

## Medical guidelines found to be anti-competitive

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The Infectious Diseases Society of America yesterday agreed to draft new Lyme disease guidelines, following an antitrust investigation by Connecticut attorney general Richard Blumenthal.

The probe found "numerous irregularities and conflicts of interests" in the ways recommendations for the current guidelines were created, which Blumenthal says constituted a violation of antitrust laws. The investigation suggested evidence of collusion among panel members to exclude certain opinions and viewpoints. Although the society's guidelines are not binding, Blumenthal says they have "sweeping and significant impacts" on Lyme disease medical care. The guidelines 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.

Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is nonexistent. But some doctors dispute such guidance. The current guidelines were produced by a panel of 12 healthcare experts. "The original panel members who compiled the guidelines had financial, contractual, consulting, public speaking, research grants and patents links pertaining to Lyme disease treatment," says Blumenthal.

Although the society has agreed to compile new guidelines in a more open way that will include more competing viewpoints, it says that it "strongly disagrees" with most of the attorney general's findings, and adds that in the original panel, competing viewpoints were not excluded.

"The Connecticut attorney general's success in reaching this settlement agreement with the IDSA underlines the importance of antitrust standard setting principles to the development of medical guidelines where guideline panelists have a commercial stake in the outcome," says **Richard Wolfram**, counsel to the complainants in this case. "Guidelines increasingly influence insurance coverage and the legal standard of care in medicine, and limit clinical discretion. Where commercial interests are involved, irregularities in guideline development will be suspect, particularly where the specialty association is dominant in its field." Wolfram adds that this is where the courts and enforcement agencies can "ensure the integrity" of the medical guideline development process, even if the application of such principles to medical guideline development is relatively novel.

Antitrust lawyers say the investigation should put health care and professional medical societies on alert to a possible new front in antitrust litigation. "There is no question that standard-setting organizations like the IDSA may have incentive to restrain

competition in the health care market, and that insurance companies as gatekeepers in this market may inadvertently increase the risk of foreclosure by relying on standard-setting bodies when deciding issues such as treatment and reimbursement," says **Jennifer Driscoll**, counsel at Mayer Brown LLP in Washington, DC. "As a result, it is especially important that the standard-setting in the health care market reflect a fair and impartial process."

The Infectious Diseases Society of America is a non-profit organisation of 8,000 US doctors.

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