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TICKED OFF

Attorney general challenges controversial Lyme disease guidelines

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A generation ago, most physicians would have doubted that antitrust rules and the clinical practice of medicine could intersect. Attorneys were of the same view about their profession until 1975 when the U.S. Supreme Court decided Goldfarb v. Virginia State Bar and threw out minimum fee schedules on restraint of trade grounds. Now, fast-forward 31 years to November 2006 when Connecticut Attorney General Richard Blumenthal initiated an investigation of the Infectious Diseases Society of America (IDSA). More particularly, the attorney general sought information about the development process of the IDSA's 2000 and 2006 guidelines on the diagnosis and treatment of Lyme disease.

The investigation did not attack the science behind the guidelines but, rather, sought to determine whether IDSA engaged in exclusionary and monopolistic conduct during their development. Blumenthal's inquiry was whether IDSA excluded legitimate but contradictory evidence and opinions on the existence of chronic Lyme disease. This is believed to be the first time a state has relied on antitrust principles to investigate a medical society's guideline process. However, it is not the first time that antitrust law has been used to challenge a medical entity's clinical stance.

In 1978, Dr. Chester Wilk and four other chiropractors sued the American Medical Association, among others, alleging Sherman Act violations because the AMA's rules prohibited allopathic doctors from referring patients to or even coordinating care with chiropractors. Nine years later, a U.S. District Court found that the AMA had tried to eliminate the chiropractic profession; essentially, it had orchestrated a group boycott. The court ordered the AMA to revise its rules. The Supreme Court upheld its decision.

It is not unusual for a professional medical organization to draft clinical guidelines. These guidelines pack a mighty punch because they are frequently employed to define the relevant standard of care. Doctors apply them in their practice and often base treatment decisions on them. Insurance companies rely on them to determine coverage and to deny reimbursement. State regulatory agencies use them in licensure and disciplinary proceedings against doctors.

The IDSA Lyme guidelines have had a sweeping impact on the diagnosis and treatment of Lyme disease, especially in Connecticut, a highly endemic area for the disease and whose quaint shoreline town gave the disease its name. Insurance companies such as United Healthcare, Health Net and others regularly rely on them to dispute the existence

of chronic Lyme disease and to deny coverage for long-term antibiotic treatment. The Centers for Disease Control and Prevention lists the IDSA guidelines on its website. In three disciplinary proceedings before the Connecticut Medical Examining Board, the Department of Public Health has offered expert witnesses who espouse the IDSA guidelines in its prosecution of physicians who believe in and treat chronic Lyme disease.

Blumenthal's investigation caused a major stir in the medical community nationally. Some, like the Lyme Disease Association, applauded because it believed that IDSA had improperly excluded evidence about the existence of chronic Lyme disease. IDSA supporters argued that Blumenthal overstepped his bounds and was improperly interfering in scientific matters.

Two Schools Of Thought

A person unfamiliar with the controversy that surrounds Lyme disease and chronic Lyme disease might not understand the significance of the attorney general's thrust. Briefly, there are two schools of thought on the diagnosis and treatment of Lyme disease. Physicians adhering to the school reflected in the IDSA guidelines

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believe that Lyme disease is easy to diagnose and treat. They contend that short-term antibiotics are the appropriate therapy. They do not believe that chronic Lyme disease exists. They stress the importance of positive laboratory tests to confirm a Lyme disease diagnosis.

Physicians subscribing to the school reflected in the International Lyme and Associated Diseases Society's guidelines believe that the diagnosis and treatment Lyme disease is complex. They maintain chronic Lyme disease is quite prevalent and may require long-term antibiotic treatment, sometimes intravenously. They dispute the accuracy and utility of available testing.

On May 1, 2008, Blumenthal announced that his investigation uncovered "serious flaws" in IDSA's guideline process. He stressed that medical groups, such as IDSA, have both a "legal and moral duty to use exacting safeguards and scientific standards." The panelists who draft the guidelines must be free of conflict, he stated, and should not exclude divergent views unless unsupported by evidence. These were the very concerns of Lyme disease activists who brought IDSA's actions to Blumenthal's attention and who were the catalyst for his investigation.

Some of the serious flaws uncovered by the attorney general's office were: (1) panelists with undisclosed financial interests were not discovered because IDSA failed to conduct a conflict of interest review; (2) panelists refused to consider information concerning the existence of chronic Lyme disease and removed a physician who disagreed with the majority opinion; (3) IDSA blocked appointments of scientists and physicians who believed in the existence of chronic Lyme disease by telling them the panel was full even though it was later expanded; and (4) IDSA appointed a chairman who was so biased about the non-existence of chronic Lyme disease he used his position to appoint like-minded individuals without oversight committee approval.

Credibility Issues

These flaws called the guidelines' credibility into question. IDSA and the attorney general's office entered into a settlement agreement under which IDSA agreed to an extensive re-examination of its 2006 guidelines. A review panel will be created to "scrutinize" the guidelines to determine whether they should be updated or revised. None of the panelists who sat on the 2006 panel are permitted to serve again. IDSA must hold an open application process. All applicants are to be screened for potential conflicts by the ombudsman approved by the Attorney General's office.

After the new panel is established, it must hold an open scientific hearing, which has yet to be scheduled, to consider information from "interested parties" approved by the attorney general's office and the ombudsman. However, the hearing is not open to the public — which has raised some eyebrows in the Lyme disease community. In lieu of a public hearing, IDSA is required to broadcast the hearing on its web site. After the hearing, the reviewers will decide whether the 2006 guidelines are supported by the evidence.

It is too early to tell whether the "redo" demanded by Blumenthal will produce a different result. Lyme activists have expressed doubt that it will. The most important lesson of the attorney general's/IDSA settlement is that regulators can no longer be expected to hang back in the face of exclusionary practices by medical clinical standard-setting bodies. The credence given to IDSA's Lyme disease guidelines by regulatory, reimbursement and professional medical groups, coupled with the hostility showed by IDSA adherents to differing views, was dramatically exposed by the attorney general's efforts. Legislation is currently pending at the General Assembly addressing the Lyme disease controversy which will be the subject, if enacted, of a future article. ■