

Connecticut Attorney General Investigation and Settlement Highlights Possible Applicability of Antitrust Standard Setting Law to the Development of Clinical Practice Guidelines



By Richard Wolfram¹

On May 1, 2008, the Office of the Connecticut Attorney General (“AG”) concluded an 18-month investigation and announced a settlement agreement with the Infectious Diseases Society of America (“IDSA”) regarding alleged anticompetitive practices by the IDSA in its development of clinical-practice guidelines for the diagnosis and treatment of Lyme disease.² The matter is unusual, and has been the subject of extensive coverage in the national and legal press,³ for its ostensible application of antitrust principles relating to standard setting—typically applied in a conventional commercial context—with respect to the competitive analysis of development of medical guidelines.

The matter raises several questions. Can antitrust principles be legitimately applied to the development of medical guidelines and, if so, in what circumstances? That is, what makes the development of medical guidelines, which are normally the result of medical, scientific debate and consensus by specialty professional associations, a matter susceptible to legal scrutiny? And given that the goal of medical guidelines is to promote consumer welfare in matters of health, what are the proper limiting principles on the application of the antitrust laws to medical guideline development? This article explores these questions from a first-hand

perspective on some of the possible antitrust theories behind the IDSA investigation and settlement, based on the views of various complainants regarding the IDSA’s conduct.⁴ Finally, the investigation and settlement send a cautionary note to professional medical specialty associations engaged in guideline development: such activity may be subject to legal scrutiny, and they therefore would be well advised to take the proverbial “ounce of prevention” by ensuring that their conduct conforms to the law, for the benefit of themselves and, ultimately, the intended beneficiaries of guidelines—health care consumers.

I. Parallel Developments: The Rising Prominence of Clinical Practice Guidelines and Antitrust Standard-Setting Principles

Clinical-practice guidelines—also referred to as medical guidelines, evidence-based guidelines, or clinical protocols—guide clinical decisions by providing criteria for diagnosis, management, and treatment of specific diseases and medical conditions. These guidelines are intended to summarize and integrate the best scientific evidence into their recommendations and standardize medical care. Most, if not all, professional medical specialty associations have established guideline committees or panels that have developed practice guidelines

pertinent to their areas of specialization. Since the 1990s, evidence-based guidelines have had a pronounced effect on health care, influencing not only clinical practice decision-making (increasingly, by limiting clinical discretion), but also insurers’ coverage of treatments and legal standards of care, which are applied in malpractice cases and used by state licensing boards and hospital credentialing committees to evaluate physicians.

When the relevant science is unsettled, medical guidelines commonly default to clinical discretion to preserve practitioner and patient choice and encourage medical innovation. Guidelines that restrict clinical discretion, however, are not merely informational; instead, they limit, if not eliminate, choice in the marketplace for medical treatment.

At the same time that medical guidelines have come to the fore in health care, there has also been an increasing number of revelations about financial conflicts of interest on the part of medical-guideline panelists, whose financial interests may have influenced their panels to reach incorrect or suspect results. This development has been widely reported on and is the subject of a growing body of scientific and public policy literature.⁵

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² See Press Release, Connecticut Attorney General’s Office, Attorney General’s Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guidelines, Install Independent Arbitrator (May 1, 2008), available at <http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284&pp=12&n=1> (hereinafter “CT AG Lyme Press Release”).

³ See, e.g., Philip Shiskin, *Medical Society Settles in Lyme Disease Dispute*, THE WALL STREET JOURNAL, May 2, 2008, at B4; Rachel Bull, *Medical guidelines found to be anti-competitive*, GLOBAL COMPETITION REVIEW, May 2, 2008; Jacqueline Bell, *Antitrust Lyme Disease Probe Sparks Debate*, COMPETITION LAW 360, June 12, 2008; *Medical Group Settles Probe into Guidelines for Lyme Disease*, 16 No. 2 Andrews Health L. Lit. Rep. 12 (June 26, 2008); Susan Landers, *Lyme treatment accord ends antitrust probe*, AM. MED. NEWS (June 9, 2008); Brian Kehrl, *Connecticut AG Calls for Review of Lyme Treatment Guidelines*, THE ENTERPRISE (May 9, 2008); Jane Brody, *A Threat in a Grassy Stroll: Lyme Disease*, N.Y. TIMES (July 15, 2008).

⁴ See *supra* note 1.

⁵ See, e.g., Richard Amerling et al., *Guidelines Have Done More Harm Than Good*, 26 BLOOD PURIFICATION 73 (2008); see, generally, JEROME KASSIRER, ON THE TAKE: HOW MEDICINE’S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (2004).

Recent prominent examples of commercial conflicts of interest influencing guidelines include the National Kidney Foundation’s panel that recommended erythropoietin in 2006, the American Society of Hypertension’s panel in 2006 that narrowed the parameters of “normal” blood pressure (while prominent panel members stood to benefit from increased sales of blood pressure-lowering drugs), and numerous examples of psychiatrists serving on guideline panels while benefiting financially from work on behalf of pharmaceutical companies making psychiatric drugs. See, e.g., Gardiner Harris & Janet Roberts, *Doctor’s Ties to Drug Makers are Put on Close View*, N.Y. TIMES (Mar. 21, 2007); Sheryl Gay Stohlberg, *Study Says Clinical Guidelines Often Hide Ties of Doctors*, N.Y. TIMES (Feb. 6, 2002).

In a parallel development, standard setting continues to play an extremely important, if unheralded, role in both high-tech and traditional industrial development. Standards can be de facto or the result of organized standards-development processes through standard-setting organizations (“SSOs”). Two of the most typical kinds of standards that SSOs develop are technological platform standards (e.g., CDMA or GSM in wireless communications) and safety standards (e.g., fire protection of electrical wiring). Standard setting typically yields significant procompetitive benefits and efficiencies, such as enhanced safety and interoperability with respect to certain technology.

Standard setting implicates antitrust principles because standard setting, by its very nature, pre-empts market choice: in developing a standard, members of an SSO—competitors and other economic actors engaged in the relevant market—are effectively making a decision for the market. By pre-empting competition in the market for the technology of choice, such as occurred between VHS and Beta video-recorder technologies in the 1980s, standard setting shifts the emphasis from the nature and quality of competition in the market to competition for the standard. Commensurately, antitrust law’s focus on the nature and quality of competition in the market turns, with respect to standard setting, on the nature and quality of competition for the standard. Since the 1980s, antitrust law has been applied to standard setting to ensure that SSOs are not “captured,” and competition subverted, through abuse of the standard-setting process.

In recognition of the procompetitive benefits and efficiencies of standard setting, antitrust law has been interpreted to give a qualified waiver to competitors in SSOs to exchange certain types of information and even to agree in advance on the cost of licensing technology that is incorporated into a standard, with certain limitations.⁶ But

antitrust law also provides a backstop for this activity, ensuring that it does not devolve into anticompetitive, exclusionary conduct. After all, private, competitive actors involved in the process are making decisions that may affect their economic interests. It is therefore imperative that SSO members with economic interests not bias the standard-setting process and stifle competition.⁷ Thus, whether intellectual property is at issue, as in patent “hold-up” cases,⁸ or not,⁹ the competitive principles of antitrust law require transparency, due process, compliance with SSO rules, and compliance with the common law principle of good faith and fair dealing. This ensures that competition for the standard itself is not distorted through economic actors’ exclusionary conduct, which, if unconstrained, can lead to their obtaining monopoly power. The rule-of-reason legal standard is applied in standard-setting cases because it weighs procompetitive benefits against alleged anticompetitive effects.

II. The Connecticut AG’s Lyme Investigation and Settlement: Where Medical Guidelines and Antitrust Standard-Setting Precedent Intersect

In light of the increased influence of guidelines on health care, the question arises: can the development of medical guidelines, which are intended to promote health and are not generally viewed as being influenced by economic interests, ever be sufficiently commercial in nature to violate the antitrust laws? The Connecticut AG’s answer appears to be “yes,” provided that the guidelines’ panelists have a material economic interest in the outcome of the guidelines-development process.

A. Central Dispute: Chronic Lyme Disease

The AG’s investigation focused on IDSA guidelines developed in 2000 and 2006 for the treatment of Lyme disease, a sometimes debilitating, tick-borne disease. Most controversially, these guidelines implicitly conclude that there is no scientific basis for “chronic Lyme disease,” a condition in

which patients suffer a range of ill effects for months or years. This conclusion is based on the view that the spirochete that carries the disease does not persist in the body long-term. As a result, the guidelines state that treatment with a course of antibiotics beyond 30 days is not appropriate and that persistent symptoms represent, at most, a “post-disease syndrome.” Although a substantial body of scientific and empirical studies reports that long-term antibiotic treatment can be effective and that the spirochete can persist in the body notwithstanding “standard” courses of antibiotics, the IDSA has dismissed these findings as unsubstantiated. Most insurance companies, citing the IDSA guidelines in support, deny coverage for antibiotic treatment beyond 30 days.¹⁰

In the view of various complainants and the AG, the guidelines effectively deny physicians the ability to use clinical discretion in diagnosing and treating Lyme disease, despite the IDSA’s general disclaimer that its guidelines are not mandatory. The guidelines also provide no additional treatment options, apart from palliative care, for patients who fail to improve under treatments identified by the IDSA’s protocol.

B. Complainants’ Legal Theory

In the view of the complainants, the IDSA, in combination with members of its Lyme disease guidelines panel, engaged in an unlawful refusal to deal in, and monopolization of, the market for the treatment of Lyme disease in violation of federal and state antitrust laws by abusing the guideline development process for Lyme disease and implementing the disease definition and treatment modality propounded by the resulting guidelines.

The complainants’ theory rests on the following claims: (1) the relevant product market is the treatment of Lyme disease; (2) members of the IDSA’s guideline panel on Lyme disease biased, and thus distorted, the standard-setting process by bringing their own commercial interests to bear and

⁶ See, e.g., Deborah Platt Majoras, Chairman, Fed. Trade Comm’n, Recognizing the Procompetitive Potential of Royalty Discussions in Standard Setting, (Sept. 23, 2005), www.ftc.gov/speeches/majoras/050923stanford.pdf.

⁷ See, e.g., *Allied Tube & Conduit v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988). *Allied Tube* teaches that the standard-setting process should be unbiased and ensure that no economic interests of persons engaged in the standard setting are permitted to subvert the process and stifle competition.

⁸ See, e.g., *Dell Computer Corp.*, 121 F.T.C. 616 (1996); *Union Oil Co. of California*, FTC Dkt. No. 9305 (2004) available at <http://www.ftc.gov/os/adjpro/d9305/index.shtml>; *Rambus*, FTC Dkt. No. 9302, Liability Opinion (2006), available at <http://www.ftc.gov/os/adjpro/d9302/060802commissionopinion.pdf>, rev’d, *Rambus v. Fed’l Trade Comm’n*, 522 F.3d 456, 468 (D.C. Cir. 2008); *Negotiated Data Solutions, LLC*, Dkt. No. 051-0094 (2007) available at <http://www.ftc.gov/os/caselist/0510094/index.shtml>; *Broadcom v. Qualcomm*, 501 F.3d 297 (3d Cir. 2007).

⁹ See, e.g., *Allied Tube*, 486 U.S. 492; *Am. Soc’y of Mech. Engr’s v. Hydrolevel Corp.*, 456 U.S. 556 (1982).

¹⁰ Quick Internet research shows that the disagreement between the IDSA and the opposing view on “chronic Lyme disease” is one of the most inflammatory and bitter disputes in contemporary medicine.

then excluding competing points of view (by stacking the panel and subsequently cutting off any debate, including by members of the panel); (3) this conduct resulted in guidelines that deny the existence of chronic Lyme disease as a separate diagnosis and exclude long-term antibiotics as an acceptable treatment; (4) the IDSA, the dominant professional association developing treatment guidelines for Lyme disease, has exercised market power through enforcement conduct intended to compel adherence to its guidelines; and (5) these actions have caused anticompetitive harm by limiting treatment options, foreclosing clinical discretion, and causing economic harm to physicians and chronic Lyme patients.

C. Findings of the Attorney General

According to the AG's press release, the investigation revealed "significant procedural deficiencies related to the IDSA's development of its 2006 Guidelines" and found that the panel and the IDSA failed to ensure that the guideline development comported with due process, as required by antitrust law when persons (or their association) involved in standard setting have an economic interest in the outcome.¹¹ In particular, the AG said the panel "improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science."¹²

The AG also found that:

- key panel members had significant conflicts of interest based on financial interests in drug companies regarding vaccine development, Lyme disease diagnostic tests, patents, and consulting arrangements with insurers and that these individuals "exclude[d] divergent medical evidence and opinion;"¹³

- the IDSA failed to conduct a conflict of interest review for any of the panelists prior to their appointment to the guideline panels;
- the IDSA did not comply with its own policies for selecting a panel chair, "enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;"
- the IDSA's 2000 and 2006 panels "refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease;"
- the IDSA "remov[ed] a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve 'consensus';"
- the IDSA "blocked appointment of scientists and physicians with divergent views on chronic Lyme;"
- the IDSA improperly sought to portray a second set of Lyme disease guidelines (issued by the American Academy of Neurology) as independently corroborating its findings, when the IDSA knew that the two panels shared key members in violation of the IDSA's own conflict of interest policy; and
- a number of insurers have used the IDSA guidelines as justification for denying reimbursement for long-term antibiotic treatment.¹⁴

Complainants also presented evidence that doctors wishing to reserve the option to treat with long-term antibiotics increasingly face the prospect of professional misconduct sanctions and the loss of hospital privileges; that far fewer doctors are now willing to provide long-term antibiotics to people suffering from long-term symptoms of Lyme disease; that the guidelines substantially foreclose clinical discretion regarding long-term antibiotic treatment; and that the resulting suppression of output and sharply

limited reimbursement by most insurance companies, in turn, have virtually foreclosed long-term antibiotics as a treatment option for significant numbers of patients.

D. Settlement Agreement: A Possible Model

Under the settlement agreement, the IDSA will form a new panel to reassess the guidelines. An ombudsman, who is a specialist in medical ethics and conflicts of interest, will be responsible for ensuring that no panel members have financial conflicts of interest. Physicians and researchers will make formal, public presentations to the panel, which will be aired live over the Internet. The panel will then determine, by supermajority vote, whether the science supports the guideline recommendations. The panel may vote to make no changes, modify the guidelines, or replace them entirely. The Connecticut AG retains general oversight over the process to ensure compliance with the settlement agreement.

III. Legal Analysis: The Conduct is Commercial in Nature, Exclusionary, and Has Contributed Substantially to the Alleged Anticompetitive Effects

Underlying the complainants' putative claims lies the substance of their antitrust theory, which is the focus of the rest of this article. The substantive points are examined here not as an anatomy of one putative case but to show, in some concrete detail, the antitrust principles applicable to the development of medical guidelines, which is a standard-setting process.

First, the IDSA panel's conduct was sufficiently commercial to trigger subject matter jurisdiction under the Sherman Act. Second, subversion of the IDSA's guideline development process constitutes exclusionary conduct under the Sherman Act. Third, the IDSA's and the panel's conduct was causally related to anticompetitive effects in the relevant market, leading to antitrust injury.¹⁵

¹¹ CT AG Lyme Press Release, *supra* note 2.

¹² *Id.*

¹³ Furthermore, in complainants' view, these economic interests were consistent with the guidelines' curtailment of recommended treatment beyond 30 days of antibiotics. Conflicts of interest in medical guidelines typically relate to panel members' commercial interests in drugs used for *treatment*. See *supra* text accompanying note 4. Here, the alleged conflicts pertain to panelists' commercial interests relating to vaccines, diagnostic tests, and insurance consultancies. Guidelines that restrict the disease definition favor vaccine manufacturers and developers because the guidelines increase the statistical rate of efficacy of the vaccines, so that fewer people taking the vaccine contract the disease. Guidelines that mandate testing to confirm a diagnosis promote the interests of those who develop and manufacture diagnostic tests. Here, the mandated test is widely alleged to be flawed, and the guidelines effectively deny that patients manifesting long-term symptoms are suffering from Lyme disease because they test negative. Finally, guidelines that effectively deny treatment to patients are favorable to insurance companies and specialists who consult for them.

¹⁴ CT AG Lyme Press Release, *supra* note 2.

¹⁵ Each of these elements, as a matter of alleged fact, would likely be disputed by the IDSA. The point here is not to try to prove the elements but to explain them as requirements of a putative case. Issues of petitioning immunity under the Noerr-Pennington doctrine may also arise, but are beyond the scope of this discussion.

A. The Conduct Must be Sufficiently Commercial to Trigger Subject Matter Jurisdiction Under the Sherman Act

For an antitrust claim regarding a professional association's development of guidelines to be viable, it must first be established that the antitrust laws apply to conduct of a professional association, such as the IDSA. Whether a professional association may be subject to antitrust scrutiny turns on whether its conduct is commercial or non-commercial in nature.¹⁶ But to say that conduct is, or is not, commercial in nature begs the question of how one makes such a determination. The courts seem to have no consensus test, apart from the need to classify conduct as commercial or non-commercial in light of the "totality of the surrounding circumstances."¹⁷ Some courts evaluate the question of commercial or non-commercial conduct on the basis of motive or intent, although this inquiry is fraught with difficulty. Nonetheless, one influential appellate court has advised that "if it had discerned a commercial intent it could well have concluded that the educational façade only camouflaged a scheme very much directed at commerce."¹⁸

In his seminal treatise on antitrust, Philip Areeda rejects intent or motive-based tests, describing them as "too difficult to employ and too easily manipulated, and involving prolonged, difficult discovery into underlying motive."¹⁹ Instead, he advocates an objective test: "[t]he most viable rule is a strong presumption that a boycott or other claimed antitrust violation is 'economic,' or commercial, when the antitrust defendants are likely to receive direct economic benefits as a result of any reduction in competition in

the market in which the target firm or firms operate."²⁰ *FTC v. Superior Court Trial Lawyers Association*²¹ supports this test. The D.C. Circuit concluded that "the claim that the boycott [by some 1,200 lawyers] was (at least ultimately) motivated in any important way by a 'political' concern . . . should be treated with skepticism in light of the obvious economic benefit to the participants."²² Applying this test, the Supreme Court found that "the undenied objective of [the] boycott was an economic advantage for those who agree[d] to participate . . . it is undisputed that their immediate objective was to increase the price that they would be paid for their services."²³

Under either the motive-based test or the *Superior Court Trial Lawyers-Areeda* objective test, the conduct of the IDSA panel was sufficiently commercial to trigger antitrust subject matter jurisdiction. The AG found that key panel members had significant conflicts of interest and, in the view of the complainants, their economic interests were consistent with the guidelines' curtailment of recommended treatment beyond 30 days of antibiotics.²⁴

B. Subversion of the Development of Medical Guidelines Can Constitute Exclusionary Conduct Under the Sherman Act

Because standard setting is an arrangement by which competitors agree to displace competition, the potential for anticompetitive harm is significant. The same is true of a professional association engaged in developing medical guidelines, where guideline panelists have an economic interest in the outcome. Where the association engaged in the standard setting

is dominant in the relevant market, it must take particular care to conduct the process in a fair, open, and unbiased manner that does not exclude its competitors.

In the view of the complainants, the IDSA and its Lyme guidelines panel, rather than comporting with these principles, deliberately excluded scientifically reputable advocates of competing treatment options from the standard-setting process. The IDSA then used its dominance in the relevant market to ensure enforcement of the standard throughout the United States.

1. Predicate Structural Elements: Market Power and Competitive Relationship

If procedures are followed to ensure that the standard-setting process is not biased by the organization's members with economic interests in stifling competition, then the rule of reason should be applied to take account of the potential procompetitive benefits.²⁵ Where the distortion of the process rises to the level of "unprincipled" or unreasonable decision-making, courts typically find a violation under the Sherman Act.²⁶ The case law limits the need to assess the reasonableness of standard setting, however, to those circumstances where the predicate structural elements of an antitrust claim are present. Even unreasonable standard setting cannot cause competitive harm unless the association has market power and a competitive relationship with persons or entities subject to the standard.

The market power element should be satisfied—even if the professional association did not drive the plaintiff, or its product, entirely from the market—if the standard setting substantially raised competitors' costs, limited their output, or

¹⁶ See, e.g., *Paul Jung, M.D. v. Ass'n of Am. Med. Colls.*, 300 F. Supp. 2d 119 (D.D.C. 2004) ("actors in the education world and/or professional associations [may be] held to be insulated from the antitrust laws if the activity is non-commercial in nature"); *Nara v. Am. Dental Ass'n*, 526 F. Supp. 452 (W.D. Mich. 1981); *Welch v. Am. Psychoanalytic Ass'n*, 1986 U.S. Dist. LEXIS 27182 (S.D.N.Y. 1986) ("distinctly non-commercial aspects of the learned professions are not, or may not be, subject to the Sherman Act").

¹⁷ See, e.g., *Jung*, 300 F. Supp. at 171 (quoting *Goldfarb v. Va. State Bar*, 421 U.S. 773, 787-88 (1975)).

¹⁸ *Ass'n for Intercollegiate Athletics for Women v. NCAA*, 737 F.2d 577, 583 (D.C. Cir. 1984).

¹⁹ IB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 262a (3d ed. 2006).

²⁰ *Id.*

²¹ 856 F.2d 226 (D.C. Cir. 1988).

²² *Id.* at 246. Endorsing the appellate court's reasoning, Areeda provides helpful guidance for determining when the federal antitrust laws apply to professional associations' conduct:

When the antitrust defendants are in a position to reap immediate, substantial economic benefits from the challenged activity, their conduct should presumptively be denied any noncommercial activities immunity or First Amendment protection. Such a presumption should be defeated only when the economic motives appear trivial in comparison with clearly established political motives.

Areeda, *supra* note 19 at ¶ 262b2.

²³ 493 U.S. 411, 425-427 (1990).

²⁴ See *supra* text accompanying note 13.

²⁵ *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988).

²⁶ XIII HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 2232 (2d ed. 2005).

lessened their competitive presence in other respects. Complainants viewed the IDSA as the dominant professional association, with respect to the diagnosis and treatment of Lyme disease. The AG found, *inter alia*, that the “IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.”²⁷

Second, the putative defendant must be in competitive relationships with the persons or entities subject to the standard. The absence thereof suggests a lack of anticompetitive purpose or likely effect.²⁸ In the case of the IDSA, the complainants saw the Lyme panelists’ commercial interests in vaccine development and diagnostic kits, among other interests, as being advanced through suppressing opposing advocates’ view that chronic Lyme disease is a definable disease category and that long-term antibiotic treatment may be appropriate in certain circumstances.

2. Substantive Exclusionary Conduct: Abuse of the Association and Common Law Rules for Guideline Development

Whether a particular standard-setting process might provide a basis for a Section 1 (or Section 2) violation is a matter of case-by-case determination. Certain principles, however, can be gleaned from *Allied Tube*²⁹ and like cases. First, the process must be free of manipulation and distortion and be characterized by integrity. It must be fair and open and unbiased by persons who are responsible for the standard setting and who have financial interests that put them in competition with the persons subject to the guidelines.³⁰ Second, the process must also adhere to internal rules on standard setting,

and literal compliance with the rules is no defense if the spirit of the rules is violated. Where internal rules are ambiguous or silent, the common law principle of good faith and fair dealing applies.

No two sets of requirements for medical guideline development are necessarily alike. Many, nonetheless, call for consensus. The JAMA Users’ Guide to the Medical Literature states that “[p]anelists which include a balance of research methodologists, practicing generalists, specialists and public representatives are more likely to have considered diverse views in their deliberations.”³¹

Even in the absence of such rules governing guideline development, the broad principles of procedural fairness prohibit economic bias. Where the SSO has promoted an open and fair debate in which various interests are allowed to state their position and rebut those of others, and neither the membership nor voting favored any particular economic interests, it would be difficult to satisfy the conduct element for an antitrust violation based on standard setting.³² On the other hand, a process which cuts off all debate about the appropriateness of a guideline, as alleged with respect to the Lyme disease panel,³³ is suspect.

In complainants’ view, the IDSA’s own rules for setting guidelines required that its guideline development process be flexible, consensus-driven, and non-exclusionary in the sense of representing a range of expert opinions on the treatment standard at issue. The AG found that the IDSA did not comply with its own guidelines for selecting a panel chair, “enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the

IDSA’s oversight committee.”³⁴ In addition, the IDSA’s 2000 and 2006 panels “refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease;” the IDSA “remov[ed] a panelist from the 2000 panel who dissented from the group’s position on chronic Lyme disease to achieve ‘consensus’” which, in the complainants’ view, made such “consensus” pretextual; and the IDSA “blocked appointment of scientists and physicians with divergent views on chronic Lyme.”³⁵

3. Antitrust Law Applies to Standard Setting Without the Need to Evaluate the Merits of the Standard Beyond Threshold Reasonableness

It is important to distinguish between the reasonableness of the standard setting process—a matter in which courts have expertise—and the technical merits of the substantive outcome, a matter in which courts typically lack substantial expertise. The defense is sometimes heard (perhaps from a blurring of this distinction) that courts and enforcement agencies lack the substantive expertise to evaluate the reasonableness of standard setting. A corollary defense is that, even if the process violates legal norms for standard setting, there is no antitrust harm if the process nonetheless results in the “scientifically” correct outcome.

The first defense was articulated by various sources in response to the Connecticut AG’s investigation, where the charge was leveled that the AG was “calling” the science.³⁶ Implicitly addressing this point, Attorney General Blumenthal commented in the press release that the state’s “investigation was always about the IDSA’s guideline process—not the science.” The state’s approach was correct. The antitrust

²⁷ CT AG Lyme Press Release, *supra* note 2.

²⁸ See Hovenkamp, *supra* note 26 at ¶ 2232d2 (“when defendants are not in a position to profit by suppressing the plaintiff’s product or service, dismissal of the antitrust complaint is appropriate without inquiry into the substantive merits of the challenged standard”).

²⁹ 486 U.S. 492.

³⁰ Hovenkamp, *supra* note 26 at ¶ 2230a (noting that “effective standard setting often implicates the discretion of people who are in competition with the firm or person to which the standard setting is to be applied: this fact is most often the one leading to competitive abuse”).

³¹ Robert S. Hayward et al., Users’ Guides to the Medical Literature. VIII. How to use clinical practice guidelines. A. Are the recommendations valid? The Evidence-based Medicine Working Group, 274 JAMA 570-74 (1995).

³² See, e.g., *Heary Bros. Lightning Prot. Co., Inc. v. Lightning Prot. Inst.*, 287 F. Supp. 2d 1038 (D. Ariz. 2003) (denying plaintiff manufacturers’ Section 1 claim regarding rejection of a standard for its lightning protection by defendant Institute on grounds that defendants’ violation of the group’s handout prohibition and inclusion of possibly false and misleading information in the handout were not fatal because both parties had an opportunity to debate the issues fully during floor debate).

³³ See CT AG Lyme Press Release, *supra* note 2.

³⁴ *Id.*

³⁵ *Id.*

³⁶ William Hathaway & Hilary Waldman, *Lyme Disease Experts: Butt Out, Blumenthal*, HARTFORD COURANT, Mar. 21, 2007.

analysis must evaluate the standard-setting process itself, without asking the litigation fact-finder to evaluate the merits of the standard.³⁷

In response to the defense that alleged subversion of a standard setting process can be justified by scientific evidence supporting the outcome, the Second Circuit has made it clear that “the objective validity of a restraint has never been a defense to an antitrust charge.”³⁸ The point of subjecting the integrity of the guideline development process to antitrust scrutiny is to ensure that the development process considers scientifically relevant and reasonable alternatives and yields the fairest result, but not to judge that result on its substantive scientific merits or “call the answer.” The rejoinder that there is no antitrust harm if the substantive outcome is technically correct presupposes knowledge of the correctness of the outcome, which can *only* be determined through a process that ensures due process. And this is exactly the rationale for the terms of the Connecticut AG’s settlement, which provides for a re-evaluation of the Lyme guidelines by a reconstituted panel based on a public presentation of the science.

C. Causation: Abuse of the Guideline Development Procedure Must Substantially Contribute to the Alleged Anticompetitive Effects

No antitrust claim based on alleged abuse of the medical-guidelines-development process is viable unless the alleged antitrust injury flows from the exclusionary conduct. This, in turn, breaks down into two key links in the chain of causation: (1) the exclusionary conduct in the guideline development and (2) additional conduct or circumstances combining to create a restraint and anticompetitive effects in the market.³⁹ For purposes of this discussion, we will assume sufficient evidence of the first link (how the guideline results from the conduct)⁴⁰ and focus on the second, which concerns how the guideline itself was used

to restrain trade or otherwise bring about anticompetitive effects.

1. The Guidelines Must be Effectively Mandatory Rather than Merely Informational

The key question is whether the suspect guideline is merely informational and thus voluntary (as the IDSA claims in a disclaimer covering the guidelines on its website) or whether it is mandatory in its language and/or through enforcement of compliance with the guideline.

Sometimes, the line between voluntary and mandatory is clear. For instance, the AMA’s rule in *Wilk* excluding chiropractors was clear.⁴¹ In other circumstances, the line between informational and mandatory guidelines may be less so, and in such cases, the law can imply coercion from the facts and circumstances. For instance, the Connecticut AG’s press release questioned the IDSA’s characterization of the Lyme guidelines as “voluntary.” The argument could be made that the IDSA “drove” a consensus for the treatment of Lyme disease through a number of activities, extending well beyond the language of the guideline itself. Whatever the merits there, however, it is well established that to show an agreement under Section 1 it is not necessary to show express coercive enforcement of a restraint where the defendant has sufficient power to enforce the restraint and the persons who would be subject to it are aware of that power. Thus, for a showing of causation, the power to restrain combined with a reduction in output can substitute for express coercive enforcement. In the Lyme matter, the IDSA’s dominance in the relevant market, combined with a marked decrease in the number of doctors willing to provide long-term antibiotic treatment, and substantially reduced availability of that treatment, arguably could substitute for evidence of express coercive enforcement of the guideline as a prohibition against treatment with long-term antibiotics (i.e., beyond the 30-day period called for by the guideline).

a. Illegal Restraint can be Inferred from Economic Influence, even without Coercive Enforcement

In *Goldfarb*,⁴² the Supreme Court explained that, even without the threat of enforcement, “the [state bar association’s ethical] opinions would have constituted substantial reason to adhere” to the bar association’s fee guidelines “because attorneys could be expected to comply in order to assure that they did not discredit themselves by departing from professional norms, and perhaps betraying their professional oaths.”⁴³ Implicit in this statement is an understanding that the association established the professional norms by which the attorneys had to abide. This finding shows that the association’s influence, rather than independent choice on the part of the bar’s members, was the cause of such adherence. And without adherence, there would effectively have been no restraint.

An analogy can be drawn to physicians who provide treatment that does not conform to the Lyme guidelines, a number of whom have been the subject of professional misconduct proceedings by state medical boards. Other physicians may reasonably surmise that they could discredit themselves professionally if they fail to comply with the IDSA guidelines and that they would thereby be putting their livelihoods at risk. Therein lies sufficient causation for an antitrust claim, assuming the requisite exclusionary conduct and other elements are present.

b. Even Absent Evidence of Compulsory Adherence to Association Rules, the Requisite Coercion May be Found

Assuming an association has sufficient power and influence, the requisite coercion for causation may be found even in the absence of express compulsory adherence or express exclusion. For instance, in *National Society of Professional Engineers v. United States*,⁴⁴ a provision of the society’s code of ethics prohibited members from providing potential clients price

³⁷ Hovenkamp, *supra* note 26 at ¶ 2235 (“To the extent possible an antitrust tribunal must assess the competitive threat of private standard setting or rule making without becoming embroiled in substantive questions of reasonableness.”).

³⁸ *Indian Head v. Allied Tube & Conduit*, 817 F.2d 938, 947 (2d Cir. 1987).

³⁹ See, e.g., *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n.9 (1969); see also IIA PHILIP E. AREEDA ET AL., ANTITRUST LAW ¶ 338a (3d ed. 2007) (“It is therefore enough that the antitrust violation contributes significantly to the plaintiff’s injury even if other factors amounted in the aggregate to a more substantial cause.”).

⁴⁰ See, *supra* discussion in Section III.B.2.

⁴¹ *Wilk v. American Medical Ass’n*, 735 F.2d 217 (7th Cir.), cert. denied, 496 U.S. 927 (1990) (holding that AMA ethical rule that allegedly forbade making referrals to or receiving referrals from chiropractors, on the grounds that they practice an “unscientific” form of medicine, violated Section 1 of the Sherman Act).

⁴² *Goldfarb*, 421 U.S. 773.

⁴³ 421 U.S. at 791, n.21.

⁴⁴ 435 U.S. 679 (1978).

information that would enable them to make price comparisons. The district court found that the society had “actively pursued a course of policing adherence to the competitive bid ban through direct and indirect communication with members and prospective clients,” and “had engaged in educational campaigns and personal admonitions to members and clients who were suspected of engaging in competitive bidding practices.”⁴⁵ In argument before the Supreme Court, however, the society contended that it had never enforced the ban on competitive bidding, although apparently it did not deny in substance that it had engaged in educational campaigns and personal admonitions. The Court held that, even absent evidence of compulsory adherence to the ban through enforcement, the lower court’s finding of educational campaigns and personal admonitions was sufficient to establish the Section 1 agreement.⁴⁶

2. Schachar: No Enforcement Restraint, Little if any Reduction of Output and a Drop in Demand

Schachar v. American Academy of Ophthalmology, Inc.,⁴⁷ is one of the leading cases highlighting the distinction between informational guidelines and guidelines that impose a significant restraint on the market. *Schachar* may appear to contradict, but on closer examination is not inconsistent with, the foregoing authority, and it is distinguishable on its facts.

a. No Restraint

Schachar concerned an informational standard. There was no enforcement, and there were no compensating market circumstances or dynamics that effectively removed consumer choice as a possible factor in acceptance of the standard in the market. The statement at issue was contained in a press release which characterized radial keratotomy—laser surgery to correct nearsightedness—as “experimental.” The court held that the press release could not, without further evidence of constraint (including, for instance, enforcement efforts by the

defendant association), constitute the type of restraint necessary to make out an antitrust claim. Writing for the panel, Judge Easterbrook succinctly summed up the absence of causation in these circumstances: “there can be no restraint of trade without a restraint.”⁴⁸

b. Press Release was Informational and Not Backed Up with Enforcement Power

In contrast to *Schachar*, the IDSA issued a guideline, not a press release. Unlike the press release, the IDSA guideline did not call the treatment—long-term antibiotic treatment—“experimental;” rather, the guideline excluded the treatment altogether by not recognizing chronic Lyme disease. Furthermore, beyond the language of the guideline itself, the IDSA has enforcement power: it has considerable authority over hospitals, which typically have an IDSA member establish and monitor their infectious disease policies. The IDSA thus arguably can and does induce hospitals to deny, or revoke, hospital privileges to physicians who do not comply with their guidelines. Likewise, the IDSA has tremendous clout with medical boards, which view its guidelines as a proxy for the legal standard of care for unprofessional conduct actions and which refer complaints out to IDSA members for a preliminary “expert opinion” before filing formal charges. The IDSA’s guideline also arguably induces insurers to withhold payments for long-term antibiotic treatment through insurers’ adoption of the guidelines for definition of “medically necessary” care and through second-opinions, rendered by IDSA members, on subscribers’ claims.

Also, none of the plaintiffs in *Schachar* was threatened with professional disciplinary action. At worst, they had a little less business than they might have had absent the press release, as consumers evidently exercised their choice to wait until the procedure was determined to be less experimental.⁴⁹ Plaintiffs may have been harmed, but it was not antitrust injury.

c. Reduction in Output in Lyme Matter, Unlike in Schachar

Schachar is distinguishable for another, important reason. The court of appeals found no reduction of output—no evidence that patients had a harder time finding someone to perform radial keratotomy. In contrast, in the case of long-term treatment of Lyme disease, complainants estimate fewer than 150 physicians in the United States are willing to endure the pressures from the IDSA and from insurance companies (by their refusal to cover long-term antibiotic treatment). This number is down considerably from previous levels. It has become significantly more difficult for patients to obtain services of physicians willing to treat long-term Lyme disease—many patients have to bear the costs of traveling long distances for treatment and then pay for their non-insured treatment. This was not the situation facing Judge Easterbrook in *Schachar*: “In a market with thousands of providers—that is, in the market for ophthalmological services—what any one producer does cannot curtail output; someone else will step in.”⁵⁰ In medicine, the standard of care is driven by custom: until there is a critical mass of practitioners using a therapeutic approach, its use may be deemed below the standard of care and adoption of the practice may entail substantial professional risk for the physician.

d. No Evidence of Drop in Demand, Unlike in Schachar

Whereas in *Schachar* there was evidence that consumer demand fell (ostensibly in response to the statement by the Academy), here, the demand for the treatment has remained constant or increased. At the same time, the willingness of practitioners to provide that treatment has been substantially reduced because physicians who offer longer term treatment approaches run the risk of losing hospital privileges, being denied malpractice insurance or having to pay higher rates for this insurance, being terminated from insurance networks, and facing professional misconduct actions.

⁴⁵ 389 F. Supp. 1193, 1200 (D.D.C. 1974).

⁴⁶ 435 U.S. at 684, n.5.

⁴⁷ 870 F.2d 397 (7th Cir. 1989).

⁴⁸ *Id.* at 397.

⁴⁹ *Id.* at 399 (absent the press release “all of the plaintiffs believe that the demand for their services would have been greater”).

⁵⁰ 870 F.2d at 399.

All of this has increased the cost and risk of providing longer term treatment and has had a chilling effect on the willingness of physicians to treat. Many physicians who provide longer term care cannot accept insurance as payment and the per-visit costs of care are substantially higher for the patient than they would be were these barriers to care not in place.

In short, in *Schachar*, the evidence clearly indicated not only a lack of enforcement but also, more importantly, a lack of economic power. The press release did not deter physicians from providing the laser eye surgery. If the Academy had had sufficient economic power to reduce output, causation would have been satisfied and the court presumably would not have needed to address the issue of enforcement. The stated basis for the court's holding was the absence of restraint.⁵¹ The court found no restraint because output was not reduced. As Judge Easterbrook put it, "[u]nless one group of suppliers diminishes another's ability to peddle its wares (technically, reduces rivals' elasticity of supply), there is not even the beginning of an antitrust case, no reason to investigate further to determine whether the restraint is "reasonable."⁵²

In contrast, the restraint in the matter of the Lyme guidelines has been palpable, with output being suppressed (few physicians willing to treat) despite rising demand for treatment. Hence, in complainants' view, causation is established in this case based on reduced output caused by the IDSA's power to drive professional norms simply by virtue of its authority and dominance in the marketplace (rather than on the merits of an open discussion, which it has the power to suppress through its influence on information distribution channels).

3. The Power of Medical "Gatekeeping"

In addition, in sharp contrast to *Schachar*, the IDSA has, in complainants' view, enforced its guidelines through the *gatekeeping roles* that its members hold. Hospital medical staff committee physician members ensure compliance with the IDSA guidelines by supporting the denial and revocation of hospital privileges of

physicians who do not comply. IDSA members also act as gatekeepers to grand round opportunities, research grants, presentations at conferences, and the publication of journal articles. IDSA physicians provide the preliminary expert external review of prospective medical board conduct actions. Insurance companies use the guidelines to exclude non-complying physicians from their networks, support second opinions from IDSA members, and to deny reimbursement of claims for treatment not following guidelines. This type of exclusionary activity suppresses the dissemination of opposing viewpoints and blocks many professional advancement opportunities. These "gatekeeper" enforcement actions send a clear message to physicians that non-compliance may have serious professional consequences. Hence, if a court were to require a showing of enforcement, evidence of gatekeeper enforcement actions, such as those described above, might well satisfy the evidentiary burden.

4. A Product Need Not be Excluded Entirely From the Market For There to be Anticompetitive Harm.

There is no antitrust requirement that a product or service—here, the treatment of chronic Lyme disease—be excluded entirely from the market before anticompetitive harm can be shown.⁵³ Thus, long-term treatment need not have been entirely driven from the market for there to be antitrust injury.

The number of physicians treating chronic Lyme disease with a longer-term course of antibiotics has been suppressed despite growing demand, and this, in turn, has raised costs for consumers and curtailed treatment options. To obtain treatment, many patients travel great distances. Thus, the fact that a few physicians continue to offer long-term antibiotic treatment for chronic Lyme disease patients does not amount to viable freedom of choice for providers or consumers in the market, or diminish the materiality of the causal connection between the exclusionary conduct and the resulting effects on the

market. Output would be far greater if non-complying physicians did not face the risk of losing hospital privileges, being denied malpractice insurance or paying higher rates for this insurance, and being terminated from insurance networks, not to mention professional misconduct actions.

5. DOJ/FTC Health Care Policy Statement on Treatment Guidelines: Coercive Enforcement Excluded from Safety Zone

Several months after the commencement of the investigation, an article in *Forbes* magazine commented that Attorney General Blumenthal's statement that the guidelines "may be in violation of antitrust laws" was "an odd charge, since a 1996 policy statement from the Federal Trade Commission and the Department of Justice says that treatment guidelines issues by medical societies do not limit competition."⁵⁴ The *Forbes* statement is incorrect. First, although the Health Care Statements⁵⁵—to which the article presumably was referring—do provide a qualified safety zone that applies to the development of medical guidelines, the agencies do not state that guidelines, or their development, never limit competition. Second, the Statements make it clear that coercion used to secure compliance with such guidelines risks antitrust challenge and falls outside of the safety zone.

The focus of the Statements is on collective conduct by health care providers—whether joint ventures, mergers, or other joint conduct. Statement 4 makes the point that the collective development of clinical guidelines is not the kind of collective conduct that normally raises any antitrust concerns. Thus, Subsection A creates an "antitrust safety zone" for the collective provision of certain non-fee-related information:

The Agencies will not challenge, absent extraordinary circumstances, providers' development of suggested practice parameters—standards for patient management developed to making—that may also provide useful information to patients, providers, and

⁵¹ *Id.* at 397 ("There can be no restraint of trade without a restraint. That truism decides this case. . . .").

⁵² *Id.* at 399.

⁵³ As Hovenkamp explains, "In order to cause competitive injury a disapproval need not be so severe as to drive the plaintiff or its product out of the market altogether. But it must be sufficient to raise its costs, limit its output, or substantially lessen its competitive presence in other ways." Hovenkamp, *supra* note 26 ¶ 2232c2.

⁵⁴ David Whelan, Ticks aren't the only parasites living off patients in borreliosis-prone areas, *FORBES*, Mar. 12, 2007.

⁵⁵ FED. TRADE COMM'N & DEPT. OF JUSTICE, STATEMENTS OF ANTITRUST ENFORCEMENT IN HEALTH CARE (1996) www.ftc.gov/bc/healthcareindustryguide/policy/statement4.htm (hereinafter "Health Care Statements" or "Statements").

assist providers in clinical decision-purchasers. Because providers' collective provision of such information poses little risk of restraining competition and may help in the development of protocols that increase quality and efficiency, the Agencies will not challenge such activity, absent extraordinary circumstances.⁵⁶

Although the "extraordinary circumstances" are not defined, there is no blanket exemption for guideline development and the agencies do not state that guideline development never limits competition.

More importantly, as explained in the next paragraph of Subsection A, *coercive enforcement* of guidelines is excluded from the safety zone:

In the course of providing underlying medical data, providers may collectively engage in discussions with purchasers about the scientific merit of that data. However, the antitrust safety zone excludes any attempt by providers to coerce a purchaser's decisionmaking by implying or threatening a boycott of any plan that does not follow the providers' joint recommendation. Providers who collectively threaten to or actually refuse to deal with a purchaser because they object to the purchaser's administrative, clinical, or other terms governing the provision of

services run a substantial antitrust risk. [...] *Similarly, providers' collective attempt to force purchasers to adopt recommended practice parameters by threatening to or actually boycotting purchasers that refuse to accept their joint recommendation also would risk antitrust challenge.*⁵⁷

As the above paragraph indicates, significant coercion used to secure compliance with the guidelines risks antitrust challenge and thus falls outside of the safety zone. Whatever protection guideline development may enjoy under Statement 4 (because of the nature of the information exchanged in guideline development) is thus removed when coercion is used to ensure compliance with guidelines.

This interpretation—and in particular that the requisite coercion to take the conduct out of the safety zone is not limited to boycotts—is supported by other agency comments.⁵⁸ No limitation on the term "coercion" is given; it is not limited by its terms to "boycotts" and it makes no sense in antitrust logic that it would be so limited, as there are other kinds of coercive conduct that could achieve the same end—that is, that could force compliance with such recommendations.

IV. Conclusion

This discussion is not aimed only at making the case for the applicability of antitrust standard-setting principles to the development of medical guidelines, as seen

through the lens of Connecticut's investigation of the Lyme guidelines. More importantly, medical associations can better protect themselves from legal risk by heeding the lessons from the AG's approach and its ostensible foundations in antitrust law. Beyond the legal imperative is the hope that the application of these principles to medical guideline development functions as an enabling mechanism, rather than any hindrance, to science in the service of health care consumer welfare. That is, by complying with the legal principles set forth above, such as due process in guideline development, medical associations should be able both to protect and promote the integrity of their guideline development and do so still in a way that appropriately draws the line on any involvement by the law in "calling" the science. Energy devoted to calls for the law to "butt out" of medical guideline development⁵⁹ is misplaced and would be more constructively directed at managing this nuanced balance for the benefit of consumer health care. The resistance in medicine to the law (and, for that matter, to anyone outside of medicine) looking over its shoulder is age-old and somewhat understandable; but in the area of medical guideline development, particularly at a time when financial interests have taken on such a large role, antitrust enforcement has a constructive role to play that is consonant with the goals of medicine itself. ■

⁵⁶ *Id.* at Statement 4.A.

⁵⁷ *Id.*

⁵⁸ See, e.g., DAVID PENDER & MARKUS MEIER, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS 84 (2005), available at <http://www.ftc.gov/bc/050802antitrusthealthcareprods.pdf> (stating, "Nor would the FTC challenge the development of suggested standards for clinical patient care by physicians. *This safety zone does not protect provider conduct to coerce compliance with recommendations. . . .*" (emphasis added)). See also, Christine Varney, Commissioner, Fed. Trade Comm'n, The Health Care and Antitrust Interface in an Era of Fundamental Industry-Wide Realignment, (1995), www.ftc.gov/speeches/varney/pitoc23.htm (stating, "Current law permits collective efforts by physicians and other health care providers to certify and set standards, implement practice guidelines, and engage in legitimate peer review programs . . . *What is forbidden under current antitrust law standards is for medical groups to coercively impose their view of what third-party payers and other consumers should want.*" (emphasis added)).

⁵⁹ See Hathaway & Waldman, *supra* note 36.