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Antitrust scrutiny of Lyme guidelines

Marcia Coyle/Staff reporter
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WASHINGTON-A state attorney general's novel investigation into the development of treatment guidelines for Lyme disease should put health care and professional medical societies on alert to a possible new front in antitrust litigation, say antitrust lawyers and others.

Connecticut Attorney General Richard Blumenthal late last year issued a subpoena to the Infectious Diseases Society of America (IDSA) for information on how it established its latest guidelines on the diagnosis and treatment of Lyme disease- guidelines that were subsequently adopted by the Centers for Disease Control and Prevention (CDC).

While IDSA has responded to the subpoena, Blumenthal said his investigation is ongoing. "We've reached no conclusion," he said.

And while some have characterized it as novel or unprecedented, Blumenthal said the inquiry involves "basic antitrust principles applied to medical care."

The antitrust implications here, he explained, are the restraint on doctor and patient choices for treatment of the disease because of the guidelines, and particularly their effect on insurance companies' willingness to pay for treatment.

Nineteen members of Congress recently sent a letter to the CDC requesting that agency to review the IDSA guidelines, which they said have "the potential to effectively shut down" all treatment of chronic Lyme disease. The IDSA reacted on Jan. 17 with a letter to Congress explaining its guideline process.

State attorneys general have been very aggressive in the health care arena in recent years, say health care and antitrust practitioners, but antitrust actions involving treatment guidelines have not been common.

"There is certainly a possibility that if a professional organization puts out a set of principles that tells you how to act, and people act in accordance with it, it could have an effect on competition," said Stephen P. Mahinka, a partner in the Washington office of Morgan, Lewis & Bockius, and chairman of the firm's life sciences interdisciplinary practice group.

The federal National Guideline Clearinghouse Web site lists more than 1,800 guidelines under the heading "disease/ condition," including the IDSA guidelines.

The backdrop to Blumenthal's investigation is an intense dispute between the IDSA and the International Lyme and Associated Diseases Society (ILADS).

The IDSA, widely recognized as the pre-eminent authority on infectious diseases in this country, does not support a separate diagnosis of "chronic" Lyme disease, nor do its guidelines support antibiotic treatment for patients on a long-term basis-for a period of months or even years.

The ILADS, a nonprofit, international, multidisciplinary medical society dedicated to the diagnosis and appropriate treatment of Lyme and its associated diseases, takes the opposite view.

The ILADS and other critics, such as the Lyme Disease Association, contend that the panel that developed IDSA guidelines excluded any opposing views of chronic Lyme disease and its treatment.

Although the IDSA says its guidelines are not mandatory, they have the effect of becoming the standard of care in the medical community, according to Lorraine Johnson, an attorney and executive director of the California Lyme

Disease Association.

The national association, she said, has received numerous complaints from patients denied reimbursement for longer-term treatment than recommended by the IDSA guidelines, and physicians who don't follow the guidelines have faced malpractice charges by medical boards.

The development of treatment guidelines is analogous to standard-setting-a hot area in antitrust today, according to New York attorney Richard Wolfram, an independent antitrust specialist assisting the California Lyme Disease Association.

Common principle

Although the relevant case law has been outside of the health care field, he said, there is a common principle. Because standard-setting by competitors supplants competition, the process must be fair, open and not subject to any bias by participants with economic interests in stifling competition, he explained, especially when the standard-setting is done by an association or other entity that is highly influential or dominant in the relevant market.

"The fundamental antitrust claim here is an abuse of the standard-setting process by which guidelines for diagnosis and treatment of Lyme disease was articulated," said Wolfram.

"We say there was at bottom a refusal to deal with certain elements of the medical community who have different points of view about treatment of the disease, particularly chronic Lyme disease, and an exclusion of treatment, particularly long-term antibiotic treatment."

Douglas A. Hastings, partner in the health care and life sciences practice in the Washington office of New York's Epstein Becker & Green, said he could see how the guidelines could be viewed as standard-setting, but, he added, an antitrust claim in this context is novel.

"Antitrust requires independent parties conspiring to do certain things to violate antitrust law and is anti-competitive," said Hastings.

"That is not something typically raised around development of practice guidelines."

The IDSA's attorney, antitrust litigator Alvin Dunn, counsel to the Washington office of Pillsbury Winthrop Shaw Pittman, said: "Our view is this is not a matter for antitrust laws or courts generally, but this is a medical question and one that doctors and scientists should be addressing if there is an issue as to whether the guidelines are proper."

The IDSA's critics challenge the guidelines' positions that there is no such thing as chronic Lyme disease and that long-term antibiotic treatment should not be given, Dunn said. "IDSA is saying that would be overtreating and clinical evidence studies don't support that. The challengers want much more treatment and reimbursement. There's no economic benefit to IDSA members getting together here."

Dunn said other professional societies that develop guidelines should find this investigation troubling.

"Today, guideline development is very common; its use is encouraged, and people think the quality of care improves if doctors and other follow these guidelines," he said. "They should be very concerned about the possibility of legal challenges if they do what they think improves patient health and safety."