

## Antitrust Lyme Disease Probe Sparks Debate

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*Monday, May 12, 2008* --- Connecticut's attorney general has settled his unprecedented antitrust investigation into an influential medical association's Lyme disease treatment guidelines, but antitrust experts say the agreement may still have an interesting side effect: putting medical professionals on notice.

While professional organizations often come under scrutiny from regulators, antitrust actions involving disease treatment guidelines are rare.

Connecticut Attorney General Richard Blumenthal's antitrust probe of the Infectious Disease Society of America's process for setting Lyme Disease diagnosis and treatment guidelines has certainly raised questions for doctors, scientists and antitrust specialists.

"It was a very significant development and it does reinforce the need to be really careful when you're setting standards and when you're developing guidelines or weighing in on anything that can have a cascading impact as anything does in health care," said Judith Harris, an antitrust partner at Reed Smith LLP.

Regulators have often applied antitrust laws in probes of standards-setting processes in other industries, but Blumenthal's investigation of a medical group's guideline development process was, in many ways, unique.

On May 1, Blumenthal announced that the antitrust investigation had been put to rest, and the Infectious Disease Society of America had voluntarily agreed to review its guidelines in an open and public manner.

But Blumenthal noted that his antitrust-based investigation had revealed a flawed process used by the organization to establish guidelines for treating Lyme disease.

The resulting guidelines, Blumenthal said, had the effect of restraining a patient's treatment options of Lyme disease since many insurance companies used the guidelines to justify limiting coverage for long-term antibiotic treatment of chronic Lyme disease.

The guidelines denied the existence of chronic Lyme disease and warned against long-term antibiotic use, recommending that the therapy be limited to 30 days.

Members of the organization's Lyme disease panel had undisclosed financial interests related to Lyme disease diagnostic tests and insurance company consulting, among other financial conflicts, Blumenthal said.

In addition, the IDSA's Lyme disease panels in both 2000 and 2006 refused to consider alternate opinions on the existence of chronic Lyme disease, the Connecticut attorney general said.

The panels blocked appointments of scientists and physicians with other views and once removed a panelist who had dissented from the group's position on chronic Lyme disease, Blumenthal said.

"The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests — in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies — to exclude divergent medical evidence and opinion," Blumenthal said in a statement.

The IDSA represents over 8,000 physicians, scientists and other health care professionals who specialize in infectious diseases.

The group voluntarily agreed to reassess the guidelines in order to put the investigation to rest but has stood behind their substance and has flatly denied the attorney general's allegations that panel members had significant conflicts of interest and excluded conflicting viewpoints.

"We recognize that medicine is always evolving, and we welcome the opportunity that the review panel provides to examine any new evidence and vet our earlier findings," IDSA President Donald Poretz

say the type of diagnostic tests pushed by the guidelines are also inaccurate and fail to identify some cases of Lyme disease.

Richard Wolfram, an independent antitrust specialist who counseled the California Lyme Disease Association, said the settlement only underlines why medical associations should keep antitrust standard-setting principles in mind when developing guidelines.

"This is where the courts and enforcement agencies can play a role: they don't 'call' the science but they can ensure the integrity of the medical guideline development process. And it's been our position that their authority for doing this is well established in antitrust law, even if the application of such principles to medical guideline development is relatively novel," Wolfram said.

Still, others said the Connecticut attorney general's investigation is unlikely to be a trend-setter.

"I don't think this suggests there's going to be a wave of antitrust investigations on guideline-setting by professional associations," said Robert Leibenluft, an antitrust partner at Hogan & Hartson LLP.

Antitrust claims brought against medical associations aren't unheard of, but courts have sometimes been leery of wading into disputes over medical recommendations, Robert Leibenluft, an antitrust partner at Hogan & Hartson LLP, said.

He pointed to the Seventh Circuit's 1989 decision in *Schachar v. American Academy of Ophthalmology Inc.*

In that case, the appeals court rejected a claim brought by a group of ophthalmologists who argued that the AAO had improperly labeled a particular eye surgery as "experimental."

"Based on what is alleged in the attorney general's press release, this would appear to be a difficult antitrust case to win," Leibenluft said. "It's unclear from the allegations how IDSA's conduct restrained competition.

"And as one court has said, in cases where a professional or trade association has only expressed its views — even if they are misleading, mistaken or incomplete — the appropriate remedy is not antitrust litigation but more speech: the so-called marketplace of ideas," he added.

Still, there is a growing attention in the U.S. on health care and its possible ills. For those who are keen to challenge the process of setting medical guidelines in the future, some experts argue the use of antitrust standards may be the clearest avenue available.

"I think you're going to see a lot of scrutiny of the process, and the antitrust laws are the only way right now of providing that scrutiny," Harris said.