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## Enlightened Regulatory Capture

David Thaw

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# ENLIGHTENED REGULATORY CAPTURE

David Thaw\*

*Abstract:* Regulatory capture generally evokes negative images of private interests exerting excessive influence on government action to advance their own agendas at the expense of the public interest. There are some cases, however, where this conventional wisdom is exactly backwards. This Article explores the first verifiable case, taken from healthcare cybersecurity, where regulatory capture enabled regulators to harness private expertise to advance exclusively public goals. Comparing this example to other attempts at harnessing industry expertise reveals a set of characteristics under which regulatory capture can be used in the public interest: (1) legislatively mandated adoption of recommendations by an advisory committee comprising private interests and “reduced-bias” subject matter experts; (2) relaxed procedural constraints for committee action to prevent internal committee capture; and (3) opportunities for committee participation to be worthwhile for representatives of private parties beyond the mere opportunity to advance their own interests. This Article presents recommendations based on those characteristics as to how and when legislatures may endeavor to replicate this success in other industries to improve both the legitimacy and efficacy of the regulatory process.

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## INTRODUCTION

Traditional academic scholarship and political discourse generally view the concept of regulatory capture in a negative light. Indeed, empirical results demonstrate many examples of regulatory capture generating results contrary to the public interest, or at least servicing a small subset of private interests at the expense of goals articulated to serve broader segments of the polity.

Despite this generally negative view, some recent scholarship speculates that regulatory capture may be used to advance more “public” goals.<sup>1</sup> This Article takes a similar position, advancing the work of Dorit Rubinstein Reiss and Lawrence Baxter by providing a concrete empirical example of regulatory capture used to advance public goals.

Cybersecurity<sup>2</sup> presents a curious case where traditional concepts of capture—in which entities with power in a regulatory process use that power to advance their private interests<sup>3</sup>—do not seem to hold. Rather than advancing their private interests at the expense of articulated public goals,<sup>4</sup> the entities used that power to ensure the production of strong and effective security regulations even at a higher cost to themselves. Stated differently, structural characteristics of the regulatory process in the cybersecurity context arguably forced alignment of these regulated entities’ interests with the “public interests” articulated by the legislature.

This Article explores the possibility of engaging private expertise

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1. See, e.g., Lawrence G. Baxter, “Capture” in *Financial Regulation: Can We Channel it Toward the Common Good?*, 21 CORNELL J.L. & PUB. POL’Y 175 (2011); Dorit Rubinstein Reiss, *The Benefits of Capture*, 47 WAKE FOREST L. REV. 569 (2012).

2. As noted by Professor Andrea Matwyshyn, “[r]eferring to all of information security, particularly in private sector contexts, as ‘cybersecurity’ is technically incorrect.” Andrea M. Matwyshyn, *Hacking Speech: Informational Speech and the First Amendment*, 107 NW. U. L. REV. 795, 817 n.99 (2013). Matwyshyn describes this misnomer as ignoring the aspects of physical security inherent in “holistic” protection of data maintained by an enterprise. *Id.* I concur with this assessment, and further suggest, as consistent with the Administrative/Technical/Physical breakdown adopted by the healthcare cybersecurity example (42 U.S.C. § 1320d-2(d)(2) (2006)), that such a characterization also overlooks the administrative aspects involved in protecting security information. See David Thaw, *Criminalizing Hacking, Not Dating: Reconstructing the CFAA Intent Requirement*, 103 J. CRIM. L. & CRIMINOLOGY 907 (2013) (discussing the distinction between purely technical restrictions on computer usage and comprehensive administrative, technical, and physical restrictions thereon). Cybersecurity remains the common term with which most readers will be familiar, and thus I utilize that term when describing the matter generally. In Part II, when considering the technical details of the cybersecurity example in context, I use the term “information security” when technologically appropriate.

3. Philip J. Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1, 43–46 (1982).

4. In this case, the “public” goals articulated in the underlying organic (or enabling) statute pursuant to which the rulemaking process in question proceeded.

through certain forms of regulatory capture to increase the legitimacy and efficacy of the regulatory process. Previous work on consensual rulemaking received mixed reviews in administrative law literature.<sup>5</sup> The seminal body of work on this type of hybrid rulemaking, conducted by Professor Philip Harter, led to the Negotiated Rulemaking Act (NRA) amendments to the Administrative Procedure Act (APA). While the results have been mixed, the balance of academic scholarship and agency choice suggests that current approaches to engaging private expertise have not achieved their full promise.

Building on Reiss' and Baxter's speculation and the groundwork laid by Harter, this Article presents cybersecurity as a successful case of engaging private expertise through legislatively encoded regulatory capture that aligned private with public interests. It contrasts this example with cases of negotiated rulemaking, a process also designed to engage private expertise but criticized for being too easily subjugated by private interests.<sup>6</sup> Based on these examinations and a thorough empirical treatment of the cybersecurity example,<sup>7</sup> I posit a set of general characteristics describing the regulatory environment/subject matter suggestive of when capture-like engagement of private expertise may succeed in aligning public and private interests. I describe this process, designed to leverage regulatory capture to harness private expertise for public goals, as Enlightened Regulatory Capture.

This Article proceeds in three Parts. Part I traces the development of consensual rulemaking and contextualizes this work within the existing debate on the NRA and regulatory capture more broadly. It examines case studies of negotiated rulemaking in action and discusses the efficacy of this process in the context of engaging private expertise to increase efficiency and legitimacy in administrative action. Part II examines the curious case of cybersecurity rulemaking under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in which representatives of private entities used their expertise to advance public interests. To the best of my knowledge, this is a unique circumstance,

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5. Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255 (1997); William Funk, *Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest*, 46 DUKE L.J. 1351 (1997); Philip J. Harter, *Assessing the Assessors: The Actual Performance of Negotiated Rulemaking*, 9 N.Y.U. ENVTL L.J. 32 (2000); Jeffrey S. Lubbers, *Achieving Policymaking Consensus: The (Unfortunate) Waning of Negotiated Rulemaking*, 49 S. TEX. L. REV. 987 (2008); Andrew P. Morriss et al., *Choosing How to Regulate*, 29 HARV. ENVTL. L. REV. 179 (2005).

6. See generally Funk, *supra* note 5.

7. David Thaw, *The Efficacy of Cybersecurity Regulation*, 30 GA. ST. U. L. REV. (forthcoming 2014), available at <http://ssrn.com/abstract=2241838>.

created possibly by Congressional accident.<sup>8</sup> This Part describes how the members of the pre-rulemaking committee, all of whom were representatives of interested parties, utilized their substantive expertise to develop the best regulations without prioritizing their entities' private interests. Finally, Part III explores the particular characteristics of the cybersecurity example that make capture an effective means to engage private expertise for public goals. Building on the work of Professor Harter, it generalizes a set of characteristics indicative of when such an approach may be successful and uses the analysis from Part I to hypothesize what other industrial sectors are suitable to regulation of this form. Finally, this Article concludes by recommending further Congressional and agency experimentation with this process and providing some suggestions for such experimentation.

In sum, this Article demonstrates two critical points. First, the concept of engaging private expertise through regulatory capture has not been a unilateral failure and deserves further consideration. Second, when properly structured and applied to suitable cases, this capture-like function may in fact have the effect opposite its traditional conception: it will increase both the representative legitimacy and the efficacy of the regulatory process.

## I. TRADITIONAL CONCEPTIONS OF REGULATORY CAPTURE

The term “regulatory capture” traditionally evokes negative connotations of backroom dealing, placement of industry-friendly individuals in key regulatory positions, and the breakdown of the regulatory process that grinds it to a proverbial halt. The concept often conflates with the idea of *any* private involvement in administrative rulemaking and adjudicatory processes. While private involvement certainly can have (and has had<sup>9</sup>) socially undesirable effects, ignoring private expertise overlooks a wealth of valuable technical information about the regulated subject matter.<sup>10</sup>

Tensions between regulators and regulated entities increased substantially during the second half of the twentieth century. Private interests, dissatisfied with regulatory outcomes, responded to this

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8. *See infra* note 134.

9. Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337 (2013); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

10. Reiss, *supra* note 1.

perceived “lack of representativeness” by engaging in various methods to exert influence over the process to achieve their private ends. This influence, commonly believed to be contrary to the public interest and at the time most easily achieved through placement of sympathetic individuals in key government positions, became known as regulatory capture.

The concept of negotiated rulemaking rose both as a response to the regulatory breakdown described above and as a compromise allowing regulated entities meaningful access to the rulemaking process. Professor Philip Harter first proposed the idea in his article, *The Political Legitimacy and Judicial Review of Consensual Rules*.<sup>11</sup> This concept of consensual rulemaking, as Harter first described it, gained legitimacy during the 1980s<sup>12</sup> and ultimately was adopted by Congress in 1990 in the NRA.<sup>13</sup> Negotiated rulemaking promised a solution to the tensions above, without the negative risks traditionally associated with regulatory capture.<sup>14</sup> Its success in this regard, however, remains the subject of dispute.<sup>15</sup>

This Part traces the evolution described above as a backdrop to Part II. Other works present excellent comprehensive historical accounts of this evolution, and this Article does not seek to replicate such accounts. Rather, this Part contextualizes portions of that history relevant to the hypothesis that attempts to harness private expertise in regulation have, thus far, been mostly counterproductive or at least inefficient. It begins with a brief examination of the history of regulatory capture and the rise of negotiated rulemaking. It then proceeds to examine cases of negotiated rulemaking, including where and why it was and was not used by agencies. There have been a few notable successes, but generally negotiated rulemaking is not characterized as successful in scholarly literature. This Part concludes by arguing that, absent the imposition of certain constraints, negotiated rulemaking and other forms of hybrid rulemaking are at high risk of the negative aspects of regulatory capture. Part II then presents the case of information security regulations as a notable counter-example escaping these negative effects.

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11. Philip J. Harter, *The Political Legitimacy and Judicial Review of Consensual Rules*, 32 AM. U. L. REV. 471, 476–85 (1983).

12. See Funk, *supra* note 5; Harter, *supra* note 5; Harter, *supra* note 11.

13. Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648, 104 Stat. 4969 (codified as amended at 5 U.S.C. §§ 561–570 (2012)).

14. Harter, *supra* note 11, at 476–77.

15. Harter, *supra* note 5 (discussing Coglianese, *supra* note 5).

A. *Classic Unfavorable Views of Regulatory Capture*

Classic views of regulatory capture consider the phenomenon to be normatively undesirable as disruptive of both democratic legitimacy<sup>16</sup> and institutional accountability in the administrative state.<sup>17</sup> The term “regulatory capture” has been used broadly throughout administrative law literature.<sup>18</sup> Some variations focus on the placement of sympathetic individuals in key positions within administrative agencies,<sup>19</sup> while others focus on the ability of private parties to influence regulatory outcomes by exerting pressure through procedural aspects of administrative processes.<sup>20</sup> Livermore and Revesz provide a perspective-neutral description of the overarching category encompassing all these views, arguing that “capture can be understood to occur when organized groups successfully act to vindicate their interests through government policy at the expense of the public interest.”<sup>21</sup>

This Article starts from the “expense of the public interest” viewpoint of regulatory capture. It then proposes a contrary position, arguing that in certain instances, private influence over administrative processes can be structured through legislation to harness private expertise not at the expense of the public interest, but rather in support of it. Thus, this Article considers procedural capture, whereby regulated entities and other private interests are able to use procedural authority, such as the threat of acting in a manner that will break down and invalidate or delay the administrative process, to achieve given outcomes contrary to the public interest. Most often this applies in the rulemaking context, such as in the case of negotiated rulemaking. Some scholars, however, describe examples in adjudicatory contexts as well.<sup>22</sup>

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16. Baxter, *supra* note 1.

17. *See* Stigler, *supra* note 9.

18. *See* Livermore & Revesz, *supra* note 9.

19. Frédéric Boehm, *Regulatory Capture Revisited—Lessons from Economics of Corruption* (Internet Centre for Corruption Research, Working Paper No. 22, 2007), available at <http://www.icgg.org/corruption.research.html>.

20. *See id.*

21. Livermore & Revesz, *supra* note 9, at 1343.

22. *See* Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking, and Accountability in the Administrative State*, 56 DUKE L.J. 377 (2006); Mark Seidenfeld, *Empowering Stakeholders: Limits on Collaboration as the Basis for Flexible Regulation*, 41 WM. & MARY L. REV. 411, 429 (2000).



### 1. *What is the “Public Interest?”*

Debate over what constitutes the “public interest” enjoys a rich history both in political theory and in political action. This Article does not engage in a debate as to what substantively constitutes the public interest. To the contrary, the hypothesis advanced in this Article suggests that the concept of the public interest need not be fully defined a priori the regulatory process. Rather, it proposes that under certain circumstances, discussed in Part III, the incentives of private parties involved in the regulatory process can be aligned such that those private parties’ goals are consistent with the hypothetical legislative process which purports to act in the public interest. This Article does not opine as to whether the legislative process in a representative republic such as the United States can, or whether the U.S. federal legislature actually does, act in such a fashion. Rather, it only takes the position that regulatory interests can be aligned to act similarly to a legislature, thereby increasing the legitimacy and efficacy of the regulatory process.

Of course, being a process of regulation, the legislature will have provided some preliminary guidance as to subject matter and goals. This is precisely consistent with a concept of the public interest that is agnostic respecting the hypothesis of this Article—the assumption is that whatever guidance the legislature provides *must* be in the public interest, and whatever details and discretion are delegated to the administrative agency should operate consistent with that public interest. This Article proposes a hypothesis for improving the process by which the agency exercises that discretion and fills in the details. By structuring the process to function as a miniature or “proxy” legislature, the agency’s regulatory outcomes retain greater legitimacy while still fulfilling their task of engaging subject matter expertise and leveraging that portion of the expertise held by private entities.

### 2. *The Rise of Regulatory Capture and Adversarial Rulemaking*

Engaging private expertise does, however, carry substantial risk of regulatory capture.<sup>23</sup> Effective engagement of private expertise requires more than just the traditional “notice and comment” informal

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23. See Sidney A. Shapiro & Rena I. Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741 (2008); David J. Sousa & Christopher McGrory Klyza, *New Directions in Environmental Policy Making: An Emerging Collaborative Regime or Reinventing Interest Group Liberalism?*, 47 NAT. RESOURCES J. 377, 427 (2007); Matthew D. Zinn, *Policing Environmental Regulatory Enforcement: Cooperation, Capture, and Citizen Suits*, 21 STAN. ENVTL. L.J. 81 (2002).

rulemaking process.<sup>24</sup> As described in the *Attorney General's Manual on the Administrative Procedure Act*, “an agency is free to formulate rules upon the basis of materials in its files and the knowledge and experience of the agency, in addition to the materials adduced in public rule making proceedings.”<sup>25</sup> Many agencies have adopted this viewpoint, determining that they are free to ignore comments submitted during informal rulemaking proceedings and promulgate regulations based on their own expertise.<sup>26</sup> Thus, to fully engage private expertise, agencies must either be subject to “capture” through the placement of sympathetic individuals in key positions within the agency,<sup>27</sup> or the regulatory process must be structured in a way that incentivizes (or even compels) the agency to engage private expertise.

As described by Professor Harter, “[b]eginning in the mid-1960s, regulatory procedure began its evolution toward [this] hybrid process.”<sup>28</sup> Both Congress<sup>29</sup> and the courts<sup>30</sup> played roles in expanding the use of hybrid rulemaking processes, which variously required more process and the development of greater factual material before an agency was permitted to promulgate a rule. This process progressed over several years, evolving agencies’ roles from what Harter described as “expert guardian[s] of the public interest”<sup>31</sup> into “umpire[s] . . . reaching policy decisions as [a] result of adversar[ial] activity [among] competing [private interests].”<sup>32</sup> Although this trend toward adversarial hybrid rulemaking was substantially mitigated by the Supreme Court’s decision

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24. Reiss, *supra* note 1, at 596.

25. U.S. DEP’T OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 31–32 (1947).

26. Steven J. Balla, *Between Commenting and Negotiation: The Contours of Public Participation in Agency Rulemaking*, 1 I/S: J.L. & POL’Y FOR INFO. SOC’Y 59, 64 (2005).

27. See Michael C. Nissim-Sabat, *Capturing This Watchdog? The Consumer Financial Protection Bureau Keeping the Special Interests Out of Its House*, 40 W. ST. U. L. REV. 1 (2012). As noted above, this type of capture generally is outside the scope of this Article, which focuses rather on *procedural* capture.

28. Harter, *supra* note 3, at 10.

29. *Id.*

30. See, e.g., *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 57 (D.C. Cir. 1977) (holding that once a notice of proposed rulemaking is issued, all ex parte communications by agency officials or employees must be documented in the public file so that interested parties may comment on said contacts); *Mobil Oil Corp. v. Fed. Power Comm’n*, 483 F.2d 1238, 1252–54, 1262–64 (D.C. Cir. 1973) (holding that rules setting minimum rates to be charged by natural gas pipeline owners were subject to more procedure than the minimal requirements of section 553 of the APA, but less than that required by sections 556 and 557).

31. Harter, *supra* note 3, at 14.

32. *Id.* at 14 n.73 (citing Williams, *Fifty Years of the Law of Federal Administrative Agencies— and Beyond*, 29 FED. B.J. 267, 276 (1970)).

in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*,<sup>33</sup> courts at the time found other methods to constrain agencies<sup>34</sup> and Congress's ability to impose additional constraints of course remained unaffected. The result was a situation in the early 1980s that Harter described as "a crisis of legitimacy that [was] the [then] current malaise."<sup>35</sup>

Harter's observations in 1980 were accurate. Scholars are split over whether the consensual regulatory responses, such as negotiated rulemaking, were ever effective in addressing the problems of the 1980s.<sup>36</sup> Regardless of which interpretation is correct, the contemporary regulatory process faces a similar challenge. The combination of political polarization,<sup>37</sup> unprecedented investment in lobbying efforts to limit or expand regulatory authority,<sup>38</sup> expansive political disagreement over regulatory capture in the financial industry and its role in the financial crisis beginning in 2008,<sup>39</sup> and other similar challenges describe a regulatory environment highly maligned by "malaise" where

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33. See generally *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519 (1978) (holding that courts could not impose additional procedural constraints on administrative agencies beyond those required under the APA or under the organic statute(s) applicable to the proceeding in question).

34. See, e.g., *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132–33 (D.C. Cir. 1995) (holding that "[n]otice of a proposed rule must include sufficient detail on its content and basis in law and evidence to allow for meaningful and informed comment" and that "[I]f, likewise, in adopting the final rule, the agency must 'articulate with reasonable clarity its reasons for decision, and identify the significance of the crucial facts'" (quoting *Greater Bos. Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970))); *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 533 (D.C. Cir. 1982) (holding that final rules must be a "logical outgrowth" of proposed rules and failure to satisfy that requirement may foreclose useful participation and make the notice-and-comment process defective).

35. Harter, *supra* note 3, at 17.

36. Cf. Coglianese, *supra* note 5; Harter, *supra* note 5. Coglianese analyzes the efficacy of negotiated rulemaking based on comparison of rulemaking time between negotiated rulemakings and ordinary notice-and-comment rulemakings, concluding that there is little difference in outcomes. Harter responds by suggesting that Coglianese's empirical metrics are incorrect, and do not properly represent efficacy gains from negotiated rulemaking.

37. James Moody & Peter J. Mucha, *Portrait of Political Party Polarization*, 1 NETWORK SCI. 119 (2013).

38. See, e.g., *Post Passage Lobbying Statistics*, AM. FOR FIN. REFORM (Aug. 2, 2013), <http://ourfinancialsecurity.org/2010/08/post-passage-lobbying-statistics/>; *Wall Street Influence, by the Numbers*, AM. FOR FIN. REFORM (May 14, 2010), <http://ourfinancialsecurity.org/2010/05/wall-street-influence-by-the-numbers/>.

39. See generally Patricia A. McCoy, *Federal Preemption, Regulatory Failure and the Race to the Bottom in US Mortgage Lending Standards*, in *THE PANIC OF 2008*, at 132 (Lawrence E. Mitchell & Arthur E. Wilmarth, Jr. eds., 2010); Stavros Gadinis, *From Independence to Politics in Financial Regulation*, 101 CALIF. L. REV. 327 (2013); Brett McDonnell, *Don't Panic! Defending Cowardly Interventions During and After A Financial Crisis*, 116 PENN ST. L. REV. 1 (2011).

at least some, if not most, parties feel disenfranchised by the process.

### 3. *Responses to Regulatory Capture*

In response to these regulatory shortcomings, Harter proposed a form of consensual rulemaking under which the regulated interests and the regulators would “negotiate” regarding a proposed rule before that rule was promulgated into the APA’s informal rulemaking process.<sup>40</sup> His proposal responded to two trends in administrative law at the time: (1) methods to force agencies to improve the analytical bases for their decision-making; and (2) methods to provide interested parties an opportunity to participate in the development of rules by *sharing in the decisions* as to rulemaking, rather than adversarial participation as described in Part I.A.2 above.<sup>41</sup> In adopting this latter method, Harter argued that both the legitimacy and the efficacy of the regulatory process could be improved.<sup>42</sup> He laid out nine factors for determining when this consensual approach—which he called “Negotiating Regulations”—would be appropriate to a given regulatory process: (1) countervailing power; (2) a limited number of parties; (3) that the issues of discussion were “mature” and “concrete”; (4) inevitability of the decision; (5) the opportunity for (parties to) gain; (6) the core issue does not turn on disputed “fundamental values”; (7) the issue allows for trade-offs in negotiation; (8) scientific research could not determine a dominant approach; and (9) the results of the negotiations would be likely to be implemented in the regulatory process.<sup>43</sup>

Harter’s proposal generally involved the formation of a pre-rulemaking advisory committee including staff from the administrative agency charged with regulatory authority. Before beginning a rulemaking proceeding, the committee would be convened and required to reach a consensus on a proposed regulation, which then would become the basis for the proposed rule and adopted into the agency’s Notice of Proposed Rulemaking under the APA.<sup>44</sup> Some agencies experimented with variations of this approach throughout the 1980s.<sup>45</sup> In

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40. See generally Harter, *supra* note 11.

41. Harter, *supra* note 3, at 27.

42. See *id.* (“[This] response is an attempt to replicate at least part of the political process through advisory committees that tap a diversity of interests and that provide advice and guidance to the agency.”).

43. *Id.* at 42–51.

44. *Id.* at 115–18; see also *id.* at 57–102 (for more precise detail on Harter’s recommendations).

45. Coglianese, *supra* note 5, at 1263 & n.34 (“In 1983, the Federal Aviation Administration

1990, Congress ultimately adopted Harter's recommendation in the NRA,<sup>46</sup> which formally was incorporated into the APA in 1996.<sup>47</sup>

Agencies, however, rarely were required to employ negotiated rulemaking and few elected to adopt it voluntarily. Some scholars have argued that this failure of implementation results from a lack of efficacy at achieving either increased efficiency in rulemaking or increased perception of legitimacy about the regulatory process.<sup>48</sup> In the Part that follows, I examine a series of negotiated rulemaking examples as backdrop to presenting the cybersecurity example I hold out as a model success of regulatory capture.

### B. *Negotiated Rulemaking*

In Part I.A.3 above, I lay out the nine factors Philip Harter proposed for when negotiated rulemaking is appropriate. In this Part, I first discuss when and why agencies use negotiated rulemaking, and then proceed to examine three examples I characterize as successful and one I characterize as a failure.<sup>49</sup> For each example, I evaluate the process according to Harter's factors. I also review existing literature discussing these examples, and compare other scholars' characterizations of these examples with how my analysis of Harter's factors predicts whether they would be successful or not. The sum of this analysis lays a backdrop for Part II, in which I introduce cybersecurity as a successful example of consensual rulemaking using regulatory capture. Taken together, the analysis here and that in Part II form the basis for my recommendations

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(FAA) initiated the first formal negotiated rulemaking. A few other agencies followed the FAA in experimenting with the alternative procedure, most prominently the EPA. Although these early attempts at negotiation were generally considered valuable experiences, by 1990 only five federal agencies had promulgated rules using negotiated rulemaking . . . . The five agencies were the Department of Education, Department of Labor, Department of Transportation, Environmental Protection Agency, and Nuclear Regulatory Commission. Three other agencies—the Department of Agriculture, Department of Interior, and Federal Trade Commission—had initiated negotiated rulemaking proceedings but had yet to issue final rules following these negotiations.”)

46. Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648, 104 Stat. 4969 (codified as amended at 5 U.S.C. §§ 561–570 (2012)).

47. *See* Administrative Dispute Resolution Act of 1996, Pub. L. No. 104-320, § 11(a), 110 Stat. 3870, 3873 (codified at 5 U.S.C. §§ 561–570).

48. Coglianese, *supra* note 5, at 1277–78 (“It may well also be that skepticism on the part of agency staff partly explains why the use of negotiated rulemaking has made only a tiny dent in the overall regulatory activity of the federal government.”); *see also id.* at 1261 (“Despite all the postulations about how negotiated rulemaking will save time and eliminate litigation, the procedure so far has not proven itself superior to the informal rulemaking that agencies ordinarily use.”).

49. Regulations pertaining to international rulemaking, such as by State Department agencies, and any agencies not subject to the APA, are outside the scope of discussion for this Article.

in Part III as to what factors predict when regulatory capture may be used to structure regulation in the public interest.

1. *The “Choice” to Use Negotiated Rulemaking*

In most cases, when agencies engage in the negotiated rulemaking process, it is an elective choice. As noted by Julia Kobick, the NRA “uses permissive rather than mandatory language”<sup>50</sup> and allows agencies to “convene a negotiated rulemaking committee when ‘it is in the public interest.’”<sup>51</sup> On occasion, an agency will be required to engage in negotiated rulemaking either by statute or by Executive Order, but such mandates are rare.<sup>52</sup>

Once selected, negotiated rulemaking involves a series of pre-rulemaking steps designed to engage certain interested parties in development of a draft rule that will be adopted as the agency’s official proposed rule in its Notice of Proposed Rulemaking pursuant to the traditional information rulemaking requirements of the APA.<sup>53</sup> These steps include: (1) publication of a notice that the agency will establish a negotiated rulemaking committee;<sup>54</sup> (2) acceptance of applications for membership on the committee;<sup>55</sup> (3) establishment of the committee;<sup>56</sup> (4) conduct of the committee’s business;<sup>57</sup> (5) ongoing support of agency through the traditional rulemaking process (optional);<sup>58</sup> and (6) termination of the committee.<sup>59</sup> The Federal Advisory Committee Act (FACA) generally governs the activities of negotiated rulemaking

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50. Julia Kobick, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food and Drug Administration*, 65 FOOD & DRUG L.J. 425, 428 (2010); *id.* at n.28 (“The plain language of the statute undermines the notion that the NRA’s procedures are mandatory.” (quoting *Tex. Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 327 (5th Cir. 2001)) (internal quotation marks omitted)).

51. *Id.* at 428 (citing 5 U.S.C. § 563 (2006)).

52. Morriss, *supra* note 5, at 179 n.2 (citing 1 KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 288 (3d ed. 1994)); *see also* Geoffrey C. Hazard, Jr. & Eric W. Orts, *Environmental Contracts in the United States*, in ENVIRONMENTAL CONTRACTS: COMPARATIVE APPROACHES TO REGULATORY INNOVATION IN THE UNITED STATES AND EUROPE 71, 73 (Eric W. Orts & Kurt Deketelaere eds., 2001) (“In any event, reg negs are relatively rare. They are required by statute in only a limited number of circumstances.” (citing Coglianesse, *supra* note 5, at 1268 & n.75)).

53. *See* 5 U.S.C. § 553 (2012).

54. *Id.* § 564(a).

55. *Id.* § 564(b).

56. *Id.* § 565.

57. *Id.* § 566.

58. *Id.*

59. *Id.* § 567.

committees unless otherwise specified by statute.<sup>60</sup>

In the parts that follow, I trace and evaluate the use of negotiated rulemaking in specific cases. Existing scholarship divides on whether negotiated rulemaking has fulfilled its goals of increasing legitimacy and efficiency of the regulatory process.<sup>61</sup> The following examples do not present a direct answer to that debate. Their purpose, rather, is to highlight the function of negotiated rulemaking. In Part II, I present by example an alternate capture-based theory for increasing regulatory legitimacy and efficacy, and in Part III, I apply that theory to these examples to compare how it will function in these cases as partial basis for my hypotheses abstracting general characteristics describing when that alternate capture theory may be effective. I categorize these examples into “successes” and “failures” solely to present a reasonable balance of *qualitative* examples. Empirical analysis to validate these hypotheses is appropriate for future work and will likely benefit from the ongoing work described by other scholars.<sup>62</sup>

## 2. *Negotiated Rulemaking “Successes”*

In analyzing the following examples as “successes,” I primarily consider whether the process resulted in a rule that was adopted as a result of the negotiations process and whether the interested parties generally viewed this process as efficient and legitimate.<sup>63</sup> These examples were selected because of the relatively short number of meetings required to develop such a rule and the fact that the process demonstrated that the parties made substantial progress toward agreement on otherwise-contested issues.

These examples also serve the purpose of providing a foil for my analysis in Part III. As canonical examples in the existing literature of

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60. See generally *id.* §§ 562–570a; Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648, § 2(6), 104 Stat. 4969 (codified as amended at 5 U.S.C. §§ 561–570).

61. Cf. Coglianese, *supra* note 5; Harter, *supra* note 5.

62. See Reiss, *supra* note 1, at 572 (noting that Professor Reiss currently has three empirical studies underway evaluating the potential benefits of certain aspects of regulatory capture).

63. The primary focus here is whether the interested parties strongly objected on the basis of feeling disenfranchised by the process. The notice-and-comment process for these examples, and the scholarly literature analyzing them, suggests a degree of perceived legitimacy whereby interested parties felt that progress toward an acceptable regulation resulted from the negotiated rulemaking process and/or that they were able to express their views more effectively than through a traditional notice-and-comment rulemaking process. In contrast, consider the example discussed in Part I.B.3.a below, in which the scholarly literature characterizes interested parties to the Department of Education’s negotiated rulemaking process for implementing the No Child Left Behind Act as feeling as though the Department suppressed their viewpoints.

negotiated rulemaking successes, I examine them here as among the strongest challenges to my proposition in this Article that the healthcare cybersecurity example is unique and original and bears investigation outside its strict technological context. As I discuss in Part III, these examples can be differentiated and the processes adopted here do not share all the key characteristics I identify in the healthcare cybersecurity example.

*a. National Park Service—Cape Cod National Seashore Off-Road Vehicle Use*

The National Park Service (NPS) is responsible for “preserv[ing] and protect[ing]” natural resources designated as national park areas as well as enabling individuals to enjoy the present use of these areas and resources.<sup>64</sup> The Cape Cod National Seashore is home to a variety of natural resources including avian species protected by the Endangered Species Act—which the NPS is charged with protecting.<sup>65</sup> This region includes a corridor designated for the use of off-road vehicles, which can pose hazards to the lifecycle of endangered avian species in the area.<sup>66</sup>

The NPS originally developed a plan to balance these competing interests and promulgated appropriate regulations in 1981, and those regulations as amended in 1985 survived judicial review in 1988 and 1989.<sup>67</sup> Changes in the regional environment and the population of the endangered avian species, however, frequently necessitated that NPS implement temporary measures substantially restricting use of the off-road vehicle corridor.<sup>68</sup> Based on the contentious history surrounding the corridor’s use, the NPS elected to engage a negotiated rulemaking process for the development of a new, updated rule governing the corridor’s use.<sup>69</sup>

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64. Cape Cod Nat’l Seashore; Off-Road Vehicle Use, 63 Fed. Reg. 9143, 9143 (Feb. 24, 1998) (codified at 36 C.F.R. pt. 7 (2012)).

65. *Id.* at 9143–44; *see also* Endangered Species Act of 1973, Pub. L. No. 93-205, 87 Stat. 884 (codified as amended at 7 U.S.C. § 136 (2012) and scattered sections of 16 U.S.C.).

66. Cape Cod Nat’l Seashore; Off-Road Vehicle Use, 63 Fed. Reg. at 9143–44.

67. *Id.* at 9143.

68. *Id.* at 9144 (noting that in the late 1980s and early 1990s, “during the time when the Seashore receives the most visitors (Fourth of July), including people wishing to use the ORV corridor, only 0.4 to 0.6 miles of the corridor has been open”).

69. *Id.* While the agency also cites (unspecified) “legislative requirements” as factoring into its decision to employ negotiated rulemaking, it appears from the available materials that the choice was *not* mandated by statute. *Id.* (“The need for a new rule and the use of negotiated process was motivated by a number of events including legislative requirements, past litigation, management issues and inflexibility of the existing rule to deal with changing conditions such as the use of the



In reporting its choice to use negotiated rulemaking, the NPS describes its objective as “front load[ing] the controversy by getting all the interested parties involved in the decision-making process from the beginning and acknowledging, if not resolving, all the issues and concerns.”<sup>70</sup> The NPS did not describe how it selected the members of the committee; however, its choice of organizations (each of which were permitted one committee representative) suggests that it included local organizations most active respecting the corridor, organizations involved in prior litigation, organizations representing business interests (e.g., tourism), and appropriate federal and state agencies.<sup>71</sup> The final committee comprised twenty-three members, and bore the goal of affording equal voices to each one of them.<sup>72</sup> NPS attempted to achieve this through the well-known “consensus process” in negotiated rulemaking, under which each member of the committee had veto authority.<sup>73</sup>

The committee’s responsibility was to develop a new proposed regulation for off-road vehicle use in the corridor. NPS committed that if consensus was reached, it would adopt the committee’s proposed regulation in its official proposed regulation to be promulgated through the ordinary rulemaking process.<sup>74</sup> If the committee failed to reach consensus, however, NPS would proceed to develop a rule on its own. While NPS stated it would do so “using the ideas, information and creativity that had been gathered from the group,”<sup>75</sup> there was no statutory requirement forcing it to do so nor was there any guarantee that such input would be usable in making a rule.<sup>76</sup> Thus, a committee member with veto power could possibly use that power to force an issue.

In this case, however, the committee was successful, and reached consensus rather quickly—in a total of three two-day meetings, spaced one month apart—resulting in a convening-to-proposal-rule time of

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corridor by the [endangered avian species].”). Most likely these “legislative requirements” refer to the “need for a new rule” and not to the “use of the negotiated process.”

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. For example, if the group failed to reach consensus because of irreconcilable and mutually exclusive positions on key points, those “ideas, information and creativity” may be useless to NPS beyond informing it of positions about which it likely already knew and almost certainly would receive formal comments about during the ordinary rulemaking process.

approximately sixty days.<sup>77</sup> Based on the report on the committee's activities by the Acting Assistant Secretary, it appears that the shared desire among the participants for a new rule that would improve on the current situation (a situation generally undesirable to all) strongly disincentivized the participants from exercising their veto power.<sup>78</sup>

*b. Implementation of the "No Child Left Behind Act" for Bureau of Indian Affairs-Funded Schools*

The No Child Left Behind Act of 2001 (NCLB) required that certain rules promulgated by the Secretary of the Interior affecting schools funded by the Bureau of Indian Affairs (BIA) be developed pursuant to a negotiated rulemaking process.<sup>79</sup> The Act designated six substantive areas that were to be the subject of negotiated rulemaking procedures, one of which was the development of definitions for reporting "Adequate Yearly Progress" for BIA-funded schools.<sup>80</sup> In this instance, the use of negotiated rulemaking was compulsory, pursuant to the statute.<sup>81</sup> Congress required negotiated rulemaking given the potentially contentious issues involved with federal oversight of local schools and the widely varying interested parties, particularly in the case of BIA-funded schools.<sup>82</sup>

The Secretary of the Interior, pursuant to the requirements of the Act, convened a negotiated rulemaking committee to develop the regulations that would codify these definitions.<sup>83</sup> The committee comprised nineteen representatives of tribal organizations and six representatives of federal agencies.<sup>84</sup> All representatives of federal agencies were from within the Department of the Interior (DOI), and the Secretary (of the Interior) did not elect to seek assistance from the Department of Education (DOE) in

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77. Cape Cod Nat'l Seashore; Off-Road Vehicle Use, 63 Fed. Reg. at 9144.

78. *Id.* Although "every organization had veto authority," the members were aware that "if consensus was reached, the consensus regulation would be put forward as a proposed rule," but "[i]f the committee was unable to reach consensus on a new regulation, then the NPS would develop a new rule." *Id.*

79. 25 U.S.C. § 2018(b) (2012); *see also* Implementation of the No Child Left Behind Act of 2001, 70 Fed. Reg. 22,178, 22,178 (Apr. 28, 2005).

80. *See* Implementation of the No Child Left Behind Act of 2001, 70 Fed. Reg. at 22,178.

81. 25 U.S.C. § 2018(b).

82. Danielle Holley-Walker, *The Importance of Negotiated Rulemaking to the No Child Left Behind Act*, 85 NEB. L. REV. 1015, 1017 (2007).

83. *See* Implementation of the No Child Left Behind Act of 2001, 70 Fed. Reg. at 22,178; Proposed Membership of the Negotiated Rulemaking Committee Under Section 1138 of the No Child Left Behind Act of 2001, 68 Fed. Reg. 23,631 (May 5, 2003).

84. Implementation of the No Child Left Behind Act of 2001, 70 Fed. Reg. at 22,178.

this regard.<sup>85</sup>

The committee divided into four work groups to address the six substantive areas for which it was charged with developing regulations, with one such work group dedicated to the “adequate yearly progress” question.<sup>86</sup> The committee met five times over a five-month period, with the work groups presenting recommendations to the full committee, and it operated with a consensus requirement (with all parties having veto power).<sup>87</sup> The committee’s recommendation was adopted for publication as a proposed rule, and the committee also handled responses to public comments—including resulting modifications to the final rule—during the traditional notice-and-comment rulemaking period.<sup>88</sup>

Like the Cape Cod National Seashore example above, the consensus requirement in this case could allow a committee member to force (or more likely prevent) a particular resolution of an issue. The statutory mandate, however, that negotiated rulemaking be used in this case, changes the incentives for committee members. The Act had separate provisions for rules promulgated by the DOE and for rules promulgated by the DOI. The provisions applicable to the Secretary of Education permitted rulemaking outside negotiated rulemaking if that process failed,<sup>89</sup> whereas the provisions applying to the Secretary of the Interior did not have such an exemption.<sup>90</sup> Additionally, while negotiated rulemaking under the NCLB by the DOE was exempt from the FACA,<sup>91</sup> negotiated rulemaking under the NCLB by the DOI was not exempt from the FACA, a distinction I discuss further below.<sup>92</sup>

These differences may suggest why, as discussed further in Part I.B.3.a below, the negotiated rulemaking mandate of the NCLB has been

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85. *Id.* The Act suggests, but does not require, that the Secretary of the Interior consult with the Secretary of Education on the development of these definitions and/or the provision of other “technical assistance.” 20 U.S.C. § 6316(g)(1)(A)(i) (2012) (“The Secretary of the Interior, in consultation with the Secretary [of Education] if the Secretary of Interior requests the consultation . . . shall define adequate yearly progress . . . .”); *id.* § 6316(g)(1)(C) (“The Secretary of Interior shall, in consultation with the Secretary [of Education] if the Secretary of Interior requests the consultation, either directly or through a contract, provide technical assistance, upon request, to a tribal governing body or school board of a school funded by the Bureau of Indian Affairs that seeks to develop an alternative definition of adequate yearly progress.”).

86. Implementation of the No Child Left Behind Act of 2001, 70 Fed. Reg. at 22,178.

87. *Id.*

88. *Id.* at 22,178–79.

89. See 20 U.S.C. § 6572(a) (2012).

90. See 25 U.S.C. § 2018 (2012).

91. 20 U.S.C. § 6571(b)(4)(B).

92. 25 U.S.C. § 2018(b)(3)(E).

characterized as a failure.<sup>93</sup> It combined the additional openness required under the FACA, the DOI's choice *not* to include the DOE,<sup>94</sup> and the inability of the DOI to promulgate rules outside the negotiated rulemaking mandate. The result likely increased at least the perceived authority (if not also the actual authority) of the members of the committee and thus contributed to its increased perceived legitimacy and success.

*c. Federal Aviation Administration Flight and Duty Time Rules*

The Federal Aviation Administration (FAA) promulgated rules in the 1950s addressing limits on active service for aircrews before rest periods were required.<sup>95</sup> Although aviation technology and use expanded substantially over the following thirty years, the FAA failed to promulgate new rules by the early 1980s in large part due to substantial opposition from nearly all interested parties during the traditional notice-and-comment rulemaking process.<sup>96</sup> As a result, the Administration elected to try a negotiated rulemaking procedure in 1983.<sup>97</sup> Unlike the other examples discussed in this Part, this election was *prior* to passage of the NRA, and was therefore both completely voluntary on the part of the agency and followed the recommendations of Philip Harter and the Administrative Conference of the United States.<sup>98</sup>

Notwithstanding this notable difference, the process employed by the FAA in 1983 remarkably parallels that used in post-NRA rulemakings.<sup>99</sup> The FAA issued a notice in the Federal Register of its intent to employ a negotiated rulemaking process,<sup>100</sup> provided notice of what parties were preselected to and what procedures would apply to become part of the committee, and details of the issues to be considered by the

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93. See generally Holley-Walker, *supra* note 82.

94. See *id.* at 1018; *infra* Part I.B.3.a (discussing how Holley-Walker proposes that the DOE's influence over the negotiated rulemaking process resulted in non-DOE officials lacking meaningful participation in the rulemaking process for areas of NCLB other than BIA-funded schools).

95. See Henry H. Perritt, Jr., *Negotiated Rulemaking Before Federal Agencies: Evaluation of Recommendations by the Administrative Conference of the United States*, 74 GEO. L.J. 1625, 1667–68 (1986).

96. *Id.*

97. *Id.* at 1667.

98. See Harter, *supra* note 3, at 52–102.

99. This similarity likely is due to the fact that Harter's recommendations were substantially adopted in the final version of the NRA.

100. At that time this was referred to as “regulatory negotiation,” a term-of-art proposed by Harter that became the basis for the colloquial term “reg-neg” often used when referring to negotiated rulemaking.

committee.<sup>101</sup> The FAA agreed to promulgate any (otherwise-permissible) rule reached by committee consensus through the traditional notice-and-comment rulemaking process.<sup>102</sup> Additionally, out of concern for misuse of the negotiated rulemaking process to delay rulemaking, the FAA placed limits on the duration of the committee's activities and indicated it would proceed with its own rulemaking if the negotiated rulemaking process failed to reach consensus.<sup>103</sup> In essence, the agency was transferring a degree of structural regulatory capture to the parties as an incentive for them to participate in a consensual process.

The committee comprised the FAA and sixteen aviation industry organizations and operators.<sup>104</sup> The committee held sixteen formal meetings and more than thirty informal meetings over a period of approximately three months in 1983.<sup>105</sup> While the committee failed to reach consensus on exact regulations, it did "succeed[] in narrowing the differences among parties and in reaching substantial agreement on some issues."<sup>106</sup> The FAA thus viewed the process as a success, and produced a proposed rule based on these deliberations. It promulgated the rule through the traditional notice-and-comment rulemaking process, in which the committee was also given the opportunity to participate.<sup>107</sup>

### 3. *Negotiated Rulemaking "Failures"*

These examples serve two purposes. First, they provide contrast to the successful examples identified above for the purpose of later analysis when I compare negotiated rulemaking to the healthcare cybersecurity example. Second, examining failures of negotiated rulemaking also provides some insight into conditions when the engagement of private interests for public ends may be inappropriate. I use these insights in Part III to suggest conditions under which regulatory capture may be used to harness private expertise for public goals.

These examples were selected based on a combination of scholarly consensus that they were failures, perception by the interested parties of

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101. Perritt, *supra* note 95, at 1668–69.

102. *Id.* at 1668.

103. *Id.*

104. Flight Time, Duty Time, and Rest Requirements for Flight Crewmembers Utilized by Air Carriers, 48 Fed. Reg. 29,771, 29,772 (Jun. 28, 1983).

105. Perritt, *supra* note 95, at 1670.

106. *Id.* (internal quotation marks omitted).

107. *Id.* at 1671.

a lack of efficiency or legitimacy,<sup>108</sup> or a failure of the process to generate or substantially contribute to an adopted regulation.

*a. Implementation of Other Provisions of the “No Child Left Behind Act”*

As discussed above in Part I.B.2.b, some administrative law scholarship characterizes the NCLB as a failure of negotiated rulemaking.<sup>109</sup> The NCLB provisions discussed above as successes were specific to rulemakings by the Department of the Interior that applied to BIA-funded schools. As noted in that Subpart, key provisions of the NCLB’s negotiated rulemaking requirements differ between DOI rulemakings and DOE rulemakings.

The DOE generally is responsible for rulemaking pertaining to all schools other than those funded by the BIA. As noted above, the DOE mandate differs in two key respects: first, the DOE has the authority to promulgate regulations that may contrast with the results of the negotiated rulemaking process if the process is unsuccessful or upon proper justification;<sup>110</sup> and second, the DOE’s negotiated rulemaking procedures are not subject to the FACA.<sup>111</sup>

Danielle Holley-Walker argues that the DOE’s use of negotiated rulemaking in satisfying the NCLB requirements failed in nearly all the respects I consider in this Part.<sup>112</sup> She describes that while it “offers the promise of collaboration between the DOE, state education officials, [and other interested parties] . . . to achieve the goals of NCLB,” it failed because “[i]nstead, the voices of the non-DOE [participants were] ignored during the negotiated rulemaking process.”<sup>113</sup> The most prominent failure related to legitimacy—resulting from inadequate representation of interested parties. Of the twenty-two people selected for the DOE’s negotiated rulemaking committee, for example, seven were designated “student representatives”; however, of those seven, five were school or state employees.<sup>114</sup> She notes that while the NCLB does not require equal representation, the legislative history does note that “the DOE should achieve an ‘equitable balance between representatives

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108. *See supra* note 63.

109. *See generally* Holley-Walker, *supra* note 82.

110. *See supra* note 89.

111. *See supra* note 91.

112. *See generally* Holley-Walker, *supra* note 82.

113. *Id.* at 1018.

114. *Id.* at 1046 (internal quotation marks omitted).

of parents and students and representatives of educators and education officials' to insure 'that the views of both program beneficiaries and program providers are fairly heard and considered.'"<sup>115</sup> She cites several examples to support the position that the DOE's actions were deliberate, including purposefully inviting the subsequent litigation filed by disenfranchised parties over the composition of the negotiated rulemaking committee.<sup>116</sup>

The reasoning behind the DOE's actions is not apparent from the evidence available; however, Holley-Walker's analysis concludes that the structure of the negotiated rulemaking process—specifically the consensus requirement—creates structural incentives for the DOE to reduce the number of divergent viewpoints to increase the efficiency of its regulatory process.<sup>117</sup> This analysis bears merit, and further suggests the ironic conclusion, discussed in greater detail in Part III, that the regulatory capture element is a key element in *legitimizing* the negotiated rulemaking committee. There is no evidence the DOE experienced greater structural incentives for efficient rulemaking than the DOI. By contrast, education is not the core competency of either the DOI or the BIA, and thus (if anything) the agency would face incentives to rapidly conclude this diversion so it could return to fulfilling its core objectives. As described above, however, the DOI lacked the flexibility to diverge from the negotiated rulemaking process that the DOE possessed.<sup>118</sup> Furthermore, as also noted above, unlike the DOI, the DOE was not subject to the constraints of the FACA<sup>119</sup> which, among other things, require it to afford greater consideration to requests for membership on the committee and provide greater transparency of the committee's actions.<sup>120</sup> Had the participants in the DOE negotiated rulemaking been afforded a greater degree of regulatory capture, as was the case in the DOI example, the DOE might have been more hesitant to so readily disenfranchise them. The fact that a lawsuit relating to the DOE's selection of the negotiated rulemaking committee failed to survive the DOE's motion to dismiss<sup>121</sup> further supports this conclusion.

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115. *Id.* (quoting H.R. REP. NO. 107-334, at 809 (2001)) (emphasis omitted).

116. *Id.* at 1046–53.

117. *Id.* at 1048.

118. *See supra* notes 91–92 and accompanying text.

119. *See supra* notes 91–92 and accompanying text.

120. *See* Federal Advisory Committee Act (FACA), Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. §§ 1–16 (2012)); *infra* Part II.A.2.

121. *See* Holley-Walker, *supra* note 82, at 1048.

## II. CYBERSECURITY REGULATION: A CURIOUS COUNTER-EXAMPLE

Part I discusses how existing administrative law scholarship generally views regulatory capture negatively. While negotiated rulemaking has produced some successes since its inception, at best the literature is mixed on its efficacy and, as described in Part I.B.3, there have been notable failures. Negotiated rulemaking developed in part as a response to social or cultural capture<sup>122</sup> stemming from dissatisfaction with agency action at the time.<sup>123</sup> Ironically, it experienced notable failures in circumstances when the agency employing it failed to yield sufficient control to the interested parties in negotiations. Regrettably, notwithstanding Harter's suggestions,<sup>124</sup> agencies or their enabling statutes, or both, often fail to accomplish this goal and leave agencies with too much control over the process.<sup>125</sup> Negotiated rulemaking may have promise when implemented properly, but its current structure alone appears insufficient.

Nonetheless, in recent years several scholars have suggested—contrary to classic scholarship—that regulatory capture may be used in ways beneficial to the public good.<sup>126</sup> This work is an important step forward in understanding how to engage private expertise to serve the two core goals discussed in this paper: efficacy and legitimacy. As noted by Reiss, however, there is a dearth of empirical data presenting examples of regulatory capture working in the public interest.<sup>127</sup>

This Part presents, to the author's knowledge, the first verifiable example discussed in scholarly literature of legislatively encoded regulatory capture functioning clearly in the public interest.<sup>128</sup> When

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122. See James Kwak, *Cultural Capture and the Financial Crisis*, in PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 71 (Daniel Carpenter & David A. Moss eds., 2013), available at <http://www.tobinproject.org/sites/tobinproject.org/files/assets/Kwak%20Cultural%20Capture%20%281.16.13%29.pdf>; Baxter, *supra* note 1, at 183–84.

123. See *supra* Part I.A.2–3.

124. See Harter, *supra* note 3, at 44–51.

125. See, e.g., Holley-Walker, *supra* note 82, at 1045–47.

126. See generally Baxter, *supra* note 1; Reiss, *supra* note 1.

127. See Reiss, *supra* note 1, at 572.

128. Verification of the success of regulatory capture at representing the public interest in this example derives from two critical points. First, a regulation did result from the “captured” committee’s (NCVHS’s) activities, and that committee handled nearly all substantive aspects of the rulemaking, as discussed in Part II.A.3. Second, and most critically, the promulgated regulation resulted in healthcare entities being nearly *four times more effective* at preventing data breaches of consumers’ Protected Health Information than in other industries subject to data breach notification regimes alone. See Thaw, *supra* note 7, at 58.



Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), it included an information security requirement for entities managing individuals' sensitive health data.<sup>129</sup> The rulemaking authority for that requirement, which ultimately resulted in the HIPAA Security Rule,<sup>130</sup> delegated substantial authority to the National Committee on Vital Health Statistics (NCVHS),<sup>131</sup> a FACA committee composed entirely of representatives of private interests and private experts.<sup>132</sup>

NCVHS, while having substantial statutory capture authority, nevertheless acted neither in the private interests of its membership nor in a least-common-denominator fashion that often plagued negotiated rulemaking committees.<sup>133</sup> Rather, in a fashion rarely seen even in negotiated rulemaking, the committee members brought all their private expertise to the table—and *checked their private agendas at the door*.

This Part explores why this virtually unheard-of circumstance occurred, suggesting two primary causes: (1) the unique structure of the enabling statute's language encoding regulatory capture; and (2) the longstanding nature and developed trust in the FACA committee to which regulatory capture was committed by statute. It proceeds first by outlining and discussing the enabling statute, the Committee, and the process by which the HIPAA Security Rule was developed. It then examines the possible causes for private actors developing cybersecurity rules in the public interest, rather than in their own. Finally, it considers whether this is a circumstance unique to cybersecurity, concluding that it is at least present in some other industrial sectors, the application to which I proceed to examine in Part III.

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129. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, sec. 262(a), § 1173(d), 110 Stat. 1936, 2025–26 (codified as amended at 42 U.S.C. § 1320d-2(d) (2006)).

130. See 45 C.F.R. §§ 164.302–.318 (2007).

131. HIPAA secs. 262(a), 264(d), § 1172(f), 110 Stat. at 2024, 2034 (codified as amended at 42 U.S.C. §§ 1320d-1, 1320d-2 note) (mandating that the Secretary “consult with” and “rely on the recommendations of the National Committee on Vital Health Statistics” in promulgating regulations respecting the privacy and security of health information).

132. See 42 U.S.C. § 242k(k)(2); HIPAA sec. 263, § 306(k), 110 Stat. at 2031 (codified as amended at 42 U.S.C. § 242k(k)(2)); Federal Advisory Committee Act (FACA), Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. §§ 1–16 (2012)).

133. Cary Coglianese, *Assessing the Advocacy of Negotiated Rulemaking*, 9 N.Y.U. ENVTL. L.J. 386, 441 (2001) (“A recent study of negotiated rulemaking conducted by Charles Caldart and Nicholas Ashford shows that in industries that are not likely to innovate in the absence of strong governmental regulation, the lowest-common-denominator problem keeps negotiated rules from promoting the technological innovation needed to improve environmental and safety performance.”).

A. *HIPAA: An Experiment in Negotiated Rulemaking Alternatives*

When HIPAA was passed, Congress had decided it wanted to address the privacy of individuals' health information, but had not yet reached agreement on any specifics.<sup>134</sup> The Act had many other important provisions, including requirements for security standards, so instead of delaying its adoption, Congress added a provision to the law that if they failed to revisit the privacy question within thirty-six months, the Department of Health and Human Services (HHS) would be directed to promulgate regulations<sup>135</sup> consistent with basic "broad stroke" aspirational goals laid out in the Act.<sup>136</sup> This direction to HHS also contained the capture-like consultation requirement discussed above.<sup>137</sup> The provisions of the Act granting HHS immediate authority to promulgate regulations governing the security of health information were subject to a similar capture-like consultation requirement.<sup>138</sup>

1. *Statutory Framework*

HIPAA provided general authority to the Secretary of Health and Human Services to adopt information security standards respecting the transmission and maintenance of health information by health (insurance) plans, healthcare clearinghouses, and healthcare providers who transmit health information electronically.<sup>139</sup> It further provided, as noted above, that if Congress failed to revisit the issue of privacy

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134. "Congress couldn't agree on the specifics, and they wrote a little sentence into the law that said if they couldn't get it done in three years the Secretary of HHS ought to do it." Donna E. Shalala, former Secretary of Health and Human Services, *The Twenty-Seventh Charles L. Decker Lecture in Leadership* (Apr. 28, 2008), in 197 *MIL. L. REV.* 145, 159 (2008).

135. "If legislation governing standards with respect to the privacy of individually identifiable health information . . . is not enacted by the date that is 36 months after the date of the enactment of this Act [(Aug. 21, 1996)], the Secretary of Health and Human Services shall promulgate final regulations containing such standards . . ." HIPAA § 264(c)(1), 110 Stat. at 2033.

136. HIPAA sec. 262(a), § 1173(d), 110 Stat. at 2025–26 (codified as amended at 42 U.S.C. § 1320d-2(d)) (listing the major goals of ensuring integrity and confidentiality of information and protecting against reasonably anticipated threats and unauthorized uses).

137. "In carrying out this section, the Secretary of Health and Human Services shall consult with . . . the National Committee on Vital and Health Statistics . . ." HIPAA § 264(d), 110 Stat. at 2034.

138. "In complying with the requirements of this part [to develop security standards], the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics . . . [and] shall publish in the Federal Register any recommendation of [the Committee] regarding the adoption of a standard under this part." HIPAA sec. 262(a), § 1172(f), 110 Stat. at 2024 (codified as amended at 42 U.S.C. § 1320d-1).

139. *See* HIPAA sec. 262(a), § 1173(d), 110 Stat. at 2025–26 (codified as amended at 42 U.S.C. § 1320d-2(d)).

protections for health information within thirty-six months, the Secretary would be directed to promulgate regulations no later than forty-two months after HIPAA was enacted.<sup>140</sup> Additionally, the Secretary was required within twelve months of HIPAA's enactment to submit a report to Congress containing "detailed recommendations on standards with respect to the privacy of individually identifiable health information."<sup>141</sup>

Privacy and security are often viewed as separate regulatory questions, and sometimes even as being in tension with one another. While this separation was technically true in the case of HIPAA—the authority described above resulted in a Privacy Rule<sup>142</sup> and a Security Rule<sup>143</sup>—the examination of the authority for both bears merit for two reasons. First, the statutory command for both is substantially similar (which I discuss in further detail below),<sup>144</sup> and second, security and privacy are inextricably linked. Many colloquial views of privacy and security place them in tension—for example, the recent debates over government surveillance programs<sup>145</sup> and long-standing disagreement over airport security measures<sup>146</sup> frame privacy and security as opponents in a zero-sum game.

This approach mischaracterizes the relationship between privacy and security. As noted by Derek Bambauer, privacy is a normative exercise in making "decisions about competing claims to legitimate access to, use of, and alteration of information."<sup>147</sup> Security, by contrast, is an objective exercise that "implements those choices . . . mediat[ing] between information and [normative] privacy selections" about the use of/access to that information.<sup>148</sup> The fact that security *implements*

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140. *See id.* § 264(c)(1), 110 Stat. at 2033 (codified as amended at 42 U.S.C. § 1320d-2 note).

141. *Id.* § 264(a), 110 Stat. at 2033 (codified as amended at 42 U.S.C. § 1320d-2 note).

142. 45 C.F.R. §§ 160–164 (2007); *see also* HIPAA § 264, 110 Stat. at 2033–34 (codified as amended at 42 U.S.C. § 1320d-2 note).

143. 45 C.F.R. §§ 164.302–318 (2007); *see also* HIPAA sec. 262(a), § 1173(d), 110 Stat. at 2025–26 (codified as amended at 42 U.S.C. § 1320d-2(d)).

144. *Cf.* HIPAA § 264, 110 Stat. at 2033–34 (codified at 42 U.S.C. § 1320d-2 note); HIPAA sec. 262(a), § 1172(f) (codified at 42 U.S.C. § 1320d-1(f)). Section 1172(f) applies to HIPAA section 1173(d) (which is codified at 42 U.S.C. § 1320d-2(d)) per the specifications of HIPAA section 1172(c)(3)(A)(ii) (which is codified at 42 U.S.C. § 1320d-1(c)(3)(A)(ii)).

145. Robert Barnes, Timothy B. Lee & Ellen Nakashima, *Government Surveillance Programs Renew Debate About Oversight*, WASH. POST (June 8, 2013), [http://articles.washingtonpost.com/2013-06-08/politics/39834570\\_1\\_oversight-programs-government-surveillance](http://articles.washingtonpost.com/2013-06-08/politics/39834570_1_oversight-programs-government-surveillance).

146. Kip Hawley, *Why Airport Security Is Broken—and How to Fix It*, WALL ST. J. (Apr. 15, 2012), <http://online.wsj.com/article/SB10001424052702303815404577335783535660546.html>.

147. Derek E. Bambauer, *Privacy Versus Security*, 103 J. CRIM. L. & CRIMINOLOGY 667, 667–68 (2013).

148. *Id.*

privacy is a critical point often lost in legal (and other) scholarship and policy debate, but one important to the context of this paper. Specifically, it explains why consideration of the legislative authority under which HHS promulgated the Security Rule and the Privacy Rule should be considered together, and why both aspects of the rulemaking process are relevant. While this Article focuses on the Security Rule, the statutory authority under HIPAA and the timeline under which HHS acted consider the implication of both privacy and security. Additionally, the importance of this relationship was *not* lost on the members of the NCVHS:

The security and privacy [sic] are very closely linked. The security is what enables privacy to be implemented and enforced. The security scope is larger in that it addresses not just confidentiality of data, but the standards also address integrity and availability of data, is the data there when you need it, is the data correct or have we made sure that it can't be inappropriately altered. Those are things that are outside of the scope of the privacy provisions. But the privacy scope is larger because it addresses paper and oral protected health information and security is only looking at electronic.<sup>149</sup>

Both the language in HIPAA providing authority for the Security Rule and the language providing authority for the Privacy Rule (if Congress failed to act, which was the case) had consultation requirements for the promulgation of those rules. These requirements included the pre-rulemaking engagement of a committee<sup>150</sup> comprising private interests and subject matter experts outside the Department—but, curiously, not only failing to engage the negotiated rulemaking statute but likely excluding the possibility of its application. The language applicable to the Security Rule was:

In complying with the requirements of this part [which includes § 1173(d)], *the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics* established under section 306(k) of the Public Health Service Act (42 U.S.C. [§] 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The

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149. Statement of Karen Trudel, Staff to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security, Transcript of the Full Committee Meeting of the National Committee on Vital and Health Statistics (Feb. 26, 2003), *available at* <http://www.ncvhs.hhs.gov/030226tr.htm>.

150. *See* 42 U.S.C. § 242k(k) (2006) (describing the National Committee on Vital Health Statistics); *infra* Part II.A.2.

*Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.*<sup>151</sup>

In Part II.A.2 below, I discuss the NCVHS in greater detail. It is sufficient to note for this analysis that the NCVHS comprised entirely private individuals, and the only federal regulators on the Committee—unlike in negotiated rulemaking committees—were assigned “staff to the committee.”<sup>152</sup> This distinction is particularly important in light of the emphasized language above—the Secretary was required to rely on the Committee’s recommendations, and doing otherwise would likely result in an invalid rulemaking. This language provides substantial regulatory capture to a committee whose voting membership comprises entirely private individuals. Additionally, the statutory language requires further consultation with “private organizations.” While affording a lesser degree of capture to non-NCVHS members, this statutory consultation requirement is a far higher threshold than that afforded interested parties during a traditional notice-and-comment rulemaking. Additionally, the requirement that any recommendation put forth by the NCVHS be published in the Federal Register (as a recommendation) supports the proposition that the Committee has capture authority in that its proposals must be published in a fashion similar to Proposed Rules. Finally, it appears from the Committee’s transcripts that the members treated their authority in this manner.<sup>153</sup>

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151. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, sec. 262(a), § 1172(f), 110 Stat. 1936, 2024 (codified as amended at 42 U.S.C. § 1320d-1(f)) (emphasis added).

152. 42 U.S.C. § 242k(k)(2) (“The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services.”); *see also* Nat’l Comm. on Vital and Health Statistics, Dep’t of Health & Human Servs., Charter (Jan. 7, 2000) [hereinafter NCVHS Charter], available at <http://www.ncvhs.hhs.gov/charter10.pdf>.

153. Note the repeated reference by the presenting NCVHS member to the Committee acting as a legislative body. While he did not necessarily have legal training (and in fact most members did not), their perspective on this process in the following quote clearly evinces a belief that the Committee had effective authority over what regulation ultimately would result:

The committee calls on everyone to work together on this in good faith . . . . The probability candidly that *we can pass a law* that will be perfect is very unlikely. I think the issue is, can we in fact *pass solid legislation* that will at least get us benchmarked and on the right track . . . . None of these benefits will be achieved unless everyone approaches *the legislative process* with a spirit of compromise.

Don Detmer, Acting Chairman of NCVHS, Remarks at Public Forum: Role of the National Committee on Vital Health Statistics (July 9, 1997) (emphasis added), available at

Although somewhat less strong than the language directly referencing the enabling authority for the Security Rule, a similar application of the consultation requirement was applicable to the Privacy Rule:

CONSULTATION. In carrying out this section, the Secretary of Health and Human Services *shall consult with* (1) *the National Committee on Vital and Health Statistics* established under section 306(k) of the Public Health Service Act (42 U.S.C. [§] 242k(k)); and the Attorney General.<sup>154</sup>

This application further emphasizes the degree to which regulatory capture was encoded into the statutory design and the authority placed by Congressional directive in the hands of private individuals.

## 2. *The National Committee on Vital and Health Statistics*

The NCVHS was established by the Public Health Service Act<sup>155</sup> to advise and assist the Secretary of Health and Human Services on a variety of policymaking issues.<sup>156</sup> The Full Committee comprises eighteen members, sixteen of which are appointed by the Secretary, one of which is appointed by the Speaker of the House after consultation with the House Minority Leader, and one of which is appointed by the President pro tempore of the Senate after consultation with the Senate Minority Leader.<sup>157</sup> The members of the Committee are experts who have distinguished themselves in various areas related to healthcare provision, statistics, healthcare information systems (specifically including privacy and security), consumer interests in healthcare, and other related areas.<sup>158</sup> The *NCVHS Charter* contemplates the possibility that federal employees may be members of the Committee.<sup>159</sup> Since 1996, however, the membership overwhelmingly comprised representatives of private industry, with additional members who were

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<http://aspe.hhs.gov/admsimp/jul9t3.htm>.

154. HIPAA § 264(d), 110 Stat. at 2033 (codified as amended at 42 U.S.C. § 1320d-2 note) (applying this consultation requirement to the regulatory authority afforded HHS in section 264(c) (codified as amended at 42 U.S.C. § 1320d-2 note § (c))) (emphasis added).

155. Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified as amended in scattered sections of 42 U.S.C.).

156. 42 U.S.C. § 242k(k)(5).

157. *Id.* § 242k(k)(3).

158. *See id.* § 242k(k)(2).

159. *See* NCVHS Charter, *supra* note 152, at 4 (“Members who are *not* full-time Federal employees shall be paid at a rate not to exceed the daily equivalent of the rate in effect for an Executive Level IV of the Executive Schedule for each day they are engaged in the performance of their duties as members of the Committee.” (emphasis added)).

leading experts (usually academics) and limited representation of State agencies.<sup>160</sup>

The Committee's primary function is to advise the Secretary and the Department on a variety of matters. This specifically includes "[s]tudy[ing] and identify[ing] privacy, security, and access measures to protect individually identifiable health information in an environment of electronic networking and multiple uses of data."<sup>161</sup> The Committee also comprises several subcommittees, which are designated to focus on specific issues. The modern NCVHS has a Subcommittee on Privacy, Confidentiality, and Security, which advises the Secretary on issues related to the Privacy Rule and the Security Rule.<sup>162</sup> When HIPAA was enacted in 1996, however, the Subcommittee on Standards and Security<sup>163</sup> had responsibility for the Security Rule, but not the Privacy Rule.<sup>164</sup>

In addition to the statutory requirements in HIPAA requiring publication of the Committee's activities respecting information security, the NCVHS is subject to the FACA.<sup>165</sup> The FACA requires certain standardized procedures for federal advisory committees,

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160. *NCVHS Calendar of Meetings*, NAT'L COMMITTEE ON VITAL AND HEALTH STAT., DEP'T OF HEALTH & HUMAN SERVS., <http://www.ncvhs.hhs.gov/calendat.htm> (last updated Apr. 10, 2014) (membership as listed in chronological meeting minutes).

161. NCVHS Charter, *supra* note 152, at 2.

162. Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Charge of the Subcommittee on Privacy, Confidentiality and Security (Dec. 2008) [hereinafter Charge of the Subcommittee on Privacy, Confidentiality and Security], *available at* <http://www.ncvhs.hhs.gov/privchrg.htm>.

163. Prior to June 1998, this subcommittee was known as the Subcommittee on Health Data Needs, Standards and Security. Following a committee-wide restructuring on June 16, 1998, the subcommittee was renamed the Subcommittee on Standards and Security. Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Transcript of the Full Committee Meeting of NCVHS (June 16, 1998), *available at* <http://www.ncvhs.hhs.gov/980616tr.htm>.

164. The Subcommittee on Standards and Security was renamed as the Subcommittee on Standards, and "Security" transferred to the Subcommittee on Privacy, Confidentiality, and Security in 2008. *Compare* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Meeting Minutes (Sept. 16–17, 2008), *available at* <http://www.ncvhs.hhs.gov/080916ag.htm> (referring to the "Subcommittee on Standards and Security"), *with* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Meeting Minutes (Oct. 14–15, 2008), *available at* <http://www.ncvhs.hhs.gov/081014ag.htm> (referring to the "Subcommittee on Standards"), *and* Charge of the Subcommittee on Privacy, Confidentiality and Security, *supra* note 162, *and* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Charge of the Subcommittee on Standards (Dec. 2008) [hereinafter Charge of the Subcommittee on Standards], *available at* <http://www.ncvhs.hhs.gov/stdschrg.htm>.

165. Federal Advisory Committee Act (FACA), Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. §§ 1–16 (2012)); NCVHS Charter, *supra* note 152, at 1 ("The Committee is governed by provisions of Public Law 92-463 . . . which sets forth standards for the formation and use of advisory committees.").

including the creation of a formal charter governing the committee's activities, that committee meetings be open with opportunity for public participation, that detailed minutes and transcripts are kept and made available for public inspection, and other requirements designed to facilitate public participation and provide democratic legitimacy to such committees.<sup>166</sup>

The Committee (and to the extent they acted formally, the subcommittees) had a notably different voting procedure than did negotiated rulemaking committees. Although the FACA does not prescribe a specific voting procedure for committee action, the NCVHS operated by majority vote—*not by required consensus*.<sup>167</sup> While they strove for consensus, one or a few parties could not hold the process hostage to a threat of breaking consensus.<sup>168</sup> Additionally, only fifty-one percent of the membership was required for quorum.<sup>169</sup> This lack of mandatory consensus is one key factor that contributed to the continued success, described below, of the NCVHS in providing regulatory assistance to HHS. Unlike negotiated rulemaking, where members could have “internal” capture over the committee,<sup>170</sup> NCVHS members could not as easily advance their own private viewpoints because they lacked the procedural ability to unilaterally derail committee progress.

The NCVHS is one of the longest-operating federal advisory committees, originally formed in the 1950s and pre-dating FACA.<sup>171</sup> Membership is generally looked upon as an honor within the healthcare field, and members take their duties very seriously. These factors,

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166. *See generally* FACA, Pub. L. 92-463, 86 Stat. 770.

167. *See* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Transcript of the Full Committee Meeting of NCVHS (June 21, 2007), *available at* <http://www.ncvhs.hhs.gov/070621tr.htm> (completing a voting procedure by majority show of hands).

168. Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Meeting Minutes of the Full Committee Meeting of NCVHS (Sept. 8–9, 1997), *available at* <http://www.ncvhs.hhs.gov/970908am.htm> (noting that Bob Gelman intended to submit a dissenting document to the Secretary of HHS on behalf of those who did not support the recommendations of the Subcommittee on Health Data Needs, Standards and Security).

169. *See* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Transcript of the Full Committee Meeting of NCVHS (Feb. 10, 2011), *available at* <http://www.ncvhs.hhs.gov/110210tr.htm> (discussing the fact that the committee of eighteen must have a quorum of ten or more for the vote to pass).

170. *See generally supra* Part I.B.

171. NAT'L COMM. ON VITAL AND HEALTH STATISTICS, DEP'T OF HEALTH & HUMAN SERVS., NCVHS AT FIFTY: A BRIEF HISTORY AND HIGHLIGHTS (2000) [hereinafter NCVHS AT FIFTY], *available at* <http://www.ncvhs.hhs.gov/ncvhsat50.htm> (“The National Committee on Vital and Health Statistics is one of the oldest and most prestigious advisory groups serving the Department of Health and Human Services.”).



combined with the effective regulatory capture described above and the FACA openness requirements contribute to the effectiveness of the NCVHS focusing on advancing public interest goals over the private interests represented by a majority of its members. Among the factors listed here, the longstanding nature of NCVHS and the degrees both of autonomy and legitimacy it is afforded by and within HHS appear most prevalent to its success at advancing public interest goals.

### 3. *Creation of the HIPAA Security Rule*

HIPAA granted HHS authority to promulgate information security regulations governing the transmission and maintenance of health information by covered entities, and contingent authority to promulgate related privacy regulations should Congress fail to revisit the issue within a specified time period.<sup>172</sup> While now considered substantially interrelated issues, at the time the separation of the regulatory authority and the structure of the NCVHS led HHS to begin moving on the Security Rule shortly after HIPAA's adoption.

HIPAA was enacted on August 21, 1996. The NCVHS Subcommittee on Standards and Security (S&S) began work the following January to investigate the issues surrounding the rules they were required advise on pursuant to HIPAA's consultation requirement.<sup>173</sup> At the time, the S&S subcommittee comprised seven individuals, three of whom were independent experts<sup>174</sup> and four of whom represented private industry.<sup>175</sup> From January through September 1997, the S&S subcommittee met and held hearings on the adoption of security standards consistent with the requirements of HIPAA section 1173(d).<sup>176</sup> In September 1998, the S&S

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172. *See supra* Part II.A.1.

173. *See* Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Meeting Minutes of the Subcommittee on Health Data Needs, Standards and Security (Jan. 21–22, 1997), available at <http://www.ncvhs.hhs.gov/970121mn.htm>.

174. Most independent experts were university faculty. Additionally, one also represented a state government. *See, e.g.*, NCVHS AT FIFTY, *supra* note 171; Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Meeting Minutes of the Subcommittee on Health Data Needs, Standards and Security (Nov. 5, 1997), available at <http://www.ncvhs.hhs.gov/971105m1.htm> (listing subcommittee members).

175. In the healthcare context, "private industry" includes non-profit healthcare organizations (e.g., Kaiser Permanente, non-profit hospitals) that are not federal, state, or local governmental organizations. *See also* NCVHS AT FIFTY, *supra* note 171.

176. *See, e.g.*, Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Subcommittee on Health Data Needs, Standards and Security Hearings on Health Information Privacy and Health Data Standards (June 3–4, 1997), available at <http://www.ncvhs.hhs.gov/970603ag.htm>; Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Subcommittee on Health Data Needs, Standards and Security Hearings on Security (Aug. 5–7,

subcommittee sent its first recommendations to the Secretary. Based on these recommendations, HHS promulgated the first Proposed Rule pursuant to HIPAA section 1773(d) in August 1998.<sup>177</sup>

The Proposed Rule received approximately 2350 public comments.<sup>178</sup> NCVHS was responsible for responding to most of these comments, with the S&S subcommittee addressing much of the technical details.<sup>179</sup> During the period when S&S addressed these comments, the Congressional deadline passed, which triggered HHS's authority to promulgate regulations respecting privacy pursuant to HIPAA section 264(c). While, as noted above, separate subcommittees of the NCVHS worked on privacy and on security, these subcommittees had overlapping membership<sup>180</sup> and often considered related questions.<sup>181</sup> As discussed above, the consultation requirement in section 264(d) lent further support to the NCVHS's role and authority in the rulemaking process.

Over the next several years, the NCVHS and the S&S held several hearings and considered the extensive comments received.<sup>182</sup> Based on these actions, the S&S recommended revisions (through the full NCVHS) to the Security Rule and HHS promulgated the Final Rule based on the NCVHS's recommendations in February 2003.<sup>183</sup> The Final

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1997), available at <http://www.ncvhs.hhs.gov/970805ag.htm>.

177. Security and Electronic Signature Standards, 63 Fed. Reg. 43,241 (Aug. 12, 1998) (codified at 45 C.F.R. pt. 142).

178. Health Insurance Reform: Security Standards, 68 Fed. Reg. 8333, 8335 (Feb. 20, 2003) (codified at 45 C.F.R. pts. 160, 162, 164).

179. See Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Transcript of the Subcommittee on Privacy and Confidentiality, Briefing on the Security Rule by the Subcommittee on Standards and Security (July 14, 2004), available at <http://www.ncvhs.hhs.gov/040714tr.htm> (discussing the process of promulgating the final rule after the proposed rule and comments received therefrom).

180. Compare Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Minutes of the Subcommittee on Privacy and Confidentiality (Feb. 25, 2000), available at <http://www.ncvhs.hhs.gov/000225tr.htm>, with Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Minutes of the Subcommittee on Standards and Security (July 13–14, 2000) [hereinafter Minutes of the Subcommittee on Standards and Security July 13–14, 2000], available at <http://www.ncvhs.hhs.gov/000713mn.htm> (listing five subcommittee members in common between the two).

181. Compare Charge of the Subcommittee on Privacy, Confidentiality and Security, *supra* note 162, with Charge of the Subcommittee on Standards, *supra* note 164 (showing similar issues “charged” to each subcommittee).

182. See, e.g., Minutes of the Subcommittee on Standards and Security July 13–14, 2000, *supra* note 180; Nat'l Comm. on Vital and Health Statistics, Dep't of Health & Human Servs., Minutes of the Subcommittee on Health Data Needs, Standards and Security (Oct. 26–27, 2000), available at <http://www.ncvhs.hhs.gov/001026mn.htm>.

183. Health Insurance Reform: Security Standards, 68 Fed. Reg. 8333.

Rule was substantially the work of the NCVHS, which essentially “ran the show” on behalf of HHS throughout the rulemaking process.

#### 4. *Management-Based Regulatory Delegation and Security Rule Compliance*

As discussed above, HIPAA employs a relatively unique regulatory framework both in the front-end rulemaking procedures described in this Part and in the back-end compliance and enforcement procedures adopted in the Security Rule. I examine these procedures in greater detail in earlier work,<sup>184</sup> but highlight here a few points relevant to this Article’s proposition regarding the engagement of private expertise to serve public interest goals.

Unlike many regulations, HIPAA adopts a flexible form of regulation I describe as Management-Based Regulatory Delegation, in which the compliance and enforcement aspects are based upon regulated entities’ obligation to develop compliance plans conforming to certain aspirations and some specific goals, and then adhere to those goals.<sup>185</sup> The compliance plans are based on requirements laid out in the Security Rule,<sup>186</sup> and the Rule specifies that the degree to which an entity’s compliance plan must cover certain items varies with the size, complexity, and capabilities of the organization and the health information it manages.<sup>187</sup>

Although not required by the statute, HIPAA certainly leaves room for this type of compliance, which has been discussed elsewhere in the literature and variously described as Management-Based Regulation.<sup>188</sup> The approach is highly flexible, well-suited to heterogeneous industries (of which healthcare is a prime example), and requires the substantial engagement of private expertise on the compliance “back-end” as each entity develops, self-enforces, and updates its information security compliance plan. It further engages private expertise by requiring individual regulated entities to determine, on a continuing basis, what

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184. See generally Thaw, *supra* note 7.

185. See *id.* at 31–37.

186. 45 C.F.R. § 160.310 (2013).

187. *Id.* § 160.306.

188. See Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC’Y REV. 691, 692 n.2, 693–94 (2003) (describing management-based regulation as a concept variously referred to as “‘enforced self-regulation’ (Braithwaite 1982), ‘mandated self-regulation’ (Bardach & Kagan 1982; Rees 1988), ‘reflexive’ regulation (Orts 1995), or ‘process-based’ (Gunningham & Grabosky 1998) and ‘systems-based’ (Gunningham 1996; Gunningham & Johnstone 1999) standards”).

are the most salient threats facing their organizations. It increases efficacy by shifting the cost of such decisions from the regulators to the individual entities and by allowing the individual entities to use their expertise to make such decisions, but subjecting them to regulatory penalty for deficiencies in so doing.<sup>189</sup> This approach increases legitimacy by allowing organizations a degree of input into their methods of compliance, thus increasing their input into the regulatory compliance process.

*B. The Security Rule: Regulatory Capture Used for the Public Interest*

In previous work, I explored the nature of information security regulations and their effect on driving security practices in private organizations.<sup>190</sup> That work examined the effects on organizations' security practices using empirical data, including in-depth, semi-structured interviews of Chief Information Security Officers (CISOs) at key U.S. organizations. These included CISOs at several healthcare organizations.

In the course of that work, I discovered that healthcare organizations—as substantially different than organizations in any other industrial sector—reported a stronger “buy-in” respecting the information security regulations to which they were subject.<sup>191</sup> They reported working with the NCVHS in developing the HIPAA Security Rule, and generally evinced positive experiences in that regard.<sup>192</sup> While negotiated rulemaking experienced some successes at increasing interested parties' perceived legitimacy of the process, regulatory agencies generally are not looked upon favorably by the industries they regulate. This sentiment generally was also true of information security regulations, other than HIPAA, applicable to the organizations represented by my interviewees.<sup>193</sup>

This Part explores what might explain this notably positive perception of HIPAA's information security regulations. It begins with an analysis of literal accounts of the process, exploring NCVHS transcripts and meeting minutes for explanations as to why the committee members

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189. For example, failure to have a proper information security risk assessment to support the information security plan used for compliance purposes would violate the requirements of 45 C.F.R. section 164.308(a)(1)(ii)(A).

190. *See generally* Thaw, *supra* note 7.

191. *See id.* at 64–66.

192. *See id.*

193. *See, e.g., id.* at 29.

worked in the public interest. It then discusses structural explanations, drawing on the details laid out above in Part II.A. Finally, it discusses technological explanations—that is, characteristics about cybersecurity itself might explain why the output of a committee dominated by private interests was so notably in the public interest.

*1. Literal Accounts “On the Ground”—HIPAA Security Rulemaking in Action*

As discussed above, membership on the NCVHS generally is viewed as a notable honor and members take their responsibilities to the public interest seriously. For example, in a July 1997 discussion regarding the role of the NCVHS in implementing the provisions of HIPAA (including the Security Rule), Don Detmer, acting Chairman of the NCVHS, described how the committee needed to act in the public interest, and while that might entail burdens for the organizations they represented, it was the committee’s responsibility to develop the rule according to public goals:

The committee calls on everyone to work together on this in good faith. This is not an easy challenge for us. . . . [W]e are one of the nation’s few industrially developed countries that does not have anything like this. . . . [W]e ought to do it because it is the right thing to do. The point is though, health information becomes available for other uses. So unless we get this in place, and get it in fairly soon, we see both risk to patients as well as risks to the record keepers themselves will grow. We believe that everyone will benefit by a well-crafted set of fair information practices. It will impose constraints and restrictions on industry, but I think those are just part of what it is going to appropriately take to be right by this, to the society at large and individual patients.<sup>194</sup>

On its face, this language might appear to be superficial. However, both the outcome of the Final Rule itself<sup>195</sup> and the comments of other members of the committee suggest otherwise, that in fact the members were focused on the public good notwithstanding their private interests. Consider the statement of one individual representing a major health insurance carrier:

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194. Detmer, *supra* note 153.

195. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, sec. 262(a), § 1173(d), 110 Stat. 1936, 2025–26 (codified as amended at 42 U.S.C. § 1320d-2(d) (2012)).

On behalf of the management of United HealthCare, I'm happy to be a part of this session and to assist in any way I can. . . . United HealthCare has consistently supported the incremental market reform principles underlying [HIPAA]. . . . In general, the Federal reforms espoused by the Act will help stabilize and sustain the private market by ensuring that all market players compete under the same high standards. United HealthCare views protecting our member's confidential information to be of the utmost importance. We have explicit information security policies and standards that are mandated by executive management and widely disseminated for compliance within the corporation.<sup>196</sup>

This response is particularly notable in the context of this Article because it demonstrates how the structure of HIPAA and the function of the NCVHS appear to have aligned private incentives with the public interest.

In addition to a general commitment to the process, the members of the S&S subcommittee also demonstrated a belief that if they failed to act, other regulators or legislators would, and that would be a sub-optimal outcome because the NCVHS was the most appropriate entity and a patchwork of inconsistent local rules would both be inefficient and possibly otherwise inferior:

I think that we really do believe that that is as important for the implementation side of this, as well as obviously the fact that if we do not do it, states will continue to do their own approach to this. . . . [T]o have a thousand or 50 different experiments going on in the country really is not necessarily in the best interests. First of all, people cross state lines a lot for health care and employment and such. A lot of the population, about 50 percent, is near a state border, so that becomes very problematic if people have different policies in all these jurisdictions.<sup>197</sup>

The minutes and transcripts of the NCVHS meetings suggest a general feeling that if they failed to advise the Secretary and suggest a rule, someone else would—and the outcome would be less than desirable. My CISO interviews support this viewpoint, and recent

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196. Randolph N. Sanovic, Director, Information Security, United HealthCare Corporation, Testimony to the National Committee on Vital and Health Statistics, Subcommittee on Health Data Needs, Standards, and Security, Hearing to Receive Input from the Health Care Industry on Recommendations for Security Standards (Aug. 5–6, 1997), *available at* <http://www.ncvhs.hhs.gov/970805tc.htm>.

197. Detmer, *supra* note 153.

informal interviews with knowledgeable parties concur.<sup>198</sup>

Additionally, the committee members viewed their work not just as “merely advisory,” but also as having the opportunity to make rules with the force of law:

The committee calls on everyone to work together on this in good faith. This is not an easy challenge for us. The probability candidly that *we can pass a law* that will be perfect is very unlikely. I think the issue is, *can we in fact pass solid legislation* that will at least get us benchmarked and on the right track . . . . None of these benefits will be achieved unless *everyone approaches the legislative process* with a spirit of compromise.<sup>199</sup>

As discussed further in Part III, this belief that the committee had effective rulemaking authority was an important component structuring the incentives for participants to put forth their best effort toward public goals. The committee members appear to view their activities with the responsibility of being a miniature legislature, as noted by the language used and their commitment to (their opinion of what is in) the public interest discussed earlier in this part.

## 2. *Structural Explanations: Statutory, Regulatory, and Incentives Analysis*

Part I and the preceding sections of this Part discuss the structure of negotiated rulemaking proceedings and of HIPAA and the NCVHS. The analysis in those portions suggests substantial differences between HIPAA and other consensual rulemaking proceedings, differences that may suggest improvements for consensual rulemaking and means by which regulatory capture may be harnessed to leverage private expertise to act in the public good. Part III explores these possibilities in detail. This Part analyzes the structural incentives present in the HIPAA Security Rule regulatory process as groundwork for that discussion in Part III.

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198. I am currently initiating a follow-on empirical research project to the original CISO interviews, which will include interviews with additional knowledgeable parties. As such work constitutes the use of human subjects, and a final protocol has not yet been approved by an Institutional Review Board, I cannot yet report the results of informal interviews or the identity of the interviewees. Additionally, consistent with the human subjects protocol approved for the CISO interviews, I cannot report the identity of the organizations represented by the individuals as doing so would likely implicitly identify the relevant individuals. As soon as this information becomes available, I will publish appropriate revisions identifying the source(s) of this information to the extent permitted under the rules of that protocol.

199. See Detmer, *supra* note 153 (emphasis added).

As discussed above, the HIPAA consultation requirement for the Security Rule gave strong capture authority to the NCVHS. The NCVHS statute requires committee composition including both private industry interests and experts in the relevant fields. The committee procedures were by majority vote, although consensus was desirable. The combination of these limitations creates an uncommon incentive structure for participants. While the committee itself does have effective strong capture over the rulemaking process, unlike negotiated rulemaking no single member has veto authority. Thus rather than driving toward a least-common-denominator rule, individual parties are incentivized to cooperate with one another as much as possible.

At a minimum, they must cooperate sufficiently to achieve a majority interest. The inclusion of subject matter experts, who usually are university faculty or similar researchers, adds an interesting dimension to this process. While in the S&S committee example, industry technically held a 4–3 majority vote, were they to exercise this power to advance private interests such action would be as clear and apparent as a lightning strike at midnight. Given the mission of the NCVHS, and the cultural norm that it operates in the public interest, such activities would likely not result in the Secretary adopting the recommendations particularly over the objections of relevant experts. Under these circumstances, a departure by HHS from the NCVHS recommendations would likely survive judicial review of the consultation requirement—a condition unlikely to be the case in the absence of dissent by experts.<sup>200</sup> Thus, representatives of private industry have statutorily created incentives to work with subject matter experts, placing meaningful limitations on their ability to advance their own private agendas. Furthermore, with most of the subject matter experts being university faculty holding tenure, those experts' job security provides an additional layer of protection against influence.<sup>201</sup>

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200. *See* *Mississippi v. EPA*, No. 08-1200, 2013 WL 3799741 (D.C. Cir. July 23, 2013) (holding that the Environmental Protection Agency (EPA) was required to provide adequate technical explanation for its departure from the recommendations of an advisory committee whose recommendations it was otherwise required by statute to adopt, and overturning regulations promulgated contrary to the recommendations of that committee on the basis that the EPA's justification was insufficient and thus violated the organic statute authorizing the Agency's regulatory authority).

201. While this protection is, of course, not absolute—some have argued that faculty might, for example, be subject to influence as a function of corporate research funding—faculty with tenure certainly are less subject to influence than any at-will employee of a private organization. Additionally, universities themselves infrequently have private agendas at the institutional level, and thus individual faculty are further isolated from having such agendas and more likely to act in (at least their own expert perception of) the public interest.



### 3. *Technological Explanations*

A core component of HIPAA and its Administrative Simplification requirements was to promote the safe and efficient interchange of health information among healthcare providers, insurers, and other related entities.<sup>202</sup> Promoting this type of information interchange remains a primary goal of the industry<sup>203</sup> and the current Executive Branch.<sup>204</sup> In a networked information exchange, however, the choices of one bad actor have implications far beyond the boundaries of that single actor. Much like a series of security guards protecting a facility, if one guard turns out to be in collusion with a gang of thieves and lets them in a back door, the activities of the other guards successfully protecting their doors will not make up for the “weak link in the chain.”

Information security is precisely similar. When health information is shared among many entities, any single one of those entities could be the “weak link” through which that information is compromised. From the perspective of an attacker, it does not matter where they obtain the information—the value is the same whether they get it from a hospital, an insurance company, or the dumpster behind a local doctor’s medical offices. From the perspective of the patient-consumer, it reflects badly upon the entire system any time there is such a compromise, because that patient-consumer likely only provided the information once—at the point-of-care.

The result is a situation in which the potential negative externalities from one organization having deficient information security measures are sufficient to incentivize other organizations to seek regulatory enforcement of reasonable levels of security for all participants in the system. For example, while United HealthCare might take the privacy and security of its consumers’ data very seriously—as suggested by the excerpt in Part II.B.1 above—a failure by one of its vendors or providers could cause that information to be compromised. Thus even though

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202. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, § 262, 110 Stat. 1936, 2021 (codified as amended at scattered sections of 42 U.S.C.).

203. *Health Information Exchange Governance*, HEALTHIT.GOV, <http://www.healthit.gov/policy-researchers-implementers/health-information-exchange-governance> (last visited Aug. 4, 2013) (discussing major health information exchange goals of interoperability, increased trust among all participants, and decreased cost and complexity).

204. *President Obama Shows Successes in Health Information Technology Field*, HEALTH INFORMATION MANAGEMENT INDUSTRY NEWS, UNIVERSITY OF ILLINOIS AT CHICAGO, <http://healthinformatics.uic.edu/president-obama-shows-successes-in-the-health-information-technology-field/> (last visited Apr. 22, 2014) (discussing President Obama’s remarks about health information exchange during his State of the Union address in 2011).

information security regulations might not be to United's specific competitive advantage, and may even impose additional regulatory compliance costs, United may nonetheless be incentivized to support such regulation so that they may have confidence in the business partners with whom they exchange information.

The result is a circumstance in which the risk of negative externalities suggests that regulated entities will accept a higher level of constraint of their private interests than otherwise might be the case. Stated differently, the nature of an interconnected information system aligns certain incentives—particularly those pertaining information security—such that private entities' interests coincide with the public interest.

### C. *Is Cybersecurity Different?*

These technological explanations beg the question whether information security is, by nature, *also* unique, thus suggesting that private actors working for the public good may be an exception not applicable to other circumstances. Before considering what lessons cybersecurity regulation may teach, therefore, I consider whether the cybersecurity example should be generalized.

There are two particularly obvious objections to generalizing from cybersecurity: (1) that it is highly technical; and (2) that cybersecurity's interconnected nature renders the negative externalities of one actor's failure disproportionately costly. While both objections bear merit, neither is dispositive and at most both serve to limit, rather than exclude, applicability of lessons learned from cybersecurity regulation.

The idea that a highly technical subject would distinguish cybersecurity regulation from other regulation overlooks one of the core purposes of administrative agencies. In a highly complex society, agencies develop and maintain the necessary expertise to fill in the technical details that legislatures simply lack the time to address.<sup>205</sup> As noted by the United States Supreme Court in *United States v. Mistretta*,<sup>206</sup> the creation of non-binding guidelines for judges sentencing convicted criminals under federal law is a highly technical topic.<sup>207</sup> As

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205. See Sidney A. Shapiro & Richard W. Murphy, *Eight Things Americans Can't Figure Out About Controlling Administrative Power*, 61 ADMIN. L. REV. 5, 6 & n.2 (2009) ("Justice Blackman noted the Supreme Court's implementation of the nondelegation doctrine has been driven by 'a practical understanding that in our increasingly complex society, replete with ever-changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives.'" (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1988))).

206. 488 U.S. 361.

207. See *id.* at 372.

noted in Part I, industries such as education, environmental protection, and aviation are also highly technical in nature. Nothing about the technical nature of cybersecurity suggests that it is any different than other highly technical subjects from a regulatory standpoint.<sup>208</sup> Thus, this objection does not suggest a limit on the applicability of lessons learned from cybersecurity regulation.

The comparatively higher cost of negative externalities from individual deficient actors in cybersecurity may suggest a limitation on the industries to which lessons learned from cybersecurity regulation are applicable. As discussed above in Part II.B.3, the potential impact on all actors of a single actor's deficiency may be substantial. The resultant incentives for actors to override their individual interests and seek more stringent regulations for all could thus be different than in industries where such potential negative externalities from deficient compliance are not present. In considering the degree to which regulatory capture in healthcare cybersecurity may be replicable for other rulemaking, therefore, the presence of increased cost from negative externalities of individually deficient actors should be considered.

### III. THE GENERAL CASE: HARNESSING PRIVATE EXPERTISE FOR PUBLIC INTEREST GOALS

When Philip Harter first proposed the concept of negotiated rulemaking and laid out the nine factors suggesting circumstances for which it was appropriate, his approach was speculative—a proposal he viewed as addressing the then-current “malaise.” As mentioned in the Introduction, in recent years some scholars have revisited this style of speculation—looking for solutions to engage private expertise and improve the legitimacy and efficacy of the regulatory process through various degrees of capture. Alternatively stated, such approaches engage a form of what Kenneth Bamberger describes as regulatory delegation, in which agencies entrust certain of their decision-making powers to private parties through various mechanisms.<sup>209</sup>

These approaches, however, lack empirical validation. Part II of this Article provides that validation—the healthcare cybersecurity example

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208. The one possible exception—that I suggest does *not* bear on the question at hand—is that the rate of development of new technology in computing and information technologies appears to notably exceed that of other industries. This rate-of-change suggests the importance of flexible regulations, *see generally* Thaw, *supra* note 7, but does not suggest that cybersecurity is any different in a manner that would incentivize representatives of private industry to act in the public interest any more than would representatives of other industrial sectors.

209. *See generally* Bamberger, *supra* note 22.

demonstrates a clear case where an administrative agency engaged private expertise through legislatively imposed regulatory capture. Notwithstanding this capture, the private interests at the table utilized their private expertise not only primarily to serve public interests, but also sometimes even at the expense of their own private interests.<sup>210</sup>

Building on that example, and preceding analysis that the healthcare cybersecurity example is not an isolated circumstance inapplicable to other cases, this Part proposes two conclusions representing important steps forward in our understanding of the interaction between regulation and private expertise. First, it proposes a set of characteristics about a regulatory problem suggestive that the healthcare cybersecurity style of capture may be effective at engaging private expertise for public goals. Second, it proposes a list of industries best suited to those characteristics—an effective research agenda for future empirical work investigating the applicability of such a “capture process” in practice. Finally, it concludes by suggesting a description of what that capture process might look like in the generic case. I describe this process as Enlightened Regulatory Capture.

A. *Enlightened Regulatory Capture: Characteristics When Regulatory Capture Can Be Used to Engage Private Expertise for Public Goals*

The healthcare cybersecurity example describes a circumstance when regulatory capture engaged private expertise to advance public goals. Though they were representatives of private interests—with legislatively mandated capture over the rulemaking process—the individuals involved in writing the HIPAA Security Rule nonetheless used their private expertise in the public interest. Their activities thus constitute a form of enlightened self-interest, suggesting the descriptive title Enlightened Regulatory Capture.

Five general characteristics of Enlightened Regulatory Capture (ERC) are present in the healthcare cybersecurity example: (1) the capture function is enforced by rule; (2) there is a perceived detriment to the participants and their industry as a whole if the process fails; (3) procedural constraints are relaxed, requiring only majority approval to act; (4) “reduced-bias” subject matter experts are mandated by rule as participants; and (5) the participants have incentives creating a commitment to the process other than the opportunity to advance their private interests.

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210. See *supra* Part II.B.1; *supra* note 194 and accompanying text.

The most critical aspect of ERC is that the capture function is enforced by rule. The participants must believe that their work will necessarily become part of the rule that is adopted. This is similar to, but more expansive than, Harter's "inevitability of decision" factor.<sup>211</sup> In Part I, I considered two cases of regulation regarding the NCLB—one by the DOI, and one by the DOE. The organic statute differs notably between these two cases—both specify the use of negotiated rulemaking, but the DOI has no exemption for it, whereas the DOE has an exemption. As discussed in the analysis of those examples, the "weaker" version of capture is likely one of the reasons the DOI example is noted as a negotiated rulemaking "success" whereas the DOE example is regarded by the literature as a negotiated rulemaking failure.<sup>212</sup> Additionally, as discussed in Part II, the consultation requirement that effectively caused HHS to turn over the rulemaking process to the NCVHS contributed both to the committee members' perception of their authority<sup>213</sup> and their willingness to act in the public interest—rather than fighting with competitors to advance their own interests.

The second characteristic is that the participants must believe they have a stake in the game—that some negative consequence will result for their individual interests or for the interests of the industry they represent as a whole, or both, should they fail. In the case of healthcare cybersecurity, a failure could exacerbate the negative externalities problem, allow the patchwork of inconsistent state laws to continue, and possibly result in a perceived loss of the prestige members felt at being nominated to serve on the NCVHS for failing to fulfill the responsibilities of their appointment. This is not dissimilar from Harter's "opportunity for gain" factor,<sup>214</sup> but is far more expansive and contemplates a countervailing opportunity for loss as well.

Third, procedural constraints must be far more relaxed than the consensus requirement present in negotiated rulemaking. As discussed throughout this Article, the consensus requirement often results in a minimization effect—where the unilateral veto power held by each participant on a negotiated rulemaking committee results in that outcome which is the least-common-denominator to all interests at the table. While this process may be desirable for certain circumstances,<sup>215</sup> it

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211. See Harter, *supra* note 3, at 47–48.

212. See generally Holley-Walker, *supra* note 82.

213. See *supra* note 199.

214. See Harter, *supra* note 3, at 48–49.

215. Ironically, Harter describes the negotiated rulemaking process as being ill-suited to circumstances when parties have differences in fundamental values. See *id.* at 49–50. Yet the

seems ill-suited to many rulemakings and (as discussed in Part I) is often the source of substantial criticism of negotiated rulemaking. In the healthcare cybersecurity example, only a majority was required for NCVHS action. As discussed in Part II, this majority requirement was a key component to forcing participants that might otherwise have private agendas to work collaboratively and to preventing any participants from gaining “internal capture” through unilateral veto power.

The fourth requirement, that there be mandatory “reduced-bias” subject matter experts as participants, strongly integrates with the third requirement of relaxed procedural rules. In the healthcare cybersecurity example, the presence of and general characteristics of these experts were mandated by statute. The concept of a “reduced-bias” expert is an individual who is less susceptible to influence as a function of their employment than is an at-will employee of a private organization or a professional whose primary compensation depends upon providing services to private organizations. The most prevalent example of this type of expert is a tenured member of a university faculty, which, as discussed above, was the case in the healthcare cybersecurity example. As discussed in more detail in Part II, the relaxed procedural rules work together with this requirement by forcing private interests to work together with these reduced-bias experts, thereby in turn reducing their ability to advance private agendas at the expense of the public interest.

The third and fourth characteristics together describe an essential component of the function and character of ERC. ERC is well-suited when interested parties, at minimum, *can* be capable of working collaboratively toward resolution. By contrast, if fundamental differences that *cannot* be overcome by restrictions on unilateral veto power that render collaboration impossible, then ERC’s suitability substantially decreases. Ironically, as discussed above, negotiated rulemaking—which Harter claims is *not* well-suited to fundamental differences—may in fact be better suited to such circumstances.<sup>216</sup>

Finally, consistent with this collaborative function, the fifth characteristic requires that the participants have a commitment to the process beyond the mere opportunity to advance their private interests.

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counter-majoritarian nature of each participant having unilateral veto power—as found in most negotiated rulemaking proceedings—is precisely the type of constraint that could force parties with fundamentally different values to come together for discussion. As discussed in Part I, this was in fact the mechanism that allowed the FAA to proceed with its negotiated rulemaking regarding flight duty/rest requirements and, notwithstanding the fact that a consensus was not reached, the process largely was regarded as a success because it brought the parties closer together. *See* Perritt, *supra* note 95, at 1670–71.

216. *See supra* note 215.

Harter describes the participants as needing to have the “opportunity to gain.”<sup>217</sup> But the mere opportunity to gain is not sufficient, as evidenced by the DOE example discussed above and in greater detail in Part I. The parties must have some other factors that incentivize them to participate in the process not just for personal gain, or private interests may ultimately take over even the best-intentioned of individuals. Several such factors were present in the healthcare cybersecurity example. As discussed in detail in Part II, committee membership on the NCVHS was considered an honor to which obligation to act in the public interest attached. Members accordingly took this responsibility quite seriously, even at times to the possible expense of the private interests they represented. The risk of negative externalities described above and in greater detail in Part II also contributed to members’ incentives in this regard. Additionally, the possibility of “getting it right” so that the continued patchwork of inefficient (and possibly technologically inferior) state-level regulations would not continue presented an opportunity for *positive* externalities to be realized by the process.

The characteristics presented here are neither an exhaustive list nor are they necessarily required for ERC to be an effective approach. They represent preliminary suggestions, generalizing characteristics from the first instance presented in the literature of a verifiable example of regulatory capture working clearly in the public interest.<sup>218</sup> As noted above, other scholars’ writing suggests they are conducting similar empirical analysis, and such work should serve as an opportunity to refine the characteristics presented here.

*B. An Empirical Research Agenda: Industries Potentially Suitable to Enlightened Regulatory Capture*

The characteristics described above and the analysis in Part I suggest some examples of industries where ERC may be capable of achieving superior results to existing rulemaking procedures. The examples presented here are not an exhaustive list—many other industrial sectors are worth exploration—but rather represent a preliminary research agenda for industries where the analysis in this Article suggests further empirical investigation, similar to that in Part II, may be appropriate.

Education is the most striking example resulting from the analysis in this Article. As noted above, key statutory differences between

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217. See Harter, *supra* note 3, at 48–49.

218. This is the first such example, to the best of the author’s knowledge, as of the time of this writing.

negotiated rulemaking requirements for the NCLB between the DOE's and the DOI's proceedings produced vastly different outcomes. This stark perceived difference in legitimacy and efficacy of the proceedings, which turned heavily on the difference in the degree of regulatory capture encoded in the statute, suggests that exploring ERC in the education context is a worthwhile endeavor. The primary characteristic described above is, as noted here, the key distinction between the success and failure in this education example. Further empirical evidence would be required to determine if the other characteristics are or could be true for education regulation.

Labor regulation may be another example where ERC can be successful. As noted in the FAA flight crew rest requirements and duty restrictions example described in Part I, strong disagreement among the parties prevented the negotiated rulemaking proceeding from reaching consensus. While the FAA had committed to publishing a rule if the committee suggested one, satisfying (at least in part) the primary ERC characteristic, the deep divisions among the committee participants and the unilateral veto authority inherent in consensual rulemaking prevented the process from achieving a regulation. If, in fact, there is a cognizable public interest in this issue—as likely there is, given the public safety and economic efficiency concerns at stake—the relaxed procedural requirements described in the third characteristic above may have facilitated better agreement. Additionally, the inclusion of reduced-bias experts in conjunction with relaxed requirements may have increased the efficacy of the process. Further empirical study of course is necessary, but labor regulation appears to be a promising example. Additionally, given the inextricably linked aspects of air traffic regulation, this example also suggests that transportation regulation may be a ripe area for examination of the applicability of ERC.

Finally, environmental regulation also seems worth exploration. As noted by Cary Coglianese<sup>219</sup> and Kenneth Bamberger,<sup>220</sup> environmental protection involves the regulation of heterogeneous industries and often involves the application of flexible standards, similar to the circumstances described in the healthcare cybersecurity example.<sup>221</sup> It bears an obvious public interest and there are reduced-bias experts on university faculties whose technical expertise could be harnessed.

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219. *See generally* Coglianese & Lazer, *supra* note 188.

220. *See generally* Bamberger, *supra* note 22.

221. *See id.* at 390; Coglianese & Lazer, *supra* note 188, at 700.



C. *Enlightened Regulatory Capture: A Hypothetical Example*

How might a legislature, wishing to adopt Enlightened Regulatory Capture, proceed in drafting statutes to enable this concept? This Part proposes a modest set of preliminary recommendations for legislators that will likely be common to any successful implementation. These recommendations come with an important cautionary note—as discussed throughout this Article, regulated entities incentives and challenges vary widely across industrial sectors and in some cases within industries. No single formula is likely to be correct, and legislators must take care to consider the incentives at play for any given implementation.

First, and perhaps most importantly, the legislature should mandate adoption of ERC by expressly requiring the administrative agency to adopt the recommendations of the committee the agency is charged to consult. Limited exceptions may be provided in the statute, but should not provide discretionary exception to override the recommendations of the committee.

Second, committee composition should also be encoded by statute. Appointments should be made primarily by the agency, but perhaps allowing for limited legislative or executive appointment as was the case in the healthcare cybersecurity example. The committee should be of manageable size, allowing for functional meetings and discussion without the need for continual, strict adherence to rules of order. Statutory authority should also direct that committee membership include reduced-bias subject matter experts in relevant fields in addition to representatives from relevant industry and other interested parties. The committee should be governed by the FACA or similar statute.

Third, procedural rules should be relaxed. As procedural rules may have many variants, legislatures may wish to delegate the precise details to the relevant agency, but with constraints at least to prevent the unilateral-veto problem present in negotiated rulemaking. If reduced-bias subject matter experts are included in sufficient number on committees, then a legislatively encoded default of majority rule may be sufficient provided agencies are given some flexibility to tailor the outcome.

Finally, the legislature should attempt to make committee participation worthwhile beyond the opportunity for participants to advance their private interests. In the healthcare cybersecurity example, the long-standing nature of the NCVHS and the opportunities it afforded resulted in a form of prestige being associated with membership on the committee. While such factors are difficult to encode directly into legislation, one modest suggestion would be to use existing, long-standing committees or, in the absence of such committees, to create by

statute a new committee that would exist for at least a specified (and sufficiently lengthy) duration to make the participants' engagement be perceived as worthwhile.

## CONCLUSION

This Article began with the proposition that, contrary to commonly accepted wisdom, certain forms of regulatory capture may be used to advance public, rather than private, goals. It examined a curious example where, in the process of authorizing HSS to promulgate healthcare cybersecurity regulations, a confluence of factors and Congressional drafting created a circumstance under which private entities with strong regulatory capture over the rulemaking process “checked their private agendas at the door” and focused on using their expertise to achieve the public goals articulated by Congress.

For several decades now, scholars have debated whether private expertise can be effectively harnessed via negotiated rulemaking to advance public goals. Some scholars reject such rulemaking procedures because of their vulnerability to internal capture. This Article presents the first verifiable empirical case of regulatory capture by an advisory committee comprising private interests being used for the public good. The empirical work surrounding the healthcare cybersecurity example is the beginning of a research effort, partially laid out in the last Part of this Article, examining methods to engage private expertise for public goals.

While further empirical research is necessary, the results presented here suggest two conclusions. First, harnessing private expertise for public goals is possible, and can be accomplished through ERC. Second, legislatures can and should experiment with this design, using the baseline framework discussed in Part III as a starting point.