

# EXPLAINING THE ABSENCE OF SURGICAL PROCEDURE REGULATION

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Orthodoxy in surgery is like orthodoxy in other departments of the mind. It starts as a tentative belief in some particular course of action but later begins [to almost challenge a] comparison with religion. It comes to be held as a passionate belief [in] the absolute rightness of that particular view.

—Sir Geoffrey L. Keynes, 1957<sup>1</sup>

## INTRODUCTION

Each year in the United States, surgeons perform approximately 64 million surgical procedures, ranging from tooth extraction to open heart surgery.<sup>2</sup> Yet, notwithstanding the frequency of surgical procedures and their often critical importance to patient health, no state or federal agency either approves the use of new surgical procedures or directly regulates existing procedures.<sup>3</sup>

The absence of surgical procedure regulation differs from the regulation of new pharmaceutical products, which can be introduced into interstate commerce only after the Food and Drug Administration (FDA) has reviewed “adequate and well-controlled [clinical] investigations” and concluded the data from those studies sufficiently establish the drug’s safety and efficacy.<sup>4</sup> Surgical procedures, by contrast, are more often conveyed from professor to student, the result being that surgical approaches may vary considerably from one geographic region to another.<sup>5</sup> Whether different techniques produce different outcomes is not always clear, in part because the absence of regulation means that evidence often has not been systematically generated or may be in a form not suitable for comparison.

Commentators have noted the differing treatment that persists between surgery and pharmaceuticals<sup>6</sup> and have offered a number of justifications. For example, they have suggested that the surgical profession should self-regulate,<sup>7</sup> that excessive regulation could deter surgeries of unproven benefit even when the surgery may be in the best interest of the

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<sup>1</sup> Geoffrey Langdon Keynes, *Carcinoma of the Breast*, 36 N.S. MED. BULL. 161, 161 (1957).

<sup>2</sup> See Thomas G. Weiser et al., *An Estimation of the Global Volume of Surgery: A Modelling Strategy Based on Available Data*, 372 LANCET 139, 142 (2008) (Table 2).

<sup>3</sup> See Robert S. Rhodes, *Should Surgery Have an FDA?*, AMA J. ETHICS (Oct. 2004), [journalofethics.ama-assn.org/2004/10/pfor2-0410.html](http://journalofethics.ama-assn.org/2004/10/pfor2-0410.html).

<sup>4</sup> 21 U.S.C. § 355(d) (2017).

<sup>5</sup> Jonathan L. Meakins, *Innovation in Surgery: The Rules of Evidence*, 183 AM. J. SURGERY 399, 399 (2002).

<sup>6</sup> David H. Spodick, *Numerators Without Denominators: There Is No FDA for the Surgeon*, 232 JAMA 35, 36 (1975).

<sup>7</sup> James W. Jones et al., *Professional Self-Regulation: Eyewitness to Incompetent Surgery*, 36(5) J. VASCULAR SURGERY 1092, 1092 (2002).

patient,<sup>8</sup> and that surgical trials could disrupt the doctor-patient relationship, such as by emphasizing uncertainty in a context where patient trust is important.<sup>9</sup> In the context of innovative (as opposed to established) surgical procedures, controlled trials might be disfavored due to concern that desperate patients might unwisely submit themselves to risky experimental treatments undertaken by overzealous researchers.<sup>10</sup> When commentators advocate for increased surgical regulation, they generally limit their calls for reform to innovative surgical procedures.<sup>11</sup> The absence of direct regulation, however, has implications for the quality of evidence available to support an optimal choice from among all of the alternatives in the surgeon's armamentarium, whether innovative or standard, and whether surgical or non-surgical.

This Article first examines the current framework of indirect regulation surrounding surgical procedures and then offers potential explanations as to why surgical procedures themselves are not already subject to direct federal regulation. Finally, it considers possible contributions of increased surgical regulation, including the identification of evidence gaps, the generation or collection of evidence to fill those gaps, and the impact on surgeon decision-making and patient consent.

## I. EXISTING INDIRECT REGULATION OF SURGICAL PROCEDURES

Although no government or private body directly regulates surgical procedures, various laws and regulations address the healthcare workers who perform surgery, the medicines and devices used during surgery, and the facilities in which surgery is performed.

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<sup>8</sup> Curtis E. Margo, *When Is Surgery Research? Towards an Operational Definition of Human Research*, 27 J. MED. ETHICS 40, 42 (2001).

<sup>9</sup> Kathryn M. Taylor et al., *Physicians' Reasons for Not Entering Eligible Patients in a Randomized Clinical Trial of Surgery for Breast Cancer*, 310 LANCET 1363, 1363 (1984); see also Jeremy Fairbank, *Randomised Controlled Trials in Surgery*, 354 LANCET 257, 257 (1999); Mike Gross, *Innovations in Surgery: A Proposal for Phased Clinical Trials*, 75-B J. BONE & JOINT SURGERY 351, 352 (1993).

<sup>10</sup> Francis D. Moore, *Ethical Problems Special to Surgery: Surgical Teaching, Surgical Innovation, and the Surgeon in Managed Care*, 135 SURGERY 14, 15 (2000).

<sup>11</sup> See generally Jeffrey S. Barkun et al., *Evaluation and Stages of Surgical Innovations*, 374 LANCET 1089 (2009); Walter L. Biffl et al., *Responsible Development and Application of Surgical Innovations: A Position Statement of the Society of University Surgeons*, 206 J. AM. C. SURGERY 1204 (2008); Haavi Morreim et al., *Surgical Innovation: Too Risky to Remain Unregulated?*, 82 ANN. THORACIC SURGERY 1957 (2006); Amer S. Ahmed, *The Last Twist of the Knife: Encouraging the Regulation of Innovative Surgical Procedures*, 105 COLUM. L. REV. 1529 (2005); John D. Casler, *Clinical Use of New Technologies Without Scientific Studies*, 129 OTOLARYNGOLOGY 674 (2003); Vicki Brower, *The Ethics of Innovation: Should Innovative Surgery Be Exempt from Clinical Trials and Regulation?* 4 EMBO REP. 338 (2003); Meakins, *supra* note 5; David C. Cronin et al., *Transplantation of Liver Grafts from Living Donors into Adults—Too Much Too Soon*, 344 NEW ENG. J. MED. 1633 (2001); *Statement on Issues to be Considered Before New Surgical Technology Is Applied to the Care of Patients*, 80 BULL. AM. C. SURGERY 46 (1995).

### A. *State Regulation of Surgeons and Facilities*

State medical boards regulate the practice of medicine<sup>12</sup> and can discipline surgeons who fail to meet professional standards.<sup>13</sup> State agencies may also promulgate regulations to address particular higher-risk procedures. For example, a regulation of the Washington State Department of Health broadly requires that, for certain surgeries requiring sedation or analgesia, physicians “be competent and qualified . . . to perform the operative procedure and to oversee the administration of intravenous sedation and analgesia.”<sup>14</sup> In addition to agency-level regulation, state lawmakers may regulate certain aspects of surgery via legislation. For example, a New York statute requires those licensed to perform office-based (i.e., non-hospital) surgery to “report adverse events to the department’s patient safety center within three business days.”<sup>15</sup> These and other surgery-related laws (such as abortion laws) are enacted under the general “police power” of the state to promote public health or morals.<sup>16</sup>

States may also regulate the facilities in which surgery is performed, such as via accreditation or licensing requirements.<sup>17</sup> Colorado, for example, confers licenses on ambulatory surgical centers only after they have furnished a certificate of compliance with fire prevention and control rules.<sup>18</sup> A Virginia statute provides that podiatrists may perform surgery using a general anesthetic only in an accredited hospital or ambulatory surgery center.<sup>19</sup>

Federal law is also a source of indirect regulation of surgical facilities. For example, hospitals must be either accredited or otherwise meet the conditions provided by federal law in order to receive Medicare payments.<sup>20</sup> The Joint Commission accredits a majority (77%) of United States hospitals.<sup>21</sup>

<sup>12</sup> See, e.g., VA. CODE ANN. § 54.1-2902 (2016).

<sup>13</sup> See, e.g., *id.* § 54.1-2408.1; see also *id.* § 54.1-2400.

<sup>14</sup> WASH. ADMIN. CODE § 246-919-601(6) (2016).

<sup>15</sup> N.Y. PUB. HEALTH LAW § 230-d(4)(a) (McKinney 2016).

<sup>16</sup> See generally Michael J. Perry, *Abortion, the Public Morals, and the Police Power: The Ethical Function of Substantive Due Process*, 23 UCLA L. REV. 689 (1975).

<sup>17</sup> Jayne O’Donnell, *States Lax in Regulating Cosmetic Surgery*, USA TODAY (Dec. 27, 2011, 7:19 AM), <http://usatoday30.usatoday.com/money/perfi/basics/story/2011-12-27/state-regulations-cosmetic-plastic-surgery-offices/52247588/1>.

<sup>18</sup> COLO. REV. STAT. § 25-3-102(3)(a) (2013).

<sup>19</sup> VA. CODE ANN. § 54.1-2939 (2016).

<sup>20</sup> 42 U.S.C. § 1395x (2016); see also Lisa Sprague, *Hospital Oversight in Medicare: Accreditation and Deeming Authority*, NAT’L HEALTH POL’Y F. (May 6, 2005), [http://www.nhpf.org/library/issue-briefs/IB802\\_Accreditation\\_05-06-05.pdf](http://www.nhpf.org/library/issue-briefs/IB802_Accreditation_05-06-05.pdf).

<sup>21</sup> *Facts About Hospital Accreditation*, JOINT COMMISSION (Jan. 24, 2017), [https://www.jointcommission.org/facts\\_about\\_hospital\\_accreditation](https://www.jointcommission.org/facts_about_hospital_accreditation).

### B. Federal Regulation of Drugs and Devices

Federal law directly regulates the medicines and devices used by surgeons. The FDA, through its Center for Drug Evaluation and Research, regulates drugs that may be administered during surgery, such as general or local anesthetics, anti-emetics, and antibiotics.<sup>22</sup> Similarly, the FDA's Center for Biologics Evaluation and Research regulates biological products used during surgery, such as blood or blood products that may be administered to compensate for blood loss.<sup>23</sup> In addition, the FDA's Center for Devices and Radiological Health regulates medical devices that are used or placed within the body during surgery, such as osteotomes, pacemakers, or stitches.<sup>24</sup>

### C. Private Regulation and Gatekeeping

Nongovernmental organizations may also exert a regulating influence over surgical practice through examinations and the conferral of certifications. The American Board of Surgery is an independent, non-profit organization<sup>25</sup> that offers board certification in seven specialty areas, including general surgery, vascular surgery, and hand surgery.<sup>26</sup> Other boards that offer certification include the American Board of Orthopaedic Surgery, the American Board of Plastic Surgery,<sup>27</sup> the American Board of Foot and Ankle Surgery,<sup>28</sup> and the American Board of Oral and Maxillofacial Surgery.<sup>29</sup> Although these boards are not governmental bodies, states may restrict the ability of surgeons to perform certain procedures unless they possess the appropriate certification.<sup>30</sup> At the local level, healthcare institutions play a more direct gatekeeping role through licensure, education, training, and experience requirements

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<sup>22</sup> 21 U.S.C. § 355 (2017); *About the Center for Drug Evaluation and Research*, FDA, <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder> (last visited Aug. 4, 2017).

<sup>23</sup> *Blood & Blood Products*, FDA, <https://www.fda.gov/BiologicsBloodVaccines/Blood-BloodProducts/default.htm> (last visited Aug. 4, 2017).

<sup>24</sup> *See Devices@FDA*, FDA, <https://www.accessdata.fda.gov/Scripts/cdrh/devicesatFDA/> (last visited Aug. 4, 2017).

<sup>25</sup> *About Us*, AM. BOARD SURGERY, <http://www.absurgery.org/default.jsp?abouthome> (last visited Feb. 27, 2017).

<sup>26</sup> *Becoming Certified*, AM. BOARD SURGERY, <http://www.absurgery.org/default.jsp?examoffered> (last visited Feb. 27, 2017).

<sup>27</sup> *Related Links*, AM. BOARD SURGERY, <http://www.absurgery.org/default.jsp?aboutlinks> (last visited Feb. 27, 2017).

<sup>28</sup> *History of the American Board of Podiatric Surgery*, AM. BOARD PODIATRIC SURGERY, <https://crmservices.abps.org/pdf/ABPS/DetailedHistory.pdf> (last visited Feb. 27, 2017); *Foot Surgery: Learn More on How to Qualify*, AM. BOARD FOOT & ANKLE SURGERY, <https://www.abfas.org/becomecertified/footsurgery> (last visited Feb. 28, 2017).

<sup>29</sup> AM. BOARD ORAL & MAXILLOFACIAL SURGERY, <https://www.aboms.org> (last visited Mar. 25, 2017).

<sup>30</sup> *See, e.g.*, UTAH CODE ANN. § 58-5a-103(3) (2016); N.Y. EDUC. LAW § 7009(2)(c) (McKinney 2016).

(“credentialing”), and by authorizing a particular scope and content of services in which a given healthcare practitioner may engage (“privileging”).<sup>31</sup>

In addition to surgical boards and local control by a surgeon’s healthcare institution, a number of broad-based private sector initiatives have emerged to promote improvements in healthcare quality, including surgical quality.<sup>32</sup> The Joint Commission, founded in 1951,<sup>33</sup> accredits nearly 21,000 health care organizations and reports clinical quality measures, such as whether antibiotics are administered within one hour before the first surgical cut.<sup>34</sup> Another organization, The Leapfrog Group, was founded in 2000 to represent the interests of large employers and others who seek to ensure their substantial healthcare expenditures are well-spent.<sup>35</sup> One of its principal initiatives, for example, is to assign letter grades to hospitals based on their patient safety records.<sup>36</sup> The Council on Surgical and Perioperative Safety, incorporated in 2007, has a stated mission of “promot[ing] excellence in patient safety in the surgical and perioperative environment.”<sup>37</sup> While these organizations generally seek to promote overall healthcare quality through the implementation of various initiatives, their principal functions do not include the development and analysis of evidence with respect to the safety and efficacy of particular surgical procedures.

## II. THE ABSENCE OF DIRECT REGULATION

Despite regulation of the drugs administered and implements used during surgery, the facilities in which surgery is performed, and the healthcare workers to whom patients entrust themselves for treatment, surgical procedures themselves remain almost wholly unregulated. There

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<sup>31</sup> See *Ambulatory Care Program: The Who, What, When, and Where’s of Credentialing and Privileging*, JOINT COMMISSION (June 21, 2016), [https://www.jointcommission.org/assets/1/18/AHC\\_who\\_what\\_credentialing\\_booklet.pdf](https://www.jointcommission.org/assets/1/18/AHC_who_what_credentialing_booklet.pdf); *Revisions to Requirements for Ambulatory Care Organizations*, 33 JOINT COMMISSION PERSPS. 5 (2013) (Standard HR.02.01.03); *Privileges v. Scopes of Practice: How to Handle AHPs*, 11 OPUS COMMISSION 1, 2 (2002) (discussing Joint Commission Standard MS.5.14).

<sup>32</sup> See Rachael A. Callcut & Tara M. Breslin, *Shaping the Future of Surgery: The Role of Private Regulation in Determining Quality Standards*, 243 ANNALS SURGERY 304 (2006).

<sup>33</sup> *Facts About the Joint Commission*, JOINT COMMISSION (July 8, 2016), [https://www.jointcommission.org/facts\\_about\\_the\\_joint\\_commission](https://www.jointcommission.org/facts_about_the_joint_commission).

<sup>34</sup> *America’s Hospitals: Improving Quality and Safety — The Joint Commission’s Annual Report 2015*, JOINT COMMISSION (2015), at 8, [https://www.jointcommission.org/assets/1/18/TJC\\_Annual\\_Report\\_2015\\_EMBARGOED\\_11\\_9\\_15.pdf](https://www.jointcommission.org/assets/1/18/TJC_Annual_Report_2015_EMBARGOED_11_9_15.pdf).

<sup>35</sup> *About Us*, LEAPFROG GROUP, [www.leapfroggroup.org/about](http://www.leapfroggroup.org/about) (last visited June 17, 2016).

<sup>36</sup> *Id.*

<sup>37</sup> *Our Team, One Goal, Surgical Patient Safety*, COUNCIL ON SURGICAL & PERIOPERATIVE SAFETY, <http://www.cspsteam.org/missionvisionvalues/missionvisionvalues.html> (last visited Feb. 28, 2017).

is no industry with members that submit application packages containing data to support the use of a given procedure. No federal agency reviews and approves procedures based upon a showing that they are safe, or even that they are effective, i.e., that they improve the patient's condition. There is no centralized database of surgical procedures that specifies indications and contraindications, sets forth standardized steps and techniques, discloses procedure-specific risks and black-box warnings, or provides available clinical trial data. No federal body systematically and continuously evaluates safety or efficacy risks of surgical procedures as evidence develops through clinical practice. As a result, patients and surgeons alike must make decisions without the benefit of patient package inserts or other readily available sources that succinctly present important safety and efficacy information.

#### A. *Why Is There No Direct Regulation of Surgical Procedures?*

A number of factors help to explain why surgical procedures have so far generally remained outside the scope of direct government regulation. These factors relate to (1) the perceived sufficiency of existing regulation, (2) patient and procedure heterogeneity, (3) special challenges in conducting surgical randomized controlled trials (RCTs), (4) the structure of the surgical marketplace, (5) a particular patent law provision affecting surgery, and (6) the U.S. Constitution's Commerce Clause.

##### 1. Existing Regulation Perceived as Sufficient

Pressure to regulate surgical procedures is reduced to the extent that the existing indirect regulatory framework is perceived as adequate to ensure acceptable surgical outcomes. The public may be generally aware of the extensive medical training and licensing requirements and the existence of board certifications, and some may have read informal reviews that patients themselves place on physician rating websites. The public may also be aware of high profile medical malpractice cases, and recognize that these suits provide a post-hoc form of oversight by imposing liability on surgeons whose failure to meet the standard of care results in patient harm.<sup>38</sup>

However, while existing regulation of surgeons may mitigate the need for more targeted regulation of the surgeries they perform, it cannot alone explain the absence of direct regulation. Physicians who prescribe medications are also subject to the elements of general regulation just mentioned, yet the pharmaceuticals they prescribe must be separately approved by the FDA. Given that both medication and surgery represent

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<sup>38</sup> See generally Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12 W.J. EMERGENCY MED. 109 (2011).

two broad categories of physician intervention, and that surgery is generally the more invasive of the two, further explanation is required.

## 2. Patient and Procedure Heterogeneity

A second explanation for the lack of direct regulation is that variation in patient condition may indicate a need for one surgical approach over another. Because patients can present with a spectrum of symptoms and characteristics, surgical procedures often must be tailored.<sup>39</sup> However, although certain parameters may need to be varied from patient to patient—for example, the length of an incision or the volume of tissue resected,<sup>40</sup> this does not foreclose government regulation of the procedure as a whole. By comparison, although pharmaceuticals are approved in defined doses and formulations, physicians can nevertheless prescribe “compounded” medicines that are tailored to a patient’s particular needs.<sup>41</sup> Similarly, well-controlled investigations conducted to evaluate a surgical procedure can, like pharmaceutical trials, utilize study inclusion and exclusion criteria to ensure uniformity of relevant patient characteristics.<sup>42</sup>

## 3. Special Challenges in Conducting RCTs

A third explanation for the absence of direct regulation involves challenges to conducting RCTs, generally considered the “gold standard” of treatment evaluation,<sup>43</sup> for surgical procedures. For example, in contrast to the administration of pharmaceuticals, a surgeon’s skill in performing (or preference for) a particular procedure or variation may complicate the randomization process.<sup>44</sup> Even when a single surgeon performs the “same” intervention on multiple subjects, the degree of variation in the precise technique may be greater than the variation from pill to pill in a pharmaceutical trial, where chemical composition can be

<sup>39</sup> Daniel J. Riskin et al., *Innovation in Surgery: A Historical Perspective*, 244 ANNALS SURGERY 686, 688 (2006) (“Most surgeons innovate on a daily basis, tailoring therapies and operations to the intrinsic uniqueness of every patient and their disease.”).

<sup>40</sup> Sally Frampton & Roger L. Kneebone, *John Wickham’s New Surgery: ‘Minimally Invasive Therapy’, Innovation, and Approaches to Medical Practice in Twentieth-century Britain*, 30 SOC. HIST. MED. 544, 548 (2016) (“[I]ndividual surgeons often had to vary incision length depending on the individual factors of each case.”).

<sup>41</sup> 21 U.S.C. § 353A (2017).

<sup>42</sup> 21 C.F.R. § 312.23(6)(iii)(c) (2016); see also FDA, *Guidance for Industry: E9 Statistical Principles for Clinical Trials*, 24 (Sept. 1998), <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073137.pdf>.

<sup>43</sup> See Laura E. Bothwell et al., *Assessing the Gold Standard—Lessons from the History of RCTs*, 374 NEW ENG. J. MED. 2175, 2175 (2016).

<sup>44</sup> See Barnaby C. Reeves, *Nonrandomized Studies to Evaluate the Effects of a Nonpharmacological Intervention*, in RANDOMIZED CLINICAL TRIALS OF NONPHARMACOLOGIC TREATMENTS 143, 146 (Isabelle Boutron et al. eds., 2012).



specified and dosage can be controlled to within certain tolerances.<sup>45</sup> In addition, it will usually be impossible to blind the surgeon, and may often be difficult to blind the patient, leading to a risk of bias.<sup>46</sup> Although placebo-controlled or “sham” surgical trials have been conducted,<sup>47</sup> their use raises questions about the ethics of exposing patients to invasive and potentially risky surgery intended to serve only as a control,<sup>48</sup> a situation that contrasts with the use of inert sugar pills in pharmaceutical RCTs. Finally, it has been suggested that the time required to recruit a sufficient number of surgical subjects may be longer than it is with pharmaceutical trials.<sup>49</sup>

These challenges are not insurmountable, however. To the extent surgeons are not equally proficient with alternate procedures or prefer one procedure over another, patients can be randomized to surgeons, rather than to procedures.<sup>50</sup> To avoid the ethical uncertainties of sham surgery, RCTs can compare alternative surgical procedures, or can compare surgical treatment to no treatment or non-surgical treatment. So long as a state of clinical equipoise exists between the procedures being tested, randomization is generally considered ethical.<sup>51</sup> Recruitment times can be shortened by leveraging large facilities with high patient volumes, or by coordination among multiple facilities at the national or international level, as is often done with pharmaceutical trials.

#### 4. Dispersed Industry Structure

While the perceived adequacy of existing regulation combined with patient and procedure heterogeneity and challenges in conducting RCTs may begin to explain why surgery has not yet been directly regulated, the most important explanation may be a matter of industry structure. Unlike the pharmaceutical industry, where a manufacturer can centrally mass-produce a drug and sell it on a national or global scale, the surgical marketplace is composed of numerous small and relatively independent surgeons for whom centralized production is impractical and for whom

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<sup>45</sup> Sally Rudicel & John Esdaile, *The Randomized Clinical Trial in Orthopaedics: Obligation or Option?*, 67-A J. BONE & JOINT SURGERY 1284, 1288 (1985).

<sup>46</sup> See generally Bruce M. Psaty & Ross L. Prentice, *Minimizing Bias in Randomized Trials: The Importance of Blinding*, 304 JAMA 793 (2010).

<sup>47</sup> See, e.g., M.K. Campbell et al., *Developing a Placebo-Controlled Trial in Surgery: Issues of Design, Acceptability and Feasibility*, TRIALS 12:50, 4 (2011).

<sup>48</sup> See generally Alex John London & Joseph B. Kadane, *Placebos that Harm: Sham Surgery Controls in Clinical Trials*, 11 STAT. METHODS MED. RES. 413 (2002); Ruth Macklin, *The Ethical Problems with Sham Surgery in Clinical Research*, 341 NEW ENG. J. MED. 992 (1999).

<sup>49</sup> See Fairbank, *supra* note 9, at 257.

<sup>50</sup> See Michael Baum, *Reflections on Randomised Controlled Trials in Surgery*, 353 LANCET S16, S16 (1999); Rudicel & Esdaile, *supra* note 45, at 1292.

<sup>51</sup> Patrick J. McDonald et al., *Ethical Issues in Surgical Research*, 53 CAN. J. SURGERY 133, 134 (2010).

declining marginal costs are less important. The industry therefore suffers from a type of collective action problem: while surgical practice as a whole might benefit from comparative studies of safety and efficacy, individual surgeons have no means of recouping investment costs via centralized sale, and there is not yet a simple, low-cost means for coordinating research activities among dispersed surgeons or medical facilities.

## 5. Patent Law

A special statutory provision that prohibits enforcement of surgical patents further complicates the recovery of investment costs. Patents protect drugs for twenty years from the date of patent filing (which often occurs several years before FDA approval), providing pharmaceutical companies the exclusive right to sell their product for a limited period of time.<sup>52</sup> The right to exclude others from selling competing products enables the patent holder to charge higher prices during the exclusivity period. Patents may be obtained to cover almost any type of subject matter, including not only products but also processes, such as methods of treating a disease or manufacturing a pharmaceutical ingredient.<sup>53</sup>

Patents on surgical methods, however, were substantially limited by statute in the 1990s following the high-profile dispute of *Pallin v. Singer*.<sup>54</sup> In that case, Arizona ophthalmic surgeon<sup>55</sup> Dr. Samuel Pallin obtained a patent on a method of performing cataract surgery that did not require stitches, thereby avoiding suture-induced astigmatism.<sup>56</sup> He reportedly envisioned a modest \$5 royalty on the \$1000 procedure, which was less than the \$17 cost of sutures,<sup>57</sup> but opponents observed that surgical patents nevertheless increase costs, limit the ability to conduct further academic research, and could cause some physicians to rationalize the use of an inferior procedure rather than pay a licensing fee, among other concerns.<sup>58</sup> Following a patent infringement suit by Dr. Pallin against Dr. Singer and the medical center where Singer worked, the American Medical Association and other physician groups successfully lobbied Congress to prohibit such patents.<sup>59</sup> In 1996, a provision was

<sup>52</sup> 35 U.S.C. § 154(a)(2) (2017).

<sup>53</sup> *Id.* § 101 (2017).

<sup>54</sup> *Pallin v. Singer*, No. 5:93-202, 1995 WL 608365 (D. Vt. May 1, 1995).

<sup>55</sup> Sabra Chartrand, *Why Is this Surgeon Suing?*, N.Y. TIMES (June 8, 1995), <http://www.nytimes.com/1995/06/08/business/why-is-this-surgeon-suing.html>.

<sup>56</sup> U.S. Patent No. 5,080,111 (issued Jan. 14, 1992).

<sup>57</sup> See Chartrand, *supra* note 55.

<sup>58</sup> *Patenting of Medical Procedures*, House of Delegates Proceedings, 144th Annual Meeting, June 18-22, 1995, Reports of Council on Ethical and Judicial Affairs, 200-06, <http://ama.nmtvault.com/jsp/browse.jsp>.

<sup>59</sup> Eric M. Lee, 35 U.S.C. § 287(c)—*The Physician Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 701, 702-04 (1997).

enacted that, while not barring surgical patents per se, prohibits their enforcement against the surgeon or the hospital in which the surgery is performed<sup>60</sup> (device manufacturers or others who induce infringement by physicians might still be liable<sup>61</sup>). By substantially reducing the ability of patent holders to monetize surgical patents, the 1996 law makes it more difficult to recoup investment costs needed to rigorously study those procedures, thereby contributing to the collective action problem mentioned above.

To address the challenges posed by industry structure and patent law, a publicly-funded organization such as the National Institutes of Health (NIH) could conduct or fund studies. Alternately, Congress could create financial incentives for private entities to study surgical procedures, as it has done to promote the study and development of drugs for rare diseases, a therapeutic category for which profitability and patient recruitment can be similarly problematic.<sup>62</sup> The government might also coordinate or facilitate the private coordination of “platform trials” to lower the transaction costs of bringing together surgical researchers who are addressing similar conditions with different approaches. Platform trials contain a single master protocol across experimental treatment arms, such that each arm shares a common statistical analysis plan and predefined efficacy criteria.<sup>63</sup> Similarly, the federal government could promote the creation of data-sharing platforms that would allow surgeons and patients to voluntarily contribute data in a standardized format that could then be aggregated and analyzed. The Precision Medicine Initiative, launched by President Obama in 2015, reflects this latter approach by encouraging private healthcare entities to use open, standardized application program interfaces that allow individual patients to contribute their data to research.<sup>64</sup>

## 6. No Interstate Commerce

Under the U.S. Constitution, the federal government has broad power to regulate interstate commerce, while regulation of *intrastate* commerce is entrusted to the states.<sup>65</sup> Although it is not always clear

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<sup>60</sup> Act of Sept. 30, 1996, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (1996) (creating 35 U.S.C. § 287(c)).

<sup>61</sup> See Elizabeth Moulton, Note, *Inducing Immune Infringement: The Interplay of Section 287(c) and Section 271(b)*, 13 COLUM. SCI. & TECH. L. REV. 206, 225–27 (2012).

<sup>62</sup> H.R. Rep. 97-840(I), at 12 (1982).

<sup>63</sup> Benjamin R. Saville & Scott M. Berry, *Efficiencies of Platform Clinical Trials: A Vision for the Future*, 13 CLINICAL TRIALS 358, 364 (2016).

<sup>64</sup> THE WHITE HOUSE OFFICE OF THE PRESS SECRETARY, FACT SHEET: OBAMA ADMINISTRATION ANNOUNCES KEY ACTIONS TO ACCELERATE PRECISION MEDICINE INITIATIVE (Feb. 25, 2016), <https://www.whitehouse.gov/the-press-office/2016/02/25/fact-sheet-obama-administration-announces-key-actions-accelerate>.

<sup>65</sup> U.S. CONST. art. I, § 8, cl. 3.

which business activities constitute interstate versus intrastate commerce, the practice of medicine has traditionally not been considered interstate commerce,<sup>66</sup> limiting the power of the federal government to regulate medicine, including surgery. The creation of an FDA analogue to regulate surgery, or an attempt to grant surgery regulation powers to the FDA itself, would therefore face legal uncertainty.

Nevertheless, the Constitution does not serve as a complete bar to regulation. Regulation may originate in state legislatures, so long as it is carried out in a manner that does not impose an undue burden on interstate commerce.<sup>67</sup> In addition, the federal government can regulate surgical research where that research is federally funded or conducted by a federal agency, as it has done by promulgating the Common Rule for the protection of clinical trial subjects.<sup>68</sup> Finally, the Constitution does not limit the federal government's ability to conduct or fund research through agencies such as the NIH.

### *B. Understanding Current Deficiencies*

Surgeons ideally recommend surgical procedures based on evidence of the safety and effectiveness of the available options, in light of a patient's particular circumstances. Unfortunately, available evidence may be sparse or inadequate, in part because there is no regulatory framework that systematically requires evidence to support the use of a particular procedure. As a result, reports of surgical procedures and outcomes may be generated, if at all, according to the varying interests and uncoordinated efforts of disparate surgeons or researchers.

The surgical literature may therefore be deficient simply by its absence. When studies are available, it may be difficult to make appropriate treatment decisions, for example, because the various reports do not describe surgical indications precisely or consistently. Important details of surgical procedures may not be reported or the number of patients may be too small to draw reliable conclusions. Researchers attempting to undertake meta-analyses may be frustrated by inconsistent protocols, such as where patient outcomes are measured at different times or using different scales, or where patient demographics vary widely between studies. Such study design and reporting attributes can produce data that are difficult to interpret or compare, leaving the surgeon with a confusing and inconclusive body of literature.

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<sup>66</sup> *Slocum v. City of Fredonia*, 8 P.2d 332, 334 (Kan. 1932); see generally Lainie R. Rutkow & Jon S. Vernick, *The U.S. Constitution's Commerce Clause, the Supreme Court, and Public Health*, 126 PUB. HEALTH REP. 750 (2011).

<sup>67</sup> *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 585 (1996).

<sup>68</sup> 45 C.F.R. § 46.101(a) (2016).

The literature addressing surgical correction of Haglund's deformity, a protrusion of bone on the back of the heel, provides an example of potential shortcomings. Although journal articles addressing Haglund's deformity date at least as far back as 1928,<sup>69</sup> the nearly nine decades since have produced mostly low-quality evidence such as case reports or suggested surgical techniques and lack data that can be systematically evaluated. In 2012, Wiegerinck et al. published results of a systematic review of the Haglund's deformity literature, with the goal of "provid[ing] a clear overview of the best available surgical treatment modality for chronic RB [retrocalcaneal bursitis]."<sup>70</sup> Although their literature search terms produced 876 unique articles, only fifteen (1.7%) retrievable articles reported relevant data for at least ten patients and included as study outcomes either a pain scale, American Orthopaedic Foot & Ankle Society score, or patient satisfaction.<sup>71</sup> None was prospective, randomized, and controlled, and Wiegerinck et al. classified all fifteen studies as either of "low" or "very low" quality on the Downs and Black<sup>72</sup> quality assessment scale, with a weighted mean score for the fifteen studies of 13.3 points out of a possible 32 points.<sup>73</sup>

Variation in study design further frustrated comparison and analysis. Follow up times within the fifteen studies ranged from three months to 240 months.<sup>74</sup> Average patient age among the studies ranged from twenty to fifty-seven years.<sup>75</sup> The non-weight bearing period following surgery ranged from zero (i.e., immediate weight bearing) to eight weeks.<sup>76</sup> Different outcome questionnaires were used and outcome measures were heterogeneous, making the classification of outcomes across studies into "excellent," "good," "fair," and "poor" difficult to interpret.<sup>77</sup> Three studies reported an endoscopic surgical technique while twelve used an open technique.<sup>78</sup> Within those twelve studies, fourteen different surgical approaches were evaluated (some studies reported the results of more than one approach).<sup>79</sup> Variables potentially related to patient outcome were not systematically varied, explained, or even re-

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<sup>69</sup> Patrik Haglund, *Beitrag Zur Klinik der Achillessehne* [Article for the Achilles' Heel Clinic], 49 ZEITSCHRIFT FÜR ORTHOPAEDISCHE CHIRURGIE 49 (1928) (Ger.).

<sup>70</sup> Johannes I. Wiegerinck et al., *Surgical Treatment of Chronic Retrocalcaneal Bursitis*, 28 J. ARTHROSCOPY & RELATED SURGERY 283, 283 (2012).

<sup>71</sup> *Id.* at 284.

<sup>72</sup> Sarah H. Downs & Nick Black, *The Feasibility of Creating a Checklist for the Assessment of the Methodological Quality Both of Randomised and Non-Randomised Studies of Health Care Interventions*, 52 J. EPIDEMIOLOGY & COMMUNITY HEALTH 377 (1998).

<sup>73</sup> See Wiegerinck et al., *supra* note 70, at 285.

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

ported.<sup>80</sup> For example, because only one study reported whether the retrocalcaneal bursa was removed, researchers were left with little evidence as to the impact of bursa excision on patient outcome.<sup>81</sup>

### C. *Improving Evidence Through Increased Surgical Regulation*

The federal government could act to address current deficiencies in the surgical literature, such as by identifying evidence gaps and generating data to fill those gaps. As a second-best alternative, regulation could maximize the value of information currently generated by existing patient populations by promoting or requiring federal adverse event reporting, standardizing terminology, and facilitating analysis of existing health record databases.

#### 1. Identifying Gaps, Data Generation

Congress could task a government body, such as the Agency for Healthcare Research and Quality (AHRQ), with identifying gaps in the available literature and generating evidence where needed. The AHRQ is already statutorily empowered to conduct research that develops and presents scientific evidence regarding the outcomes and effectiveness of health care practices, including surgery.<sup>82</sup> The agency could be specifically directed, for example, to identify the most common or important medical conditions for which surgery is potentially indicated as well as the surgical and non-surgical treatments for these conditions, and to synthesize the available evidence with respect to the outcomes associated with these treatments. Where efforts by the AHRQ show the evidence to be insufficient, the AHRQ or another government agency could be directed to undertake or fund studies to produce relevant data.

Studies already undertaken by the AHRQ confirm the need for such data generation. In a systematic review commissioned by the AHRQ addressing surgical and non-surgical treatment of rotator cuff tears, the review found it was not possible to reach firm conclusions as to the value of the various treatment options due to such factors as sparse data, low study quality, incomplete follow-up, the absence of control groups, high risks of bias, and other problems.<sup>83</sup> In particular, the review noted a paucity of evidence with respect to the key variable of early versus delayed surgery, an important consideration for healthcare providers when advis-

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<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> 42 U.S.C. §§ 299, 299b-5(a)(3) (2016).

<sup>83</sup> See MARY BUTLER ET AL., AGENCY FOR HEALTHCARE RESEARCH & QUALITY, PUB. NO. 13-EHC050-EF, NONOPERATIVE AND OPERATIVE TREATMENTS FOR ROTATOR CUFF TEARS: FUTURE RESEARCH NEEDS (Feb. 2013), <https://effectivehealthcare.ahrq.gov/ehc/products/505/1394/rotator-cuff-tears-future-130627.pdf>.

ing patients whether to pursue non-operative options before turning to surgery.<sup>84</sup> Despite recognition of the lack of evidence, a follow-up report four years after the initial review found very few studies had subsequently been published.<sup>85</sup>

## 2. Improving Data Capture Through Adverse Event Reporting

A relatively simple measure to capture high-level adverse event data associated with surgical procedures is to require surgeons or hospitals to report adverse event data to a government body tasked with monitoring such data. Models for facilitating similar data capture already exist in the context of pharmaceuticals and medical devices, where the Federal Adverse Event Reporting System<sup>86</sup> (pharmaceuticals) and Manufacturer and User Facility Device Experience<sup>87</sup> (devices) allow physicians, and require manufacturers, to report serious adverse events to the FDA. A similar system could be implemented in the surgical context. Although some states already require reporting of adverse events following surgery,<sup>88</sup> state-level efforts are generally focused on capturing and preventing adverse events that result from serious errors, such as performing surgery on the wrong part of the body or on the wrong patient, rather than on determining whether one surgical option results in better outcomes or more serious or more frequent adverse events than another, even when each is properly performed.<sup>89</sup> Moreover, each state captures only a portion of the surgical adverse event data generated nationwide each year, making it difficult to evaluate less common surgical interventions.

## 3. Improving Data Quality Through Standardization

To the extent that government funded research and data capture are infeasible or inadequate, the federal government could take steps to enhance the utility of data generated by researchers who are already active in conducting studies. Standardized terms could be encouraged for medi-

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<sup>84</sup> *Id.* at ES-1.

<sup>85</sup> Agency for Healthcare Research & Quality, *Comparative Effectiveness of Non-Operative and Operative Treatments for Rotator Cuff Tears 3* (Mar. 20, 2014), <https://effectivehealthcare.ahrq.gov/ehc/assets/File/rotator-cuff-tear-nomination-140925.pdf>.

<sup>86</sup> U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS ON FDA'S ADVERSE EVENT REPORTING SYSTEM, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm2007060.htm> (last visited Aug. 4, 2017).

<sup>87</sup> U.S. FOOD & DRUG ADMIN., MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE DATABASE, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm> (last visited Aug. 4, 2017); *Medical Device Reporting*, FDA, <https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/#voluntary> (last visited Aug. 4, 2017).

<sup>88</sup> *See, e.g.*, N.Y. PUB. HEALTH LAW § 230-d(4) (McKinney 2016).

<sup>89</sup> *See* DANIEL R. LEVINSON, DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF THE INSPECTOR GENERAL, ADVERSE EVENTS IN HOSPITALS: STATE REPORTING SYSTEMS, Dec. 2008, at 22.

cal conditions, procedures, devices, and techniques to reduce confusion and increase cross-study comparability.<sup>90</sup> For example, where multiple terms are used to describe a single medical condition (e.g., “myocardial infarction,” “heart attack”), meta-analyses of the existing literature may fail to capture all relevant data where less common terms are used (e.g., “cardiac infarction”).<sup>91</sup> Similarly, where different reports use imprecise terms or terms for which meaning has changed over time, it may be difficult to determine whether outcomes are comparable, or whether they can be appropriately combined into pooled analyses.

The clear benefit of a consistent vocabulary combined with the general absence of federal regulation has left a gap that others have already begun to fill. In 2007, nine charter countries<sup>92</sup> established the International Health Terminology Standards Development Organisation (IHTSDO) to promote the consistent use of clinical terminology.<sup>93</sup> In the United States, the National Library of Medicine (NLM), a part of the NIH<sup>94</sup> and also the U.S. representative to IHTSDO, serves as the national coordinating body for clinical terminology standards such as the IHTSDO’s Systematized Nomenclature of Medicine (SNOMED) and the World Health Organization’s (WHO) International Statistical Classification of Diseases and Related Health Problems (ICD).<sup>95</sup>

Despite the efforts of NLM, IHTSDO, WHO and others at achieving a uniform lexicon, concern over inadequate standardization of terminology remains.<sup>96</sup> Regulations could disseminate standardized terminology more effectively, or require aspiring researchers to acknowledge their intent to follow identified standards (such as those of IHTSDO) as a condition of receiving federal funding.

More ambitious regulation might extend standardization to test variables, study protocols, and outcome measures via recommended guide-

<sup>90</sup> See generally James J. Cimino, *Desiderata for Controlled Medical Vocabularies in the Twenty-First Century*, 37 *METHODS INFO. MED.* 394 (1998).

<sup>91</sup> See Russell Buchanan & Marc Koehn, *Building the Business Case for SNOMED CT*, INT’L HEALTH TERMINOLOGY STANDARDS DEV. ORG., 2014, at 17.

<sup>92</sup> *Member Countries*, SNOMED INT’L, <http://www.snomed.org/about/member-countries> (last visited Feb. 28, 2017).

<sup>93</sup> *Objectives and Results*, SNOMED INT’L, <http://www.ihtsdo.org/about-ihtsdo/objectives-and-results> (last visited Feb. 28, 2017).

<sup>94</sup> NAT’L INST. OF HEALTH, LIST OF NIH INSTITUTES, CENTERS, & OFFICES, <https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices> (last visited Feb. 28, 2017).

<sup>95</sup> *NLM Health Data Standards Executive Summary for 2015*, NAT’L LIBRARY OF MED., Jan. 15, 2016, <https://www.nlm.nih.gov/healthit/executive-summaries/2015/index.html>; *United States*, SNOMED.ORG, <http://www.ihtsdo.org/member/United-states> (last visited Feb. 28, 2017).

<sup>96</sup> See, e.g., Eivind Berge, *Can We Agree on a Standard Terminology for Catheter-Based Interventions for Acute Ischemic Stroke?*, 45 *STROKE* e42, e42 (2014); Philip J. Kroth et al., *Using LOINC to Link Ten Terminology Standards to One Unified Standard in a Specialized Domain*, 45 *J. BIOMEDICAL INFORMATICS* 674 (2012).



lines. For example, for each condition routinely addressed by surgery, a government regulator might establish suggested test variables to be reported (e.g., patient age, duration of symptoms), study protocols (e.g., time until follow-up), and outcome measures (e.g., Numerical Rating Scale for pain). Based in the United Kingdom, the publicly-funded COMET Initiative has already made efforts to achieve such standardization through the development of “core outcome sets” that represent the minimum outcomes that should be measured and reported in all clinical trials.<sup>97</sup>

#### 4. Big Data Analytics

The 64 million surgical procedures performed each year generate a tremendous volume of data that could serve to illuminate safety and efficacy, given a means of capturing and analyzing it. Congress has already recognized the value of incorporating patient feedback, as reflected in its recent enactment of the 21st Century Cures Act, which requires the FDA to consider the use of “patient experience data” in regulatory decision-making.<sup>98</sup> Congress has also directed the FDA to establish a post-market risk identification system, known as Sentinel, based on the analysis of patient records, including health insurance claims records.<sup>99</sup> The Sentinel initiative has resulted in the creation of an infrastructure for systematically mining databases of hospitals and insurance companies for information that can help to identify drug risks.<sup>100</sup> Although not without limitations, such as incomplete reporting and data quality problems, the Sentinel initiative could provide lessons on how best to mine large data sets to generate patient-relevant safety and efficacy data associated with surgical procedures.

### CONCLUSION

Systematic evaluation of both existing and innovative surgical procedures is needed to make important safety and efficacy data available to surgeons, facilitating optimal treatment decisions. High quality risk-benefit data is also essential if the healthcare system is to honor its obligation to inform patients of relevant benefits and risks prior to obtaining their consent to treatment.

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<sup>97</sup> *Overview*, COMET INITIATIVE, <http://www.comet-initiative.org/about/overview> (last visited Aug. 4, 2017).

<sup>98</sup> Pub. L. No. 114-255, §§ 3001–3004, 130 Stat. 1033, 1083–86 (2016) (codified at 21 U.S.C. § 360bbb-8c).

<sup>99</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 944 (2007) (codified at 21 U.S.C. § 355(k)(3)(B) (2016)).

<sup>100</sup> Jonathan J. Darrow, *Crowdsourcing Clinical Trials*, 98 MINN. L. REV. 805, 839–42 (2014).

Yet for a variety of reasons, surgical procedures are not subject to direct regulation. As a result, surgeons consulting the available literature may find it inadequate to answer fundamental questions about optimal treatment choices. This failure of information increases the chance that, for years or even generations, patients will undergo painful or risky surgeries until further study eventually exposes them as either inferior to alternatives, or worse, as causing more harm than good. Unfortunately, history has repeatedly borne witness to such medical embarrassments, from the centuries-old practice of bloodletting to the disconcertingly recent examples of radical mastectomies and autologous bone marrow transplants, among many others.<sup>101</sup>

The federal government is well-positioned to support needed surgical research activities at the national level, both through the identification of evidence gaps and the funding of studies to fill those gaps. The government is also well-positioned to coordinate the private surgical research marketplace through activities such as the aggregation of country-level adverse event data and the setting of standards for medical terminology and guidelines for study protocols. In partnership with state governments and private organizations, the federal government can contribute to appropriate regulation that improves evidence development without imposing disproportionate burdens on surgeons or others.

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<sup>101</sup> RICHARD A. RETTIG ET AL., FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER (2007); J. Bruce Moseley et al., *A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee*, 347 NEW ENG. J. MED. 81 (2002); Joel Braslow, *Therapeutic Effectiveness and Social Context: The Case of Lobotomy in a California State Hospital, 1947–1954*, 170 W.J. MED. 293 (1999); HJM Barnett et al., *Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke: Results of an International Randomized Trial*, 313 NEW ENG. J. MED. 1191 (1985); J.L. Turk & Elizabeth Allen, *Bleeding and Cupping*, 65 ANN. ROYAL C. SURGEONS ENG. 128 (1983); Umberto Veronesi et al., *Comparing Radical Mastectomy with Quadrantectomy, Axillary Dissection, and Radiotherapy in Patients with Small Cancers of the Breast*, 305 NEW ENG. J. MED. 6 (1981); Leonard A. Cobb et al., *An Evaluation of Internal-Mammary-Artery Ligation by a Double-Blind Technic*, 260 NEW ENG. J. MED. 1115 (1959).