

on the use of antireflux medications overestimates the failure rate. Fourth, for an operation that usually requires a 23-hour stay, surgeon's volume rather than the hospital volume should be assessed.

In conclusion, we think that laparoscopic antireflux surgery, when performed for the proper indications by expert surgeons, is an effective treatment as it offers complete relief of symptoms to the majority of patients.

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In Reply We do not believe that our view of the use of antireflux surgery is very different from that of Drs Patti and Schlottmann, but we would like to respond to the 4 potential limitations of the study that were brought to our attention.

First, it is correct that we had no information about the preoperative workup of each individual in this large cohort of patients. However, it is mandatory to conduct a careful preoperative assessment of each patient considered for antireflux surgery in Sweden, including symptom assessment, endoscopy, and 24-hour manometry and pH measurement. Only patients with objectively verified gastroesophageal reflux disease who have not benefited from medical treatment with proton pump inhibitor are considered for antireflux surgery. Second, we agree that antireflux surgery is often conducted in individuals with particularly severe symptoms or with incomplete relief of symptoms using medical therapy. Considering this, we also agree that the rate of reflux recurrence after antireflux surgery was indeed low in our study, even lower than in most previous studies on this topic, despite the complete follow-up of an unselected cohort.

The third comment concerns our assessment of recurrence of reflux after antireflux surgery. Assessing the presence or absence of gastroesophageal reflux disease is

sometimes difficult, but both endoscopy and 24-hour pH measurement have low sensitivity and specificity to assess this disease. Assessment of reflux symptoms also has a limited specificity, but it has a considerably higher sensitivity. Thus, current guidelines recommend that the diagnosis of gastroesophageal reflux disease is best established using typical reflux symptoms.¹ Based on this, we believe that reflux symptoms and use of antireflux medication are still the best currently available means of defining reflux recurrence after antireflux surgery. Fourth, Patti and Schlottmann suggest that surgeon volume would be a better assessment than hospital volume when evaluating the role of annual antireflux surgery volume. We did not have data on the individual operating surgeon, and hospital volume is still a reliable measure of annual surgery volume. Additionally, surgeon volume and hospital volume usually correlate quite strongly, particularly in Sweden where each department of surgery that conducts laparoscopic antireflux surgery contains very few surgeons specialized in antireflux surgery.

We agree that laparoscopic antireflux surgery is an excellent and probably underused treatment in many patients with gastroesophageal reflux disease, but patients and surgeons should be aware of the risk of recurrence.

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Self-regulation of the Medical Profession and Maintenance of Certification

To the Editor The Viewpoint¹ regarding maintenance of certification (MOC) requirements and Texas Senate bill (SB) 1148 asked practicing physicians to make a leap of faith that many cannot accommodate. Unfortunately, that leap of faith is central to the author's argument.

As Dr Johnson pointed out, self-regulation is a core attribute of the learned professions. It encompasses the responsibility and authority to establish and enforce standards of education, training, and practice. Physicians routinely defend that responsibility and authority in advocating against the intrusion of all third parties (such as government, private insurers, or hospital administrators) into the practice of medicine.

However, as evidenced by their comments at the Texas Medical Association and American Medical Association House of Delegates and at the committee hearings on SB 1148, many physicians today simply do not acknowledge the certifying boards as "self." They are, instead, profit-driven organizations beholden to their own financial

interests.² The MOC process is too expensive,³ requires physicians to take too much time away from their patients and families, and, most importantly, lacks sufficient research to document the benefits to patient care. Many physicians say the information studied and tested has little applicability to their day-to-day practice.⁴

Thus, the certifying boards, for all their talk of ensuring physician competence in a world of rapidly expanding scientific and clinical knowledge, are not “self.” In fact, they are now one of the outsiders intruding into the practice of medicine.

Until and unless the boards acknowledge their position as outsiders and completely overhaul their processes, finances, and lack of transparency, physicians in Texas and across the nation will have no choice but to continue to seek statutory defenses against these third-party intrusions into the medical profession.

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To the Editor Dr Johnson opposed Texas SB 1148, legislation negating most economic and professional consequences of MOC nonparticipation.¹ Several statements presented in support of this position are debatable.

The Viewpoint stated that MOC participation is “associated with improved patient care.” However, in the study cited, MOC participation had no effect on the primary end point, ambulatory care-sensitive hospitalizations among Medicare beneficiaries.² More generally, data linking MOC participation to clinically important outcomes is lacking for most disciplines.³ It is difficult to argue that SB 1148 will have any discernable effect on health outcomes based on current evidence.

Similarly, it is asserted that “participation in MOC can instill a sense of professional responsibility and a measure of confidence” and that patients expect “physicians to undergo periodic recertification.”¹ However, in a 2015-2016 survey, most physicians viewed MOC activities as burdensome, of limited relevance, and chiefly as a vehicle for specialty boards to generate revenue.⁴ Not surprisingly, these respondents thought that MOC status was of little consequence to patients.

Furthermore, Johnson argued that SB 1148 “weakens the claim to self-regulation” by the profession. This argument

would be more compelling if there existed greater alignment between those organizations dedicated to ensuring the competence of physicians (ie, the educational community) and those responsible for professional oversight (ie, state licensing boards). Such alignment is virtually nonexistent. For example, although board certification eligibility for a primary care specialty requires 3 years of postgraduate education (the fewest years of training of any specialty), physicians can practice independently after completing a 1-year internship in most states.⁵ This disconnect suggests that the profession's claim to self-regulation is already weak; anti-MOC legislation simply exemplifies this weakness.

Finally, the Viewpoint characterized the passage of SB 1148 as a “pyrrhic” victory that may establish “a precedent for additional governmental intervention into the practice of medicine.”¹ An alternative interpretation is that SB 1148 is the culmination of a strategic political grassroots organization in response to an issue about which physicians feel tremendous passion, and represents pushback against national entities perceived as out-of-touch, unresponsive, and conflicted. Statutes comparable with SB 1148 have now been enacted in several states. By liberating physicians to pursue continuous professional development activities tailored to their individual practices, such legislation has the potential to enhance both quality of care and professional satisfaction.

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In Reply I agree with Dr Cardenas' statement that self-regulation is a “core attribute of the learned professions.” No doubt it is one of the principal reasons why more than 800 000 licensed US physicians have elected to be certified by a board of the American Board of Medical Specialties.¹ I also agree with him and with Dr Freeman that there is a level of disaffection with the certifying boards that stems in part from concerns related to the relevancy of MOC as well as board “processes, finances, and lack of transparency.” To that end, certifying boards are making concerted

efforts to improve the MOC experience and to respond to these valid concerns.² For example, the American Board of Internal Medicine (ABIM) recently reorganized its governance structure.³ This effort was undertaken in part to enhance program relevancy by increasing the number of practicing nonacademic physicians participating at all levels of governance. More than 70% of current ABIM governance members spend more than half their time in clinical care. Over the past 3 years, ABIM staff has changed examination blueprints in all disciplines based on critical review by thousands of physicians across the country.⁴ Earlier this year, in response to diplomate feedback, ABIM announced plans to roll out 2-year Knowledge Check-Ins taken at home or in the office as an option to the traditional MOC examination.⁵ To ensure full transparency, comprehensive ABIM financial information—including tax form 990 and the audited financial statement—is freely available online, along with a reader's guide to help interested parties find the information of interest.⁶ Of note, ABIM carries a platinum rating for transparency from GuideStar, a designation attained by less than 0.1% of all nonprofit organizations. I believe these actions are indicative of the good faith efforts certifying boards are pursuing to address the specific concerns outlined by Cardenas and Freeman.

Freeman suggests self-regulation is already weakened due to a misalignment between medical licensure and specialty competence. He is correct that state medical boards determine an individual's legal ability to practice "medicine and surgery," but physicians, through their specialty boards, define and curate the standards that define familiar disciplines (eg, ophthalmology or cardiology) and are widely used to create public confidence that physicians are actually trained to do what they do. In theory, without established specialty standards, any licensed physician would be free to perform a laser procedure or administer chemotherapy or perform a heart transplant. Such was the state of affairs at the beginning of the 20th century—at the very time when physicians opted to create specialty boards to establish the standards that defined the specialties practiced today. Laws designed to weaken board certification do not advance the medical profession.

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The Nuremberg Code and Informed Consent for Research

To the Editor The Viewpoint by Dr Moreno and colleagues¹ understated the precedential value of the International Medical Tribunal's decision in the trial of Nazi doctors accused of war crimes that established the Nuremberg Code and the code's influence on common law development of the legal duty of researchers to secure informed consent from their research participants. The refusal in 1987 of the US Supreme Court, in the case of an army sergeant who had secretly been dosed 4 times and claimed to have been injured in an lysergic acid diethylamide (LSD) experiment, to adopt or apply the code is noninformative because the majority on the Court held that soldiers may not sue the government or military leadership for monetary damages for injuries sustained while serving. My review of case law identified 19 published opinions from state and federal courts (applying federal law as well as the laws of Arizona, Florida, California, Illinois, Maryland, Massachusetts, Michigan, New York, and Pennsylvania) that recognize the duty of researchers to secure an informed consent from research participants. Four of those courts favorably recited the International Medical Tribunal decision or the code among other sources for establishing the duty.²⁻⁵ Other sources cited include the Declaration of Helsinki, other professional codes of ethics, federal regulations, the special nature of the participant-researcher relationship, and perhaps most importantly, concerns about non-consensual invasions of bodily integrity.

Without exception, every court in which the issue has been presented on the merits has found that research participants have the right to consent. The only courts that have not so concluded are those that found plaintiffs' claims barred by statutes of limitation or other policies limiting the civil liability of the federal government. Although not binding and dispositive, the International Medical Tribunal's decision and the Nuremberg Code nonetheless are recognized authoritative sources of law for courts throughout the United States.

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