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# Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice

Daniel J. Gilman

Julie Fairman

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# ANTITRUST AND THE FUTURE OF NURSING: FEDERAL COMPETITION POLICY AND THE SCOPE OF PRACTICE

*Daniel J. Gilman and  
Julie Fairman†*

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## I. BACKGROUND

### A. *Nursing Practice and Competition Policy*

In 2011 the Institute of Medicine released a major report on the nursing profession and its present and potential roles in U.S. health

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† Daniel J. Gilman, J.D., Ph.D., is an attorney advisor in the Federal Trade Commission's Office of Policy Planning. Julie Fairman, Ph.D., R.N., FAAN, is Nightingale Professor in Nursing and Director of the Barbara Bates Center for the Study of the History of Nursing, at the University of Pennsylvania, School of Nursing. She served as staff to the IOM Committee on the Future of Nursing. Her work on this manuscript was funded in part by the RWJF Research Manager Program. Thanks are due to Leemore Dafny for helpful comments on a prior draft of this paper. The paper represents the views of the authors alone, and does not necessarily reflect the views of the Federal Trade Commission, any individual Commissioners, the FTC Office of Policy Planning, or the Robert Wood Johnson Foundation or its programs.

care: *The Future of Nursing: Leading Change, Advancing Health*.<sup>1</sup> Prominent in the report was concern about undue or excessive limitations on nurses' scope of practice: the first of the report's four "key messages" stated that "[n]urses should practice to the full extent of their education and training."<sup>2</sup> The first of the report's eight recommendations was to "remove scope of practice barriers" so that they might do so.<sup>3</sup> The message and recommendations were based on an assessment that "[r]estrictions on scope of practice . . . have undermined the nursing profession's ability to provide and improve both general and advanced care."<sup>4</sup> The gist of the Institute of Medicine (IOM)'s claim is that nurses' regulatory scope of practice, which varies state by state,<sup>5</sup> often proves to be narrower than the socially desirable or medically prudent scope of practice and that the space between the regulatory standard and the ideal is large enough that it is a substantial health policy problem.

To ameliorate the problem, the IOM suggests, among other things, that regulatory restrictions on the scope of practice receive attention from the federal antitrust agencies.<sup>6</sup> This paper considers what such antitrust therapy might entail, chiefly by explaining some of what antitrust law and policy have had to say about licensure and scope of practice already. We focus, in particular, on a species of soft antitrust intervention employed by one of the nation's two competition authorities,<sup>7</sup> the Federal Trade Commission (FTC). As noted by the IOM, regulatory restrictions on advanced practice registered nurses (APRNs) have been a special area of interest for the FTC's competition advocacy program.<sup>8</sup>

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1. INST. OF MED., *THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 2* (2011) [hereinafter *IOM FUTURE OF NURSING REPORT*], available <sup>at</sup> [http://www.thefutureofnursing.org/sites/default/files/Future%20of%20Nursing%20Report\\_0.pdf](http://www.thefutureofnursing.org/sites/default/files/Future%20of%20Nursing%20Report_0.pdf).
  2. *Id.* at 4.
  3. *Id.* at 9.
  4. *Id.* at 4.
  5. *Id.* at 96-103, 157-61.
  6. *Id.* at 10-11, 279.
  7. "Antitrust" and "competition" often are used interchangeably with regard to antitrust law and policy – "antitrust" perhaps the more frequent default in the U.S. and "competition" elsewhere. We intend no special usage but hope the term "competition advocacy" will highlight that such work aims to further the competition policy goals underlying the antitrust laws, unbound by the procedural and substantive limits of, e.g., the Sherman and Clayton Acts.
  8. *IOM FUTURE OF NURSING REPORT*, *supra* note 1, at 5, 105. In most areas of the economy, including many healthcare industries, the FTC and the Department of Justice share antitrust authority and have long-

Most state practice laws recognize APRNs as a distinct category of nursing professionals.<sup>9</sup> APRNs are nurses with graduate degrees trained to provide a broad range of services, including diagnosis and treatment of acute and chronic illnesses.<sup>10</sup> They are licensed by the states in which they practice, attend accredited programs, and are certified by nationally accredited certifying boards.<sup>11</sup> There are four types of APRNs: nurse practitioners (NPs), nurse midwives (NMWs), nurse anesthetists (NAs or CRNAs), and clinical nurse specialists (CNSs).<sup>12</sup>

The competitive impact of licensure and scope of practice restrictions has been a matter of ongoing concern to the FTC and its staff. In recent years, FTC staff have issued a series of competition policy analyses addressing the IOM's concern about over-strict limits on nurses' scope of practice.<sup>13</sup> The staffs of the FTC's Office of Policy

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standing arrangements to avoid inconsistent or duplicative efforts. The IOM correctly identifies the potential for both agencies to address anticompetitive restrictions on nursing practice *and* accurately cites to a record that, for historical reasons, chiefly comprises FTC advocacy.

9. Professional titles and nomenclature (e.g., “APRN,” “ARNP,” “nurse practitioner,” etc.) as well as APRN licensure criteria and scope of practice rules have been converging nationally, although they still vary across the states. The National Council of State Boards of Nursing posts updated maps of states that recognize “APRN” as a professional title, states that permit independent APRN practice, and states that permit independent APRN prescribing. *APRN Maps*, NAT'L COUNCIL OF STATE BDS. OF NURSING, <https://www.ncsbn.org/2567.htm> (last updated Feb. 2014). *See, e.g.*, LA. REV. STAT. ANN. § 37:913(3)(a)(b) (2012); LA. ADMIN. CODE tit. XLVII, § 4505 (2012) (exemplifying state regulation of APRNs).
10. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 23, 26.
11. *See generally* APRN CONSENSUS WORK GROUP & NAT'L COUNCIL STATE BDS. OF NURSING, CONSENSUS MODEL FOR APRN REGULATION: LICENSURE, ACCREDITATION, CERTIFICATION, AND EDUCATION (2008), *available at* [https://www.ncsbn.org/july\\_2008\\_consensus\\_model\\_for\\_aprn\\_regulation.pdf](https://www.ncsbn.org/july_2008_consensus_model_for_aprn_regulation.pdf). We adopt the consensus nomenclature throughout this paper, although we note some remaining variation in state regulations.
12. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 23, 41-42.
13. *See, e.g.*, Letter from Susan S. DeSanti et al., Dir., Office of Policy Planning, FTC, to Thomas P. Willmott & Patrick C. Williams, Reps., La. House of Reps. (Apr. 20, 2012) [hereinafter Louisiana FTC Letter], *available at* <http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf> (commenting before the Louisiana House of Representatives on the likely competitive impact of House Bill 951 concerning APRNs). This is discussed in detail, along with the larger body of competition advocacies regarding APRNs generally, specialist APRNs such as CRNAs, and “limited service” or “retail” clinics, which frequently are staffed by APRNs, in Part II.B of this article.

Planning, Bureau of Economics, and Bureau of Competition<sup>14</sup> have observed that: (1) many geographic areas (or markets) are subject to primary care workforce shortages; (2) market forces may be slow to clear those shortages due to regulatory impediments to competition, among others; (3) such shortages may impinge upon both price and non-price competition between health care service providers; (4) in some places, such shortages may impede patient access to primary care services and may, in the limit, drive the supply of certain services to nil; and (5) scope of practice restrictions on APRNs appear under-rationalized (at best), where they purport to rest upon patient protection concerns that are not based on demonstrated patient harms or empirically grounded assessments of substantial patient risks.<sup>15</sup> Because restrictions on APRNs' licensure and scope of practice may come at a substantial competitive cost, FTC staff have recommended that such limits not be more stringent than patient protection requires.<sup>16</sup> In broad strokes, they have asked that state policymakers account for competitive costs when considering scope of practice restrictions, and they have suggested that certain costs

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14. Competition advocacies often are issued jointly by the staffs of the FTC's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. Formally, advocacies may be issued by either the Commission or its staff, although the distinction may sometimes be unclear. Individual Commissioners may review comments differently, depending on the intended signatories, and the Commission may disclaim that staff comments represent the Commission's own views. Still, both Commission and staff advocacy entail the Commission's review of (and editorial input into) analyses researched and drafted by the staff, and neither type of comment is issued without a vote to authorize issuance by the Commission. Advocacy letters commonly note: "This staff letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. The Commission, however, has voted to authorize staff to submit these comments." *Id.* at 6 n.1.
  15. *See generally infra* Part II.B. As discussed below, state policy makers might seek to balance, e.g., patient safety concerns with competition concerns, or they might seek to account for service quality (including safety) within a competition analysis. In either case, competitive impact should be considered, and countervailing consumer protection or patient safety concerns ought to be well-founded, rather than speculative or pretextual. *See, e.g., infra* notes 140, 173 - 192 and accompanying text.
  16. For a summary of these FTC staff recommendations as they apply to APRNs generally, see DANIEL J. GILMAN & TARA ISA KOSLOV, FED. TRADE COMM'N, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (2014), *available at* <http://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicy.pdf>.

should not be imposed on the public absent an evidence-based promise of countervailing consumer protection benefits.<sup>17</sup>

Our discussion will further clarify these analyses, both in their particulars and as they comprise a species of policy instrument that is often effective but sometimes misunderstood. More broadly, because competition issues may be thinly treated in some health policy discussions to which they are relevant, our paper will illustrate how a competition perspective can frame diverse health policy issues,<sup>18</sup> such as barriers to health care access, cost and price moderation, innovation in health care delivery models, and health care workforce labor supply.<sup>19</sup> Moreover, a competition perspective may be especially useful for flagging and analyzing cases where regulatory costs are significantly higher for one group of competitors than another or even, in some circumstances, as they are imposed *on* one group of competitors *by* another.<sup>20</sup>

Although we pay special attention to licensure and scope-of-practice restrictions for APRNs, this is not a brief on behalf of any particular group of professionals.<sup>21</sup> Rather, we seek to better align

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17. The term “countervailing consumer protection benefits” is not meant to distinguish between competition benefits, which should accrue to consumers, and consumer protection benefits, much less to draw an agency-specific distinction between, say, the FTC’s competition (antitrust) mission and its particular consumer protection mission. Rather, we ask whether there are good grounds to anticipate particular offsetting benefits, such as consumer harms avoided or risks diminished. The benefits thereby offset are themselves consumer protection benefits, as they protect consumer access to the benefits of price and non-price (qualitative) competition. If the IOM and FTC staff are correct, scope of practice restrictions distill the sense in which competition is a consumer protection concern, in that artificial or excessive restrictions on health care can deprive some consumers of access to basic health care.
  18. See William M. Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFS. 31, 31 (2003) (“[C]ompetition law has long been the forgotten stepchild of health care quality.”).
  19. See generally FTC & U.S. DEP’T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION 1-2 (2004) [hereinafter A DOSE OF COMPETITION], *available at* <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (tying such health care competition concerns to health policy issues).
  20. See generally Steven C. Salop et al., *A Bidding Analysis of Special Interest Regulation: Raising Rivals’ Costs in a Rent Seeking Society*, in THE POLITICAL ECONOMY OF REGULATION: PRIVATE INTERESTS IN THE REGULATORY PROCESS 102 (1984); Steven C. Salop & David T. Scheffman, *Raising Rivals’ Costs*, 73 AM. ECON. REV. 267 (1983).
  21. Neither are the scope of practice competition comments opposed to any particular professional practice. Antitrust does not, in itself, constrain the practice of medicine. Of course, any action by an antitrust enforcer may be more or less advantageous for one party, or class of competitors,

certain areas of health policy planning with competition policy.<sup>22</sup> To that end, we also outline various empirical questions that might be important to further antitrust applications, including research, competition advocacy, and, potentially, law enforcement. Such questions address both the effects of past agency action and the economic costs and benefits of the types of practice restrictions such action has targeted.

Three background sections follow: Section B sketches the FTC's jurisdiction, interest, and experience in health care competition generally, and as applied to licensure and scope of practice in particular; Section C outlines the pertinent antitrust sense of competition between and amongst physicians and APRNs; and Section D focuses on certain limits to the reach of antitrust: the "state action doctrine" and the "Noerr-Pennington doctrine." This background is important, given the bridgework that this paper seeks to construct, but readers well-versed in competition law and economics may choose to skim or skip it. The paper's main discussion, in Part II, addresses both general competition concerns about licensure and scope of practice regulations and the Commission and its staff's analyses of such concerns.

*B. A Very Brief Background on FTC Jurisdiction, Interest, and Experience*

Concerns about professional licensure and scope of practice are at the nexus of competition and consumer protection policy. This is a special area of interest for the FTC as the FTC Act gives the Commission broad authority with regard to both competition and consumer protection matters in most sectors of the economy.<sup>23</sup> The

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than another. That should not obscure the underlying principle that the purpose of the antitrust laws is "the protection of competition, not competitors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962). The scope of practice restrictions are not *per se* anticompetitive, and *any* licensure schemes- for health care professions or any others- may raise competitive concerns. Analogous concerns have been raised about the "unauthorized practice of law." *See, e.g.*, Letter from Scott D. Hammond, Acting Assistant Att'y Gen., Dep't of Justice, to Haw. Judiciary Pub. Affs. Office (Apr. 20, 2009), *available at* <http://www.ftc.gov/os/2009/04/V080004hiunauthorizedpracticeoflaw.pdf>.

22. In doing so, this paper does not claim that competition issues exhaust, or are the most important, policy considerations for licensure and scope of practice determinations for nurses or any other health care professionals.
23. The FTC's authority is defined broadly to deal with "methods . . . acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1) (2012). But for particular market sectors expressly excluded from the FTC's enforcement authority, the FTC's authority ranges broadly over "commerce," without restriction to particular segments of the economy. *Id.* at § 45(a)(2).

Act prohibits “[u]nfair methods of competition” and “unfair or deceptive acts or practices,”<sup>24</sup> and the FTC has a statutory mandate “to prevent persons, partnerships, or corporations” from engaging in such prohibited methods, acts, and practices.<sup>25</sup>

The FTC’s interest in health care competition dates back to the Commission’s inception, or nearly so, and the Supreme Court has recognized the importance of competition and the application of antitrust principles to health care since its 1943 decision in *American Medical Association v. United States*.<sup>26</sup> The FTC’s contemporary health care competition program may be traced to a 1970s case concerning restrictions on advertising and pricing.<sup>27</sup> Since then, the FTC and its staff have investigated restrictions on the business practices of health care providers,<sup>28</sup> scrutinized proposed mergers,<sup>29</sup> and brought enforcement actions against health care providers that have violated federal competition law.<sup>30</sup> For example, the FTC has targeted attempts by provider-controlled licensing boards to limit competition to the detriment of health care consumers.<sup>31</sup> Not incidentally, anticompetitive misuse of credentialing and privileging has been the target of law enforcement<sup>32</sup> as well as private litigation.<sup>33</sup>

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24. *Id.* at § 45(a)(1). In 1994, Congress defined an “unfair” act or practice over which the FTC has authority as one that “causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.” *Id.* at § 45(n).
  25. *Id.* at § 45(a)(2).
  26. 317 U.S. 519, 528-29 (1943).
  27. Patrick Thompson, *Interview with William E. Kovacic, Chairman, Federal Trade Commission*, ANTITRUST SOURCE 2-3 (Aug. 2008), [www.ftc.gov/speeches/kovacic/2008kovacicintrvwc.pdf](http://www.ftc.gov/speeches/kovacic/2008kovacicintrvwc.pdf).
  28. See MARKUS H. MEIER ET AL., FTC, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS 1 (2013), *available at* <http://www.ftc.gov/bc/healthcare/antitrust/hcuupdate.pdf>.
  29. See, e.g., Evanston Nw. Healthcare Corp., Docket No. 9315 (FTC Aug. 6, 2007) (Opinion), *available at* <http://www.ftc.gov/os/adjpro/d9315/070806opinion.pdf>.
  30. See, e.g., Colegio de Optometras, et al., Docket No. C-4199 (FTC Sept. 11, 2007) (Decision and Order), *available at* <http://www.ftc.gov/os/caselist/0510044/070730decision.pdf> (addressing price fixing and a concerted refusal to deal with vision and health plans by optometrists).
  31. See, e.g., S.C. State Bd. of Dentistry v. Fed. Trade Comm’n, 455 F.3d 436, 439 (4th Cir. 2006).
  32. See Med. Staff of Mem. Med Ctr., 110 F.T.C. 541 at \*1-2 (1998) (consent order) (addressing allegations of anticompetitive combination or conspiracy to deny credentials to nurse midwife).

Congress also has assigned to the FTC a research, education, and policy mission. Section 6 of the FTC Act gives the Commission the authority to conduct investigations in the service of FTC enforcement actions.<sup>34</sup> Section 6 also provides a more general authority to investigate and report on market developments in the public interest and gives the Commission the authority to make legislative recommendations based on those investigations.<sup>35</sup> Economic and policy research<sup>36</sup> and competition advocacy<sup>37</sup> thus are at the core of the FTC's statutory mission, alongside the Commission's civil law enforcement responsibilities.<sup>38</sup>

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33. *See, e.g.*, *Boczar v. Manatee Hosps. & Health Sys., Inc.*, 993 F.2d 1514, 1516 (11th Cir. 1993) (reversing judgment notwithstanding the verdict because, on de novo review, "there was evidence from which a jury could reasonably infer that the hospital conspired with members of its medical staff and peer review committees . . . to restrain trade in violation of the Sherman Act."). *Cf.* *Nurse Midwifery Assocs. v. Hibbett*, 918 F.2d 605, 617 (6th Cir. 1990) (reversing summary judgment for certain defendant physicians and physician insurance company on Sherman Act conspiracy claim).
  34. 15 U.S.C. § 46 (2012).
  35. *Id.* at §§ 46(b), (f).
  36. *See* PAULINE M. IPPOLITO & JANIS K. PAPPALARDO, FTC, ADVERTISING NUTRITION & HEALTH: EVIDENCE FROM FOOD ADVERTISING 1977 – 1997, at E-1 (2002), available at [http://www.ftc.gov/be/healthcare/wp/20\\_Ippolito\\_AdvertisingNutrition&Health.pdf](http://www.ftc.gov/be/healthcare/wp/20_Ippolito_AdvertisingNutrition&Health.pdf); A DOSE OF COMPETITION, *supra* note 19, at 1 (noting a report jointly issued by the antitrust agencies analyzing diverse competition issues in health care services and goods industries).
  37. FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, or amicus briefs. *See, e.g.*, Letter from Susan S. DeSanti, Dir., Office of Pol'y Planning, FTC, et al., to Sam Jones, Rep., La. House of Reps. (May 22, 2009), available at [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-louisiana-house-Rep.s-concerning-louisiana-house-bill-687-practice/v090009louisianahb687amendment.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-louisiana-house-Rep.s-concerning-louisiana-house-bill-687-practice/v090009louisianahb687amendment.pdf) (regarding proposed restrictions on mobile dentistry); FTC & DEP'T OF JUSTICE, ILLINOIS CERTIFICATE OF NEED LAWS: HEARING BEFORE THE ILLINOIS TASK FORCE ON HEALTH PLANNING REFORM (2008) [FTC & DOJ ILLINOIS STATEMENT], available at <http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf>; Brief for FTC as Amicus Curiae Supporting Appellants, *Ciprofloxacin Hydrochloride Antitrust Litig. v. Bayer AG and Bayer Corp.*, 466 F.3d 187 (2d Cir. 2005).
  38. Calling for the creation of a federal trade commission before a joint session of Congress in 1914, Woodrow Wilson envisioned an "indispensable instrument of information and publicity, a clearing house for the facts by which both the public mind and the managers of great business undertakings should be guided, and as an instrumentality for

This research, advocacy, and education mission complements the FTC's law enforcement mission but may have a broader purview than law enforcement itself.<sup>39</sup> Any number of legal or pragmatic issues can militate against litigation in circumstances raising competitive concerns, and the reach of antitrust law enforcement is narrower than the pro-competition policy goals that such enforcement aims to protect.<sup>40</sup> Advocacy may, in particular, address regulatory impediments to effective competition, which sometimes prove especially effective and durable but may or may not be actionable under the federal antitrust laws.<sup>41</sup> To help provide both information and analytic tools to lower such barriers, whether subject to the antitrust laws or not, the FTC and its staff have issued reports regarding various segments of the health care industry.<sup>42</sup> The Commission and its staff also have intervened as amici curiae in private controversies.<sup>43</sup> Finally, in response to requests from federal and state policy makers, the FTC and its staff may examine the potential competitive impact of particular policy proposals, such as bills or proposed rules, that may affect consumers' spending on, choices of, or even basic access to health care services. Such comments have addressed, for example,

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doing justice to business where the processes of the courts or the natural forces of correction are inadequate." H.R. Doc. No. 625, at 6 (1914).

39. See, e.g., Maureen K. Ohlhausen, *Identifying, Challenging, and Assigning Political Responsibility for State Regulation Restricting Competition*, 2 COMPETITION POL'Y INT'L 151, 156-57 (2006) (describing competition advocacy as "beyond enforcement" of the antitrust laws); James C. Cooper et al., *Theory and Practice of Competition Advocacy at the FTC*, 72 GEO. MASON ANTITRUST L.J. 1091, 1102-04 (2005) (describing competition policy as a means to address "political market failure" and ameliorate consumer harm). See also WILLIAM E. KOVACIC, FTC, THE FEDERAL TRADE COMMISSION AT 100: INTO OUR 2ND CENTURY THE CONTINUING PURSUIT OF BETTER PRACTICES 92-109, 121-24 (2009) (discussing policy research and development and the role of the FTC advocacy program).
40. See, e.g., Cooper et al., *supra* note 39, at 1110-11 nn. 65-67.
41. Ohlhausen, *supra* note 39, at 152. See also *infra* Part I.D (providing a very brief sketch of the Noerr-Pennington and State Action doctrines).
42. See, e.g., FTC, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbbenefitript.pdf>; A DOSE OF COMPETITION, *supra* note 19, at 1. Staff reports also have addressed, in particular, competitive issues associated with professional licensure. See, e.g., CAROLYN COX & SUSAN FOSTER, FTC, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION iv (1990), available at <http://www.ftc.gov/be/consumerbehavior/docs/reports/CoxFoster90.pdf>.
43. See, e.g., Brief of FTC as Amicus Curiae, Nurse Midwifery Assocs. v. Hibbett, 918 F.2d 605 (6th Cir. 1990).

regulatory costs associated with state certificate of need requirements,<sup>44</sup> pharmacy benefits regulations,<sup>45</sup> and proposals to exempt certain health care providers from antitrust scrutiny.<sup>46</sup>

More directly pertinent to nursing, and discussed at greater length below, these competition advocacy comments have addressed restrictions that would be imposed on “retail” or “limited service” clinics (RCs or LSCs),<sup>47</sup> which typically are staffed by APRNs, as well

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44. *E.g.*, *Hearing on S.B. 2326 Before the Florida State Senate*, 2008 Leg., Reg. Sess. (Fla. 2008) (statement of FTC), *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf); FTC & DOJ ILLINOIS STATEMENT, *supra* note 37.
45. *E.g.*, Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to James L. Seward, Senator, New York Senate (Aug. 8, 2011), *available at* <http://www.ftc.gov/os/2011/08/110808healthcarecomment.pdf> (concerning New York Assembly Bill 5502-B, proposed to regulate use of mail order pharmacies by health plans offering prescription drug coverage).
46. *E.g.*, Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to John J. Bonacic, Senator, New York Senate 4 (Oct. 20, 2011), *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-john-j.bonacic-concerning-new-york-s.b.3186-allow-health-care-providers-negotiate-collectively-health-plans/111024nyhealthcare.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-john-j.bonacic-concerning-new-york-s.b.3186-allow-health-care-providers-negotiate-collectively-health-plans/111024nyhealthcare.pdf) (concerning New York S.B. 3186-A, which proposed to allow health care providers to negotiate collectively with health plans).
47. *E.g.*, Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Jill Brown, Ky. Cabinet for Health and Fam. Servs. 1 (Jan. 28, 2010) [Kentucky FTC Letter to Brown], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-kentucky-cabinet-health-and-family-services-concerning-proposed-rule-regulate/100202kycomment.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-kentucky-cabinet-health-and-family-services-concerning-proposed-rule-regulate/100202kycomment.pdf) (concerning a proposed rule to regulate RCs or “limited service clinics”); Letter from Maureen K. Ohlhausen, Dir., Office of Pol’y Planning, FTC, et al., to Elaine Nekritz, Rep., Illinois House of Reps. 1 (May 29, 2008) [hereinafter Illinois FTC Letter], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-representative-elaine-nekritz-illinois-general-assembly-concerning-h.b.5372-regulate-retail-health-facilities/v080013letter.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-representative-elaine-nekritz-illinois-general-assembly-concerning-h.b.5372-regulate-retail-health-facilities/v080013letter.pdf) (concerning H.B. 5372 to regulate retail health facilities); Letter from Maureen K. Ohlhausen, Dir., Office of Pol’y Planning, FTC, et al., to LouAnn Stanton, Mass. Dep’t of Pub. Health 1 (Sept. 27, 2007) [hereinafter 2007 Massachusetts FTC Letter], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-massachusetts-department-public-health-concerning-proposed-regulation-limited/v070015massclinic.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-department-public-health-concerning-proposed-regulation-limited/v070015massclinic.pdf) (regarding proposed regulation of “limited service clinics” in Massachusetts).

as restrictions expressly aimed at APRNs<sup>48</sup> or specific types of APRNs, such as nurse midwives (NMWs)<sup>49</sup> and nurse anesthetists (CRNAs).<sup>50</sup> For example, in 2012 – at the request of Louisiana state

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48. *E.g.*, Letter from Andrew Gavil, Dir., Office of Pol’y Planning, FTC, et al., to Kay Khan, Rep., Mass. House of Reps. (Jan. 17, 2014) [hereinafter 2014 Massachusetts FTC Letter], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf); Letter from Andrew Gavil, Dir., Office of Pol’y Planning, FTC, et al., to Theresa W. Conroy, Rep., Conn. House of Reps. (Mar. 19, 2013) [hereinafter Connecticut FTC Letter], *available at* <http://ftc.gov/os/2013/03/130319aprnconroy.pdf>; Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Paul Hornback, Senator, Ky. Senate 1, 3 (Mar. 26, 2012) [hereinafter Kentucky FTC Letter to Hornback], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-letter-honorable-paul-hornback-senator-commonwealth-kentucky-state-senate-concerning/120326ky\\_staffletter.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-paul-hornback-senator-commonwealth-kentucky-state-senate-concerning/120326ky_staffletter.pdf) (concerning Kentucky Senate Bill 187 and the regulation of advanced practice registered nurses); Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Rodney Ellis & Royce West, Senators, Tex. State Senate 1-3 (May 11, 2011) [hereinafter Texas FTC Letter], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-letter-honorable-rodney-ellis-and-honorable-royce-west-senate-state-texas-concerning-texas/v110007texasaprn.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-rodney-ellis-and-honorable-royce-west-senate-state-texas-concerning-texas/v110007texasaprn.pdf) (concerning Texas Senate Bills 1260 and 1339 and the regulation of Advanced Practice Registered Nurses); Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Daphne Campbell, Rep., Fla. House of Reps. 1-3 (March 22, 2011) [hereinafter Florida FTC Letter], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-letter-honorable-daphne-campbell-florida-house-representatives-concerning-florida-house/v110004campbell-florida.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-daphne-campbell-florida-house-representatives-concerning-florida-house/v110004campbell-florida.pdf) (concerning Florida House Bill 4103 and the regulation of ARNPs); *Hearing on Review of West Virginia Laws Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions Before Subcomm. A of the Joint Comm. on Health, W. Va. Legislature* (W. Va. 2008) (statement of FTC) [hereinafter *West Virginia Testimony*], *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-testimony-subcommittee-wv-legislature-laws-governing-scope-practice-advanced-practice/120907wvatestimony.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-testimony-subcommittee-wv-legislature-laws-governing-scope-practice-advanced-practice/120907wvatestimony.pdf); *Hearing on Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses Before the Council of the District of Columbia* (Nov. 1985) (statement of FTC) [hereinafter *FTC D.C. Comment*].
49. Brief of FTC as Amicus Curiae, *Nurse Midwifery Assocs. v. Hibbett*, 918 F.2d 605 (6th Cir. 1990).
50. *See* Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Jeanne Kirkton, Rep., Missouri House of Reps. (Mar. 27, 2012) [hereinafter Missouri CRNA Letter], *available at* <http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf>; Letter

representatives – FTC staff addressed the likely competitive impact of a bill that would have removed, for APRNs practicing in medically underserved areas, the need to establish a formal, written collaborative practice agreement with a supervising physician before providing services otherwise within APRNs’ scope of practice.<sup>51</sup> The staff did not seek to specify or redraw that scope of practice. Rather, it identified the potential costs of such agreements *as statutory requirements* for APRN practice, and the potential impact of those costs on the availability and price of primary health care services, and it asked the legislature to consider whether there was evidence of countervailing health or safety benefits adequate to offset competitive costs.<sup>52</sup>

### C. Competitors and Competition

The antitrust sense of “competitors” is somewhat specialized. Thorough explication goes well beyond the scope of this paper, which should not founder on the complexities of market definition or, for that matter, questions about when or to what extent market definition may be critical to antitrust analysis.<sup>53</sup> We note some core concepts nonetheless, not least to offset common contentions that APRNs cannot function as substitutes for physicians.<sup>54</sup> Antitrust is

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from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Gary Odom, Rep., Tenn. House of Reps. (Sept. 28, 2011) [hereinafter Tennessee FTC Letter to Odom], *available at* <http://www.ftc.gov/os/2011/10/V11001tennesseebill.pdf>; Letter from Susan S. DeSanti, Dir., Office of Pol’y Planning, FTC, et al., to Patricia E. Shaner, Office of Gen. Counsel, Ala. State Bd. of Med. Exam’rs (Nov. 3, 2010) [hereinafter Alabama FTC Letter], *available at* <http://www.ftc.gov/os/2010/11/101109alabamabrme.pdf>.

51. Louisiana FTC Letter, *supra* note 13, at 2. Although certain certification standards are established nationally for APRNs, state law varies on the particulars of APRN scope of practice and on the question of whether APRNs must establish such collaborative practice agreements to offer services within that state-specific scope of practice. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 96-103, 157-61. *See also* 2014 Massachusetts FTC Letter, *supra* note 48 (addressing nurse anesthetist regulations as well as nurse practitioner regulations).
52. Louisiana FTC Letter, *supra* note 13, at 2, 5.
53. *See, e.g.*, Jonathan B. Baker, *Market Definition: An Analytical Overview*, 74 ANTITRUST L.J. 129 (2007); U.S. DEP’T OF JUSTICE AND FTC, HORIZONTAL MERGER GUIDELINES 9-15 (2010) [hereinafter HORIZONTAL MERGER GUIDELINES], *available at* <http://ftc.gov/os/2010/08/100819hmg.pdf>. *See also* Steven C. Salop, *The First Principles Approach to Antitrust, Kodak, and Antitrust at the Millennium*, 68 ANTITRUST L.J. 187 (2000) (regarding an integrated or “first principles” approach).
54. *See, e.g.*, Jeffrey Cain, Letter to the Editor, *Addressing the Doctor Shortage*, N.Y. TIMES (Oct. 30, 2012), <http://www.nytimes.com/2012/10/31/opinion/addressing-the-doctor->

concerned with the process of competition and, in particular, with the competitive effects of mergers or certain types of conduct that impinge upon consumer welfare.<sup>55</sup> To determine competitive effects, the agencies and the courts often begin with market definition,<sup>56</sup> that is, describing product or service markets and geographic areas in which competition takes place. Market participants – potential competitors – are those entities earning revenue in the relevant market.<sup>57</sup>

Fundamental to market definition is the economic measure of demand substitution.<sup>58</sup> Demand substitution is consumers' (buyers') ability and willingness to switch between particular goods or services, from *a* to *b*, in response to a price increase or a non-price change (such as a perceived change in quality or convenience) associated with *a*.<sup>59</sup> Competitors are firms (or professionals) offering substitute services or goods to an extent that is economically significant. Competing services or goods are those that function – or likely would

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shortage.html (“[A] nurse practitioner is not a physician and is not a substitute for a physician.”).

55. See, e.g., Salop, *supra* note 53, at 188 (“[C]ompetitive effect is the true core of antitrust.”). Cf. Robert H. Bork, *Legislative Intent and the Policy of the Sherman Act*, 9 J.L. & ECON. 7, 10 (1966) (noting that the legislative history of the Sherman Act “contains no colorable support for application by courts of any value premise or policy other than the maximization of consumer welfare”); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007) (holding that “[i]n its design and function” the rule of reason approach that dominates antitrust analysis “distinguishes between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer’s best interest”).
56. See, e.g., HORIZONTAL MERGER GUIDELINES, *supra* note 53, at 9. The analysis may be iterative: determination of competitive effects need not merely be the output of an analytic process commencing with market definition; economic evidence of competitive effects also may be used to test putative market definitions. *Id.* at 7. In certain contexts it can trump them. Salop, *supra* note 53, at 188-89.
57. HORIZONTAL MERGER GUIDELINES, *supra* note 53, at 21.
58. See *id.* at 7 (“Market Definition focuses solely on demand substitution factors . . . .”); see also *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956); Baker, *supra* note 53, at 132-38 (discussing primacy of demand – or buyer side – substitution but also noting circumstances considering the supply side).
59. HORIZONTAL MERGER GUIDELINES, *supra* note 53, at 7. That may be determined by econometric estimates of own-price elasticity (demand elasticity). Cross elasticity of demand may also be used to identify potential substitutes in a market. See generally, Baker, *supra* note 53, at 138-41 (discussing the determinations of econometric estimates of own-price elasticity (demand elasticity) and cross elasticity of demand, which may also be used to identify potential substitutes in a market).

function – as substitutes (or alternatives) to an extent that is economically significant.<sup>60</sup> APRNs already provide, and receive compensation for, some primary care services also provided by physicians.<sup>61</sup> Moreover, estimates of the range of primary care services that APRNs might provide easily suggest that such practitioners are at least potential competitors to primary care physicians.<sup>62</sup> And one recent study suggests that the share of primary care treatment undertaken by APRNs depends on the state regulatory environment in which they practice.<sup>63</sup>

Hence, *if* they exert or are likely to exert significant competitive pressure on each other, primary care physicians and nurse practitioners may be competitors *even if*: they often work in collaboration; they do not offer an identical range of services; and many consumers do not value their services equally.<sup>64</sup> That is, to say such professionals are competitors is to say that their services are potential substitutes, but to say that services are potential substitutes is not to say that they are indistinguishable. We do not suppose that these groups of competitors are perfect substitutes across the full range of services they offer

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60. Readers unfamiliar with antitrust law and economics may wish to consult the Horizontal Merger Guidelines for a sketch of the “hypothetical monopolist” test and the “SSNIP” test (regarding a hypothetical monopolist’s ability to impose a small but significant increase in price) and their iterative application in market definition. HORIZONTAL MERGER GUIDELINES, *supra* note 53, at 11-16.
61. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 1, at 26 tbl. 1-1.
62. *See, e.g.*, OFFICE OF TECH. ASSESSMENT, OTA-HCS-37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE-MIDWIVES: A POLICY ANALYSIS 39 (1986) [hereinafter OTA HEALTH TECH. CASE STUDY] (“Most observers conclude that most primary care traditionally provided by physicians can be delivered by NPs and PAs.”). Hence, at least for a substantial range of primary care services, APRNs might collect revenues in some of the same geographic and service markets as some physicians, if permitted by law and regulation to do so.
63. Yong-Fang Kuo et al., *States with the Least Restrictive Regulations Experienced the Largest Increase in Patients Seen by Nurse Practitioners*, 32 HEALTH AFFS. 1236, 1238-40 (2013) (reporting on a study based on a five-percent sample of Medicare claims data). For various reasons, particular treatments conducted by APRNs may not be accurately reflected in the claims data. *See* David I. Auerbach, *Nurse Practitioner Billing Practices Could Obscure True Numbers*, HEALTHAFFAIRS (July 18, 2013), <http://content.healthaffairs.org/content/32/7/1236/reply>. Still, these do not impugn the general direction of the reported results, which suggests that greater substitution occurs under less restrictive regulatory regimes.
64. Certainly, there is no normative suggestion that they ought to do so.

or even for any particular service.<sup>65</sup> We do not suppose that substitution is equally (or even significantly) effective across the whole geographic area in which each competing professional (or firm) does business. And we do not suppose that competitors are professionals (or firms) who do not, or should not, collaborate or offer complementary services.<sup>66</sup>

Indeed, questions about competitive effects may remain independently of questions about whether or to what extent the practice of medicine and the practice of nursing comprise competing or complementary services. Investing one group of professional service providers with regulatory authority over another might raise competitive concerns if the services offered by the two groups are competing ones *or* complements.<sup>67</sup> For example, one might be concerned about

65. Several authors have suggested that expanding APRN scope of practice might have, among others, the salutary competitive effect of prompting some physicians to focus more efficiently on their relative competitive advantages. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 1, at 76, 98; FTC D.C. Comment, *supra* note 48, at 4. That seems generally plausible, although we express no opinion on the extent to which primary care physicians would shift the mix of services they provide or the relative weighting of services within the mix.
66. Competition law and policy recognize that particular collaborations among competitors may yield pro-competitive and pro-consumer efficiencies, and contemporary antitrust is not generally hostile to vertical integration. FTC & U.S. DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (2000), *available at* <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; U.S. DEP'T OF JUSTICE & FTC, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996) [hereinafter DOJ & FTC POLICY STATEMENTS], *available at* <http://www.justice.gov/atr/public/guidelines/0000.pdf>. *Cf.* Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026, 67,026-28 (Oct. 28, 2011) (exemplifying statutory and policy goals to permit potentially pro-competitive clinical integrations while seeking to protect both Medicare beneficiaries and commercially insured patients from anticompetitive harm).
67. That these professionals *may* offer complementary services should be trivial and that they should do so under a particular model is evidenced in AMA comments about constraining the role of APRNs as “health care delivery is evolving to a physician-led team approach to ensure better care coordination and outcomes for patients.” Letter from James L. Madara, Am. Med. Ass'n, to the Hon. David G. Perry and the Hon. Dan Foster, W. Va. Legislature Joint Comm. on Health Subcomm. A, at 1 (Sept. 10, 2012) [Madara Letter], *available at* <http://www.ama-assn.org/resources/doc/arc/ama-letter-ftc-wv.pdf>. Competitive concerns may be distinct in the case of complementary services. *See, e.g.*, Dennis W. Carlton & Michael Waldman, *The Strategic Use of Tying to Preserve and Create Market Power in Evolving Industries*, 33 RAND J. ECON. 194, 194 (2002) (regarding complements and tying more generally).

the costs to competition when the law requires that APRNs enter into formal collaborative practice agreements with physicians, even if many APRNs would seek and contract for collaborative arrangements absent the legal requirement.<sup>68</sup> Voluntary collaborative agreements could, in theory, encompass widely varying arrangements. Under such arrangements even independently practicing APRNs might pay for chart review or consultation up to the value of those inputs to the APRN's practice. But where collaborating physicians are in short supply – or where supply is effectively restricted by regulation<sup>69</sup> – there is a risk that the costs of such agreements may tend to rise and that the quality of collaborative input may fall.<sup>70</sup> In brief, the legal requirement for an agreement – imposed on one of the contracting parties but not the other – might well encourage physician rent-seeking, raising the costs of both nursing services and collaboration between physicians and APRNs above market levels. Those costs may sometimes be prohibitive, deterring entry for some APRNs or making some existing practices nonviable. Not incidentally, such regulations may constrain the ability of providers to innovate in developing new models of health care delivery.<sup>71</sup>

*D. Exogenous Limits: Noerr-Pennington and the State Action Doctrine*

The Noerr-Pennington<sup>72</sup> and State Action Doctrines<sup>73</sup> are judicial doctrines that limit the application of the federal antitrust laws to

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68. See, e.g., Louisiana FTC Letter, *supra* note 13, at 3, 5. Many APRNs would contract independently for certain collaborative or supervisory services or would do so *de facto* through employment by a health care service provider that has internalized various collaborative or supervisory practices in its administrative structure and procedures. Regarding the potential diversity of collaborations. See, e.g., PAMELA MITCHELL ET AL., CORE PRINCIPLES & VALUES OF EFFECTIVE TEAM-BASED HEALTH CARE 11 (2012), available at <https://www.nationalahec.org/pdfs/VSRT-Team-Based-Care-Principles-values.pdf>.
  69. See IOM FUTURE OF NURSING REPORT, *supra* note 1, at 157-61 tbl. 3-A1 (describing state-by-state limits on the number of nurse practitioners with whom a physician may establish a collaborative practice agreement (or whom a physician may supervise)).
  70. See, e.g., Louisiana FTC Letter, *supra* note 13, at 3, 5. That is, either effect may be observed at the margin. We do not suggest that such effects are necessary or typical.
  71. *Id.*; see also Julie Fairman, Professor of Nursing & Dir. of the Barbara Bates Center for the Study of the History, Factors Influencing Value – Enhancing Entrepreneurship in Health Care Delivery, Address at RAND Policy Symposium (Oct. 4, 2011) (transcript on file with author).
  72. The doctrine takes its name from the first two in a line of Supreme Court cases articulating its principles: *E. R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

certain private conduct and state government decisions respectively. Each of these doctrines describes core exemptions or immunities, contemplates exceptions, and ranges over problematic or contentious areas of application that we cannot engage, much less resolve, in this paper.<sup>74</sup> We offer the following sketch to help distinguish, in a general way, areas in which either competition advocacy or law enforcement may be viable from areas in which competition advocacy may apply more broadly than federal law enforcement authority.

In brief, the Noerr-Pennington Doctrine seeks to avoid a conflict between competition values and First Amendment speech and petitioning rights by restricting the application of the antitrust laws to private acts that urge, even to anticompetitive ends, government action. The State Action Doctrine, partly on federalism grounds, shields some anticompetitive conduct undertaken by the states themselves from federal antitrust scrutiny. In particular, it shields sovereign state acts of the legislature and certain other conduct implementing sovereign state policies.<sup>75</sup> For example, certain forms of coordinated conduct are discouraged under the antitrust laws with some deemed *per se* unlawful collusion to fix prices or limit output; however, under Noerr-Pennington, private parties acting jointly through a trade association may seek anticompetitive advantages before the legislature, including some that they could not seek to implement privately.<sup>76</sup> Such immunity does not, however, extend to lobbying that is “ostensibly directed toward influencing governmental action [that] is a mere sham to cover what is actually nothing more

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73. The State Action Doctrine is articulated in *Parker v. Brown* and its progeny. 317 U.S. 341, 342-43 (1943). In *Parker*, the Court found the Sherman Act’s reach limited by a legislative intent to reach “individual and not state action.” *Id.* at 352.
74. For more complete accounts of both core doctrines as well as discussion of difficult, unsettled, or contentious areas of application, see, e.g., FTC, ENFORCEMENT PERSPECTIVES ON THE NOERR-PENNINGTON DOCTRINE (2006), *available at* <http://www.ftc.gov/reports/P013518enfperspectNoerr-Penningtondoctrine.pdf>; FTC, OFFICE POL’Y PLANNING, REPORT OF THE STATE ACTION TASK FORCE (2003), *available at* [http://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/report-state-action-task-force/stateactionreport.pdf](http://www.ftc.gov/sites/default/files/documents/advocacy_documents/report-state-action-task-force/stateactionreport.pdf).
75. FTC, REPORT OF THE STATE ACTION TASK FORCE, *supra* note 74, at 1.
76. In *Noerr Motor Freight, Inc.*, for example, the Court held that the application of the Sherman Act to the railroads’ publicity and lobbying campaign at issue was precluded by the right of petition, independent of the campaign’s motivation. 365 U.S. at 138. More generally, “the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly.” *Id.* at 136.

than an attempt to interfere directly with the business relationships of a competitor.”<sup>77</sup>

Under the State Action Doctrine, a state legislature may enact laws that directly diminish or even supplant competition, although it cannot simply authorize private parties to violate the antitrust laws or declare such violations lawful by fiat.<sup>78</sup> Certain “legislative” acts of a state supreme court also are deemed sovereign state acts.<sup>79</sup> Other entities may enjoy some measure of immunity,<sup>80</sup> derived from the deference accorded the sovereign state, although to a lesser degree than that accorded the state itself. Municipalities or state-authorized hospital boards, for example, may be shielded to the extent that they act “in furtherance or implementation of clearly articulated and affirmatively expressed state policy.”<sup>81</sup> Other state sanctioned entities

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77. *Id.* at 144. *Compare* Cal. Motor Transp. Co. v. Trucking Unltd, 404 U.S. 508, 515-16 (1972) (holding that *Noerr* protection does not extend to a combination of entrepreneurs aiming “to harass and deter their competitors from having ‘free and unlimited access’ to the agencies and courts” and “to defeat that right by massive, concerted, and purposeful activities of the group”), *with* Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 51 (1993) (“[L]itigation cannot be deprived of immunity as a sham unless the litigation is objectively baseless.”).
78. *Parker v. Brown*, 317 U.S. 341, 351 (articulating the general principle of the exemption and qualifying that “a state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful”).
79. *Hoover v. Ronwin*, 466 U.S. 558, 568 (1984) (explaining “*Parker’s* basic reasoning” exempts the direct acts of a state legislature or a state supreme court, acting in its legislative rather than judicial capacity); *Goldfarb v. Va. State Bar*, 421 U.S. 773, 790 (1975) (“The threshold inquiry in determining if an anticompetitive activity is state action of the type the Sherman Act was not meant to proscribe is whether the activity is required by the State acting as sovereign.”).
80. Whether this is deemed an exemption (from antitrust liability) or immunity (from antitrust suit) has sometimes been controversial. *S.C. State Bd. of Dentistry v. F.T.C.*, 455 F.3d 436, 445 (4th Cir. 2006) (“[W]e cannot conclude that the Court’s occasional after-the-fact use of the term ‘*Parker* immunity’ created an immunity from suit.”).
81. For example, “Cities are not themselves sovereign; they do not receive all the federal deference of the States that create them.” *Commc’ns Co. v. City of Boulder*, 455 U.S. 40, 50-51 (1982) (quoting *Lafayette v. La. Power & Light Co.*, 435 U.S. 389, 412-13 (1978) (holding that cities are granted extensive “home rule” authority by state statute and are not thereby entitled to state action immunity)). *City of Boulder* did not reach the question of whether municipalities had to satisfy both prongs of the test imposed on state-authorized private parties. *See id.* at 51. The Court later resolved this issue in *Town of Hallie v. City of Eau Claire*. 471 U.S. 34, 47 (1985) (“Once it is clear that state authorization exists, there is no need to require the State to supervise actively the municipality’s execution of what is a properly

and those private parties whose conduct is “prompted” by state action<sup>82</sup> are only shielded to the extent that they meet two general conditions: “First, the challenged restraint must be ‘one clearly articulated and affirmatively expressed as state policy’; second, the policy must be ‘actively supervised’ by the State itself.”<sup>83</sup> Independent state boards, in particular, are not themselves sovereign and may sometimes be fully subject to antitrust scrutiny.<sup>84</sup>

State statutory law requiring that certain educational criteria be met before a person may be licensed as a physician or a nurse may be both a substantial barrier to entry and a valid exercise of the state’s

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delegated function.”). In *FTC v. Phoebe Putney Heath System, Inc.*, a unanimous Court recently held that “Georgia’s grant of general corporate powers to hospital authorities does not include permission to use those powers anticompetitively . . . [and hence] that the clear-articulation test is not satisfied and state-action immunity does not apply.” 133 S.Ct. 1003, 1007 (2013).

82. *Goldfarb*, 421 U.S. at 791 (1975) (holding that “[i]t is not enough that ... anticompetitive conduct is ‘prompted’ by state action” and that the state bar is not generally immune from antitrust scrutiny even if the “State Bar is a state agency for some limited purposes . . .”). See also *Patrick v. Burget*, 486 U.S. 94, 101-02 (1988) (holding that actions of a hospital peer review board are not state action and are not protected by the state action doctrine).
83. *Cal. Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).
84. For example, in *North Carolina Board of Dental Examiners v. FTC*, the Fourth Circuit held that “state agencies ‘in which a decisive coalition (usually a majority) is made up of participants in the regulated market,’ who are chosen by and accountable to their fellow market participants, are private actors and must meet both *Midcal* prongs.” 717 F.3d 359, 368 (2013) (agreeing with the FTC’s determination and citing Phillip E. Areeda & Herbert Hovenkamp, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* 501 (3d ed. 2009). See also *F.T.C. v. Monahan*, 832 F.2d 688, 690 (1st Cir. 1987) (denying *ipso facto* immunity); *Mass. Bd. of Registration in Optometry*, 110 F.T.C. 549, 612-13 (1988) (holding that the state optometry board is “not entitled to immunity as the sovereign” and that there is no clear articulation of intent to displace competition in authorizing statute). *But see Green v. State Bar of Tex.*, 27 F.3d 1083, 1087 (5th Cir. 1994) (holding that the state’s Unauthorized Practice of Law Committee was immune from scrutiny). Then-Judge Breyer, writing for the majority in *FTC v. Monahan*, held that both clear legislative articulation and active supervision are required when board activity comprises “essentially” private action and that “[w]hether any ‘anticompetitive’ Board activities are ‘essentially’ those of private parties depends upon how the Board functions in practice, and perhaps upon the role played by its members. . . .” 832 F.2d at 689-90. The Supreme Court, as noted above, has plainly held that other types of independent, but statutorily-created, health care authorities may be subject to federal antitrust scrutiny. *Phoebe Putney Heath System, Inc.*, 133 S.Ct. at 1007.

traditional police powers and, as such, immune from federal antitrust scrutiny under the state action doctrine.<sup>85</sup> If a private trade association recommends such barriers to entry to the legislature, the request itself may be protected under the Noerr-Pennington doctrine. In either case, competition advocacy might nonetheless raise the question whether some particular proposed requirement seems excessive, under-rationalized, or baseless as a health and safety protection and substantial as a barrier to entry. A similar substantive standard, if set by an independent regulatory board under a general grant of authority from the state, may not receive the same deference.<sup>86</sup> Enactment of a licensing scheme may entail (and hence render “foreseeable”) some barriers to entry in professional services markets. The doctrine imposes, however, both “procedural and substantive limitations on the state’s ability to confer antitrust immunity.”<sup>87</sup> Depending on the particular facts and circumstances at issue, such standards may be questioned in the course of competition advocacy, subject to law enforcement scrutiny, or both.<sup>88</sup>

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85. This is not to evaluate any particular piece of legislation. The general principle that acts of a state legislature are valid, except insofar as they exceed the legislature’s powers under the federal Constitution, is articulated in *Parker* itself. 317 U.S. at 350-51. *See also* Hoover v. Ronwin, 466 U.S. 558, 567-68 (1984). The idea that state legislatures can regulate commerce through health laws dates to *Gibbons v. Ogden*. 22 U.S. (9 Wheat.) 1, 71 (1824). *See also* Wilson v. Black Bird Creek Marsh Co., 27 U.S. (2 Pet.) 245, 249-50 (1829).
86. Although there may be some lack of uniformity across the U.S. Courts of Appeals on the question of *when* such regulators may be accorded state action immunity, it is well settled that there are circumstances under which state regulatory boards – and certainly an independent board comprised substantially of financially interested parties or members of the profession regulated by the board in question – are not themselves sovereign and hence may be subject to federal antitrust scrutiny. *See, e.g.*, Goldfarb v. Va. State Bar, 421 U.S. 773, 791 (1975). *See also* Monahan, 832 F.2d at 689-90; *Mass. Bd. of Registration in Optometry*, 110 F.T.C. at 612-13.
87. William H. Page & John E. Lopatka, *State Regulation in the Shadow of Antitrust: FTC v. Ticor Title Ins. Co.*, 3 SUP. CT. ECON. REV. 189, 219 (1993) (discussing the active supervision prong of *Midcal* in the wake of *F.T.C. v. Ticor Title Insurance Co.* and analogizing state action doctrine to the general antitrust approach to ancillary restraints).
88. Numerous competition advocacy comments have been submitted to executive agencies and independent regulatory boards authorized by state legislation, and such comments may be issued independently of the question whether a given agency may be subject to *Midcal*’s two pronged-test. A particular set of facts may give rise to law enforcement, private antitrust litigation, and competition advocacy. *Compare* Complaint, State Volunteer Mutual Ins. Co., Inc., Docket No. C-3115, 102 F.T.C. 1232 (Sept. 28, 1983) (alleging violation of Section 5), *with* Brief of FTC as Amicus Curiae, *Nurse Midwifery Assocs. v. Hibbett*, 918 F.2d 605 (6th Cir. 1990).

## II. DISCUSSION

### A. *Competition, Licensure, and Scope of Practice*

For the health care professions, licensure and scope of practice regulations are two sides of the same coin: licensure restricts entry (or ongoing participation) in a given profession, and scope-of-practice restrictions help describe the metes-and-bounds of licensure – what a given professional license permits a person to do and, often, prohibits others from doing.<sup>89</sup> In that regard, general competition considerations for licensure may provide a useful baseline when considering the potential costs and benefits of particular scope of practice restrictions. First, professional licensure works as a barrier to entry when it works at all.<sup>90</sup> That is not necessarily a bad thing: not all barriers to entry are substantial or durable, much less excessive or unlawful, and it does not follow from the very nature of licensure that it necessarily is anticompetitive, fails to provide consumer benefits, or fails, on balance, to be cost-justified.<sup>91</sup> On the other hand, any particular licensing regime or provision may evidence any or all of those failings.

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89. Plainly, a complete code specification for medical or nursing practice is likely intractable, if not impossible. Scope of practice tends to be defined partly in the breach and partly through an admixture of general and specific categories of permitted and excluded conduct across statutory law, regulation, administration, and litigation. Perhaps equally plain is that scope of practice rules are not the only legal or regulatory restrictions on professional practice. Diverse provisions running from, e.g., the Stark anti-kickback law, 42 U.S.C. §1320a-7b(b)(2012) and implementing regulations at 42 C.F.R. §1001.952 (2010) to HIPAA privacy rules, Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. pts. 160, 164 (2013), all serve to constrain practice in various ways. State law tort claims may rest on a much broader set of issues than licensure or scope of practice *per se*.
90. Licensure is a process that guards entry into an occupation and requires the license seeker to obtain the permission of a government agency before providing professional services in that agency's jurisdiction. Typically, the state licensing authority requires the license-seeker to demonstrate a minimum degree of competence in turn. *See Joint Hearing on Health Care and Competition Law and Policy Before the FTC and Dep't of Justice* 33-34 (Jun. 10, 2003), available at [http://www.ftc.gov/sites/default/files/documents/public\\_events/health-care-competition-law-policy-hearings/030610ftctrans.pdf](http://www.ftc.gov/sites/default/files/documents/public_events/health-care-competition-law-policy-hearings/030610ftctrans.pdf) (statement of Dr. Morris Kleiner); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 18-20 (1971) (providing a general account of the "capture theory" of regulation applied to professionals' interest in limiting entry via licensure).
91. Adriana D. Kugler & Robert M. Sauer, *Doctors without Borders? Relicensing Requirements and Negative Selection in the Market for Physicians*, 23 J. LAB. ECON. 437, 438 (2005) ("Licensing may improve the average quality of service offered by practitioners when the entry of less competent practitioners is prevented or when less competent practitioners are forced to increase their investments in human

Licensure also can be an efficient response to several potential types of market failure such as when there are information asymmetries between professionals and consumers and quality information is costly;<sup>92</sup> when externalities are striking;<sup>93</sup> or when professionals play the dual roles of diagnostician and treatment provider.<sup>94</sup> In health care, market failure sometimes implicates health and safety concerns. For example, to the extent that lower-quality care entails significant health or safety risks, consumers may be subject to poorer outcomes associated with those risks, and providers may have less incentive to minimize those risks when providing quality information is costly.<sup>95</sup> Licensure may not cure this problem, but it can provide consumers with some critical quality information by setting and certifying

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capital.”). See also Keith B. Leffler, *Physician Licensure: Competition and Monopoly in American Medicine*, 21 J.L. & ECON. 165, 166, 185-86 (1978) (examining approaches to physician licensure and finding “no clear answer” to the question of who benefits from the medical profession’s licensure requirements).

92. For example, various ratings and patterns of referral notwithstanding, it may be very difficult for consumers to assess the relative quality of competing physician services (or services competing *with* physician services). If so, some professionals may be insulated against the competitive disadvantages of offering lower quality services while others may be unable to capture the gains associated with higher quality services. See, e.g., COX & FOSTER, *supra* note 42, at 5-6. Cf. Hayne E. Leland, *Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards*, 87 J. POL. ECON. 1328, 1329 (1979).
93. COX & FOSTER, *supra* note 42, at 9-10.
94. *Id.* at 11. Health care law deals with special cases of this, as in restricting physician ownership of certain diagnostic facilities. However, the concern is more general, as patients typically rely on service providers to recommend further services. Especially when there are third-party payers, when pricing is per service, and when the service is highly technical, there may be a bias toward overconsumption: providers may tend to offer more services than necessary to consumers who often are poorly equipped to evaluate the marginal value of additional services and are insulated from some of the costs of overconsumption. James C. Cooper, *Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction with a Difference*, 3 J.L. ECON. & POL’Y 331, 343-44 (2007).
95. For example, at the extreme, consumers may be unable to identify substantial risks of morbidity or mortality when, e.g., they lack information on impaired providers or hospitals with unusually high post-operative infection rates. See A DOSE OF COMPETITION, *supra* note 19, at 17-21 (regarding the broader competitive problem of information costs and asymmetries in health care). Regulation against fatal risks is a classical justification for regulatory costs more generally. See, e.g., RICHARD POSNER, *ECONOMIC ANALYSIS OF LAW* 383-84 (6th ed. 2003).

minimum quality standards or qualifications regarded as proxies for such standards.<sup>96</sup>

At the same time, licensure may be used by incumbent professionals to insulate themselves from competition.<sup>97</sup> By restricting the entry of competitors, licensure can restrict supply, which can increase the income of incumbents (at consumer expense) or decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience.<sup>98</sup> On this model, licensure is not an

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96. See, e.g., Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 966 (1963) (noting licensure may increase consumer confidence in the quality of the licensed service). That is, licensure may specify educational, training, or other entry requirements that may be associated or presumed associated with a quality floor. We are agnostic with respect to the question of what such requirements ought to be for physicians or APRNs. There is also an open question of whether there is any empirical basis to suppose that particular requirements are associated with a particular quality of care or diminution of risk. Cf. Leland, *supra* note 92, at 1342 (1979) (noting that in markets with asymmetric information, minimum quality constraints or licensing may be welfare-enhancing, although they are not the first-best solution, but where constraints are set by a regulated industry or profession, standards are likely to be set too high).
97. To be clear, we are not suggesting that the larger population of physicians cynically or consciously seeks to raise their income and suppress APRN income via licensure and scope of practice restrictions. Rather, to the extent that such restrictions are in the economic self-interest of some physicians, those physicians might be biased in favor of such policies. Other factors, such as historically entrenched forms of training and care delivery, dated or erroneous beliefs about the training or performance of unfamiliar professions, or even professional bias, may contribute to advocacy on behalf of excessive APRN regulation. See, e.g., IOM FUTURE OF NURSING REPORT, *supra* note 1, at 27, 107-14; Barbara J. Safriet, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing Quality, Cost-Effective Health Care*, in IOM FUTURE OF NURSING REPORT, *supra* note 1, at 451-57. Moreover, pro- and anticompetitive models of licensure may simultaneously apply to any particular set of licensing requirements and scope of practice restrictions. To suppose that a given bundle of restrictions comprises both certain baseline standards that ameliorate likely market failure and others that impose undue costs is hardly incoherent.
98. Stigler, *supra* note 90, at 13-14 (discussing the income variable in professional licensing). See also COX & FOSTER, *supra* note 42, at 18-20 (arguing that income is a significant factor in professionals' desire for regulation via licensing); Morris M. Kleiner, *Occupational Licensing*, 14 J. ECON. PERSP. 189, 192 (2000) ("The most generally held view on the economics of occupational licensing is that it restricts the supply of labor to the occupation and thereby drives up the price of labor as well as of services rendered."). This approach to licensure is generally consistent with what has also been called "the economic theory of regulation" (ETR). See generally Cooper et al., *supra* note 40 (discussing competition advocacy and ETR); Sam Peltzman, *Toward a*

efficient response to market failure but an example of legislative or regulatory “capture” by concentrated professional interests.<sup>99</sup> Recent research results are “consistent with the hypothesized role by members of an occupation to raise wages by using the powers of government to drive up requirements and capture work for the regulated workers for larger geographic areas.”<sup>100</sup>

Licensure and scope of practice regulations thus have a consumer protection<sup>101</sup> rationale that we cannot gainsay and, at the same time, may serve the more parochial interests of the very professionals whose conduct they govern. They may foster safe care by setting education, certification, and accreditation standards that assure patients (health care consumers) that a provider has a basic level of knowledge or skill (or by setting practice boundaries concomitant with that level of skill). However, regulations may provide that assurance only roughly or at substantial cost – say, by offering over-broad assurances about some service providers or over-broad restrictions on others, or by imposing excessive barriers to entry, whether into the profession, across professions,<sup>102</sup> or across jurisdictional boundaries (such as state

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*More General Theory of Regulation*, 19 J.L. & ECON. 211, 213(1976); Gary S. Becker, *A Theory of Competition Among Pressure Groups for Political Influence*, 98 Q.J. ECON. 371, 371-72 (1983).

99. See Kleiner, *supra* note 98, at 192 (suggesting that members of professions use state legislatures or local governments to control entry via licensing); Stigler, *supra* note 90, at 13-18 (providing a detailed analysis of the manner in which members of an occupation can use political processes to improve their positions).
100. Morris M. Kleiner & Alan B. Krueger, *Analyzing the Extent and Influence of Occupational Licensing on the Labor Market* 24 (Nat'l Bureau of Econ. Research, Working Paper 14979, 2011), available at <http://www.nber.org/papers/w14979.pdf> (finding substantially higher wages associated with licensure of a profession at the state or federal, instead of local, level, adjusting for educational attainment, age, experience, and other variables, consistent with a monopoly theory of licensure –a result that is not inconsistent with the claim that licensure may provide for higher quality services).
101. See *supra* note 17 regarding our use of “consumer protection.”
102. As noted already, special competition concerns may be raised when one group of competitors seeks to regulate another. In addition, although licensure may generally have an exclusive aspect, the question whether or to what extent one professional board may regulate the conduct of another profession sometimes raises complex legal questions under state law. See, e.g., *Mo. Ass'n of Nurse Anesthetists v. State Bd. of Registration for the Healing Arts*, 343 S.W.3d 348, 358 (Mo. 2011) (noting the Missouri board is “without authority to make policies, interpretations or determinations that define the scope of practice for APNs” under Missouri law).

lines).<sup>103</sup> If so, they may provide fewer social benefits at greater cost than necessary. Perhaps in some cases, or for some professions, the light they shine on professional qualifications is not worth the candle.<sup>104</sup>

Both threads may be evident in the history of medical licensure. Certification of medical schools and the development of state licensure acts in the late nineteenth and early twentieth centuries were built on serious professional concerns about inadequate institutions and untrained practitioners, on public aspirations for better, less abusive, and safer medical treatment, and on a growing acceptance of science as the basis for medical care and education.<sup>105</sup> The rise of licensure also comprised substantial jockeying for market share, with physicians sometimes lobbying jointly with, and sometimes against, other types of practitioners, such as homeopaths.<sup>106</sup>

Of course, the present policy discussion does not present a stark choice between competing models of regulation,<sup>107</sup> which are not mutually exclusive, or answer the question whether to maintain or

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103. See, e.g., Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL'Y 87, 89 (2011) (regarding some of the costs of state line barriers imposed by non-portable physician licensure).
104. The suggestion is not often made with regard to physician or nursing licensure in particular, and we do not make it here. *But see generally* Daniel B. Hogan, *The Effectiveness of Licensing: History, Evidence, and Recommendations*, 7 LAW & HUM. BEHAV. 117, 117 (1983) (arguing that licensure has not effectively accomplished its purpose and that there may be more efficient means to provide for minimum standards and curtail quackery); Charles H. Baron, *Licensure of Health Care Professionals: The Consumer's Case for Abolition*, 9 AM. J.L. & MED. 335, 341-42 (1983) (arguing licensure has failed to produce lasting net benefits in quality and has led to increased health care costs).
105. For a general account, see W.F. Bynum et al., *The Rise of Science in Medicine, 1850-1913*, in THE WESTERN MEDICAL TRADITION 1800-2000, at 132-35, 165-75 (2006); see also Clinton Sandvick, *Enforcing Medical Licensing in Illinois: 1877-1890*, 82 YALE J. BIO. & MED. 67 (2009). The ability of the states to set forth criteria for licensure was upheld by the Supreme Court in *Dent v. West Virginia*. 129 U.S. 114, 124 (1889) (holding there is no deprivation of due process in generally applicable licensing criteria that are not arbitrary but adopted and enforced by established means).
106. See Bynum et al., *supra* note 105, at 132-35, 165-75.
107. "When properly designed . . . occupational licensing can protect the public's health and safety by increasing the quality of professionals' services through mandatory entry requirements . . . . At the same time, many occupational licensing restrictions do not appear to realize the goal of increasing the quality of professionals' services." COX & FOSTER, *supra* note 42, at v.

abandon licensure for physician or nursing practice generally.<sup>108</sup> Rather, examining the competitive impact of licensure regulations helps sharpen our focus on the benefits and costs associated with our present regulations and the likely marginal effects of potential changes to those rules on competition and health care consumers. For example, some research regarding state dentistry regulations suggests that increasingly stringent licensing requirements may not be associated with better dental health outcomes but may be associated with fewer dentists per capita.<sup>109</sup> That does not impugn the general notion of licensure for dentists but does call into question whether certain strictures provide any net benefits, much less adequate ones, to offset their competitive costs.<sup>110</sup> Regarding APRNs, there also is some evidence that relatively stringent scope of practice rules are associated with fewer per capita practitioners.<sup>111</sup> Again, that does not suggest wholesale repudiation of scope of practice limits but does suggest that we carefully examine the countervailing health and safety benefits that may (or may not be) associated with particular policies.

At the most general level, relaxing the regulatory limits on APRN scope of practice should tend to increase the supply of providers who are willing and able to offer certain services at any given price. This frequently is termed a “supply expansion.”<sup>112</sup> In underserved areas and

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108. *But see* Hogan, *supra* note 104, at 117.

109. Morris M. Kleiner & Robert T. Kudrle, *Does Regulation Affect Economic Outcomes? The Case of Dentistry*, 43 J. L. & ECON. 547, 575-76 (2000). *But see* ARLENE HOLEN, CTR. FOR NAVAL ANALYSES, THE ECONOMICS OF DENTAL LICENSING 21 (1978), *available at* <http://www.cna.org/sites/default/files/research/0203440000.pdf> (finding some positive correlation between stringency of certain dental rules and a proxy for quality of care – lower average malpractice insurance rates – although reaching no conclusions about net benefits). Here too, we must be careful to distinguish two distinct claims: Kleiner and Kudrle’s observation –that certain more stringent licensing requirements are not associated with improved health care outcomes –is *not* a claim that there are no quality gains associated with an initial move to establish minimum licensure standards for dentists. In fact, no such regulatory transition was examined (not least because, in the period studied, all states required licensure for the practice of dentistry). *See* Kliener & Kudrle, *supra*, at 576.

110. Kliener & Kudrle, *supra* 109, at 576.

111. Edward S. Sekscenski et al., *State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners, and Certified Nurse-Midwives*, 331 NEW ENG. J. MED. 1266, 1266 (1994).

112. Either of two sorts of regulatory changes will tend to have the same directional effect on supply. First, to the extent that scope of practice rules change to permit APRNs to deliver a given type of service previously prohibited to them, the population of providers increases. Second, when the APRN scope of practice already includes a given service, but the regulatory costs of APRN service provision are lowered

for underserved populations, the benefits of expanding supply are clear. Even in well-served areas, the supply expansion will tend to lower prices for any given quantity demanded, thus lowering healthcare costs.<sup>113</sup> Conversely, additional and unnecessary restrictions impose a supply contraction where access problems are more likely to be exacerbated and some patients deprived of basic care.

There remains the larger question of how to incorporate a competition analysis into a regulatory discussion of health and safety policy issues. Some form of cost-benefit analysis might be helpful in both framing and evaluating a policy proposal. Health care antitrust law frequently wrestles with the question of how to account for potential pro-consumer efficiencies, which may include qualitative improvements in care, when evaluating mergers or conduct under the rule of reason.<sup>114</sup> At some level, any evaluation of potential efficiencies or inefficiencies in health care must account for quality of care, if only via a tacit assumption, in discussions focused on price or output, that quality remains constant. Acknowledging important work on market concentration and health care quality,<sup>115</sup> antitrust tends not to grapple with healthcare safety or risk management details.<sup>116</sup>

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(e.g., by removing particular physician supervision requirements), the supply of professionals willing to offer those services at any given price also increases.

113. The National Governors Association (NGA) emphasized APRNs' critical role in expanding access to care. NAT'L GOVERNORS ASS'N, THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE 11 (2012), available at <http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf> ("Expanded utilization of NPs has the potential to increase access to health care, particularly in historically underserved areas.").
114. See, e.g., Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011); DOJ & FTC POLICY STATEMENTS, *supra* note 66, at 35 (acknowledging potential efficiencies that may incorporate improvements in patient safety). Advisory opinions have considered, e.g., whether joint conduct may enhance providers' potential to meet quality of care benchmarks. See, e.g., Letter from Markus H. Meier, Asst. Dir., FTC, to Christi J. Braun and John J. Miles (Sept. 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf>.
115. See Martin Gaynor & Robert J. Town, *Competition in Health Care Markets* 50-82 (Nat'l Bureau of Econ. Research, Working Paper 17208, 2011), available at <http://www.nber.org/papers/w17208> (providing a very useful discussion and literature review).
116. Quality metrics raise complex and often contentious issues that both parties to a controversy might choose to set aside. For various reasons, competition analysis of various qualitative factors may often appear thin and tends to defer to extra-competitive metrics. See, e.g., Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,

If we ask about the extent to which society ought to trade some improvement in health outcomes ( $O_a > O_b$ ) for some increase in the cost of entry ( $E_a > E_b$ ), then part of our question has to do with basic social welfare values and the extent to which society is willing to pay for them. In practice, that is sometimes the question when we want antitrust analysis to step aside, in favor of a broader policy discussion.<sup>117</sup> But this does not mean that such policy discussions ought to lose track of the competitive costs of the policies at issue any more than they ought to ignore implementation or compliance costs. One type of limiting case should be clear: when countervailing consumer benefits are nil, non-trivial competitive costs – like non-trivial regulatory costs more generally – are not justified, and highly speculative (or poorly demonstrated) countervailing benefits are, at best, highly speculative (or poorly demonstrated) justifications.<sup>118</sup>

Similar arguments have developed through a consistent judicial refusal, since *National Society of Professional Engineers*, to consider speculative consumer protection rationales adequate to defend private anticompetitive behavior.<sup>119</sup> In *Professional Engineers*, the Court categorically refused to countenance an argument that competition itself poses a “potential threat . . . to the public safety” and professional ethics.<sup>120</sup> Following that decision, both the FTC and the

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76 Fed. Reg. 67026 (Oct. 28, 2011) (referring to CMS eligibility criteria and monitoring for ACOs). Cf. Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 548 (2002) (“[W]hile courts deal assertively with health antitrust cases and employ standard economic tools in their analyses, they seldom address quality as a specific competitive dimension, rather than as a regulatory matter.”); Douglas Ginsburg, *Nonprice Competition*, 38 ANTITRUST BULLETIN 83, 83 (1993).

117. Cf. Hammer & Sage, *supra* note 116, at 548 (“[W]hile courts deal assertively with health antitrust cases and employ standard economic tools in their analyses, they seldom address quality as a specific competitive dimension, rather than as a regulatory matter.”).

118. The policy argument, as explained in the paragraph immediately following, also has a juristic analogue in *National Society of Professional Engineers v. United States* and its progeny. 435 U.S. 679 (1978). It also may be analogized to the antitrust treatment of ancillary restraints in private commerce. See, e.g., ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 28 (1978) (discussing Judge Taft’s opinion, in *Addyston Pipe & Steel v. United States*, 175 U.S. 211 (1899), as comprising an insight that “is, or should be, central to modern antitrust”). “[E]ven restraints ancillary in form would be illegal if they were part of a general plan to gain monopoly control of a market.” *Id.*

119. *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 695 (“Exceptions to the Sherman Act for potentially dangerous goods and services would be tantamount to a repeal of the statute.”).

120. *Id.*

Supreme Court rejected putative health and safety justifications for anticompetitive conduct in *Indiana Federation of Dentists*.<sup>121</sup> There, mere opinion testimony about potential health and safety concerns – proffered as offsetting “noncompetitive” benefits – was deemed inadequate to defend joint or concerted anticompetitive conduct in a case where no evidence of actual consumer harm or any systematic evidence of substantial consumer risk had been presented.<sup>122</sup> As the Fourth Circuit put it in a case involving supervision requirements for clinical psychologists, “Forewarned by the decision in *National Society of Professional Engineers* . . . that it is not the function of a group of professionals to decide that competition is not beneficial in their line of work, we are not inclined to condone anticompetitive conduct upon an incantation of ‘good medical practice.’”<sup>123</sup>

*B. The Nursing Advocacies*

The FTC competition advocacy program has applied this framework in considering the likely competitive impact of proposed changes to various occupational regulations. APRNs, like other health care professionals, are subject to various categories of state regulation. In all states and the District of Columbia, APRNs face licensure requirements that determine who may enter the profession.<sup>124</sup> Related scope of practice rules further define the types of services APRNs may provide and the extent to which they may practice independently.<sup>125</sup> While entry qualifications for APRNs are increasingly common from state to state, the regulations that define APRN scope of practice continue to vary widely.<sup>126</sup> Some scope of practice restrictions are procedure-oriented, limiting APRNs’ ability to prescribe medicines; refer for, order, or perform certain tests or procedures; or treat certain indications.<sup>127</sup> Other restrictions focus on the types of patients APRNs

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121. *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447 (1986).

122. *Id.* at 463-64. This is a lower bar or limiting case: it does not follow that antitrust demands any particular level of substantiation or that antitrust concerns evaporate in the presence of any demonstrable consumer risk.

123. *Va. Acad. of Clinical Psychologists v. Blue Shield of Va.*, 624 F.2d 476, 485 (4th Cir. 1980).

124. For a general discussion of these and other types of professional regulations, see, e.g., COX & FOSTER, *supra* note 42.

125. TRACY YEE ET AL., NAT’L INST. FOR HEALTH CARE REFORM, PRIMARY CARE WORKFORCE SHORTAGES: NURSE PRACTITIONER SCOPE-OF-PRACTICE LAWS AND PAYMENT POLICIES 2 (2013), available at <http://www.nihcr.org/PCP-Workforce-NPs>.

126. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 98. See also NAT’L GOVERNORS ASS’N, *supra* note 113, at 2.

may see. For example, APRNs may not be allowed to “examine a new patient, or a current patient with a major change in diagnosis or treatment plan, unless the patient is seen and examined by a supervising physician within a specified period of time.”<sup>128</sup>

In addition, more than half of U.S. states maintain physician supervision requirements for APRNs.<sup>129</sup> In other words, besides limits on the types of patients APRNs may see or the types of procedures APRNs may perform, these states’ scope of practice rules restrict the degree to which APRNs may practice independently. Supervision may be required for all APRN practice<sup>130</sup> or for particular practice activities such as prescribing medications.<sup>131</sup>

Advocacy has been viewed as a response to the economic theory of regulation (ETR). ETR “posits that because of relatively high organizational and transaction costs, consumers will be disadvantaged relative to businesses in securing favorable regulation,”<sup>132</sup> and advocacy comprises a sort of regulatory self-monitoring that may partly offset that comparative disadvantage. Competition advocacy can identify and make public both the competitive advantages sought by particular businesses and the potential impact of those advantages on

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127. For example, under Florida law, an APRN may “[m]onitor and alter drug therapies” but may not prescribe controlled substances. FLA. STAT. §§ 464.012(3)(a), 83902(2), 8390.5(1) (2013) (restricting controlled substance prescription to certain “practitioners” and defining practitioners to include physicians, but not APRNs).
  128. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 101. The report catalogues various regulatory restrictions on nursing practice. *Id.* at 100-02 fig. 3-1, 157-61.
  129. *See id.* at 157-61 (specifying state-by-state requirements for supervision or mandatory “collaborative practice” for APRN treatment, diagnosis, or prescribing). According to the National Council of State Boards of Nursing, twenty-seven states require supervision or a collaborative practice agreement for APRN practice. *See APRN Maps, supra* note 9 (reporting that twenty-two states plus District of Columbia permit independent practice).
  130. *See, e.g.*, FLA. STAT. § 464.012(3) (2013) (providing that an APRN can perform functions within her scope of practice only after “entering into a supervisory relationship with a physician” and subsequently filing established practice protocol with the regulator); LA. REV. STAT. ANN. § 37:913(8) (2012) (requiring a formal written collaborative practice agreement for both “acts of medical diagnosis and prescription”).
  131. *See APRN Maps, supra* note 9; *see also, e.g.*, LA. REV. STAT. ANN. § 37:913(8) (2012) (requiring a formal collaborative practice agreement for prescribing); W.Va. CODE §§ 30-7-15(a)-(b) (2013) (requiring a signed collaborative practice agreement with physician for APRN prescribing).
  132. Cooper et al., *supra* note 40, at 1092 n.4 (citing W. KIP VISCUSI ET AL., ECONOMICS OF REGULATION AND ANTITRUST 313-35 (2000)).

consumers.<sup>133</sup> Particular questions have been raised about regulatory restrictions that one group of professional competitors (physicians or specialist physicians) may impose on another (APRNs or CRNAs), either directly (as when physicians dominate or wholly constitute an independent board of regulation)<sup>134</sup> or indirectly (as where physicians or physician groups lobby for statutory restrictions).<sup>135</sup>

Although recent advocacies are salient, FTC concerns about potentially undue restrictions on health care professionals date back several decades.<sup>136</sup> For example, 1985 comments before the District of Columbia Council expressed concern about the potential over-regulation of “expanded role nurses” and, in particular, about undue supervision requirements for Certified Registered Nurse Anesthetists (CRNAs).<sup>137</sup> Not incidentally, the general thrust of those 1985 staff comments presaged the IOM’s present policy concerns:

In view of the potential benefits of the practice of expanded role nurses in conformance with their education, training, and experience, we believe that any [provisions] that might unnecessarily restrict these professionals in their work with physicians, or un-

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133. *Id.*

134. *See supra* note 84 and accompanying text.

135. *See, e.g., Hearing on Review of West Virginia Laws Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions before Subcomm. A of the Joint Comm. on Health, W. Va. Legislature (W. Va. 2008) (statement of Am. Med. Ass’n), available at <http://www.ama-assn.org/resources/doc/arc/ama-letter-ftc-wv.pdf>; Letter from Am. Soc’y of Anesthesiologists to Susan S. DeSanti et al., Dir. of Bureau of Econ., FTC (Jan. 19, 2011) [hereinafter Am. Soc’y of Anesthesiologists Letter], available at <http://www.asahq.org/For-Members/Advocacy/Washington-Alerts/~media/For%20Members/Advocacy/ASA%20in%20Washington/ASA%20FTC%20Pain%20letter%201-19-11.ashx>.*

136. *See Med. Staff of Mem. Med Ctr., 110 F.T.C. 541 at \*1-2 (1998) (consent order) (addressing allegations of anticompetitive combination or conspiracy to deny credentials to nurse midwife); FTC D.C. Comment, supra* note 48.

137. *See generally FTC D.C. Comment, supra* note 48. Also, in 1988 the Commission filed an amicus brief in an antitrust suit against State Volunteer Medical Insurance Company, a physician-owned malpractice insurance company, and against certain hospitals and doctors, alleging that the defendants unlawfully acted in concert to prevent the establishment of independent nurse-midwifery practice in Tennessee, and thereby unreasonably restrained competition in the provision of obstetrical care, in violation of Section 1 of the Sherman Act. Brief of FTC as Amicus Curiae, State Volunteer Mut. Ins. Corp., 102 F.T.C. 1232, 1232 (1983). That advocacy, in the form of an amicus brief, was related to a prior law enforcement action involving related facts and a common defendant.

necessarily limit the procedures that they are allowed to perform, should be analyzed very carefully.<sup>138</sup>

Staff suggested, in particular, that:

mandating the physical presence of an anesthesiologist whenever services are provided by a nurse anesthetist . . . regardless of the circumstances or necessity for such supervision . . . likely would raise the cost of anesthesia services and possibly make them more difficult to obtain.<sup>139</sup>

Although more recent nursing-related advocacies from the FTC and its staff address more complex policy considerations, the core competition arguments are the same and are perhaps – from an antitrust perspective – so simple as to be uninteresting. Certain impediments to competition (barriers to entry in particular) are identified; if the impediments are not trivial, we move to the question whether they are justified by countervailing consumer health or safety benefits or other pro-consumer efficiencies.<sup>140</sup>

Since 2010 those issues have been raised in a series of FTC staff comments that address roughly three sets of regulations: (1) those imposing supervision requirements on APRNs, including those requiring that APRNs enter into formal written “collaborative practice” agreements with physicians as a condition of offering services otherwise within the APRNs’ scope of practice;<sup>141</sup> (2) those limiting the abilities of CRNAs to provide interventional pain treatment;<sup>142</sup> and (3) those that restrict practice in limited service or

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138. *FTC D.C. Comment, supra* note 48, at 3.

139. *Id.* at 7-8.

140. GILMAN & KOSLOV, *supra* note 16. *Cf.* *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 459 (1986) (quoting *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978)) (“[N]o elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement.’ . . . Absent some countervailing procompetitive virtue . . . such an agreement limiting consumer choice by impeding the ‘ordinary give and take of the market place,’ . . . cannot be sustained under the Rule of Reason.”).

141. *See* 2007 Massachusetts FTC Letter, *supra* note 47; *West Virginia Testimony, supra* note 48; Kentucky FTC Letter to Hornback, *supra* note 48; Texas FTC Letter, *supra* note 48; Florida FTC Letter, *supra* note 48.

142. *See* Missouri CRNA Letter, *supra* note 50; Tennessee FTC Letter to Odom, *supra* note 50; Alabama FTC Letter, *supra* note 50; 2007 Massachusetts FTC Letter, *supra* note 47 (addressing nurse anesthetist (or CRNA) supervision requirements, but many of these have to do with core anesthesia and pain management procedures in surgical and perioperative settings).

“retail” clinics, which typically are staffed by APRNs.<sup>143</sup> In no case has the FTC or its staff sought to specify an ideal or recommended scope of practice for APRNs.<sup>144</sup> Underlying all of them was a concern that existing or proposed restrictions on APRN scope of practice appeared to be overbroad, under-rationalized, or both.

### 1. APRN Regulations

FTC staff comments on a 2012 Louisiana bill are illustrative of the competitive concerns associated with APRN supervision requirements.<sup>145</sup> Louisiana law requires that an APRN must practice under a formal written collaborative practice agreement if he or she is to work to the full extent of APRN scope of practice, including performing “acts of medical diagnosis and prescription” as otherwise permitted under Louisiana law.<sup>146</sup> Physicians are not similarly required to collaborate with APRNs or other health care professionals.<sup>147</sup> The bill in question would have removed the collaborative practice require-

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143. See 2007 Massachusetts FTC Letter, *supra* note 47; Illinois FTC Letter, *supra* note 47; Kentucky FTC Letter to Hornback, *supra* note 48.

144. Competition analysis and law enforcement generally tend to avoid stipulating such regulations just as they tend, on the private side, to eschew industrial planning. See, e.g., BORK, *supra* note 118, at 69-70 (“The antitrust laws are wholly prohibitory and passive in nature, so that they are effective only to screen conduct that private parties themselves originate. Unlike many other laws, therefore, antitrust is wholly unable to serve values that must be implemented by requiring or inducing affirmative conduct which the self-interest or capabilities of private persons do not cause or permit them to undertake.”).

145. Louisiana FTC Letter, *supra* note 13; Connecticut FTC Letter, *supra* note 48; 2014 Massachusetts FTC Letter, *supra* note 48. Although staff comments regarding APRN regulations in Florida, Texas, Kentucky, and West Virginia addressed somewhat varied restrictions, they all had to do with the basis for supervision requirements imposed on APRN practice.

146. A collaborative practice agreement, required under Louisiana law, is “a formal written statement addressing the parameters of the collaborative practice which are mutually agreed upon by the advanced practice registered nurse and one or more licensed physicians or dentists . . . .” LA. REV. STAT. ANN. § 37:913(8)-(9) (2012).

147. Such asymmetrical “collaborative practice” requirements may often amount to, and sometimes expressly require, supervision requirements. See Lauren E. Battaglia, Note, *Supervision and Collaboration Requirements: the Vulnerability of Nurse Practitioners and Its Implications for Retail Health*, 87 WASH. U. L. REV. 1127, 1137-38 (2010) (discussing the relationship between supervision and collaboration requirements).

ment for certain APRNs practicing in medically underserved areas or treating medically underserved populations.<sup>148</sup>

The underlying empirical basis for the staff's analysis was straightforward. First, staff noted both federal and state findings of primary care provider and service shortages throughout much of the state: "Recent reports indicate that more than half of Louisiana's population lives in a federally-designated Health Professional Shortage Area (HPSA). All 64 Louisiana Parishes contain HPSAs, and 53 entire Parishes comprise primary care shortage areas."<sup>149</sup> Such shortages were – and are – expected to persist<sup>150</sup> and were linked to significant problems in health care access and delivery in Louisiana.<sup>151</sup> Healthcare reform promised

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148. H.B. 951, 2012 Leg., Reg. Sess. (La. 2012), *available at* <http://www.legis.la.gov/Legis/ViewDocument.aspx?d=780847>.
149. Louisiana FTC Letter, *supra* note 13, at nn. 25-28. *See also* LA. DEP'T HEALTH AND HOSPS., 2009 LOUISIANA HEALTH REPORT CARD 203 (2010), *available at* [http://new.dhh.louisiana.gov/assets/oph/CentERS/healthstats/DHHHlthCreRprtCrd\\_2009.pdf](http://new.dhh.louisiana.gov/assets/oph/CentERS/healthstats/DHHHlthCreRprtCrd_2009.pdf); *Guidelines for Primary Medical Care/Dental HPSA Designation*, U.S. DEP'T HEALTH AND HUMAN SERVS., HEALTH RES. & SERVS. ADM'N, <http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/medicidentalhpsaguidelines.html> (last visited Jan. 6, 2014) (providing a general description of HPSAs); *Find Shortage Areas: HPSA by State & County*, U.S. DEP'T HEALTH AND HUMAN SERVS., HEALTH RES. & SERVS. ADM'N, <http://hpsafind.hrsa.gov/HPSASearch.aspx> (last visited Jan. 6, 2014) [hereinafter *Find Shortage Areas*]; *Health Insurance Coverage Status 2008-2010, American Community Survey 3-Year Estimates*, U.S. CENSUS BUREAU, [http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS\\_10\\_3YR\\_S2701&prodType=table](http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_10_3YR_S2701&prodType=table) (last visited Jan. 6, 2014).
150. Louisiana FTC Letter, *supra* note 13, at 3 (citing KAISER COMM'N ON MEDICAID AND THE UNINSURED, IMPROVING ACCESS TO ADULT PRIMARY CARE IN MEDICAID: EXPLORING THE POTENTIAL ROLE OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS 1 (2011), *available at* <http://www.kff.org/medicaid/upload/8167.pdf>); U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. AND SERVS. ADM'N, THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND 70-74 ex. 51-53 (1998), [hereinafter HRSA PHYSICIAN WORKFORCE REPORT], *available at* <http://bhpr.hrsa.gov/healthworkforce/reports/physwffissues.pdf>.
151. Louisiana FTC Letter, *supra* note 13, 3 nn. 7-8, 21-22 ("With respect to Louisiana specifically, the Louisiana Department of Health and Hospitals has observed that '[s]hortages affecting the accessibility and availability of primary-care physicians . . . pose a significant problem in the delivery of healthcare in Louisiana.' Louisiana also faces a shortage of APRNs – as it does with other primary care professionals."); *Primary Care HPSA Map of Louisiana*, LA. DEP'T HEALTH & HOSPS., [http://new.dhh.louisiana.gov/assets/oph/pcrh/10-03-2012\\_PC\\_MAP.jpg](http://new.dhh.louisiana.gov/assets/oph/pcrh/10-03-2012_PC_MAP.jpg) (last visited Jan. 6, 2014) (indicating primary care

in some regards to exacerbate the shortages as more Louisiana consumers gain health insurance and seek access to primary health care services.<sup>152</sup>

Second, staff noted that APRNs might help to alleviate such shortages.<sup>153</sup> APRNs – observed to be the fastest growing segment of the primary care professional workforce in the United States<sup>154</sup> – already were providing primary care services throughout Louisiana, and in many other states, they were doing so without regulatory requirements of direct supervision or formal collaborative practice

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shortages in most of the state of Louisiana); LA. DEP'T HEALTH AND HOSPS., *supra* note 149, at 224-26 (describing large portion of the state as a “Health Professional Shortage Area” under Louisiana criteria and as MUA or MUP under federal criteria); *Find Shortage Area*, *supra* note 149 (indicating shortage areas throughout Louisiana’s 64 Parishes using HRSA criteria).

152. Louisiana FTC Letter, *supra* note 13, at 2 (citing LA. STATE BD. OF NURSING, LA. CTR. FOR NURSING, NURSING WORKFORCE DEMAND REPORT 1, 3 (2012)). *Cf.* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 150, at 70-74 (projecting increased shortages of specialists, including anesthesiologists, as well as primary care physicians, especially if public expectations and ability to pay for care increase). Several studies estimate the extent to which primary care provider shortages are likely to be exacerbated by health care reform, including the Patient Protection and Affordable Care Act (PPACA). *See, e.g.,* Adam N. Hofer et al., *Expansion of Coverage Under the Patient Protection and Affordable Care Act and Primary Care Utilization*, 89 MILBANK Q. 69, 84 (2011) (estimating predicted demand for primary care utilization stimulated by PPACA and predicting a shortfall of 4,307 to 6,940 primary care physicians in 2019, subject to “considerable” geographic variation); Elbert S. Huang & Kenneth Finegold, *Seven Million Americans Live in Areas Where Demand for Primary Care May Exceed Supply by More Than 10 Percent*, 32 HEALTH AFFS. 614, 614 (2013); Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025*, 10 ANNALS FAM. MED. 503, 506-07 (2012) (projecting 2025 shortfall of 52,000 primary care physicians based on increased coverage and, to greater extent, population growth and aging of population); Leighton Ku et al., *The States’ Next Challenge – Securing Primary Care for Expanded Medicaid Populations*, 364 NEW ENG. J. MED. 493, 493-94 (2011) (estimating state-by-state primary care needs based on projections for expanded Medicaid populations). All but one of the states that have thus-far received FTC staff comments regarding APRN or CRNA-related issues – Texas, Louisiana, Kentucky, Alabama, Florida, Tennessee, and Missouri – are projected to have greater than average “access challenge scores,” reflecting “higher than average Medicaid expansions relative to their current primary care capacity.” *Id.* at 494.
153. Louisiana FTC Letter, *supra* note 13, at 3-4.
154. *See* KAISER COMM’N ON MEDICAID AND THE UNINSURED, *supra* note 150, at 3.

agreements.<sup>155</sup> APRNs make up a greater share of the primary care workforce in less densely populated, less urban, and lower income areas, as well as in HPSAs.<sup>156</sup> Also, APRNs are more likely than primary care physicians to practice in underserved areas and to care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients.<sup>157</sup> In Louisiana there were approximately 3,500 licensed APRNs, and most of the state's designated HPSAs contained practicing APRNs.<sup>158</sup> Hence, the potential benefits associated with the bill appeared amplified in markets that, from a health care access perspective, are most disadvantaged. Correspondingly, competitive concerns about the costs of undue regulations might be greater in markets or areas where health care needs are greatest.

Third, staff noted that the statutory requirement of a formal, written collaborative practice agreement could impede the ability of APRNs to help fill this gap (or meet this demand).<sup>159</sup> There were at least *ad hoc* reports that some APRNs were paying very high fees to enter into and maintain collaborative practice agreements and that

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155. According to the CDC, by 2006, 11.9% of U.S. primary care visits were attended solely by a nurse practitioner (APRN or NMW) or physician assistant. ESTHER HING ET AL., NATIONAL AMBULATORY MEDICAL CARE SURVEY: 2006 OUTPATIENT DEPARTMENT SUMMARY 6 (2008), available at <http://www.cdc.gov/nchs/data/nhsr/nhsr004.pdf>. See IOM FUTURE OF NURSING REPORT, *supra* note 1, at 96-103, 157-61 (regarding supervision). Sixteen states and the District of Columbia fully permit independent APRN practice, requiring neither physician-signed collaboration agreements nor any other form of formal physician supervision, a seventeenth (Utah) requires collaboration agreements only for Schedule II-III controlled substances, and an eighteenth (Colorado) generally permitting independent practice, but requiring a preceptor and mentoring period for new prescribers and a one-time signed plan. *Id.* at 3-12 fig. 3-3. See also *Consumer Access and Barriers to Primary Care Physician-Nurse Practitioner Restrictive Collaboration Requirements by State*, INITIATIVE ON THE FUTURE OF NURSING, [http://www.thefutureofnursing.org/sites/default/files/Image-%20Restrictive%20Collaboration\\_1.jpg](http://www.thefutureofnursing.org/sites/default/files/Image-%20Restrictive%20Collaboration_1.jpg) (last visited Apr. 15, 2014).
156. See KAISER COMM'N ON MEDICAID AND THE UNINSURED, *supra* note 150, at 3; IOM FUTURE OF NURSING REPORT, *supra* note 1, at 107-08.
157. *Id.*; Christine M. Everett et al., *Division of Primary Care Services Between Physicians, Physician Assistants, and Nurse Practitioners for Older Patients with Diabetes*, 70 MED. CARE RESEARCH REV. 531, 536-37 (2013) ("Panels with PA/NPs as usual providers appear to have a higher proportion of socially complex patients, when defined according to poverty (Medicaid), disability, and comorbid dementia and depression.").
158. LA. STATE BD. OF NURSING, 2010 ANNUAL REP. 23 (2011), available at <http://www.lsbn.state.la.us/Portals/1/Documents/annualreport/annualreport2010.pdf>.
159. Louisiana FTC Letter, *supra* note 13, at 2-4.

some practicing APRNs found it difficult to secure a replacement agreement and continue their treatment of patients when a collaborating physician retired, moved, or died.<sup>160</sup>

The competition analysis was simpler still. An existing undersupply – likely due, at least in part, to regulatory barriers to entry – appeared substantial.<sup>161</sup> Reducing some of those barriers – in particular, the statutory requirement of a collaborative practice agreement for APRNs serving medically underserved areas or treating underserved patient populations – could “improve access and consumer choice for primary care services, especially for rural and other underserved populations.”<sup>162</sup> In brief, reducing such barriers could increase the supply of service providers and lower average costs of production, at least for some basic primary care services. At the margin, in underserved areas, the effect could be the provision of services not otherwise available. Hence, “[g]iven the potential benefits of eliminating unwarranted impediments to APRN practice, [FTC staff] recommend[ed] that the Louisiana legislature seek to ensure that statutory limits on APRNs are no stricter than patient protection requires.”<sup>163</sup>

Moreover, staff suggested that the bill could facilitate innovation in health care delivery.<sup>164</sup> In fact, collaboration between APRNs and

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160. Connecticut FTC Letter, *supra* note 48, at 5 nn. 34, 37 (citing difficulties some APRNs faced in securing agreements and anecdotal evidence that high fees were demanded of other APRNs, including one case where a physician reportedly demanded seventy percent of an APRN’s reimbursements as compensation to enter into a collaborative practice agreement); Louisiana FTC Letter, *supra* note 13, at 2. *See also West Virginia Testimony, supra* note 48, at 5 n. 33; Kentucky FTC Letter to Hornback, *supra* note 48, at 4. We are not suggesting that conscious attempts to suppress independent APRN practice are the norm, any more than conscious attempts to charge supra-competitive prices. As noted above, the more general concern is that, freed from normal competitive constraints, the prices of such collaborative agreements will be biased upwards and the qualitative terms of such agreements will not. Moreover, even atypical or outlier physician demands can make a big impact in a highly underserved area, and there are at least ad hoc reports of striking demands made by particular “collaborating” physicians. Although the particular impact on supply or price in individual practice areas needs study, there is at least general evidence that relatively stringent scope of practice restrictions may restrict APRN supply at the state level. *See* Sekscenski et al., *supra* note 111, at 1266.

161. Louisiana FTC Letter, *supra* note 13; *supra* notes 22-29 and accompanying text.

162. *Id.* at 2.

163. *Id.*

164. *Id.* at 4.

MDs is common.<sup>165</sup> Even in states that do not require any formal collaborative or supervisory arrangement, APRNs frequently consult with or refer patients to physicians, and many APRNs are employed by physician practices or institutional providers that privately implement various collaboration and oversight arrangements.<sup>166</sup> Such collaboration may be highly varied, a locus of considerable innovation, and, often, uncontroversial.<sup>167</sup> But statutory requirements may constrain, rather than implement, enable, or enhance such practices. For example, in tying collaboration to specific formal agreements between individual APRNs and individual physicians<sup>168</sup> or restricting the number of APRNs with whom a physician may collaborate (or supervise),<sup>169</sup> the state may constrain the ability of an institutional provider to experiment with flexible oversight and collaboration arrangements or to accommodate staffing changes across central and satellite facilities in real time (or its administrative facsimile).<sup>170</sup>

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165. See OTA HEALTH TECHNOLOGY CASE STUDY, *supra* note 62, at 13 tbl. 1-2 (regarding diverse practice settings and collaboration); IOM FUTURE OF NURSING REPORT, *supra* note 1, at 23, 58-59, 65-67, 72-76.
166. See *id.*; Julie Sochalski & Jonathan Weiner, *Health Care System Reform and the Nursing Workforce: Matching Nursing Practice and Skills to Future Needs, Not Past Demands*, in IOM FUTURE OF NURSING REPORT, *supra* note 1, at 375-400.
167. See IOM FUTURE OF NURSING REPORT, *supra* note 1, at 92-94 (regarding APRN primary care initiatives at the Department of Veterans Affairs, Geisinger Health System, and Kaiser Permanente); ROBERT WOOD JOHNSON FOUND., HOW NURSES ARE SOLVING SOME OF PRIMARY CARE'S MOST PRESSING CHALLENGES (2012), *available at* <http://www.rwjf.org/content/dam/files/rwjf-web-files/Resources/2/cnf20120810.pdf> (describing use of APRNs/NPs in HealthPartners' "Care Model Process," which employs standardized best practices and telemedicine to coordinate care, as well as public initiatives in Pennsylvania and Vermont). Cf. MITCHELL ET AL., *supra* note 68, at 13 (discussing diverse team approaches and innovation and noting that questions of team roles and leadership may often be less problematic in the field than when tied to policy debates about, e.g., scope of practice restrictions).
168. LA. REV. STAT. ANN. § 37:913(3)(a) (2012); *see also* LA. ADMIN. CODE tit. 46, § 4505 (2006).
169. See, e.g., FLA. STAT. § 458.348(4)(a)-(b) (2013) (restricting the number of offices primary and specialty care physicians may supervise); MO. CODE REGS. ANN. tit. 20, § 2150-5.100 (2010) (allowing no more than three APRNs per collaborating medical doctor).
170. Louisiana specifies relatively few conditions of collaboration. Such agreements must, for example, specify the "[a]vailability of the collaborating physician . . . for consultation or referral, or both." LA. REV. STAT. ANN. § 37:913(9)(a) (2012). But they need not include any particular form, frequency, or quantity of that availability. The law constrains the nature of collaboration insofar as agreements must be formalized and tethered to individual licensed physicians, but the law

Similarly, by restricting the permissible physical distance between APRNs and supervising doctors, the State of Florida restricts the ability of providers to develop new models of networked or telemedicine-facilitated collaboration.<sup>171</sup> Diverse public and private experiments with the roles that APRNs might play in primary care delivery suggest quality of care benefits associated with the use of APRNs as primary care providers.<sup>172</sup> They suggest, in turn, not just particular roles that APRNs might fill in delivering safe, high-quality primary care services but a further policy question of whether this type of institutional innovation ought to be constrained by any particular supervision regulations.

Evidence that the collaborative practice agreements were necessary to protect patients (or even helpful in that regard) appeared to be non-existent. No record of patient harms associated with expired or defective collaborative practice agreements in Louisiana was in evidence.<sup>173</sup> More telling was a sort of natural experiment across the

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otherwise affords providers a substantial degree of freedom with regard to their implementation of collaboration. The concern is that relatively bare bones requirements – imposed on one of the contracting parties but not the other – might prompt correspondingly pure cases of physician rent-seeking, at least in certain markets. More detailed requirements may, if well designed, assure that at least some value is associated with the collaborative agreement, but they do so by constraining the ability of providers to develop new models of collaboration (and, not incidentally, increasing the cost of compliance). *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 1, at 157-61 tbl. 3-A1 (providing an overview of some of the variation in requirements across the states).

171. FLA. STAT. § 458.348(4)(c) (2013); *see also* MO. CODE REGS. ANN. tit. 20, § 2150-5.100(2)(A)-(B) (2010) (requiring that a collaborating physician “not be so geographically distanced . . . as to create an impediment to effective collaboration” and that “an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons” not be more than fifty miles by road in federally-designated health professional shortage areas and not more than thirty miles by road otherwise). Institutional providers ranging across state lines are doubly restricted, as supervision may not take place across state lines, unless a supervising physician holds multiple licenses. *See* Gilman, *supra* note 101, at 89 (regarding competitive issues raised by physician licensure and telemedicine).
172. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 1, at 92-94 (regarding APRN primary care initiatives at the Department of Veterans Affairs, Geisinger Health System, and Kaiser Permanente).
173. One might wonder about the number of unsupervised cases (or those outside collaboration) available to create such a record. Critically, we do have access to the interstate record. In addition, we might wonder what a fine-grained investigation of Louisiana practice itself might reveal about the operation of collaborative practice agreements on the ground. The IOM Report observes that Louisiana law imposes no requirements for on-site supervision of APRNs, the frequency or extent to which

United States. As the IOM observed, APRNs had long provided diverse primary care services and had done so, in many jurisdictions, without anything analogous to Louisiana’s “collaborative practice” requirement. Yet “the contention that APRNs are less able than physicians to deliver care that is safe, effective, and efficient is not supported by the decades of research that has examined this question.”<sup>174</sup> To the contrary, a large body of empirical research strongly suggests that APRNs are safe and effective providers of diverse primary care services.<sup>175</sup> Note, further, that one of the defining criteria for independent practice – and an ongoing source of contention – is independent prescribing of legend drugs.<sup>176</sup> Studies that examine APRN prescribing suggest comparable outcomes for APRN- and MD-provided care.<sup>177</sup> We are not aware of countervailing empirical

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physicians must review the charts of APRN patients, or the maximum number of APRNs with whom a physician may have collaborative arrangements. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 158 tbl. 3-A1. Given that leeway, actual supervision or collaboration under such agreements may vary greatly.

174. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 111.
175. See Robin P. Newhouse et al., *Advanced Practice Nurse Outcomes 1990-2008: A Systematic Review*, 29 NURSING ECON. 1, 18 (2011) (“APRNs provide effective and high-quality patient care.”); Eileen M. Sullivan-Marx et al., *Long-term Outcomes of Advanced Practice Nursing*, in NURSE PRACTITIONERS: EVOLUTION AND FUTURE OF ADVANCED PRACTICE 93 (2010); Frances Hughes et al., *Research in Support of Nurse Practitioners*, in NURSE PRACTITIONERS: THE EVOLUTION AND FUTURE OF ADVANCED PRACTICE 65, 68 (Eileen M. Sullivan-Marx et al. eds., 2010); Miranda Laurant et al., *Substitution of Doctors by Nurses in Primary Care*, THE COCHRANE LIBRARY, July 15, 2004, at 2; Sue Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BRIT. MED. J. 819, 822 (2002); Mary O. Munding et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial*, 283 JAMA 59 (2000); Pamela Venning et al., *Randomised Controlled Trial Comparing Cost Effectiveness of General Practitioners and Nurse Practitioners in Primary Care*, 320 BRIT. MED. J. 1048, 1050 (2000) (“There was no significant difference in patterns of prescribing or health status outcome. . .”); Sharon Brown and Deanna Grimes, *A Meta-Analysis of Nurse Practitioners and Nurse Midwives in Primary Care*, 44 NURSING RESEARCH 332 (1995).
176. See Louisiana FTC Letter, *supra* note 13, at 3, 5; *West Virginia Testimony*, *supra* note 48, at 3-6; cf. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 110-11 (regarding physician and AMA opposition).
177. See, e.g., Munding et al. *supra* note 175, at 61 (finding no significant difference in patients’ health status or physiologic test results in a study comparing outcomes for 1316 ambulatory care patients randomly assigned to APRN and MD primary care providers where APRNs had “same authority to prescribe, consult, refer, and admit patients”); Elizabeth R. Lenz et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: Two-year Follow-up*, 61 MED.

evidence suggesting special patient harms or risks associated with APRN prescribing.<sup>178</sup>

No other countervailing policy benefits appeared to be at issue, and no substantial implementation costs were associated with the bill. Yet the bill did not escape committee. Given the impact of provider shortages across much of Louisiana, we prefer to find that result baffling. Of course, none of this is to suggest that APRNs should not consult, collaborate with, or refer patients to physicians. None of this suggests that a consumer might not prefer an MD practitioner as a primary care service provider or the locus of a “medical home.”<sup>179</sup> None of this suggests that APRNs and primary care physicians ought to share a single, uniform scope of practice. The question, rather, is whether there are adequate grounds – or even any substantial grounds – on which to circumscribe APRN scope of practice in the way that the legislature did and thus to impose substantial health care access costs on the public.

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CARE RESEARCH REV. 332 (2004) (stating that the two-year follow-up data for Mundinger et al.’s study was consistent with the preliminary results); Ann B. Hamric et al., *Outcomes Associated with Advanced Nursing Practice Prescriptive Authority*, 10 J. AM. ACAD. NURSE PRAC. 113, 117 (1998) (evaluating safety and effectiveness in a study of thirty-three APRNs in twenty-five primary care sites); Venning et al., *supra* note 175 (“There was no significant difference in patterns of prescribing or health status outcome . . .”).

178. The history of prescribing restrictions may be at least as puzzling. These began narrowly with the Harrison Anti-Narcotic Act in 1914. More general prescribing requirements emerged between rulemaking implementing the 1938 enactment of the Food, Drug, and Cosmetic Act (if on dubious statutory authority) and 1953 amendments to the FDCA. This history suggests legitimate health and safety concerns about, e.g., patent medicines. Equally, however, it suggests mixed economic motives on the part of regulatory advocates and, for some time, a muddy empirical basis for claims about medicine’s expertise or consumer health benefits associated with prescribing restrictions. Compare Peter Temin, *The Origin of Compulsory Drug Prescription*, 22 J. L. AND ECON. 91 (1979), with Harry M. Marks, *Revisiting “The Origins of Compulsory Drug Prescriptions,”* 85 AM. J. PUB. HEALTH 109, 109-10 (1995).
179. For example, a recent report recommends that U.S. patients transition (more fully) to a medical home model of care, with a primary care physician leading each “patient-centered” team. AM. ACAD. OF FAM. PHYSICIANS, PRIMARY CARE FOR THE 21ST CENTURY 1 (2012), available at [http://www.aafp.org/online/etc/medialib/aafp\\_org/documents/membership/nps/primary-care-21st-century/whitpaper.Par.0001.File.dat/AAFP-PCMHWhitePaper.pdf](http://www.aafp.org/online/etc/medialib/aafp_org/documents/membership/nps/primary-care-21st-century/whitpaper.Par.0001.File.dat/AAFP-PCMHWhitePaper.pdf). That model may be advantageous in many regards. Still, that does not establish a particular supervision scheme as optimal or efficient, much less – given shortages acknowledged by the report itself – identify alternative models of care as so universally deficient or dangerous that the law should not permit them.

## 2. Retail Clinic Regulations

Reification of supervisory arrangements also has been a point of concern with the regulation of “retail” or “limited service” clinics (RCs). RCs – which tend to be staffed by APRNs – are health care clinics located in retail settings (such as pharmacies and supermarkets) that offer consumers a convenient way to obtain basic medical care at transparent and competitive prices.<sup>180</sup> RCs tend to offer a limited subset of the primary care services available at primary care centers, ambulatory care clinics, and urgent care centers.<sup>181</sup> Evidence indicates that RC care, although limited, tends to be high quality.<sup>182</sup>

States have, in various ways, made room for RCs in their clinic or facilities regulations, and FTC staff members have not found competition concerns where proposed RC rules “mirror basic consumer protection standards that are imposed on competing providers of basic health care services.”<sup>183</sup> Heightened restrictions on care delivered under a particular business model have, however, raised concerns both as they may discriminate against an innovative model of delivery and as they may work as *de facto* scope of practice restrictions on those professionals employed under the model. For example, an Illinois bill stipulated that RCs appoint a physician director and that “[a] physician may be a medical director of no more than 2 facilities”<sup>184</sup> – potentially a costly and unnecessary limitation on the organization and operation of retail clinics. Moreover, FTC staff were concerned

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180. See 2007 Massachusetts FTC Letter, *supra* note 47, at 2; see generally, William M. Sage, *Might the Fact that 90% of Americans Live within 15 Miles of a Wal-Mart Help Achieve Universal Health Care?*, 55 U. KAN. L. REV. 1233, 1238 (2008) (describing the size and scope of RCs).
181. See, e.g., Ateev Mehrotra et al., *Comparing Costs and Quality of Care at Retail Clinics with That of Other Medical Settings for 3 Common Illnesses*, 151 ANNALS OF INTERNAL MED. 321, 326 (2009) (providing an analysis of fourteen quality metrics for commonly treated ailments: otitis media [ear infection], streptococcal pharyngitis [strep], and urinary tract infections). Cf. Ateev Mehrotra & Judith R. Lave, *Visits to Retail Clinics Grew Fourfold From 2007 To 2009, Although Their Share of Overall Outpatient Visits Remains Low*, 31 HEALTH AFFS. 2123, 2123-24 (2012) (noting decline in percentage of acute care visits and increase in preventive care since 2009 study).
182. See Mehrotra et al., *supra* note 181, at 325-26 (explaining that evidence shows that the quality of care in LSCs is “similar to that provided in physician offices and urgent care centers and slightly superior to that of emergency departments”).
183. Kentucky FTC Letter to Brown, *supra* note 48, at 2. For example, in comments regarding wide-ranging LSC regulations proposed by the Massachusetts Department of Public Health, FTC staff comments addressed only proposed advertising restrictions. See generally 2007 Massachusetts FTC Letter, *supra* note 48, at 1.
184. Illinois FTC Letter, *supra* note 47, at 6.

that the two-clinic limit could be read to impose special supervisory requirements on licensed APRNs working in retail settings.<sup>185</sup>

The cost of undue clinic restrictions might be substantial. A 2009 study conducted for the Commonwealth of Massachusetts considers, among other things, the savings potentially associated with increased use of retail clinics, contingent on regulatory reform.<sup>186</sup> The reported upper bound savings for Massachusetts, between 2010 and 2020, is \$6 billion (0.9% of total spending).<sup>187</sup>

Elsewhere, proposals to restrict the scope of practice in RCs raised more particular concerns. For example, under rules proposed in Kentucky, an APRN (indeed even a physician) practicing at an RC could provide a physical examination for sports or camp but not for school.<sup>188</sup> The same practitioner could provide a school or camp physical at a comparable clinic, however.<sup>189</sup> The proposed rule also would have prohibited – only at RCs – the vaccination of any patient under the age of 16 and, generally, the treatment of any person with any chronic or recurring ailment, including indications that the same professionals could treat in similar limited care settings, such as urgent care clinics.<sup>190</sup>

One might imagine that special practice limitations are associated with small, stand-alone clinics with limited physical resources. RC regulations *could* address such limitations. Sometimes, however, that consumer safety rationale seems wholly unavailable. As noted, RC quality ratings are high<sup>191</sup> – perhaps unsurprising, as the range of LSC services is considerably narrower than the scope of APRN practice.<sup>192</sup>

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185. *Id.* at 6.

186. CHRISTINE E. EIBNER ET AL., RAND HEALTH REPORT SUBMITTED TO THE COMMONWEALTH OF MASSACHUSETTS, DIV. HEALTH CARE FIN. & POL'Y, CONTROLLING HEALTH CARE SPENDING IN MASSACHUSETTS: AN ANALYSIS OF OPTIONS 83-90 (2009) (considering both relaxed supervision requirements for APRNs/NPs and changes in the laws governing the “corporate practice of medicine”).

187. *Id.* at 87 (explaining that the lower bound projection is zero based on the assumption that retail clinics “do not takeoff as a business strategy and have no noticeable effect on health spending”).

188. Kentucky FTC Letter to Brown, *supra* note 47, at 6.

189. *Id.* at 6.

190. 902 Ky. Admin. Reg. 20:400 (Dec. 15, 2009) (“A clinic shall not: (a) Treat a person with a recurring or chronic illness; or (b) Refill a prescription for a patient who requires continuity of care.”).

191. *See* Mehrotra et al., *supra* note 181, at 325-26.

192. *See* Kentucky FTC Letter to Brown, *supra* note 47, at 6-7; *see also* Mehrotra & Lave, *supra* note 181, at 3-5, ex. 5 (noting that despite some changes in case mix, the vast majority of retail clinic visits remain for basic preventive care – 40.8% for vaccinations alone – and a very limited set are primary acute care visits); Mehrotra et al., *supra* note

Hence, the competition question is not whether RCs and the professionals staffing them should be subject to any regulation. Rather, the question is whether particular restrictions imposed only on RCs are justified sufficiently to restrict the ability of price-sensitive patients to seek very basic care there – perhaps during off-work hours when, for some, an over-taxed and inefficient emergency room represents the only practicable alternative.<sup>193</sup>

### 3. Nurse Anesthetist Regulations

Some twenty-five years after the FTC staff addressed the District of Columbia's regulation of nurse anesthetists, they returned to the topic, discussing limits on CRNA pain treatment proposed in several states.<sup>194</sup> Recent CRNA-related comments have addressed more varied restrictions than the APRN supervision requirements discussed above. For example, in January 2014, FTC staff issued comments on a Massachusetts bill that proposed to lift requirements that CRNAs providing basic perioperative care – anesthesia and pain medicine before and after surgery – order tests and therapeutics, and prescribe medication, only under a formal supervisory agreement with a physician.<sup>195</sup> In 2012, the FTC staff issued comments on a Missouri bill, which stipulated that only physicians could treat pain through use of injections around the spine or spinal cord guided by imaging technology.<sup>196</sup> That would limit CRNA scope of practice by *de facto* prohibition of those interventional pain treatments where imaging guidance was established or recommended practice. FTC staff also addressed proposed rules in Alabama that would have prevented *all* interventional treatment of chronic pain by CRNAs, even treatments

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181, at 326 (stating that generally retail clinics provide high quality care and that there is no difference between physician and NP-provided care).

193. Mehrotra & Lave, *supra* note 181, at 3 (“Approximately one quarter (28.9 percent) of weekday visits occurred during hours when physician offices are typically closed. Adding weekend visits to that proportion, we found that 44.4 percent of the retail clinic visits in our data occurred when physician offices are likely to be closed.”) Mehrotra and Lave also observed an increased proportion of LSC visits by patients aged 65 or older. *Id.* See also EIBNER ET AL., *supra* note 186, at 85 (“Retail clinics could produce savings in the health care system by reducing ED utilization for routine conditions.”).
194. See Missouri CRNA Letter, *supra* note 50; Tennessee FTC Letter to Odom, *supra* note 50; Alabama FTC Letter, *supra* note 50; 2014 Massachusetts FTC Letter, *supra* note 48.
195. 2007 Massachusetts FTC Letter, *supra* note 47, at 3.
196. See Missouri CRNA Letter, *supra* note 50 (regarding H.B 1399, 96th Gen. Assemb., 2d Reg. Sess., (Mo. 2012)).

supervised by physicians<sup>197</sup> and a Tennessee bill imposing stringent supervision requirements on CRNA practice but only in certain types of facilities and excepting certain procedures.<sup>198</sup>

Here, too, an underlying concern has to do with workforce supply issues, with undersupply tied to inadequate access to basic health care services. Staff noted, for example, a separate IOM study that examines pain as a public health problem.<sup>199</sup> There, the IOM observes widespread under-treatment of pain – with pain itself estimated to affect “tens of millions of Americans and contribute[ ] substantially to morbidity, mortality, disability, demands on the health care system, and significant economic burdens for the nation.”<sup>200</sup> The IOM also observed significant access problems, especially, but not only, for vulnerable populations.<sup>201</sup> To put that assessment of under-treatment and provider shortage in context, we consider the IOM’s cost estimates:

A regression analysis . . . revealed that the annual cost of pain in the United States is *\$560-635 billion* in 2010 constant dollars . . . . This estimate combines the incremental cost of health care (\$261-300 billion) and the cost of lost productivity (\$11.6-12.7 billion) attributable to pain. The \$560-635 billion range is a conservative estimate because it excludes the costs of pain affecting institutionalized individuals (including nursing home residents and corrections inmates), military personnel, children under age 18, and personal caregivers (such as spouses who miss

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197. Alabama FTC Letter, *supra* note 50, at 1 (regarding Alabama State Board of Medical Examiners’ Proposed Rule 540-X-15 on Interventional Pain Management).

198. *See* Tennessee FTC Letter to Odom, *supra* note 50, at 1, 4 (regarding the bill’s requirement of direct on-site physician supervision of interventional pain management services delivered in certain federal health care facilities and in smaller clinics and offices not subject to TENN. CODE ANN. § 68-11-204’s licensure requirements). The Tennessee bill applied to a wide range of interventional pain treatments but expressly excepted epidurals for surgical anesthesia or labor analgesia.

199. *See generally* INST. OF MED., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 55 (2011) [hereinafter IOM PAIN REPORT], *available at* [http://www.nap.edu/openbook.php?record\\_id=13172](http://www.nap.edu/openbook.php?record_id=13172).

200. *Id.*

201. *See id.* at 64-84, 119-20, 170-80 (regarding disparate impact and access issues and undersupply of appropriately trained practitioners). *Cf.* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 150, at 70-74 (projecting increased shortages of specialists, including anesthesiologists, as well as primary care physicians, especially if public expectations and ability to pay for care increase). There are, of course, questions about how best to assess and project shortages. *Id.* at 62-74.

work while caring for people with pain), as well as the lost productivity of workers younger than 24 and older than 65.<sup>202</sup>

In their Missouri comments, FTC staff noted state findings that both hospitals and full-time physicians were “relatively scarce in Missouri’s rural areas”<sup>203</sup> and that rural facilities often lack specialists.<sup>204</sup> Staff also noted testimony that CRNAs were the *only* licensed providers of anesthesia services in thirty-one Missouri counties.<sup>205</sup> Similarly, FTC staff had addressed interventional pain treatment restrictions proposed in Tennessee, where testimony indicated that CRNAs were the only licensed providers of anesthesia services in thirty-nine counties.<sup>206</sup> Nationally, CRNA practices disproportionately serve rural patients.<sup>207</sup>

Evidence of shortages – and attendant access issues – thus dovetailed with evidence about the potential competitive impact of the legislation. The proposed restrictions appeared to encompass services already provided by CRNAs, including services for which CRNAs were nationally certified.<sup>208</sup> Some stakeholders had expressed concern

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202. IOM PAIN REPORT, *supra* note 199, at 91-92 (describing its own estimate and discussing measurement issues at Appendix C of the Report and also describing a 2010 NIH study estimating “\$100 billion as the total U.S. cost of pain, including health care expenses, lost income, and lost productivity”).
203. Missouri CRNA Letter, *supra* note 50, at 3 (citing MO. DEPT. OF HEALTH AND SENIOR SERVS., MISSOURI RURAL HEALTH BIENNIAL REPORT 2010-2011, at 3 (2011), available at <http://health.mo.gov/living/families/ruralhealth/pdf/biennial2011.pdf>).
204. *Id.*
205. *Id.* (citing *SB682 Hearing Before the Mo. Subcomm. on Health, Mental Health, Seniors and Families*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Vicki Coopmans, Mo. Ass’n Nurse Anesthetists)).
206. Tennessee FTC Letter to Odom, *supra* note 50, at 3 n. 33.
207. See Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians*, 29 HEALTH AFFS. 1469, 1469 (2010) (“CRNAs provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals.”); Missouri CRNA Letter, *supra* note 50, at 7 n. 22 (quoting J.P. Abenstein & Mark A Warner, *Anesthesia Providers, Patient Outcomes, and Costs*, 82 ANESTHESIA & ANALGESIA 1273, 1279 (1996)) (“Nurse anesthetist-only practices found predominantly in smaller, rural hospitals.”).
208. Missouri CRNA Letter, *supra* note 50, at 6 n. 13 (“National certification of CRNAs is administered by the National Board on Certification and Recertification of Nurse Anaesthetists (NBCRNA), which determines eligibility requirements for the certification exam, and formulates and administers the National Certification Exam for CRNAs.”); IOM FUTURE OF NURSING REPORT, *supra* note 1, at 41 (stating that CRNAs

that the bill's restriction of injections "around the spine or spinal cord" could apply to a wide range of common procedures, including epidural injections administered to manage pain during labor and delivery or in post-surgical pain management.<sup>209</sup> Two Missouri hospitals testified to their dependence on CRNAs to provide certain pain management treatments associated with labor and delivery and to aid with imaging technology for certain surgical procedures.<sup>210</sup> Missouri CRNAs testified that ultrasound technology, in particular, was integral to their treatment of both acute and chronic pain.<sup>211</sup>

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"[a]dminister anesthesia and provide related care before and after surgical, therapeutic, diagnostic, and obstetrical procedures, as well as pain management").

209. See Missouri CRNA Letter, *supra* note 50, at 6 (quoting *SB682 Hearing Before the Missouri Subcomm. on Health, Mental Health, Seniors and Families*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Matt Wenzel, Hendrick Med. Ctr.) [hereinafter *Wenzel Testimony*] ("[Bill's definitions are] so broad in scope that we believe it will be applied to the OB and surgical procedures for which we use CRNA anesthesia.")); *Hearing on H.B. 1399 Before Mo. House Comm. on Licensure and Professional Regulation*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Gary Jordan) [hereinafter *Jordan Testimony*]; Missouri CRNA Letter, *supra* note 50, at 6-7 (quoting *SB682 Hearing Before the Mo. Subcomm. on Health, Mental Health, Seniors and Families*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Vicki Coopmans, Mo. Ass'n Nurse Anesthetists) (expressing "concerns about the Bill's impact on the ability of CRNAs ability of CRNAs [sic] 'to perform many procedures to treat or prevent acute pain, such as epidurals for women in labor or certain nerve blocks after surgery'")); *Hearing on Review of West Virginia Law Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions Before Subcomm. A of the Joint Comm. on Health, W. Va. Legislature* (W. Va. 2008) (statement of FTC).
210. *Wenzel Testimony*, *supra* note 209; *Jordan Testimony*, *supra* note 209.
211. See Missouri CRNA Letter, *supra* note 50, at 7 (quoting *Hearing on H.B. 1399 Before Mo. House Comm. on Licensure and Professional Regulation*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Joe Dietrick, CRNA)) ("Ultrasound, particularly, is a commonly used and extremely safe form of imaging used not just by physicians, but also by CRNAs, and even Registered Nurses. This device can help us with difficult epidural or spinal placement for surgery or obstetrical patients. Although clearly within our Scope of Practice, our plans for acute post-operative pain techniques using ultrasound guidance for patients of our Orthopedic Surgeon may be impeded. It is also used for placement of central venous catheters."). See also *id.* at 6-7 (quoting *SB682 Hearing Before the Mo. Subcomm. on Health, Mental Health, Seniors and Families*, 2012 Leg., 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012) (statement of Vicki Coopmans, Mo. Ass'n Nurse Anesthetists)) (noting that the language of the bill could be interpreted to prevent CRNAs from providing chronic and acute pain treatments).

Under those conditions, the bill at issue – although not the version eventually passed into law – would have prohibited CRNAs from treating both acute and chronic pain patients with the aid of any established imaging technology.<sup>212</sup>

As with the more general primary care practices of APRNs addressed in Louisiana and elsewhere, there did not appear to be any record of patient harms driving the proposed restrictions.<sup>213</sup> That is not to suggest that baseline risks evaporate in the presence of CRNAs.<sup>214</sup> One could raise any number of health and safety concerns about pain management. Recent events involving injectable pain medicines have raised terrible questions about the integrity of the available pharmacopeia,<sup>215</sup> and there have been ongoing national concerns about diversion and misuse of pain medicines.<sup>216</sup> The litera-

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212. As introduced, Missouri HB 1399 covered “the injection of therapeutic substances around the spine or spinal cord for the treatment of acute and chronic pain syndromes” when guided by “fluoroscopic, computerized axial tomography (CAT) scan, magnetic resonance imaging (MRI), or ultrasound.” The law ultimately enacted did not include any express restriction on CRNA treatment of acute pain, but rather expressly limited its application to treatment “outside of a surgical, obstetrical, or post-operative course of care.” H.B. 1399, 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012).

213. In addition to a dearth of literature documenting pertinent harms or risks, neither systematic nor ad hoc reports of patient harms in the state was evident in the legislative record. FTC staff expressly made a similar point in comments regarding proposed Alabama pain management rules. Alabama FTC Letter, *supra* note 50, at 6 n. 31. The American Society of Anesthesiologists comments submitted to the Alabama legislature identify risks generally associated with interventional pain management and include an abstract observation that interventions administered in the upper spine involve more risks, such as “allergic reactions, infections, bleeding, nerve damage, spinal cord injuries (e.g., paraplegia or quadriplegia), brain stem infarctions, and even death.” Am. Soc’y of Anesthesiologists Letter, *supra* note 135 (citing no evidence of harms caused by prior Alabama regulations).

214. *See, e.g.*, Am. Soc’y of Anesthesiologists Letter, *supra* note 135 (identifying general background risks and alleging, although not documenting, special risks associated with CRNA treatment).

215. *See generally Multistate Fungal Meningitis Outbreak Investigation*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Oct. 23, 2013), <http://www.cdc.gov/HAI/outbreaks/meningitis.html> (providing links to information regarding multistate outbreak of fungal meningitis and other infections among patients who received contaminated steroid injections).

216. *See, e.g., Prescription Drug Diversion: Combating the Scourge: Hearing before the House Subcomm. on Commerce, Manufacturing and Trade of the House Comm. on Energy and Commerce*, 112th Cong. 78-89 (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm’r, Drug Enforcement Admin., U.S. Dep’t Justice); Nora D. Volkow et al.,

ture identifies various medical risks associated with certain pain management procedures<sup>217</sup> and raises concerns about the costs and benefits of interventional pain management and imaging technology in varying medical contexts.<sup>218</sup> Moreover, although numerous studies suggest that CRNAs are safe practitioners of the procedures that they tend to provide,<sup>219</sup> data regarding certain pain treatments appears

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*Research Letter: Characteristics of Opioid Prescriptions in 2009*, 305 JAMA 1299, 1300 (2011) (noting increases in opioid prescriptions and associated increases in abuse and overdoses as cause of concern and area for further research); Andrea M. Trescot et al., *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines*, 11 PAIN PHYSICIAN S5, S20-5 (2008). Looking at distinct (or partly distinct) populations, one might be simultaneously concerned about both abuse and under-treatment. "Ironically, while many people with pain have difficulty obtaining opioid medications, nonmedical users appear to obtain them far too easily . . . so much so that the diversion of opioid analgesics has become a national public health problem." IOM PAIN REPORT, *supra* note 199, at 146.

217. See, e.g., ROBIN HASHIMOTO ET AL., WASH. STATE HEALTH CARE AUTH., SPINAL INJECTIONS: HEALTH TECHNOLOGY ASSESSMENT (2011), available at [http://www.hca.wa.gov/hta/documents/updated\\_final\\_report\\_spinal\\_injections\\_0310-1.pdf](http://www.hca.wa.gov/hta/documents/updated_final_report_spinal_injections_0310-1.pdf) (reviewing evidence of efficacy, safety, and cost-effectiveness for diverse spinal injections); see also James P. Rathmell et al., *Injury and Liability Associated with Cervical Procedures for Chronic Pain*, 114 ANESTHESIOLOGY 918, 918 (2011) (reporting that "injuries related to cervical interventional pain treatment were often severe and related to direct needle trauma to the spinal cord"); Dermot R. Fitzgibbon et al., *Chronic Pain Management*, 100 ANESTHESIOLOGY 98, 98 (2004) ("[F]requency and payments of claims associated with chronic pain management by anesthesiologists increased in the 1990s. Brain damage and death were associated with epidural steroid injection only when opioids or local anesthetics were included.").
218. See HASHIMOTO ET AL., *supra* note 217. Regarding effectiveness in different clinical contexts, compare Stephen Choi & Richard Brull, *Is Ultrasound Guidance Advantageous for Interventional Pain Management? A Review of Acute Pain Outcomes*, 113 ANESTHESIA & ANALGESIA 596, 596 (2011) (concluding that "at present, there is insufficient evidence in the contemporary literature to define the effect of US [ultrasound] guidance on acute pain and related outcomes compared with traditional nerve localization techniques for interventional acute pain management"), with John Antonakakis et al., *Ultrasound Guided Regional Anesthesia for Peripheral Nerve Blocks: An Evidence-based Outcomes Review*, 29 ANESTHESIOLOGY CLINICS 179 (2011) (observing some advantages for block-related outcome variables).
219. See, e.g., Dulisse & Cromwell, *supra* note 207, at 1474 (observing declining mortality and adverse outcomes with increased CRNA services); Michael Pine et al., *Surgical Mortality and Type of Anesthesia Provider*, 71 AANA J. 109, 111 (2003) (observing low mortality rates and no significant differences in risk-adjusted mortality rates by type of anesthesia provider or type of anesthesia practice). Cf. A.F. Smith et al.,

lacking, and the empirical literature regarding safety and effectiveness, across the full range of pain indications and available treatments, cannot be considered comprehensive.<sup>220</sup> Some of these issues *could* comprise countervailing patient safety concerns, potentially offsetting certain competitive costs or figuring in a cost-benefit analysis of pain treatment regulations. Any of them might raise complex considerations for nursing or medical education, training, and practice.<sup>221</sup> Any or all might prompt a measure of regulatory caution.

FTC staff comments did not, however, repudiate antecedent concerns that policymakers might have about interventional pain treatment, the capabilities of those who offer various pain treatment services, or the contexts in which such services are provided.<sup>222</sup> Neither did the staff seek to preempt the state's policy process or priorities.<sup>223</sup> Against the backdrop of an extremely broad and evolving field of pain management science, practice, and training,<sup>224</sup> there remained nonetheless the question whether the restrictions at issue addressed health and safety concerns or offered any other consumer benefits. Under a competition analysis, such benefits, *if established*, would need to offset the competitive costs or consumer harm associat-

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*Comparative Effectiveness and Safety of Physician and Nurse Anaesthetists: A Narrative Systematic Review*, 93 BRIT. J. ANAESTHESIA 540, 544 (2004) (examining U.S. and foreign studies finding “no recent, high-level evidence that there are significant differences in safety between different anaesthesia providers”); Paul F. Hogan et al., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 NURSING ECON. 159, 161 (2010) (“[T]here are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes.”).

220. *Cf.* Smith et al., *supra* note 219, at 541 (finding that the studies were “. . . too dissimilar to [admit] formal meta-analysis”).

221. *See generally* IOM PAIN REPORT, *supra* note 199, at 170-216 (discussing “Education Challenges”).

222. *See, e.g.*, Missouri CRNA Letter, *supra* note 50, at 3-4 (recognizing health and safety concerns and asking that legislators take a balanced regulatory approach, considering competitive costs, when addressing them).

223. *Id.*

224. IOM PAIN REPORT, *supra* note 199, at 24-31, 113-36 (discussing the diversity of pain indications). *See, e.g.*, *Pain Management*, AM. SOC'Y ANESTHESIOLOGISTS, <http://www.lifelinetomodernmedicine.com/Anesthesia-Topics/Pain-Management.aspx> (last visited Jan. 4, 2014); *Q&A: Chronic Pain*, Am. Soc'y Anesthesiologists, <http://www.lifelinetomodernmedicine.com/Anesthesia-Topics/QA-Chronic-Pain.aspx> (last visited Jan. 4, 2014); *Q&A: Acute Postoperative Pain Medicine*, AM. SOC'Y ANESTHESIOLOGISTS, <http://www.lifelinetomodernmedicine.com/Anesthesia-Topics/QA-Acute-Postoperative-Pain-Medicine.aspx> (last visited Jan. 4, 2014).

ed with the restrictions at issue. Yet there is no reason to think that significant numbers of CRNAs provide (or attempt to provide) the full range of pain treatments offered by board certified pain specialists.<sup>225</sup>

We suggest that a rule's costs and benefits chiefly have to do with the changes in behavior that it prompts, or is likely to prompt, rather than its theoretical reach.<sup>226</sup> Against both very general concerns about pain treatment and incomplete literature, we note considerable evidence suggesting that CRNAs are safe providers of those anesthesia and pain treatments that they commonly offer.<sup>227</sup> And there does not appear to be countervailing evidence that CRNAs generally, or in particular chronic care contexts, are unsafe. In their Missouri comments, staff also noted that the Department of Health and Human Services (HHS) had several times reviewed the available literature on the integrity of anesthesia services in publishing rules regarding the provision of hospital anesthesia services under the Medicare and Medicaid programs. In 2001, the Centers for Medicaid and Medicare Services (CMS) concluded that anesthesia services generally were safe and, in particular, that there was "no need for Federal intervention in State professional practice laws governing CRNA practice" and "no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of [state-licensed CRNAs]."<sup>228</sup> By 2012, CMS had clarified its reimbursement policy expressly to include coverage for those chronic pain management services provided by CRNAs that are within the scope of their

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225. *Cf.* Missouri CRNA Letter, *supra* note 50, at 6-7 (describing CRNA training and practice in Missouri).

226. On that view, if CRNAs universally or overwhelmingly avoid, e.g., surgical interventions in the cervical spine, then expressly removing such treatments from their scope of practice may cost little beyond the costs of the rule's adoption. At the same time, the benefits of such prohibitions may equal or approach zero. More important, a concatenation of such prohibitions should not obscure basic appraisal of a rule's likely costs and benefits (as, for example, in suggesting either that the majority of (*nominally*) prohibited practices are beyond CRNAs' training and experience or are relatively novel or high-risk procedures).

227. *See supra* note 219 and accompanying text.

228. Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 4674, 4674-76 (Jan. 18, 2001) (to be codified at 42 C.F.R. pts. 482.52 and 485). *Cf.* Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 56762, 56762-63 (Nov. 13, 2001) (to be codified at 42 C.F.R. pts. 416, 482, and 485) (repeating observations on safety literature but noting potential utility of independent study of question whether safety or quality effects are associated with state regulations permitting independent CRNA practice).

practice, as determined under state law. In doing so, CMS observed both that chronic pain management is “an evolving field” and that changes in CRNA practice and training have been ongoing.<sup>229</sup> Eschewing rigid categorical limits in that context, CMS noted that its decision to reimburse CRNA-administered treatment “is consistent with the Institute of Medicine’s recommendation that Medicare cover services provided by advanced practice nurses to the full extent of their state scope of practice.”<sup>230</sup>

One could have raised a countervailing safety consideration. By limiting the provision of imagery-guided interventional pain treatments to physicians, the bill effectively barred CRNAs from providing such services, a subset of which seemed to be an established part of their training and practice. The bill did not bar *any* physicians – however trained and experienced – from practicing interventional pain medicine.<sup>231</sup> No board certification in pain management or anesthesia was required. That raised the question whether non-specialist physicians and osteopaths might sometimes substitute for newly restricted CRNAs. We do not argue that specialist certification ought to be required of all pain treatment by physicians.<sup>232</sup> Still, the question of who would fill the gap, considered against background risks, calls to mind some of the concerns raised in the IOM’s 2011 Pain Report: “[T]here are strong indications that pain receives insufficient attention in virtually all phases of medical education,”<sup>233</sup> and in the report from an American Medical Association Pain Summit: “[P]hysician training in pain care . . . was seen as poor or ‘not leading to competency’ at both the undergraduate and residency levels in all suggested areas of pain treatment.”<sup>234</sup> That should raise serious questions about the

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229. 42 C.F.R. §§ 410, 414, 415, 421, 423, 425, 486, 495; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013, 77 Fed. Reg. 68892, 69006 (Nov. 16, 2012).

230. Medicare Program; Revisions to Payment Policies, 77 Fed. Reg. at 69,008.

231. Missouri H.B. 1399 simply amended Missouri Section A, Chapter 334 to provide that services “shall only be performed by a physician licensed under this chapter.” H.B. 1399, 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012).

232. See IOM PAIN REPORT, *supra* note 199, at 119-20.

233. *Id.* at 191 (citing Phillip M. Lippe et al., *The First National Pain Medicine Summit—Final Summary Report*, 11 PAIN MED. 1447 (2010) (noting report submitted by Chair of AMA Pain and Palliative Medicine Specialty Section Council)).

234. *Id.*

quality of care physician substitutes might provide across various treatment contexts.<sup>235</sup>

#### 4. Results: Impact of Competition Advocacies

The FTC has tracked the competition advocacy program and, in various ways, attempted to assess its effects.<sup>236</sup> The question of how to measure the impact of advocacy comments is not trivial. As Cooper, Pautler, and Zywicki observe, “The value of competition advocacy should be measured by (1) the degree to which comments altered regulatory outcomes and (2) the value to consumers of those improved outcomes. However, (1) and (2) are impossible to determine with any degree of certainty.”<sup>237</sup> Certainly, there are cases where legislative or regulatory results are more or less in agreement with staff recommendations, and sometimes there are reasonably clear indications that staff comments were influential. For example, as noted above, the first set of FTC staff comments regarding proposed LSC regulations were submitted to the Massachusetts Department of Public Health.<sup>238</sup> The final rule issued by the Department was consistent with FTC staff recommendations. The Department’s supporting documents noted:

The proposed regulations had included a requirement that all advertising for LSCs be submitted to the Department for approval prior to use. . . . The most compelling piece of testimony came from the Federal Trade Commission, which suggested instead that the Department would be on firmer regulatory ground if it merely prohibits false or misleading advertising.

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235. FTC staff also addressed proposed Alabama rules that raised similar concerns, as they would have prohibited even CRNA administration of treatments delegated directly to them by supervising physicians: “It is possible that the Proposed Rule may, on balance, reduce patient safety. As noted, economic or geographic access problems may place some Alabamans at risk of inadequate care. Also, if CRNA pain management specialists are sometimes replaced not by board certified anesthesiologists, but by physicians and osteopaths who do not specialize in pain management, the average quality of interventional pain management in Alabama, or certain parts of Alabama, could be reduced.” Alabama FTC Letter, *supra* note 50, at 7.

236. *See, e.g.*, FTC, PERFORMANCE & ACCOUNTABILITY REPORT FISCAL YEAR 2011, at 41 (2011), available at <http://www.ftc.gov/opp/gpra/2011parreport.pdf>; FTC, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2010, at 40 (2011), available at <http://www.ftc.gov/opp/gpra/2010parreport.pdf>; KOVACIC, *supra* note 39, at 121-24.

237. Cooper et al., *supra* note 39, at 1105.

238. *See* Missouri CRNA Letter, *supra* note 50; Tennessee FTC Letter to Odom, *supra* note 50; Alabama FTC Letter, *supra* note 50.

Staff is heeding this advice and proposing the suggested change to 105 CMR 140.1001(I)(2).<sup>239</sup>

Still, the degree to which final policies model FTC staff recommendations varies, and signals from decision makers and other stakeholders about the efficacy of staff comments vary, too.<sup>240</sup> A tally of subjective comments about the utility or impact of a given FTC staff issuance can provide a useful, if rough, sense of impact, but, as a general proposition, “[T]here is no means to measure a comment’s marginal impact in the decision-making process.”<sup>241</sup>

There is the further question of what effect to expect. With law enforcement, one seeks to enforce the law. When doing so, one seeks a favorable resolution, which may comprise a favorable settlement or a favorable decision in a case litigated to its conclusion. Although productivity measurement issues abound here, too,<sup>242</sup> it is important to recognize that the lowest hanging fruit may be important: even a “slam dunk” may constrain conduct or transactions that are, or would be, harmful to competition and consumers. But the FTC does not initiate or conduct state legislation or rulemaking, for which stakeholders may be diverse, and there may be little point to researching, drafting, and marshaling Commission approval of advocacy comments that pile-on (or under) a political “slam dunk,” especially since a “win” may have no precedential value.<sup>243</sup> Hence, both case selection criteria and expectations may be different for advocacy matters than for law enforcement matters – and not just because of the broader scope of competition policy. In addition, where the FTC and its staff recommend that policymakers include competitive effects *among* what may be complex policy considerations, it is at least possible that the recommendation will be followed, on the way to approval of a policy

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239. Memorandum from Paul I. Dreyer, Director, Bureau of Health Care Safety & Quality, to Commissioner John Auerbach and Members of the Public Health Council, Mass. Dep’t Pub. Health (Dec. 12, 2007), *available at* <http://www.mass.gov/eohhs/docs/dph/legal/phc-memo-dec12.doc>.

240. Even a direct citation by a decision maker may be a noisy signal of actual influence on the decision making process as it may in some cases be an attempt to, e.g., “seek political cover,” rather than report on an actual weighing of influences. Cooper et al., *supra* note 39, at 1103.

241. *Id.* at 1105.

242. *See generally* KOVACIC, *supra* note 39, at 144-74.

243. Certainly, legislative and rule making inputs and results may exert some influence on future decision making within and without the jurisdiction in question. Still, FTC staff comments cannot establish legal precedents in the same way that decisions of the Commission or a court can, and where we cannot reliably measure the incremental effects of staff comments, we cannot systematically track such effects across legislative sessions, state lines, etc.

that remains concerning from a competition point of view.<sup>244</sup> Although the FTC and its staff track diverse responses to their competition comments, they have steered sensibly clear of attempts to measure the extent to which such comments may improve the decision making processes of state regulators. Still, evaluating the impact of such comments on a “culture of competition” among policymakers should in some way take a long view and remain mindful that “competition advocacy is a complex and difficult process, and outright victories are relatively rare.”<sup>245</sup>

Stakeholders commonly report that FTC staff competition comments are “useful.”<sup>246</sup> As noted, there typically is no way to measure the incremental effects of staff comments on a decision making process that may be complex and, in some of its fundamentals, opaque. If we catalogue “efficacy” on a simpler measure – a sort of “happy results plus” basis, counting (a) whether near-term legislative or regulatory decisions match or partially match FTC staff recommendations plus (b) some extrinsic evidence that staff comments figured in the decision-making – then the nursing-related advocacies discussed in this paper have been substantially successful – split roughly evenly between matters where staff comments were either “successful” or “partially successful” and matters where they were “unsuccessful.”<sup>247</sup>

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244. Note that political considerations might be complex and not just policy considerations. As Cooper, Pautler, and Zywicki have pointed out, “[A]lthough advocacy provides regulators with information concerning the likely economic consequences of a policy choice, the FTC is not a constituent . . . [and] cannot provide political support in the form of votes or campaign contributions.” Cooper et al., *supra* note 39, at 1104.

245. Timothy J. Muris, Chairman, FTC, Creating a Culture of Competition: The Essential Role of Competition Advocacy, Address Before the Int’l Competition Network Panel on Competition Advocacy and Antitrust Auths. (Sept. 28, 2002), *available at* <http://www.ftc.gov/public-statements/2002/09/creating-culture-competition-essential-role-competition-advocacy>.

246. For example, in 2010 and 2011 surveys of stakeholders, 100% of respondents found advocacy comments to be “useful” to the decision making process. PERFORMANCE & ACCOUNTABILITY REPORT FISCAL YEAR 2011, *supra* note 236, at 41; PERFORMANCE & ACCOUNTABILITY REPORT FISCAL YEAR 2010, *supra* note 236, at 40.

247. For example, whereas the Massachusetts and Illinois LSC comments were deemed “successful,” the Kentucky LSC comments were deemed “partially successful” as the regulator acknowledged FTC staff comments and, in its final regulations, addressed some (but not all) of the competitive concerns raised therein. By our tally of recent matters based on both published FTC reports and internal documents, CRNA-related results were as follows: Alabama (successful); Tennessee (unsuccessful); Missouri (partially successful). A 50-50 split roughly matches past reports of the impact of the advocacy program more generally. *See, e.g.,* Arnold C. Celnicker, *The Federal Trade Commission’s Competition and Consumer Advocacy Program*, 33 ST.

Notably, however, none of the seven recent comments addressing supervision restrictions imposed on APRNs generally has successfully urged lessening restrictions that many states do without and that the IOM has suggested are both an impediment to adequate access to primary care and unnecessary for patient protection.<sup>248</sup>

Assessing the economic impact of such advocacies remains an important topic, however difficult. Indeed, assessing the economic impact of policy changes addressed in the advocacy comments is fundamental to good government and not just the selection and evaluation of advocacy opportunities going forward. Whatever the marginal contribution of FTC staff comments – at whatever cost – there remain basic questions about the larger economic costs and benefits associated with diverse licensure and scope of practice rules and, at the margin, with regulatory change. These comprise not just compliance costs but, for example, traditional questions about effects on wages or compensation and, ultimately, labor supply.<sup>249</sup>

As noted above, there is some evidence suggesting that relatively stringent APRN practice rules are associated with fewer per capita practitioners.<sup>250</sup> Analogous evidence regarding licensure strictures on specialized APRNs<sup>251</sup> and allied professions<sup>252</sup> is broadly consistent

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LOUIS U. L.J. 379, 391 (1989) (reporting a survey of recipients of advocacy comments according to which 6% were rated “totally effective,” 33% were rated “moderately effective,” and 11% “slightly effective”).

248. That is, we have not observed positive results in the general APRN advocacy comments issued since the 2011 comments to Representative Daphne Campbell and the Florida House of Representatives: Florida, Texas, Kentucky, Louisiana, and West Virginia. The West Virginia testimony may be regarded as provisional, rather than a failure, as it addressed potential reform of the State’s regulations generally and was not necessarily tied to any particular bill.

249. *See, e.g.*, MILTON FRIEDMAN & SIMON KUZNETS, *INCOME FROM INDEPENDENT PROFESSIONAL PRACTICE* (1954); Stigler, *supra* note 90, at 13-14 (discussing the income variable in professional licensing); Kleiner & Kreuger, *supra* note 100, at 24 (finding substantially higher wages associated with licensure of a profession at the state or federal, instead of local, level, adjusting for educational attainment, age, experience, and other variables, consistent with a monopoly theory of licensure); *see also* COX & FOSTER, *supra* note 42, at 18-20 (arguing that income is a significant factor in professionals’ desire for regulation via licensing); Kleiner, *supra* note 98, at 192 (“The most generally held view on the economics of occupational licensing is that it restricts the supply of labor to the occupation and thereby drives up the price of labor as well as of services rendered.”).

250. *See, e.g.*, Sekscenski et al., *supra* note 111, at 1266.

251. *See id.* (regarding certified nurse-midwives); Eugene R. Declercq et al., *State Regulation, Payment Policies, and Nurse-Midwife Services*, 17 *HEALTH AFFS.* 190 (1998) (reporting that NMW rules that were

with this finding. Evidence regarding, e.g., effects on wages or compensation is slight, however, and its implications unclear.<sup>253</sup> Moreover, we have less evidence by far on the question of how such scope of practice restrictions may affect basic measures of access to primary care, in turn. For example, do particular types of supervision requirements change the number or distribution of APRNs in underserved areas? Do they affect out-of-pocket prices, wait times, or average distances travelled for basic care? In the future, we mean to examine the relationship between regulatory change and one direct measure of primary care access – that is, the number of primary care office visits that actually take place per population or geographic

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“supportive” of NMW practice were associated with increased distribution of NMWs and NMW services).

252. For example, some research regarding state dentistry regulations suggests that increasingly stringent licensing requirements may not be associated with better dental health outcomes but may be associated with fewer dentists per capita. Kleiner & Kudrle, *supra* note 109, at 575-76. *But see* HOLEN, *supra* note 109, at 21 (finding some positive correlation between stringency of certain dental rules and a proxy for quality of care – lower average malpractice insurance rates – although reaching no conclusions about net benefits).
253. Several papers attempt to correlate relatively strict (or lax) APRN scope of practice restrictions with physician and APRN income, although they do not purport to study the causal effects of either imposing or relaxing such restrictions. *See* Patricia Pittman & Benjamin Williams, *Physician Wages in States with Expanded APRN Scope of Practice*, 2012 NURSING RESEARCH AND PRAC. 1, 1 (2012) (“[P]reliminary analysis revealed no evidence of differences in [physician] earnings across the two groups of states.”). Regarding APRN effects, compare Michael J. Dueker et al., *The Practice Boundaries of Advanced Practice Nurses: an Economic and Legal Analysis*, 27 J. REGULATORY ECON. 309, 327 (2005) (finding relaxed restrictions associated with lower APRN wages and higher physician assistant wages), with John Perry, *The Rise and Impact of Nurse Practitioners and Physician Assistants on their Own and Cross-Occupation Incomes*, 27 CONTEMP. ECON. POL’Y 491, 497 (2009) (noting increased APRN prescriptive authority associated with slight increase in NP earnings and decrease in PA and MD earnings). Dueker et al. conjecture that various factors that may contribute to lower average APRN wages in states with relatively relaxed scope of practice restrictions, including the increased supply of APRNs and APRN services observed by Sekscenski et al., *supra* note 111, and Declercq et al., *supra* note 251. Dueker et al., *supra*, at 2. Note that average state effects may be subject to considerable averaging effects, especially as rent seeking may be substantially moderated in more competitive markets or by certain institutional providers and payers. Although ad hoc reports may represent outlier observations, our concern about access suggests attention to the question of whether wage, price, and other economic effects are concentrated in medically underserved areas and not just statewide averages.

area.<sup>254</sup> Also important, ultimately, is the question of whether certain licensure or scope of practice policies have measurable effects on particular health care compliance, outcomes, or process quality measures, such as those regarding availability/utilization of prenatal care (or corresponding rates of complications), pediatric inoculation, compliance with diabetes management guidelines, or rates of hospital readmission.

Follow-up empirical research should help to answer these questions, informing both competition analyses and health policy and regulation more generally. Identifying salient measures is, of course, critical. Also suggested by our concern with health care access – and by general antitrust methods – is that the scale at which we look for state-law-based effects may be critical, as effects on consumers and providers may vary considerably within any given state.

5. Some Persistent Concerns about Competition and Nursing Regulations

The notion that patently anticompetitive restrictions on professional services – like substantial regulatory costs generally – ought to be adequately justified should not be dismissed off-hand because questions of adequacy might sometimes be contentious. Recall our discussion of *National Society of Professional Engineers* and its progeny.<sup>255</sup> Whereas the AMA has argued that “scope-of-practice actions of state medical boards are, and should be, immune from successful antitrust challenge under the antitrust state action exemption doctrine, even if the board consists primarily or entirely of practicing physicians,”<sup>256</sup> the Supreme Court squarely has rejected “the argument that because of the special characteristics of a particular industry, monopolistic arrangements will better promote trade and commerce than competition.”<sup>257</sup> Second, the Fourth Circuit held, based on *National Society of Professional Engineers*, “that it is not the function of a group of professionals to decide that competition is not beneficial in their line of work” and noted that it is not “inclined to condone anticompetitive conduct upon an incantation of ‘good

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254. See, e.g., Hofer et al., *supra* note 152, at 72-73 (noting primary care visits with physicians according to certain demographic factors and health condition indicators); see also Huang & Finegold, *supra* note 152, at 615; Petterson et al., *supra* note 152, at 508.

255. See *supra* Part II.A.

256. *Federal Trade Commission (FTC) State Engagement*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/advocacy/state-advocacy-arc/state-advocacy-campaigns/ftc-engagement.page> (last visited Jan. 4, 2014).

257. *Nat'l Soc'y Prof'l Eng'rs v. United States*, 435 U.S. 679, 689 (1978).

medical practice.”<sup>258</sup> That is, apparently anticompetitive restrictions require not just a rationale but substantiation.<sup>259</sup>

The rationale commonly offered on behalf of disparate treatment of APRNs turns on what are supposed to be qualitative and quantitative superiority in physician training and education. For example, in comments submitted to West Virginia legislators, the AMA recently argued as follows:

By virtue of their education and training, physicians are best qualified to lead health care teams. Physicians and nurses complete their education and training with different types of knowledge, skills, and abilities that are complementary, not equivalent. Physicians receive far more education, clinical training, and continuing medical education to ensure they are well equipped to diagnose and manage patient care. For example, a primary care physician gains 21,700 hours of clinical education and training, compared to an average of 5,350 hours of clinical education and training for APRNs. This difference in education and training matters.<sup>260</sup>

Indeed, difference in education and training may matter in many ways, but why “this difference” for this policy choice? Suppose we take the AMA tallies at face value.<sup>261</sup> What patient health or safety

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258. *Va. Acad. of Clinical Psychologists v. Blue Shield of Va.*, 624 F.2d 476, 485 (4th Cir. 1980).

259. As noted above, this is a claim that potentially countervailing consumer protection concerns must, at a minimum, be well-founded. It does not follow that antitrust demands any particular type of evidence or level of substantiation or that antitrust concerns evaporate in the presence of any demonstrable consumer risk.

260. Madara Letter, *supra* note 67, at 2.

261. It is unclear how the AMA arrives at this tally. A recent report cites the same number of hours for both professional groups. GREG MARTIN, AM. ACAD. OF FAM. PHYSICIANS, EDUCATION AND TRAINING: FAMILY PHYSICIANS AND NURSE PRACTITIONERS, *available at* <http://www.aafp.org/dam/AAFP/documents/news/NP-Kit-FP-NP-UPDATED.pdf>. Mr. Martin’s numbers are presented as estimates, and his 21,700 hours appears to sum not merely clinical training but all education, training, and study hours – including both classroom and estimated studying time for the pre-clinical years – from the beginning of medical school through residency. *Id.* at 2. In fact, required training hours appear to vary at least somewhat according to differences in state regulations, training programs, certification, etc. For a general overview of training and education requirements, compare NAT’L COUNCIL STATE BDS. OF NURSING, CONSENSUS MODEL FOR APRN REGULATION: LICENSURE, ACCREDITATION, CERTIFICATION & EDUCATION (2008), *available at* [https://www.ncsbn.org/Consensus\\_Model\\_for\\_APRN\\_Regulation\\_July\\_2008.pdf](https://www.ncsbn.org/Consensus_Model_for_APRN_Regulation_July_2008.pdf), with ACCREDITATION COUNCIL FOR GRADUATE MED. EDUC. (ACGME), COMMON PROGRAM REQUIREMENTS (2011), *available at*

benefits accrue, and in what practice contexts, as one moves from 5,350 hours (as attributed to APRN and prior training) to 21,700 (as attributed to MD training)?<sup>262</sup> Do such benefits accrue demonstrably (even plausibly) across all health care services or are they associated primarily with particular indications, procedures, or practice environments?

FTC staff comments typically have been submitted where evidence of such benefits in the legislative or regulatory record were slight or wholly absent. Viewed from the competition policy perspective, this seems a regulatory failing *independent* of the question of what the evidence might suggest were it gathered and considered. Generalist or specialist physicians may enjoy diverse relative competitive advantages and future research may help to delineate such advantages, perhaps to the mutual benefit of physicians and health care consumers. Evidence linking particular differences in education and training to deficits in APRN practice seems chronically lacking, however.<sup>263</sup> Rather, “[e]ducational standards . . . support broader practice by all types of APRNs.”<sup>264</sup>

None of this should disparage the clinical and basic science learning that medical schools have to offer or the long drive towards qualitative improvement in medical education seen since Abraham

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[http://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramResources/Common\\_Program\\_Requirements\\_07012011\[1\].pdf](http://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramResources/Common_Program_Requirements_07012011[1].pdf).

262. The raw number of hours may be less important than their constitution, and the best configuration of didactic and experiential hours has been a moving target. Some medical schools are pushing the debate by shortening their pre-clinical curricula. Baylor Medical School, for example, has a one-and-a-half year pre-clinical curriculum and shortened clinical curriculum. *See Curriculum That Allows You to Customize Your Education*, BAYLOR COLL. OF MED., <http://www.bcm.edu/medschool/curriculum.html> (last visited Jan. 4, 2014). Even the IOM has questioned whether traditional programs overemphasize basic science content as a foundation for training that is responsive to health care needs of most citizens. Even the IOM has questioned whether traditional programs overemphasize basic science content as a foundation for training that is responsive to health care needs of most citizens. INST. OF MED., *HEALTH PROFESSIONS EDUCATION: A BRIDGE TO QUALITY* 81-82 (Ann C. Greiner & Elisa Knebel eds., 2003).

263. Eileen T. O’Grady, *Advanced Practice Registered Nurses: The Impact on Patient Safety and Quality*, in DEP’T HEALTH & HUMAN SERVS., *PATIENT SAFETY & QUALITY: AN EVIDENCE-BASED HANDBOOK FOR NURSES*, § 43, at 8 (Ronda G. Hughes ed., 2008) (“[H]igh degree of variation suggests that the regulatory framework for APN practice is not evidence-based and that States are not promulgating APN regulations with a coherent patient safety orientation.”).

264. IOM *FUTURE OF NURSING REPORT*, *supra* note 1, at 98.

Flexner's 1910 report to the Carnegie Foundation.<sup>265</sup> The educational institutions that Flexner reviewed – and in many cases derided – badly needed reform. Medical schools, into the early decades of the twentieth century, frequently were proprietary and entrepreneurial – many of them had dubious entry (or graduation) requirements and lacked essential components, such as qualified teachers, clinical teaching facilities, and laboratories.<sup>266</sup> As such, they could not have provided the classic economic justification for minimum entry requirements, as assurances provided to uninformed consumers facing daunting information costs.<sup>267</sup>

To ask about the empirical underpinnings of entry restrictions or any other health care regulations is not to advocate for competition from pre-Flexner internists (or pre-Lister surgeons, or pre-1953 medical geneticists). If principles of institutional design suggest that innovations and operations be subject to measurement and evaluation,<sup>268</sup> neither such principles nor any from antitrust suggest that innovation cannot precede an empirical demonstration of need, much less that we should expect such demonstrations to be decisive. Setting a regulatory floor – and thereby prohibiting both the provision and the consumption of certain services – is a different matter, however. Perhaps it is worth noting that even Flexner came to question his early dismissal of access issues, “convinced that the distribution of physicians was a more serious problem than he had originally anticipated.”<sup>269</sup>

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265. ABRAHAM FLEXNER, *MEDICAL EDUCATION IN THE UNITED STATES AND CANADA: REPORT TO THE CARNEGIE FOUNDATION FOR THE ADVANCEMENT OF TEACHING* (1910), available at [http://www.carnegiefoundation.org/sites/default/files/elibrary/Carnegie\\_Flexner\\_Report.pdf](http://www.carnegiefoundation.org/sites/default/files/elibrary/Carnegie_Flexner_Report.pdf). See also *BEYOND FLEXNER: MEDICAL EDUCATION IN THE TWENTIETH CENTURY* (Barbara Barzansky & Norman Gevitz eds., 1992) (regarding the influence of the Flexner report).

266. FLEXNER, *supra* note 265, at 84, 102.

267. Flexner's observations on Alabama were hardly the worst of these. Nonetheless, he described entrance requirements for Birmingham Medical College as “nominal,” and his summary of the state's two offerings began as follows: “The foregoing account makes it clear that really satisfactory medical education is not now to be had in Alabama. The entrance standards are low; the schools are inadequately equipped; and they are without proper financial resources. To get together their present numbers, standards must be kept low; in consequence, the medical schools do nothing to promote or share the secondary school development of the state.” *Id.* at 185-86.

268. See KOVACIC, *supra* note 39, at 16-19, 144-77 (applying such principles to the FTC itself).

269. PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 124-27 (1982) (discussing post-Flexner disparities).

More broadly, while competition principles may identify competitive costs – sometimes to the detriment of policy proposals and sometimes to the detriment of certain commercial conduct or proposed transactions – they do not stipulate, or provide mechanisms for determining, optimal regulations. Antitrust fundamentally is not a regulatory model,<sup>270</sup> just as it is not a means of industrial planning or market design. Antitrust defers generally to the process of competition, which it seeks to protect by intervening to prevent (*ex ante*) or remedy (*ex post*) certain practices or proposals that would impede competition (sufficiently and in certain ways deemed remediable).<sup>271</sup>

Our general discussion of licensure early in this paper listed various potential costs and benefits to professional regulation but left much unsettled. One nagging question has to do with a sort of regulatory burden of proof that one or another dominant theory of licensure may imply.<sup>272</sup> Supposing one wants licensure restrictions to rest on some substantial empirical ground, one might adopt a generally permissive regime, permitting wide latitude in practice except where there is evidence of substantial harm or risk. In the alternative, one might begin with a cramped notion of professional privilege and require justification for each categorical expansion of that privilege.

Construed broadly, the nursing advocacies identify competition concerns raised by a radically divided approach to the regulation of health care professionals. That approach would adopt a highly permissive regime when regulating physicians and would be very careful about – and hesitant to impose – any categorical restrictions on the “practice of medicine.” But when regulating nurses, the approach would begin with a very well-cabined notion of the “practice of nursing” and would be very cautious about any expansion of that practice, especially any expansion that may impinge upon the professional prerogatives of physicians. Certainly, a conservative approach to regulation is not per se offensive to competition principles.<sup>273</sup> We

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270. See, e.g., BORK, *supra* note 118, at 69-70 (“The antitrust laws are wholly prohibitory and passive in nature, so that they are effective only to screen conduct that private parties themselves originate. Unlike many other laws, therefore, antitrust is wholly unable to serve values that must be implemented by requiring or inducing affirmative conduct which the self-interest or capabilities of private persons do not cause or permit them to undertake.”).

271. See *id.*

272. If neither theory determines a model of regulation, much less particular rules, we note that the capture theory may be generally suspicious of substantial barriers to entry implemented in licensing or scope of practice rules, while the market failure theory may be generally conciliatory of such restrictions.

273. Former FTC Chairman Louis Engman put it the other way: “Though most government regulation was enacted under the guise of protecting the consumer from abuse, much of today’s regulatory machinery does

may be concerned, however, when a minimalist approach applies to one group of competitors and a maximalist approach to another. We may be especially concerned when members of one profession work consistently, and concertedly, to secure such a divided approach.

The roots of this bifurcated regulatory approach run long if not deep. Early medical practice acts required licensure and perhaps training at an accredited institution but did little to define or constrain the scope of medical practice.<sup>274</sup> An early case notes simply, “There is nothing . . . evidencing a legislative intent that the term ‘practicing medicine’ should bear other than its common meaning. It will be observed that the Act . . . embraces ‘the practice of the healing art,’ instead of merely ‘the practice of medicine and surgery.’”<sup>275</sup> Later medical practice acts, while more detailed, were not especially confining of medical practice.<sup>276</sup>

Early nursing acts were much more constrained. Like medical practice acts, they required registration or certification and restricted at least the title “registered nurse” to those meeting certain educational or training requirements.<sup>277</sup> Scope of practice, however, was defined narrowly, or as dependent on the direction of a licensed physician.<sup>278</sup> APRNs and CRNAs simply did not exist, as APRN types of training and certification programs, and corresponding regulatory classifications, did not emerge until the 1960s.<sup>279</sup>

The IOM summarizes the present situation as follows:

Because virtually all states still base their licensure frameworks on the persistent underlying principle that the practice of medicine encompasses both the ability and the legal authority to

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little more than shelter producers from the normal competitive consequences of lassitude and inefficiency.” Lewis A. Engman, Chairman, FTC, Address before 1974 Fall Conference of the Financial Analysts Federation (Oct. 7, 1974).

274. See STARR, *supra* note 269, at 104. Antecedents to these medical practice acts date back further still, including an eighteenth century Maryland law creating a Board of Medical Examiners and a 1639 Virginia law restricting prices charged for medical services. See Hogan, *supra* note 104, at 118.

275. *Rubin v. United States*, 37 F.2d 991, 992 (D.C. Cir. 1930).

276. Barbara J. Safriet, *Closing the Gap between Can and May in Health-Care Providers’ Scopes of Practice: A Primer for Policymakers*, 19 YALE J. ON REG. 301, 306-07 (2002) (“Once medicine’s scope of practice was thus comprehensively defined in law, almost any activity directed at ‘health or sickness’ . . . was deemed to be the practice of medicine.”).

277. Safriet, *supra* note 97, at 454 (citation omitted).

278. *Id.*

279. *Id.* at 423-24; JULIE FAIRMAN, MAKING ROOM IN THE CLINIC: NURSE PRACTITIONERS AND THE EVOLUTION OF MODERN HEALTH CARE (2008).

treat all possible human conditions, the scopes of practice for APRNs (and other health professionals) are exercises in legislative exception making, a “carving out” of small, politically achievable spheres of practice authority from the universal domain of medicine.<sup>280</sup>

The IOM argues that the results of this approach have been widely off the mark. Although some states have reformed scope of practice rules to keep pace with changes in medicine and nursing, in most states, “[W]hat nurse practitioners are able to do once they graduate varies widely for reasons that are related not to their ability, education or training, or safety concerns, but to the political decisions of the state in which they work.”<sup>281</sup>

Regulatory development often exhibits a certain path-dependency, and existing rules may reflect the historical context of their origins as much as contemporary assessments of patient care. Neither history nor habit is much of a rationale, however, much less an adequately substantiated rationale.<sup>282</sup>

## CONCLUSION

The Institute of Medicine’s *Future of Nursing* report identifies an important health policy role for the federal antitrust agencies, notably the FTC. But while the report identifies some of the potential benefits of health care competition,<sup>283</sup> it is not concerned with competition *per se*. Rather, it assesses the current state of nursing education, training, and practice, and it considers potential qualitative improvements to all of them, including improvements to the larger social or economic environment within which nurses practice. Improving the ability of nurses to work to both present and future potentials is important because of extant unmet needs for basic health care services. Such needs are understood in health policy terms – both medical and political – that may be distinguished from a competition-based notion of artificially suppressed supply, even if reference cases may be coincident.

The nexus between the IOM project and the FTC’s is a baseline concern with consumer welfare. Antitrust law is concerned with the competitive effects of mergers or certain types of conduct that

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280. IOM FUTURE OF NURSING REPORT, *supra* note 1, at 97.

281. *Id.* at 5.

282. Neither, of course, is professional or other social bias. *Id.* at 107-11; Barbara J. Safriet, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing Quality, Cost-Effective Health Care*, in IOM FUTURE OF NURSING REPORT, *supra* note 1, at 452-54, 456-60.

283. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 1, at 5.

impinge upon consumer welfare,<sup>284</sup> where conduct *sometimes* comprises regulation. Competition policy is concerned with competitive effects on consumers more broadly, as it escapes some of the particular statutory and doctrinal limits associated with the Sherman and Clayton Acts. Access problems are a special concern for competition – as well as other areas of health policy – because of the baseline concern with consumer welfare and because of the outsize impact of access to basic or essential services on consumer welfare. Concomitant with basic notions of the decreasing marginal utility of money and other valued commodities, one takes (or gives) the most when one takes (or gives) a consumer's  $n^{\text{th}}$  unit as  $n$  approaches 1.<sup>285</sup>

With Commission approval, FTC staff have issued a series of advocacy comments addressing regulatory strictures imposed on nurses' scope of practice. Acknowledging measurement difficulties, it appears that state regulators typically have identified FTC staff recommendations as useful to their deliberations and have followed those recommendations roughly half of the time.

The advocacy comments represent a species of soft administrative intervention providing critical competition analyses to state policy makers – a sort of nudge – that may be distinguished from more typical Agency guidance in at least two fundamental regards. First, competition advocacies tend to address government officials, rather than industry stakeholders or consumers. Second, the advocacies apply an Agency understanding of the competition principles underlying the antitrust laws, but are not confined to interpreting those laws or recommending compliance with them. In particular, they have asked that state policy makers account for competitive costs when considering scope of practice restrictions, and they have recommended that substantial competitive costs – especially those associated with diminished access to basic health care services – not be imposed on the public absent an evidence-based promise of countervailing consumer protection benefits.

They have done so in cases where the evidentiary basis for regulatory costs imposed on health care consumers appears to be inadequate. Consider the following from the Louisiana State Board of Medical Examiners:

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284. See generally Salop, *supra* note 53; Baker, *supra* note 53; HORIZONTAL MERGER GUIDELINES, *supra* note 53.

285. For analogous reasons, last dollar fraud is a special concern for the FTC's consumer protection mission. See, e.g., Edith Ramirez, Comm'r, FTC, Address at Women in Housing & Finance, Last Dollar Fraud: The FTC's Response to the Foreclosure Crisis (Jan. 27, 2011), <http://www.ftc.gov/speeches/ramirez/110127whf.pdf>.

The Board's opinion is not and cannot be altered by representations that a particular CRNA [Certified Registered Nurse Anesthetist] has received postdoctoral training in such areas or has performed such activities in this or another state. A non-physician may have education, training, and, indeed, expertise in such an area but expertise cannot, in and of itself, supply authority under law to practice medicine.<sup>286</sup>

As a legal matter, the analysis may be trivially correct: education, training, experience, and expertise do not, in themselves, bestow legal authority or lift statutory prohibitions. As a policy matter, however, we might wonder about the bases on which we both assign and limit the authority to meet demand – unmet needs – for health care. However we allocate research resources, tolerate uncertainty, and calibrate substantiation standards, we might say this much when substantiation appears to approach zero: based on competition principles *at least*, nothing *ought* to beget nothing, except, perhaps, scrutiny.

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286. Safriet, *supra* note 97, at 454.