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Science, Politics, and Values: The Politicization of Professional Practice Guidelines

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the war of nature, from famine and death, the most exalted object which we are capable of conceiving, namely, the production of the higher animals, directly follows. There is grandeur in this view of life, with its several powers, having been originally breathed into a few forms or into one; and that, while this planet has gone cycling on according to the fixed law of gravity; from so simple a beginning endless forms most beautiful and most wonderful have been, and are being, evolved.1

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ten attributed to chronic Lyme infection; and the absence of benefit from, and the serious adverse effects of, long-term treatment. The CDC and National Institutes of Health concurred in the judgment that long-term antibiotic use is not justified: “despite extensive study, no clear evidence has emerged to support the contention that CLD results from a past or persistent Lyme disease infection.” American Academy of Neurology treatment guidelines for Lyme disease affecting the nervous system reached the same conclusion.

The International Lyme and Associated Diseases Society (ILADS), a CLD advocacy group, immediately protested and asserted the superiority of its alternative guidelines, which others have suggested were based on substandard review methods. Shortly after, Connecticut Attorney General Richard Blumenthal launched an investigation of IDSA’s guideline writing process, alleging it violated state antitrust laws by excluding differing viewpoints from its guideline creation process and including members who had financial interests in, or ties to, Lyme diagnostic and treatment makers. IDSA did disclose its panel members’ potential conflicts of interest in its published guidelines, even though there is no evidence that any conflicts altered the guidelines’ content. Meanwhile, the committee that created the ILADS guidelines included the president of a company that manufactures an alternative Lyme disease diagnostic test and multiple physicians whose practices are listed with a CLD advocacy group’s patient referral service—but ILADS did not disclose the conflicts in its guideline document.

Antitrust laws are designed to ensure legitimate commercial competition and protect against predatory corporate practices due to inappropriate restraints on trade. Professional organizations, such as IDSA, can violate antitrust laws if their standard-setting is an unreasonable attempt to advance their members’ economic interests by suppressing competition. Applying the antitrust “rule of reason,” a challenger must show that the professional organization both possesses substantial market power and that the anticompetitive effects of its standards outweigh patient benefits. Even assuming IDSA wielded sufficient market power through its nonbinding guidelines to meet the first part (which is questionable considering that insurers and clinicians can independently choose which treatments to cover and prescribe), the second part of the rule of reason cannot be met because IDSA guidelines substantially advanced patients’ interests.

The courts should defer to professional medical associations when standards are set on the basis of valid science aimed at protecting patient health or safety. A precisely on-point federal case (though one that does not bind Connecticut courts interpreting the state antitrust law) upheld the American Academy of Ophthalmology guidelines attaching the label “experimental” to radial keratotomy, a surgical procedure for correcting nearsightedness. “Antitrust law is about consumers’ welfare,” said the court, so ultimately professional guidelines are a “medical not a legal question.” That truism should decide antitrust cases, so that when a professional organization bases its work on the weight of science there can be no improper restraint of trade.

After spending more than a quarter of a million dollars on legal expenses, IDSA agreed to settle with the attorney general (without admitting any fault), assenting to an ombudsman-reviewed panel to assess the 2006 guidelines. While it is unlikely IDSA’s guidelines will change due to the investigation, the daunting potential for litigation by those unhappy with the outcomes of treatment guidelines may well chill the willingness of medical associations to make appropriate scientific evaluations of controversial topics—a development that would significantly threaten patient care and increase medical costs.

Science, Values, and Politics

At the heart of this controversy is the conflict between the positive nature of science and the normative function of value systems and political thought. Science is, and can only be, descriptive and explanatory. Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and whether that finding is replicable. The scientific process is not democratic—no amount of desire for different results can establish them—and inconsistent findings create true controversy only when their methods are of comparable validity.

At the same time, the sciences cannot be normative. They can establish context and a factual base for normative discourse, but scientific findings cannot entail any particular normative conclusion without reference to outside systems of thought. Science, for example, cannot resolve the never-ending debate over abortion in the United States. Medical science can describe the maternal health risks of pregnancy, elucidate fetal development, and establish risks of birth defects and complications. Nothing, however, inherently follows from any of these; rather, policy makers must look outside science, to moral, religious, ethical, and legal norms—eg, when aggregated cells become human life or what the relationship between citizens and their government should be. Medical science can, and should, inform these discussions, and in a vibrant and healthy society, such value questions will be vigorously debated.

However, all too often, the normative and positive blend into one another. Positive assertions are presented in a normative light—for example, that the cost of treating a condition surpasses a benchmark of cost-effectiveness, hence it should not be used. This really consists of 3 separate assertions: the cost of treatment equals a particular amount (a positive claim); treatments costing more than a certain amount are not cost-effective; and cost-effectiveness should guide the allocation of health care resources. All these claims may be justifiable, but only the first can be established through scientific methods.

The converse—when normative views are passed off as positive assertions—is even more problematic, such as the well-documented issue of abortion and breast cancer in the
Bush administration. Multiple adequately powered and well-designed and analyzed studies investigated the putative association between abortion and breast cancer and found no evidence of its existence. However, from 2002 to 2003, information was placed on the National Cancer Institute Web site suggesting a link between abortion and breast cancer, based largely on older epidemiologic studies that failed to sufficiently control for recall bias.15

The Connecticut attorney general’s action against IDSA falls into this latter category. The CLD advocacy community understandably seeks answers for the symptoms attributed to Lyme disease. But when high-quality research repeatedly was inconsistent with the group’s hypotheses, the community should have sought other answers. Instead, many advocacy organizations—and the attorney general—insisted (against the weight of evidence) on a link between the symptoms and chronic infection and continued to call for long-term antibiotic treatments. Even this was perhaps defensible—after all, medical studies cannot prove the non-existence of a phenomenon—although physicians in the CLD community should treat their patients based on the best-available evidence. But when political leaders using the force of law sued IDSA for its appropriate scientific conclusions that differed with the results they desired, they abused the public good.

A wall of separation is needed between science, norms, and politics. Science should inform normative discussions and provide the evidentiary base for political choices. Likewise, values will always be important in deciding how science is applied for human benefit. But neither should be permitted to distort the other—limits on the outer boundaries of what questions each can answer must be respected when making public policy. Medical science, and the health of patients who depend on it, are too important to be subjected to political ideologies.

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REFERENCES