[i]n the event of an outbreak of a vaccine-preventable disease[,]” administrators are “empowered . . . to exclude from attendance unimmunized students.”

While these rules sound reasonable enough, opponents argue they still rob parents of the right to make autonomous health care decisions for their children.²⁵ Vaccinations are the only medical procedures mandated for healthy individuals—individuals who pose no threat to society,²⁶ the sheer number of required vaccines continues to increase,²⁷ and not all vaccines are safe for everyone.²⁸ Proponents, on the other hand, argue that mandatory vaccinations are necessary to protect society from disease outbreaks.²⁹ With both sides unwavering in their convictions, the balance between individual autonomy and general societal welfare has become so strained that the question of whether it can even be restored is not unreasonable.

B. SB-277

SB-277, sponsored by Democratic Senators Richard Pan and Ben Allen following the infamous measles outbreak at Disneyland at the end of 2014 and into the beginning of 2015,³⁰ is an amendment to California's Health and Safety Code.³¹ Its elimination of all non-medical exemptions for school-mandated vaccinations is arguably what made it the most contentious bill to come out of the California Legislature in 2015. In what the media termed as one of Sacramento's "largest grassroots movements," hundreds of people spilled into the hallways of the State Capitol and thousands more descended on its grounds in opposition to the bill, but their efforts were for naught.³² The California Legislature was steadfast in its

25. See COLGROVE, *supra* note 10. See also Mahesh Vidula, *Individual Rights vs. Public Health: The Vaccination Debate*, ANGLES (Feb. 5, 2016), http://web.mit.edu/angles/2010_Mahesh_Vidula.html (citing parents' desire to be the decision makers for their children. One Chicago mother asked, "[w]hat right does the government have over my children? . . . I have the right to choose what's best for them").

26. See Escobar, *supra* note 1, at 264–65.

27. See Garde, *supra* note 6, at 524–26; Michael E. Horwin, Comments, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 CAL. W. L. REV. 321, 325–26 (2001).

28. See INST. OF MED., *supra* note 2, at 4; see also Sofia Morfopoulou et al., *Deep Sequencing Reveals Persistence of Cell-Associated Mumps Vaccine Virus in Chronic Encephalitis*, 133 ACTA NEUROPATHOLOGICA 139, 139 (2017).

29. See Poreda, *supra* note 5, at 774.

30. *California Lawmakers Pass Vaccine Bill Amid Emotional Debate*, CNSNEWS.COM (June 9, 2015, 11:10 PM), <http://www.cnsnews.com/news/article/california-lawmakers-pass-vaccine-bill-amid-emotional-debate>; see also Jennifer Zipprich et al., *Measles Outbreak—California, December 2014–February 2015*, 64 MORBIDITY & MORTALITY WKLY. REP. 153, 153–54 (2015).

31. S.B. 277, 2015–2016 Reg. Sess. (Cal. 2015).

32. Shannon Kroner & Tim Donnelly, *Let Voters Decide About Vaccination Law*, L.A. DAILY NEWS (Aug. 5, 2015), <http://www.dailynews.com/2015/08/03/let-californians-decide-about-vaccinations-shannon-kroner-and-tim-donnelly/>; see also CNSNEWS.COM, *supra* note

resolve to pass SB-277 and did so just after five short hours of debate.³³ On June 30, 2015, three weeks later, California Governor Jerry Brown and the Secretary of State, Alex Padilla, signed and filed the same.³⁴

In pertinent part, SB-277, which went into effect on July 1, 2016, states that a student or pupil of “any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center” shall not be admitted unless he or she has been fully immunized against: (1) diphtheria, (2) Haemophilus influenzae type b (Hib), (3) measles, (4) mumps, (5) pertussis (whooping cough), (6) poliomyelitis (polio), (7) rubella, (8) tetanus, (9) hepatitis B, (10) varicella (chickenpox), and (11) any other disease deemed appropriate by the Department of Health.³⁵ Exemptions for diseases (1) through (10) are permitted for medical reasons only,³⁶ and authorities may temporarily exclude any student with good cause to believe that he or she has been exposed to a disease for which there is no proof of immunization.³⁷

To date, there have been a number of attempts to stop the enforcement of SB-277.³⁸ And in every case, the defendants, including the State of California, its departments and agencies, and various individuals in their official capacities, have looked to courts to apply the holdings in *Jacobson v. Massachusetts*³⁹ and its progeny.⁴⁰ A United States Supreme Court case from 1905, *Jacobson* is semi-important not just because it was the first to address mandatory vaccination laws, but also because courts have not deviated from its basic tenets in well over one hundred years.⁴¹ Interestingly

30 (reporting that one individual went so far as to shout at lawmakers, which resulted in her removal from the hearing).

33. CNSNEWS.COM, *supra* note 30.

34. S.B. 277, 2015–2016 Reg. Sess. (Cal. 2015).

35. *Id.* § 2(a)–(b).

36. *See id.* § 1(c). Note that SB-277’s introduction states that it will allow exemptions for future immunization requirements to be based on medical reasons or personal beliefs.

37. *Id.* § 5(b).

38. *See, e.g.,* Whitlow v. Cal., Dep’t of Educ., 203 F. Supp. 3d 1079 (S.D. Cal. 2016); Complaint for Declaratory, Injunctive, or Other Relief, Torrey-Love v. Cal., Dep’t of Educ., No. 5:16-cv-02410 (C.D. Cal. Nov. 21, 2016).

39. 197 U.S. 11 (1905).

40. *See* State Defendants’ Consolidated Opposition to Plaintiffs’ Motion for Preliminary Injunction at 9–10, Whitlow v. Cal., Dep’t of Educ., 203 F. Supp. 3d 1079 (S.D. Cal. 2016) (No. 16cv1715 DMS (MED)) (citing *Zucht v. King*, 260 U.S. 174 (1922) and *Prince v. Massachusetts*, 321 U.S. 158 (1944)); Memorandum of Points and Authorities in Support of Defendants’ Motion to Dismiss Plaintiffs’ Complaint at 8–9, Torrey-Love v. Cal., Dep’t of Educ., No. 5:16-v-02410 (C.D. Cal. Dec. 1, 2016) (citing the same).

41. Wendy E. Parmet, Richard A. Goodman & Amy Farber, *Individual Rights Versus the Public’s Health—100 Years After Jacobson v. Massachusetts*, 7 NEW ENG. J. MED. 652, 652 (2005).

enough, there exists a wholly separate, equally authoritative, and largely ignored line of cases in *Jacobson's* shadow that, if applied, could yield very different results.⁴²

The next two subsections summarize, chronologically, the holdings of both lines of cases. The cases in subsection C, which attest to *Jacobson's* indisputable influence on the evolution of vaccination jurisprudence, stand in contrast to those in subsection D, which illustrate the development of privacy and bodily integrity rights in adjacent areas of law. Viewed side by side, the question becomes whether SB-277 improperly infringes on well-established fundamental rights.

C. *Cases Courts Have Come to Rely on in Upholding Mandatory Vaccination Laws*

1. *Jacobson v. Massachusetts and Zucht v. King*

Decided in 1905, the issue before the United States Supreme Court was the constitutional validity of a Massachusetts vaccination statute.⁴³ In an attempt to neutralize a smallpox outbreak, the City of Cambridge's board of health adopted a regulation requiring those who had not been vaccinated against smallpox as of March 1, 1897, to be vaccinated or revaccinated.⁴⁴ Henning Jacobson refused to comply, so the Commonwealth charged him and ordered him to pay a five-dollar fine.⁴⁵ Jacobson argued the Commonwealth had invaded his liberty by imposing an "unreasonable, arbitrary, and oppressive" compulsory vaccination law in contravention of his inherent right to care for his own body and health.⁴⁶ The Court disagreed and stated that Massachusetts had the authority to enforce the statute via its state police power—a power permitting reasonable regulation for the protection of public health and safety.⁴⁷ Explaining further, the Court stated that Massachusetts was free to employ whatever modes and manners it saw fit to achieve this goal, as long as none would infringe upon any individual's constitutional rights.⁴⁸ The liberty of which Jacobson spoke was not an absolute right, as there would always be circumstances where the common

42. See discussion *infra* Section II.D.

43. *Jacobson*, 197 U.S. at 12.

44. *Id.* at 12–13.

45. *Id.* at 13.

46. *Id.* at 26.

47. *Id.* at 25.

48. *Id.*

good would take precedence.⁴⁹ Thus, to guard the public from additional smallpox outbreaks, Massachusetts's restraint on Jacobson's liberty was necessary.⁵⁰

*Zucht v. King*⁵¹ came seventeen years later. At issue there was a San Antonio ordinance prohibiting any person from attending school "without having first presented a certificate of vaccination."⁵² Rosalyn Zucht, who sought admission to both public and private school, not only lacked the required certificate, but also refused to be vaccinated.⁵³ In her charge against public officials for her exclusion from school, she alleged the following: (1) there was no occasion for requiring the vaccination; (2) the ordinance, by its compulsory nature, deprived her of her liberty without due process of law; and (3) the ordinance gave unfettered discretion to the officials in determining the conditions for enforcement.⁵⁴ The Court ruled in favor of the public officials, reiterating *Jacobson's* holding that the state had police power to enforce compulsory vaccinations.⁵⁵ Then, in postscript fashion, the Court added: (1) a state has the power to determine the conditions under which health regulations should become operative; and (2) a state can vest in its authorities "broad discretion in matters affecting the application and enforcement of . . . health law[s]."⁵⁶ The Court held that San Antonio's ordinance was required for the protection of public health. Thus, Zucht's exclusion could not be deemed "arbitrary."⁵⁷

2. *Prince v. Massachusetts, Matter of Christine M., Phillips v. City of New York, and the Doctrine of Parens Patriae*

The doctrine of *parens patriae*, which allows a state to provide "protection to those unable to care for themselves,"⁵⁸ did not appear in vaccination jurisprudence until *Prince v. Massachusetts*⁵⁹ in

49. *Id.* at 26.

50. *Id.* at 28. See also Christopher Richins, *Jacobson Revisited: An Argument for Strict Judicial Scrutiny of Compulsory Vaccination*, 32 J. LEGAL MED. 409, 414 (2011) (stating that much of the evidence Jacobson attempted to introduce discussed the potential risks of vaccination, not the specific risks he would face personally, which might have been the death knell for his case).

51. 260 U.S. 174 (1922).

52. *Id.* at 175.

53. *Id.*

54. *Id.*

55. *Id.* at 176.

56. *Id.*

57. *Id.* at 177.

58. *Parens patriae*, BLACK'S LAW DICTIONARY (10th ed. 2014).

59. 321 U.S. 158 (1944).

1944. Although the case involved child labor laws, subsequent vaccination cases relied on *Prince's* holding as a means of vesting in states an additional layer of authority to protect children's health and safety—even to the point of restricting parents' control by requiring school attendance and regulating mandatory vaccination laws.⁶⁰ By the end of the twentieth century, *Jacobson*—along with *Zucht* and *Prince*—had implicitly become the controlling legal standard in upholding mandatory vaccination laws. Two cases from 1992 and 2015—*Matter of Christine M.*⁶¹ and *Phillips v. City of New York*,⁶² respectively—make this clear.

In *Matter of Christine M.*,⁶³ where a father refused to have his daughter immunized during a measles outbreak for personal and religious reasons, the family court of Kings County, New York, citing *Jacobson*, *Zucht*, and *Prince*, concluded that government interference with the right of parents to nurture and manage their children was grounded in both the state's general police power⁶⁴ and in the doctrine of *parens patriae*.⁶⁵

Then, in *Phillips*, where a group of parents challenged New York's requirement that all children be vaccinated before attending public school, the United States Court of Appeals for the Second Circuit rejected the plaintiffs' allegations that the state's mandate violated their substantive due process and Free Exercise Clause rights.⁶⁶ To their substantive due process claim, the court stated that what the plaintiffs were asserting was no more compelling than it was over a century ago in *Jacobson*.⁶⁷ And to their Free Exercise Clause claim, the court stated that their right to practice religion did not include the liberty to expose the public to communicable diseases.⁶⁸

Under *Jacobson's* precedent, SB-277's constitutionality is solid. Courts have found,⁶⁹ and will likely continue to find, it difficult to conclude otherwise.⁷⁰ Under the precedents set forth by the next

60. *Id.* at 166; see also Escobar, *supra* note 1, at 264.

61. 595 N.Y.S.2d 606 (N.Y. Fam. Ct. 1992).

62. 775 F.3d 538 (2d Cir. 2015).

63. *Matter of Christine M.*, 595 N.Y.S.2d 606.

64. *Id.* at 611.

65. *Id.*

66. *Phillips*, 775 F.3d at 540 (explaining that the plaintiffs additionally alleged violations of the Equal Protection Clause, the Ninth Amendment, as well as state and municipal laws but the Second Circuit determined these to be meritless or waived).

67. *Id.* at 542.

68. *Id.* at 543 (citing *Prince v. Massachusetts*, 321 U.S. at 166–167).

69. *Whitlow v. Cal., Dep't of Educ.*, 203 F. Supp. 3d 1079, 1092 (S.D. Cal. 2016).

70. See Dorit Rubinstein Reiss, *Attacking SB277 with Another Lawsuit—Torrey-Love v. State of California*, SKEPTICAL RAPTOR (Dec. 1, 2016), <http://www.skepticalraptor.com/skepticalraptorblog.php/attacking-sb277-another-lawsuit-torrey-love-v-state-california/>; *SB277*

line of cases, however, SB-277's constitutionality may sound entirely differently.

D. Cases Courts Have Overlooked in Upholding Mandatory Vaccination Laws

In *Jacobson's* shadow is a line of cases dating back from 1891 that involve common law principles of battery, assault, and informed consent, as well as fundamental privacy and bodily integrity rights.⁷¹ Despite their authority, these cases' holdings have oddly wielded little influence over vaccination jurisprudence.⁷²

1. Cases on Battery, Assault, and Informed Consent

In the 1891 case *O'Brien v. Cunard Steam-Ship Co.*,⁷³ the question before the Supreme Judicial Court of Massachusetts was whether Cunard's onboard surgeon committed an assault on Mary O'Brien by giving her a vaccination en route to Boston.⁷⁴ The court held that if O'Brien's behavior—by way of her overt acts and manifestation of feelings—indicated consent, then the surgeon was justified in his act.⁷⁵ O'Brien understood she was going to be vaccinated, never expressed any desire not to be, and allowed herself to be vaccinated without objection.⁷⁶ Thus, the surgeon's act was lawful.⁷⁷

In 1914, in *Schloendorff v. Society of New York Hospital*,⁷⁸ the question was whether an operation on an unconscious Mary Schloendorff constituted an assault when she had expressly desired an examination only.⁷⁹ While the Court of Appeals of New York ultimately affirmed the trial judge's ruling in favor of the defendant hospital because the surgeons who performed the operation were not the hospital's agents, it stated that “[e]very human being . . . has a right to determine what [should] be done with his own body.”⁸⁰

Litigation, A VOICE FOR CHOICE, <http://avoiceforchoice.org/sb277-litigation/> (last visited Jan. 24, 2017).

71. This is merely a road map for the cases that will follow.

72. *Id.*

73. 28 N.E. 266 (Mass. 1891).

74. *Id.* at 266.

75. *Id.*

76. *Id.*

77. *Id.*

78. 105 N.E. 92 (N.Y. 1914).

79. *See id.* at 93. While Schloendorff was a patient at the hospital, the house physician, Dr. Bartlett, discovered a lump. *Id.* The character of the lump could not be determined without an examination. *Id.* Schloendorff consented to an exam, but said there could be no operation. *Id.*

80. *Id.*

Thus, a surgeon who performs an operation on a patient without the patient's consent is liable.⁸¹

In the 2003 case *Duncan v. Scottsdale Medical Imaging, Ltd.*,⁸² a patient required a magnetic resonance imaging examination and specifically told the nurse she could only accept Demerol or morphine for sedation. The patient received fentanyl, which led to serious complications, so she sued for lack of informed consent and battery.⁸³ Although the Supreme Court of Arizona ultimately remanded the case,⁸⁴ it stated that a health care provider commits a battery whenever a medical procedure is performed without a patient's consent.⁸⁵

2. *Cases on Privacy and Bodily Integrity Rights Decided by the United States Supreme Court*

In the 1891 case *Union Pacific Railroad Co. v. Botsford*,⁸⁶ the defendant railroad company filed a motion to order a passenger—who allegedly suffered head injuries after an upper berth fell on her—to submit to a surgical examination if she desired the defendant's presence at trial.⁸⁷ The United States Supreme Court held that no right is “more sacred, or . . . more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others . . .”⁸⁸ Moreover, without lawful authority, it was a trespass to “compel any one . . . to lay bare [his or her] body” or to submit it to a stranger's touch.⁸⁹

Then, in *Meyer v. Nebraska*⁹⁰ and *Pierce v. Society of the Sisters of the Holy Names of Jesus and Mary*,⁹¹ decided in 1923 and 1925, respectively, the Court held that parents have the right to control their children's upbringing as part of their privacy rights within their right to liberty.⁹² The Court expanded this right of privacy in

81. *Id.*

82. 70 P.3d 435 (Ariz. 2003).

83. *Id.* at 437–38.

84. *See id.* at 442–43. The Supreme Court of Arizona ultimately remanded the case because Arizona's medical malpractice statute abolishing the right to bring an action in battery violated the anti-abrogation clause of the state's constitution. *Id.*

85. *Id.* at 438.

86. 141 U.S. 250 (1891).

87. *Id.* at 250.

88. *Id.* at 251.

89. *Id.* at 252.

90. 262 U.S. 390 (1923).

91. 268 U.S. 510 (1925).

92. *Pierce*, 268 U.S. at 534 (establishing the right of parents to decide which schools their children should receive education from); *Meyer*, 262 U.S. at 399–400 (establishing the right of teachers to teach and the right of parents to engage teachers in teaching their children).

1973, in *Roe v. Wade*,⁹³ to include the right of pregnant women to choose abortion,⁹⁴ and expanded it again in 1990, in *Washington v. Harper*,⁹⁵ to include the right of inmates to refuse certain medication.⁹⁶ In *Cruzan by Cruzan v. Director, Missouri Department of Health*,⁹⁷ decided that same year, the Court inched closer to declaring the right to decline medical treatment as fundamental,⁹⁸ but it was not until *Washington v. Gluck*,⁹⁹ seven years later, that the Court finally said outright: “[T]he right to refuse unwanted medical treatment [is] so rooted in our [nation’s] history, tradition, and practice” that it should “require special protection under the Fourteenth Amendment.”¹⁰⁰

3. *Cases on Privacy and Bodily Integrity Rights Decided by the Supreme Court of California*

California’s state courts may also have a say in SB-277’s constitutionality. Thus, their stance on privacy and bodily integrity rights is an important one to understand. Two cases from 2004 and 2005—*In re Qawi*¹⁰¹ and *Coshov v. City of Escondido*¹⁰²—are revealing.

In *In re Qawi*,¹⁰³ where a prisoner challenged his involuntary antipsychotic medication, the Supreme Court of California stated that: (1) the right of a competent adult to refuse medical treatment is grounded in both state constitutional and common law; and (2) this right of privacy guarantees “the freedom to . . . reject, or refuse to consent to, intrusions of . . . bodily integrity.”¹⁰⁴ In *Coshov*, where city residents sued the City of Escondido, California and the Department of Health Services for violating their constitutional rights by allegedly exposing residents to health risks via plans to fluoridate the city’s drinking water, the California Court of Appeals for the Fourth District stated: “There is no dispute [that] the right

93. 410 U.S. 113 (1973).

94. *Id.* at 153.

95. 494 U.S. 210 (1990).

96. *See id.* at 241 (stating that “a competent individual’s right to refuse . . . medication is a fundamental liberty interest deserving the highest order of protection”).

97. 497 U.S. 261 (1990).

98. *Id.* at 269 (stating that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . .”).

99. 521 U.S. 702 (1997).

100. *Id.* at 721 n.17 (1997) (citing *Cruzan by Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278–79 (1990)).

101. 81 P.3d 224 (Cal. 2004).

102. 34 Cal. Rptr. 3d 19 (Cal. Ct. App. 2005).

103. 81 P.3d at 224.

104. *Id.* at 230–31.

to bodily integrity is a *fundamental* right”—a right which “limits the traditional police powers of the state.”¹⁰⁵

III. VACCINATION’S ADVANTAGES AND DISADVANTAGES

A. *The Well-Known Advantages*

The upsides to vaccination are widely known and have been tirelessly expounded on by the CDC, Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics, and American Academy of Family Physicians, as well as mainstream media. From the significant reduction rates in infection and mortality to the total and near eradication of certain infectious diseases,¹⁰⁶ there is no doubt that the practice is a major public health achievement.¹⁰⁷ To drive the point home, Table 1 lays out some compelling “before and after” statistics compiled by the CDC:

Location	Disease	Reported Cases Before Mass Inoculation	Reported Cases After Mass Inoculation
United States	Tetanus	486 in 1950	26 in 2013
United States	Mumps	152,209 in 1968	584 in 2013
United States	Rubella	46,975 in 1966	9 in 2013
United States	Paralytic Polio	33,300 in 1950	1 in 2013

Table 1. Reported Cases of Various Diseases from Vaccine Preventable Diseases.¹⁰⁸ The last two columns to the right compare the number of reported cases for specific diseases before and after mass inoculation.

105. *Coshov*, 34 Cal. Rptr. 3d at 30 (emphasis added). In its ultimate ruling for the defendants, the court distinguished fluoridating water as rationally related to the state’s interest in protecting dental health from other invasive and highly personalized medical treatments like smallpox vaccinations. *Id.*

106. *See supra* notes 1–5 and accompanying text.

107. *See supra* note 4 and accompanying text.

108. CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES app. E, at E–1 to E–4 (Jennifer Hamborsky, Andrew Kroger & Charles Wolfe eds., 13th ed. 2015).

Additionally, there is the benefit of herd immunity, the phenomenon heralded by the pro-vaccine camp as immunization's biggest advantage, which refers to whole-community protection against infectious diseases when enough of the population is vaccinated.¹⁰⁹ Typically, when eighty to ninety-five percent of a community is immunized,¹¹⁰ the risk of disease will decrease, resulting in protection for all.¹¹¹ However, when too many people opt out, everyone becomes vulnerable.¹¹² The biggest threat to herd immunity occurs once the cumulative percentage of those willing to be immunized falls below the eighty to ninety-five percent threshold.¹¹³ Because some people cannot be vaccinated due to medical contraindications, the argument is that it is imperative to keep vaccination rates high enough in those who can be vaccinated.¹¹⁴

The counterargument to herd immunity is twofold. First, unvaccinated individuals may still be at risk for contracting the vaccine's targeted disease via germ shedding by vaccinated individuals.¹¹⁵ Second, immunity from vaccination inevitably wears off over time.¹¹⁶ Therefore, at some point, all vaccinated persons will once again become susceptible to contracting, carrying, and passing along the communicable disease for which they were previously immune.¹¹⁷

B. The Lesser-Known Disadvantages

To start, it is important to note that many anti-vacciners do not oppose the practice of vaccination in its entirety. Rather, their concerns are with particular aspects of the practice.¹¹⁸ In the interest of concision, this comment will only explore a few concerns—

109. Poreda, *supra* note 5, at 775.

110. *Id.* See also Jason L. Schwartz, Commentary, *Unintended Consequences: The Primacy of Public Trust in Vaccination*, 107 MICH. L. REV. 100, 102 (2009).

111. Escobar, *supra* note 1, at 258.

112. Garde, *supra* note 6, at 521.

113. See Escobar, *supra* note 1, at 258.

114. Schwartz, *supra* note 110, at 102.

115. Garde, *supra* note 6, at 521–22; see also BARBARA LOE FISHER, NAT'L VACCINE INFO CTR., THE EMERGING RISKS OF LIVE VIRUS & VIRUS VECTORED VACCINES: VACCINE STRAIN VIRUS INFECTION, SHEDDING & TRANSMISSION 12–13 (Nov. 2014), <http://www.nvic.org/Vaccines-and-Diseases.aspx> (explaining that individuals who receive live virus vaccines like the MMR, chickenpox, influenza nasal spray, rotavirus, and shingles vaccines can continue to shed and transmit vaccine strain live attenuated viruses for days, weeks, or even months depending on the vaccine as well as the health and other host factors of the vaccinated person).

116. Garde, *supra* note 6, at 522.

117. *Id.*

118. Poreda, *supra* note 5, at 805.

whether vaccines are safe, whether too many are administered too early on, and whether they are all equally important.

1. *Safety Concerns: Life-Threatening Side Effects, Complications, and Toxic Constituents*

Consider the tragic story of Sean Leary.¹¹⁹ On March 7, 1984, Sean Leary—a healthy two month and three week old baby—received his first dose of a combination vaccine for diphtheria, whooping cough, and tetanus (DPT).¹²⁰ On May 9, he received a second dose; and on August 22, he received a third.¹²¹ Beginning almost immediately after his third, Sean began exhibiting signs of discomfort, fussiness, restlessness, and general withdrawal.¹²²

Sean's mother, Mrs. Leary, noted he had vomited after only having taken half his bottle and showed no interest in eating for the rest of the day.¹²³ Sean was awake, but not active, and did not want to play or interact.¹²⁴ At approximately 7:00 p.m. on the night of August 23, Mrs. Leary laid Sean in his crib where he dozed off and on.¹²⁵ Beginning at midnight, he cried out every fifteen minutes or so until 2:00 a.m., when he retched violently.¹²⁶ Sean settled down by 4:00 a.m., but by then his breathing was faster than normal.¹²⁷ As soon as the doctor's office opened on the morning of August 24, Mrs. Leary took Sean in, but by the time they arrived, it was apparent something was horribly wrong.¹²⁸ At the doctor's office, Sean's skin exhibited a yellow-looking tinge, his eyes suddenly rolled back in his head, and his rapid breathing stopped.¹²⁹ Though he was rushed to the emergency room, Sean was pronounced dead at 1:44 p.m.¹³⁰

Although uncommon, Sean Leary's case illustrates the point that vaccines can cause injury—even death—in some situations.¹³¹ Thus, despite proponents' claim that vaccines are safe and effective,

119. *See* Leary v. Sec'y of Dep't of Health & Human Servs., No. 90-1456V, 1994 WL 43395 (Fed. Cl. Jan. 31, 1994).

120. *Id.* at *1.

121. *Id.*

122. *Id.* at *2.

123. *Id.* at *1-2.

124. *Id.* at *2.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

131. *See* Garde, *supra* note 6, at 512. *See also* Poreda, *supra* note 5, at 793-94; *Vaccines & Immunizations: Possible Side-Effects from Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2, 2016), <https://www.cdc.gov/vaccines/vac-gen/side-effects.htm>.

the reality is that they are far from being “*perfectly safe [or] perfectly effective.*”¹³² Table 2 below lists other adverse effects of vaccines, as detailed by a 2011 report entitled, *Adverse Effects of Vaccines: Evidence and Causality*, by the Health and Medicine Division of The National Academies of Sciences, Engineering, and Medicine¹³³:

Name of Vaccine	Proven Adverse Effect(s)
Varicella zoster live vaccine	Meningitis or encephalitis (inflammation of the brain)
Mumps, measles, and rubella combination (MMR) vaccine	Measles inclusion body encephalitis and febrile seizures
MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus-containing vaccines	Anaphylaxis

Table 2. Summary of Adverse Effects of Vaccines According to the Institute of Medicine.¹³⁴ The table lists adverse effects of various vaccines for which there is convincing evidence to support a causal relationship.

An additional safety concern is the constituents that make up vaccines. Mercury and aluminum are the most widely discussed.¹³⁵ Regarding mercury, a 2014 article entitled “Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe,” which was published in the journal *BioMed Research International*, provides evidence linking mercury to death, poisoning, allergic reactions, malformations, autoimmune reactions, developmental delays, and neurodevelopmental disorders like tics, language delay, attention deficit disorder, and autism in infants and children.¹³⁶ Regarding aluminum, various studies

132. Escobar, *supra* note 1, at 265 (emphasis added).

133. INST. OF MED., *supra* note 2, at 2–3. The Health and Medicine Division, formerly known as the Institute of Medicine, is a division of the National Academies of Sciences, Engineering, and Medicine. The Academies are private, nonprofit institutions that provide independent and objective analysis and advice for the purpose of informing the nation’s public policy decisions. More information can be found at: <http://www.nationalacademies.org/hmd/About-HMD.aspx>.

134. INST. OF MED., *supra* note 2, at 2–3.

135. See Horwin, *supra* note 27, at 333.

136. Brian Hooker et al., *Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe*, 2014 BIOMED RES. INT’L 1, 1 (2014). See also A Shot of Truth, *CDC’s Vaccine Safety Research Is Exposed as Flawed and Falsified in*

have demonstrated that the element interferes with a variety of cellular and metabolic processes in the nervous system and in other tissues.¹³⁷ Even in diluted amounts,¹³⁸ aluminum has the potential to stimulate autoimmune syndromes,¹³⁹ chronic kidney failure,¹⁴⁰ and neurological dysfunction.¹⁴¹

2. *The Concern: "Too Many, Too Early On"*

Considering the potential side effects and complications of vaccines then, many opponents have expressed genuine concern that in today's world, giving children so many vaccines so early on might have negative consequences.¹⁴² To illustrate, compare the CDC's immunization schedules at various points in history.¹⁴³ Back in 1983, the CDC's immunization schedule recommended only nineteen doses of vaccines for both males and females.¹⁴⁴ By 2009, the number had jumped to 139 and 142 for males and females, respectively.¹⁴⁵ Although the number of recommended doses in the CDC's latest 2016 schedule is not vastly different from its 2009 schedule, it is startling that a person born in the 1960s only received vaccinations for polio, chickenpox, and DPT; while a person born today will

Peer-Reviewed Scientific Journal, HEALTH IMPACT NEWS (June 12, 2014), http://www.bizjournals.com/prnewswire/press_releases/2014/06/13/MN48236. This press release discusses BioMed Research International's article and points out the contradictions between the 165 studies demonstrating thimerosal's dangers and the 6 CDC coauthored and sponsored papers declaring thimerosal "safe." In it, Brian Hooker, the article's lead author, states: "This type of cherry-picking of data by the CDC . . . to support flawed and dangerous vaccination policies should not be tolerated." *Id.*

137. Horwin, *supra* note 27, at 333 & n.87.

138. *Id.* at 333. See also Paul Thomas, *A Sad Day for Medical Freedom: California Joins West Virginia and Mississippi in Removing Religious and Personal Vaccine Exemptions*, DR. THOMAS'S BLOG (July 2, 2015), <http://paulthomasmd.com/2015/07/02/a-sad-day-for-medical-freedom-california-joins-west-virginia-and-mississippi-in-removing-religious-and-personal-vaccine-exemptions/>. In his blog, Dr. Paul Thomas, M.D., a board-certified pediatrician in Portland, Oregon, points out that the hepatitis B vaccine contains 250 micrograms of aluminum, which far exceeds what the Food and Drug Administration (FDA) deems safe. Under the FDA's own guidelines, a newborn weighing 10.4 pounds should not get more than 25 micrograms. *Id.* Alarming, the hepatitis B vaccine is one of the very first administered to newborns.

139. Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y, L. & ETHICS 39, 71 & n.233 (2012).

140. Committee on Nutrition, *Aluminum Toxicity in Infants and Children*, 78 PEDIATRICS 1150, 1150 (1986).

141. *Id.*

142. Poreda, *supra* note 5, at 773; see also Horwin, *supra* note 27, at 327–28.

143. See *infra* notes 144–46.

144. Garde, *supra* note 6, at 526.

145. *Id.*

receive additional vaccinations for hepatitis B, rotavirus, Hib, pneumococcal conjugate, seasonal influenza, hepatitis A, human papillomavirus, and meningococcal.¹⁴⁶

Proponents dismiss the “too many too early” concern by arguing that the delay of vaccination provides no benefit,¹⁴⁷ all childhood vaccines are important,¹⁴⁸ and any concerns are scientifically unfounded.¹⁴⁹ While the first two arguments are debatable, the third is not. Science has never had a monopoly on facts—the scientific community makes enormous mistakes on a regular basis.¹⁵⁰ In other words, just because something has not been scientifically proven yet does not preclude its truth. To illustrate this point, consider the classic example of cigarette smoking.¹⁵¹

As far back as 1917, doctors attested to the safety of cigarette smoking.¹⁵² In the article, “Are Tobacco and Cigarettes Injurious?,” author and doctor P.C. Remondino wrote that he had “never observed any injuries blamable to the use of tobacco [or cigarettes].”¹⁵³ Corroborating this line of thought some sixteen years later, the *Journal of the American Medical Association (JAMA)* published its first cigarette advertisement stating it had done so only “after care-

146. See *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years, United States, 2015*, CTRS. FOR DISEASE CONTROL & PREVENTION fig.1, <http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (last visited Jan. 21, 2016). In the current schedule, the CDC recommends: three doses of hepatitis B; up to three doses of Rotavirus; five doses of Diphtheria, tetanus, and acellular pertussis (DTaP); one dose of tetanus, diphtheria, and acellular (Tdap); four doses of haemophilus influenzae type b (Hib); four doses of Pneumococcal conjugate; four doses of inactivated poliovirus; annual doses of influenza; two doses of measles, mumps, and rubella (MMR); two doses of varicella; two doses of hepatitis A; three doses of Human papillomavirus; and two doses of meningococcal. *Id.* But see Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900–1999: Control of Infectious Diseases*, 48 MORBIDITY & MORTALITY WKLY. REP. 621 (1999), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm> (stating that improved sanitation, hygiene, sewage disposal, water treatment, food safety, and public education about hygienic practices beginning in the 1900s have already significantly decreased the incidence of diseases. What is odd is that the number of required vaccines for children keeps increasing when society’s standards of living have never been higher).

147. Aaron E. Carroll, *Not up for Debate: The Science Behind Vaccination*, N.Y. TIMES (Sept. 17, 2015), http://www.nytimes.com/2015/09/18/upshot/not-up-for-debate-the-science-behind-vaccination.html?smid=fb-nytimes&smtyp=cur&_r=0.

148. *Id.*

149. Poreda, *supra* note 5, at 773.

150. Mike Adams, *Infographic: Vaccine Industry Science Lies Are Nothing More Than Recycled Big Tobacco Science Lies*, NATURAL NEWS (Mar. 3, 2015), http://www.naturalnews.com/048847_Big_Tobacco_science_lies_vaccine_propaganda.html.

151. See P.C. Remondino, *Are Tobacco and Cigarettes Injurious?*, 33 MEDICO-LEGAL J. 9, 13 (1917).

152. See *id.*

153. *Id.*

ful consideration of the extent to which cigarettes were used by physicians in practice.”¹⁵⁴ By 1941, not only had smoking gained near universal acceptance and appeal,¹⁵⁵ but it also had the full support of the American Medical Association.¹⁵⁶ There was virtually no scientific evidence to the contrary¹⁵⁷ until 1950, when the *JAMA* published its first major study linking smoking to lung cancer.¹⁵⁸ To apply pro-vacciners’ reasoning is akin to saying that cigarette smoking was not dangerous before 1950 because science had not yet discovered it to be so.¹⁵⁹

3. *Not All Vaccines Are Equally Important*

Not all vaccines are equally important. Unlike measles or whooping cough, which can spread rapidly through schools and pose serious corollary health problems, some diseases, like hepatitis B, are less severe,¹⁶⁰ which raises the question of whether vaccines for such diseases are essential.¹⁶¹

Hepatitis B, caused by the hepatitis B virus (HBV), is a liver infection that can be passed to uninfected persons via blood, semen, or some other bodily fluid.¹⁶² Sexual contact and the sharing of drug paraphernalia with those infected are the most common ways to

154. Mike Adams, *Doctors, American Medical Association Hawked Cigarettes as Healthy for Consumers*, NATURAL NEWS (July 25, 2007), <http://www.naturalnews.com/021949.html>.

155. See Allan M. Brandt, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA 2* (2007); see also graphicsfx, *More Doctors Smoke Camels Than Any Other Cigarette*, YOUTUBE (Nov. 11, 2006), <https://youtu.be/gCMzjJjuxQI>.

156. See Mike Adams, *Big Tobacco Ad from 1953 Sums Up the Scientific Fraud of the Entire Vaccine Industry Today*, NATURAL NEWS (Mar. 3, 2015), http://www.naturalnews.com/048846_science_lies_Big_Tobacco_vaccine_industry.html.

157. See Adams, *supra* note 154 (stating that a 1930 study in Cologne, Germany, was the only research at the time to make a statistical correlation between cancer and smoking, but the tobacco industry dismissed it as anecdotal).

158. Morton L. Levin, Hyman Goldstein & Paul Gerhardt, *Cancer and Tobacco Smoking: A Preliminary Report*, 143 *JAMA* 336, 336 (1950). See also Adams, *supra* note 154.

159. See Michael Schuller, *A Toxic History Lesson*, CNN (June 3, 2010, 6:53 PM), <http://www.cnn.com/2010/HEALTH/06/03/ddt.toxic.america/index.html> (naming lead and dichlorodiphenyltrichloroethane (DDT) as other things that were assuredly safe before science discovered they were not). See also Sanjay Gupta & Elizabeth Cohen, *Formaldehyde Among Substances Added to Cancer List*, CNN (June 13, 2011), <http://thechart.blogs.cnn.com/2011/06/13/formaldehyde-among-those-added-to-cancer-list/> (reporting the official addition of formaldehyde to the National Toxicology Program’s “list of substances known to cause cancer” and adding that the “move [came] after years of delays prompted by critics, including the chemical industry, who [claimed] the studies used to establish the link to cancer [were] not based on science”).

160. Poreda, *supra* note 5, at 806.

161. See *id.* at 773–74.

162. *Viral Hepatitis*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 31, 2015), <http://www.cdc.gov/hepatitis/hbv/index.htm>.

contract the disease,¹⁶³ but newborns are also at risk if their mothers have the HBV.¹⁶⁴ This is precisely why medical professionals routinely test pregnant women and implement protective safeguards for the babies whose mothers test positive.¹⁶⁵ In light of the fact that the individuals who are most vulnerable are those who share intravenous needles, engage in promiscuous unprotected sex, or work in the health care sector, then¹⁶⁶ it is a mystery why the HBV vaccine is one of the first vaccines that the CDC recommends to *every single* newborn within the first twelve hours of birth—even before hospital discharge.¹⁶⁷

IV. WHAT THIS MEANS FOR SB-277

A. *Open to Constitutional Attack?*

Time and again,¹⁶⁸ courts have looked to *Jacobson* to uphold mandatory vaccination laws.¹⁶⁹ Its impact has been far reaching to say

163. See Thomas, *supra* note 138.

164. Holland, *supra* note 139, at 67. See also *Viral Hepatitis: Perinatal Transmission*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 19. 2017), <https://www.cdc.gov/hepatitis/hbv/perinatalexmtn.htm>.

165. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 164.

166. Horwin, *supra* note 27, at 334.

167. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 108, at 161. See generally Holland, *supra* note 139, at 68–76 & nn.237 & 268. Holland’s article reports that in 1982, the ACIP only recommended the HBV vaccine to those at substantial risk—approximately five percent of the American population. By 2005, however, the ACIP was recommending the vaccine to *all* infants. To get to the bottom of this, the Association of American Physicians and Surgeons (Association) filed a Freedom of Information Act request, seeking all of the CDC’s safety data on the vaccine. Still awaiting an answer in 2011, and armed with evidence linking HBV vaccines to autism, the Association issued a statement that the ACIP’s failure to respond was “damning”—at-birth HBV vaccine recommendations had been made “without conducting proper safety studies in babies beforehand.” Additionally, considering that revenues in the United States from HBV vaccines totaled \$468.1 million in 2003, some scholars have concluded that the ACIP’s dramatic change in tune could have only been financially motivated. There was no medical rationale for introducing the vaccine to infants and young children. Vaccinating this group to avoid disease later on in adulthood, especially when immunity tended to wear out, did not make medical sense.

168. Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 577 & 578 tbl.1 (2005) (counting 69 times that *Jacobson* was cited). See also *Whitlow v. Cal., Dep’t of Educ.*, 203 F. Supp. 3d 1079 (S.D. Cal. 2016).

169. See, e.g., *supra* notes 61–62 and accompanying text. See also *Whitlow*, 203 F. Supp. 3d at 1083.

the least.¹⁷⁰ As long as states pay respect to the floor of constitutional protections established by the *Jacobson* Court,¹⁷¹ even coercive vaccine mandates¹⁷² have generally passed constitutional muster.¹⁷³ Add to this the doctrine of *parens patriae*, which entered the vaccination jurisprudence scene in 1944,¹⁷⁴ and one might even argue that a state's power nowadays to enforce vaccination laws is absolute. Accordingly, proponents of vaccines should feel confident that courts would uphold SB-277 in the same fashion then, right? Not so fast. While it is true that the United States District Court for the Southern District of California has already denied a motion for a preliminary injunction enjoining the state of California from enforcing SB-277,¹⁷⁵ the bill may still be susceptible to attack.

1. *Disallowing Non-Medical Exemptions Disregards Established Fundamental Liberty Interests and Relying on Jacobson Requires Adherence to Outdated Legal Principles*

The first ground on which SB-277 could be susceptible to constitutional attack is if courts continue to rely on *Jacobson*¹⁷⁶ despite the bill's disregard for established fundamental liberty interests.¹⁷⁷ Government action that allegedly infringes upon a fundamental liberty interest demands strict scrutiny review,¹⁷⁸ but this is not what the *Jacobson* Court employed.¹⁷⁹ By deeming the board of health's authority not "unreasonable or arbitrary,"¹⁸⁰ the Court, in actuality, employed a primitive version of rational basis review.¹⁸¹

Understandably, the Supreme Court could not have applied strict scrutiny review back in 1905—neither the current standards of review nor any of the privacy and bodily integrity rights at stake here

170. Richins, *supra* note 50, at 416.

171. Gostin, *supra* note 168, at 576 (stating that the floor of constitutional protections consist of four standards: necessity, reasonable means, proportionality, and harm avoidance).

172. Poreda, *supra* note 5, at 795.

173. See Gostin, *supra* note 168, at 576.

174. See *supra* notes 58–59.

175. See *Whitlow v. Cal., Dep't of Educ.*, 203 F. Supp. 3d 1079 (S.D. Cal. 2016).

176. Gostin, *supra* note 168, at 578 tbl.1.

177. See S.B. 277, 2015–2016 Reg. Sess. (Cal. 2015) (infringing on privacy and bodily integrity rights by mandating vaccines notwithstanding objections based on personal beliefs).

178. See *Zablocki v. Redhail*, 434 U.S. 374, 381 (1978); *Moore v. City of E. Cleveland, Ohio*, 431 U.S. 494, 548 (1977); *Poe v. Ullman* 367 U.S. 497, 543 (1961); Richins, *supra* note 50, at 420.

179. See *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905).

180. *Id.*

181. Ben Horowitz, *A Shot in the Arm: What a Modern Approach to Jacobson v. Massachusetts Means for Mandatory Vaccinations During a Public Health Emergency*, 60 AM. U. L. REV. 1715, 1733; see also Richins, *supra* note 50, at 422.

existed then.¹⁸² Today though, courts are in much different positions. Where fundamental rights are at issue, courts must apply the heightened standard of analysis.¹⁸³ Foregoing it in favor of *Jacobson*'s age-old irrelevant one is inappropriate¹⁸⁴—maybe even erroneous. As some scholars have aptly stated, the century-old doctrines of *Jacobson* are so incompatible with modern judicial developments¹⁸⁵ that a large part of the Court's analysis should be considered a “relic of a bygone era” when civil liberties were not so important.¹⁸⁶

2. *SB-277's HBV Vaccine Mandate Fails Strict Scrutiny Review and Implicates Equal Protection Issues*

The second ground on which SB-277 is susceptible to constitutional attack has to do with its mandate for the HBV vaccine.¹⁸⁷ Because fundamental liberty rights demanding strict scrutiny review are at stake,¹⁸⁸ California must come up with a narrowly tailored “compelling interest and least restrictive means” argument¹⁸⁹ to justify the vaccine's inclusion. For the following reasons, California may find it difficult to do so.

First, to assert a compelling state interest, California would have to show that preventing school-aged children from contracting the HBV infection is a necessity¹⁹⁰—a necessity so “overbalancing” and “weighty” on the constitutional scale¹⁹¹ that it would justify limiting fundamental privacy and bodily integrity rights. Studies indicate

182. See *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 n.4 (1938) (demonstrating that it took thirty-three years after *Jacobson* for the United States Supreme Court to even hint at a heightened standard of judicial review: “[P]rejudice against discrete and insular minorities may be a special condition, . . . which may call for a correspondingly more searching judicial inquiry”). See also *supra* Sections II.D.2–3 (outlining the evolution of privacy and bodily integrity rights).

183. Today, strict scrutiny analysis is well established. *Planned Parenthood of Southeastern Pennsylvania v. Casey* sets forth the test like so: “[L]imitations on the right of privacy are permissible only if . . . the governmental entity imposing the restriction can demonstrate that the limitation is both necessary and narrowly tailored to serve a compelling governmental interest.” 505 U.S. 833, 929 (1992).

184. Horowitz, *supra* note 181, at 1733.

185. *Id.* at 1749.

186. *Id.* at 1733. See also Note, *Towards a Twenty-First-Century Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1835 (2008).

187. S.B. 277, 2015–2016 Reg. Sess. (Cal. 2015).

188. Horowitz, *supra* note 181, at 1749.

189. See *Roe v. Wade*, 410 U.S. 113, 155 (1973).

190. Holland, *supra* note 139, at 81.

191. *Braunfeld v. Brown*, 366 U.S. 599, 613–14 (1961) (Brennan, J., concurring and dissenting) (describing “compelling state interest” as an interest so “overbalancing” and “weighty [on] the constitutional scale” that it justifies government limitation on established fundamental freedoms. In this case, free exercise of religion was the right at issue).

the opposite is true though. The incidence of HBV infection among children is extremely low,¹⁹² which means two things: (1) children are not the ones most at risk,¹⁹³ and (2) the HBV vaccine is of little benefit to them.¹⁹⁴ So, while California could point to the vaccine's approval by the Food and Drug Administration (FDA) and ACIP as demonstrative of its reasonableness,¹⁹⁵ a reasonable state interest is barely a compelling one.¹⁹⁶

Second, supposing California could even pass the first hurdle, it would then have to prove that the HBV vaccine mandate is the least restrictive means of achieving its ultimate goal—prevention of the entire population, not just children, from contracting the disease.¹⁹⁷ Because immunity from the HBV vaccine inevitably wears off by adulthood,¹⁹⁸ mandating the vaccine for children alone¹⁹⁹ can hardly be argued as the least restrictive means.

That being said, imposing the HBV vaccine solely on this age group may also give rise to equal protection issues.²⁰⁰ As the group who has the least risk for contracting the disease, children are the ones who must bear the risks that are associated with vaccination.²⁰¹ A child petitioner might very well make a case for discrimination, seeing as how the adult population, which is demonstrably at far greater risk, is exempted.²⁰²

192. Holland, *supra* note 139, at 81. *See also supra* Section III.B.3 and accompanying notes.

193. *See* Holland, *supra* note 139, at 81.

194. *See supra* Section III.B.3 and accompanying notes.

195. *See* Holland, *supra* note 139, at 81.

196. *See id.* at 81, 84.

197. S.B. 277, 2015–2016 Reg. Sess. § 1(a) (Cal. 2015); Ctrs. for Disease Control & Prevention, *The Adult Hepatitis Vaccine Project—California, 2007–2008*, 59 MORBIDITY & MORTALITY WKLY. REP. 514 (2010).

198. *See* Thomas, *supra* note 138 (reporting that only twenty-four percent of people who received the HBV vaccine as infants still had immunity as teenagers).

199. *See* Holland, *supra* note 139, at 84; *supra* Section III.B.3. California does not mandate the HBV vaccine for adults—even those at high risk. For example, in the context of industrial safety, California merely provides that employers must make the HBV vaccine available to employees who, through their occupation, get exposed to blood borne pathogens. If an employee declines the HBV vaccine, he or she only has to sign a statement of acknowledgment. *See* CAL. CODE REGS. tit. 8, §§ 5160, 5193(f)(2)(D) & app. A (1993).

200. Holland, *supra* note 139, at 84.

201. *Id.* at 81.

202. *Id.* at 84.

B. *Suggestions for Amendments*

1. *Allow for Non-Medical Exemptions with Safeguards to Protect Against Abuse and Make the HBV Vaccine Optional*

Non-medical exemptions help balance public health and personal liberty interests.²⁰³ They allow parents who sincerely disagree with one or more aspects of an immunization program to opt out of compliance.²⁰⁴ Although the bill's supporters argue that the exclusion of all non-medical exemptions prevents abuse by those likely to invoke exemptions for non-valid and non-sincere reasons,²⁰⁵ there is a better way.

Studies show an inverse relationship between the complexity of requirements and the proportion of parents claiming exemptions for their children.²⁰⁶ Thus, states with the most complex procedures for obtaining exemptions exhibit the lowest opt-out rates.²⁰⁷ The non-medical exemption framework ("Framework") proposed by the Johns Hopkins group²⁰⁸ in Arkansas in the aftermath of *Boone v. Boozman*²⁰⁹ would carry over well if applied to SB-277.

The Framework requires parents wishing to invoke non-medical exemptions to prove that their beliefs are sincere and well informed,²¹⁰ and the best way to do this is to make exemptions difficult to obtain.²¹¹ In a nutshell, the hurdles proposed by the Framework include having to meet with a doctor or public health official for individual counseling, annually renewing the exemption, and composing a statement stating: (1) the reason for requesting the exemption; (2) the parent's belief that the vaccination is inappropriate for the child; (3) the duration the parent has held the belief; (4) the parent's understanding that the child may be removed from school in the event of an outbreak; and (5) the parent's confirmation that

203. Poreda, *supra* note 5, at 780.

204. *See id.* at 780–81.

205. *See* Melissa Jenco, *FAAP Helps Change California Vaccine Law*, AAP NEWS (June 30, 2015), <http://aapnews.aapublications.org/content/early/2015/06/30/aapnews.20150630-1>. *See also* Poreda, *supra* note 5, at 792.

206. Jennifer S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645, 647 (2001).

207. *Id.* at 647 fig.1; Poreda, *supra* note 5, at 791.

208. Poreda, *supra* note 5, at 798 & n.235.

209. *Boone v. Boozman*, 217 F. Supp. 2d 938 (2002). *See* Poreda, *supra* note 5, at 798 & n.230.

210. Poreda, *supra* note 5, at 807.

211. *Id.* at 799.

he or she has received counseling concerning the vaccine's risks and benefits.²¹² Obviously, the inconvenience is deliberate.²¹³

If California adopts the Framework, it can better balance parents' interests with its own. Face to face counseling will assure that parents are not making uninformed decisions to opt out while the annual renewal process will assure that parents who do opt out re-evaluate their decision in subsequent years.²¹⁴ California will have the added bonus of affording itself the opportunity to educate parents and dispel so-called misperceptions about vaccines.²¹⁵ And on the flip side, doctors and public health officials will be able to learn more about parents' concerns and the bases for these concerns.

Regarding the HBV vaccine, the solution is simpler. Because it is not likely to survive a strict scrutiny analysis, California should make it optional or exclude it altogether from SB-277's mandatory list.

V. CONCLUSION

As a sponsor of SB-277, Senator Richard Pan expressed hope that the bill would cause parents to receive information about vaccines, engage in meaningful conversations with health care professionals, rethink their concerns about vaccines, and become more open to listening to actual science and facts whilst turning away from the "misinformation that's been peddled [about] by too many people."²¹⁶ What Senator Pan has turned a blind eye to, though, is the fact that SB-277's current exclusion of all non-medical exemptions adheres to an outdated legal standard that fails to take into account established fundamental personal liberty interests. Furthermore, SB-277's inclusion of non-essential vaccines like the HBV vaccine is not narrowly tailored enough—the specific mandate will likely not survive strict scrutiny analysis.

Add to this the sentiment shared by many people that SB-277 was rushed through California's Legislature by lawmakers who used the Disneyland measles outbreak as an excuse to increase government control.²¹⁷ For this group, the question is not whether to

212. *Id.* at 800.

213. *Id.*

214. *Id.*

215. *Id.* at 793.

216. Jenco, *supra* note 205.

217. Kroner & Donnelly, *supra* note 32 (reporting that "[i]t wasn't 'responsible Californians' who voted to deny parents' rights to make informed decisions about their child[ren's] health; it was 24 California senators who used the Disneyland measles outbreak as an excuse to increase government control . . ." and also: "[T]here were 125 confirmed cases Of

vaccinate, but whether parents should have the right to make informed medical decisions about their children's health.²¹⁸

California can certainly enact SB-277 but its makers should be mindful about aspects of the bill that could falter under constitutional attack. Even though courts have relied on *Jacobson* up until this point to uphold mandatory vaccination laws, they may face increasingly difficult problems in continuing to do so, especially in light of the judiciary's growing recognition of fundamental privacy and bodily integrity rights. SB-277 has a much better chance at withstanding constitutional attack if it allows for non-medical exemptions and makes the HBV vaccine optional. Procedural obstacles will safeguard against abuse, and the bill, as a whole, will stand a better chance of surviving a heightened standard of review.

those 125 cases, 110 patients were California residents and only 49 were totally unvaccinated. This means that more than 50 percent of those who actually got the measles were, in fact, vaccinated").

218. *Id.*



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