



## Connecticut AG Calls For Review Of Lyme Treatment Guidelines

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May 9, 2008 - 10:22:20 AM

Conflicts of interest, refusing to consider contrary information, and other major procedural flaws marred the development of prominent but highly controversial medical guidelines for treating Lyme disease, according to the results of an investigation released last week by Connecticut Attorney General Richard Blumenthal.

In a deal that grew out of the investigation, the Infectious Diseases Society of America, which released guidelines for treating Lyme disease in 2006, agreed to conduct a thorough, highly controlled review of the guidelines.

“My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists. The IDSA’s guideline 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,” Mr. Blumenthal said in a press release.

The IDSA, however, downplayed the results of the investigation and an accompanying agreement to reconsider the guidelines. In a statement released last week, the 8,000-member national group denied the existence of conflicts of interest and portrayed the deal as a sort of victory in providing a chance to clear the cloud over its controversial guidelines.

“The agreement ends the investigation of IDSA and its volunteer guideline panel members without the filing of a complaint for the entry by a court of factual or legal findings, with IDSA paying any fines or penalties, and without imposing on IDSA any restrictions on its right to promulgate guidelines for Lyme disease or any other disease or condition in the manner it believes best serves the public health,” according to the statement.

Local advocacy groups that have criticized the guidelines for being too restrictive and for denying the existence of a chronic form of Lyme disease claimed the investigation and the agreement as a major victory of its own.

“We are finally vindicated in a sense,” said Nancy B. Wood, co-chairman of the Cape Cod chapter of the Lyme Disease Association. “We are ecstatic about it. They will finally be forced to include in their deliberations all evidence regarding ongoing infections and treatments.”

Brenda J. Boleyn of Truro, a founding member and co-chair of the Cape and Islands Lyme Disease Task Force, said, “The important thing to think about is that the attorney general was focusing on the process, on the way the guidelines were developed. Doctors who disagree with the IDSA will now have a chance to have their voices heard because until now their voices have been stifled.

“This is quite unprecedented. I am not a historian, but it would be difficult for me to believe that anything like this has ever happened before,” Ms. Boleyn said.

Cape Cod and the surrounding areas are the epicenter of Lyme disease in Massachusetts, which has among the highest rates of infection in the nation. The rate of infection per 100,000 residents in Barnstable County increased from 54.1 in 1999 to 101.1 in 2005. Statewide cases of the disease have exploded recently, from 148 cases in 1993 to 2,336 in 2005. Reported cases increased by almost 50 percent between 2004 and 2005, and many Lyme-awareness advocates believe the number of cases is still significantly underreported.

“It is an enormous problem here. I don’t even know how to convey how serious it is. I have been here for 16 years, as a resource for people suffering from Lyme and other tick-borne ailments, and I have heard from many thousands of people, many of whom have no choice but to leave the state in order to get treated,” said John F. Coughlan, president of the Massachusetts Lyme Disease Awareness Association, an advocacy group based in Mashpee.

The investigation and the agreement highlight an extremely controversial aspect of Lyme: whether it can resist standard antibiotic treatments and become a chronic disease.

Some doctors and an active community of advocates have argued that despite an initial course of antibiotics, some patients can remain infected by the spiral-shaped bacteria for years on end, suffering bouts of crippling arthritis, memory loss, and mood swings. Known as “chronic Lyme,” the disease is treated with multiple, months-long courses of powerful antibiotics.

“What they have done is turn their back on the many thousands of patients who do not recover in 30 days, and go on to have debilitating symptoms for many years,” Ms. Wood said.

Ms. Wood said more than 35,000 people nationwide signed a petition opposing the guidelines when they were first released.

Other doctors and the IDSA guidelines deny the existence of chronic Lyme, arguing that the bacteria cannot survive the initial round of antibiotics and that subsequent symptoms are the result of “post-Lyme syndrome,” not an active infection. Long-term antibiotic courses can have serious side effects.

According to the IDSA, “A small group of physicians outside the medical mainstream and their patients endorse such long-term treatment, despite the compelling medical evidence that it is ineffective and can have serious, life-threatening complications—and, furthermore, is extremely expensive.”

Adding to the controversy, health insurance companies, including United Healthcare, Health Net, and Kaiser Foundation Health Plan, have used the guidelines to defend refusing to cover expensive, long-term antibiotic treatments for patients diagnosed with chronic Lyme, according to the attorney general’s statement.

Clinical guidelines, which define diseases, identify symptoms, explain diagnoses, and establish standards of care, are a reference source for doctors. They take on outsized importance for diseases such as Lyme that many doctors are not entirely familiar with.

Because of the IDSA guidelines, and the refusal of some insurance companies to pay for long-term treatment, many local residents cannot find doctors willing to treat persistent symptoms, according to Mr. Coughlan.

Mr. Blumenthal, who came under criticism for injecting politics into a scientific debate, said the deal with IDSA “vindicates” the 18-month inquiry and emphasized that the focus was on the process used to develop the guidelines, rather than the guidelines themselves.

Mr. Blumenthal found that several of the panelists who developed the guidelines had financial conflicts of interest with drug development and other medical industries. The IDSA did not review the panelists for potential conflicts and violated its own rules for appointing them.

“The IDSA’s 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group’s position on chronic Lyme disease to achieve ‘consensus,’” according to the press release.

The guideline review will be conducted by an entirely new panel, overseen by an ombudsman, and include an open hearing to be broadcast live on the IDSA’s website. The new panel will decide whether to maintain, revise, or completely replace the current guidelines.

IDSA’s president, Dr. Donald Poretz, said in a press release, “IDSA has agreed to this unique, singular review of our guidelines because the panel will consist solely of physicians and scientists.

“IDSA is voluntarily agreeing to this extra scrutiny in the hope that it will help put to rest assertions that have been made—all of them unfounded—that IDSA has ignored divergent opinions in developing its Lyme disease guidelines,” according to the press release.

The local advocates applauded Mr. Blumenthal for pursuing the investigation and said they were hopeful the review will produce a new, more expansive set of guidelines.

“I would hope that it would be more open-minded and recognize the fact that the infection for some people, not for everyone, but for some people Lyme disease can persist longer than what they are saying, which is that it is easily diagnosed and easily treated and that it is not really chronic,” Mr. Coughlan. “The science is there to show it. They just need to be willing to look at it.”

Ms. Boleyn said much is still unknown about the pathogen that causes Lyme disease, which makes the imperative of hearing multiple viewpoints all the more important.

Ms. Boleyn said, “I hope to see that physicians who have different views and wish to treat more aggressively will be permitted to do their work.”

However, the significance of the review remains to be seen, Ms. Boleyn said.