



News from

Office of the Attorney General
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Attorney General

Richard Blumenthal

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Release

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ATTORNEY GENERAL'S INVESTIGATION REVEALS FLAWED LYME DISEASE GUIDELINE PROCESS, IDSA AGREES TO REASSESS GUIDELINES, INSTALL INDEPENDENT ARBITER

Attorney General Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America's (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbiter.

The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They 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.

"This agreement vindicates my investigation -- finding undisclosed financial interests and forcing a reassessment of IDSA guidelines," Blumenthal said. "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.

"The IDSA's Lyme guideline process lacked important procedural safeguards requiring complete reevaluation of the 2006 Lyme disease guidelines -- in effect a comprehensive reassessment through a new panel. The new panel will accept and analyze all evidence, including divergent opinion. An independent neutral ombudsman -- expert in medical ethics and conflicts of interest, selected by both the IDSA and my office -- will assess the new panel for conflicts of interests and ensure its integrity."

Blumenthal's findings include the following:

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- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;
- 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";
- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded;
- The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

IDSA has reached an agreement with Blumenthal's office calling for creation of a review panel to thoroughly scrutinize the 2006 Lyme disease guidelines and update or revise them if necessary. The panel -- comprised of individuals without conflicts of interest -- will comprehensively review medical and scientific evidence and hold a scientific hearing to provide a forum for additional evidence. It will then determine whether each recommendation in the 2006 Lyme disease guidelines is justified by the evidence or needs revision or updating.

Blumenthal added, "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. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result, medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.

“Our investigation was always about the IDSA’s guidelines process -- not the science. IDSA should be recognized for its cooperation and agreement to address the serious concerns raised by my office. Our agreement with IDSA ensures that a new, conflicts-free panel will collect and review all pertinent information, reassess each recommendation and make necessary changes.

“This Action Plan -- incorporating a conflicts screen by an independent neutral expert and a public hearing to receive additional evidence -- can serve as a model for all medical organizations and societies that publish medical guidelines. This review should strengthen the public’s confidence in such critical standards.”

THE GUIDELINE REVIEW PROCESS

Under its agreement with the Attorney General’s Office, the IDSA will create a review panel of eight to 12 members, none of whom served on the 2006 IDSA guideline panel. The IDSA must conduct an open application process and consider all applicants.

The agreement calls for the ombudsman selected by Blumenthal’s office and the IDSA to ensure that the review panel and its chairperson are free of conflicts of interest.

Blumenthal and IDSA agreed to appoint Dr. Howard A. Brody as the ombudsman. Dr. Brody is a recognized expert and author on medical ethics and conflicts of interest and the director of the Institute for Medical Humanities at the University of Texas Medical Branch. Brody authored the book, *“Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry.”*

To assure that the review panel obtains divergent information, the panel will conduct an open scientific hearing at which it will hear scientific and medical presentations from interested parties. The agreement requires the hearing to be broadcast live to the public on the Internet via the IDSA’s website. The Attorney General’s Office, Dr. Brody and the review panel will together finalize the list of presenters at the hearing.

Once it has collected information from its review and open hearing, the panel will assess the information and determine whether the data and evidence supports each of the recommendations in the 2006 Lyme disease guidelines.

The panel will then vote on each recommendation in the IDSA’s 2006 Lyme disease guidelines on whether it is supported by the scientific evidence. At least 75 percent of panel members must vote to sustain each recommendation or it will be revised.

Once the panel has acted on each recommendation, it will have three options: make no changes, modify the guidelines in part or replace them entirely.

The panel's final report will be published on the IDSA's website.

ADDITIONAL FINDINGS OF BLUMENTHAL'S INVESTIGATION

IDSA convened panels in 2000 and 2006 to research and publish guidelines for the diagnosis and treatment of Lyme disease. Blumenthal's office found that the IDSA disregarded a 2000 panel member who argued that chronic and persistent Lyme disease exists. The 2000 panel pressured the panelist to conform to the group consensus and removed him as an author when he refused.

IDSA sought to portray a second set of Lyme disease guidelines issued by the American Academy of Neurology (AAN) as independently corroborating its findings. In fact, IDSA knew that the two panels shared key members, including the respective panel chairmen and were working on both sets of guidelines at the same time -- a violation of IDSA's conflicts of interest policy.

The resulting IDSA and AAN guidelines not only reached the same conclusions regarding the non-existence of chronic Lyme disease, their reasoning at times used strikingly similar language. Both entities, for example, dubbed symptoms persisting after treatment "Post-Lyme Syndrome" and defined it the same way.

When IDSA learned of the improper links between its panel and the AAN's panel, instead of enforcing its conflict of interest policy, it aggressively sought the AAN's endorsement to "strengthen" its guidelines' impact. The AAN panel -- particularly members who also served on the IDSA panel -- worked equally hard to win AAN's backing of IDSA's conclusions.

The two entities sought to portray each other's guidelines as separate and independent when the facts call into question that contention.

The IDSA subsequently cited AAN's supposed independent corroboration of its findings as part of its attempts to defeat federal legislation to create a Lyme disease advisory committee and state legislation supporting antibiotic therapy for chronic Lyme disease.

In a step that the British Medical Journal deemed "unusual," the IDSA included in its Lyme guidelines a statement calling them "voluntary" with "the ultimate determination of their application to be made by the physician in light of each patient's individual circumstances." In fact, United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the guidelines as justification to deny reimbursement for long-term antibiotic treatment.

State of Connecticut

RICHARD BLUMENTHAL
ATTORNEY GENERAL



Hartford

February 1, 2010

Richard J. Whitley, MD, FIDSA,
Infectious Disease Society of America
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209

Dear Dr. Whitley:

I am writing to express my concern that the Infectious Diseases Society of America ("IDSA") may soon approve an improper voting procedure implemented by the Lyme disease Review Panel and its Chairperson in violation of the settlement agreement and Action Plan ("AP") with my office.

As you are aware, during an antitrust investigation of the IDSA my office uncovered significant procedural deficiencies relative to the IDSA's 2006 Lyme disease clinical practice guidelines. These process deficiencies raised serious questions as to whether the recommendations made in the 2006 guidelines reflected the best available scientific and medical evidence on the subject. In order to address the deficiencies uncovered during the investigation, my office and the IDSA negotiated a settlement, which included an AP. The essence of the AP was fairly simple: Step 1 to establish a stringent procedure for identifying and vetting a completely new review panel whose responsibility would be to, Step 2: assess by voting whether each of the original 2006 guidelines' recommendations are medically and scientifically justified in light of all the available evidence collected through an open collection process, and Step 3: through a vote, determine whether to make revisions to any of those recommendations or recommend a complete re-write of the 2006 guidelines.

Because my office determined that the IDSA had excluded consideration of divergent evidence and participation of individuals from the 2006 guidelines panel who held dissenting opinions, the cornerstone of the AP and the "principle function" of the Review Panel established thereunder, was to look anew and "make an individual determination whether each of the recommendations in the 2006 Lyme disease guidelines is medically/scientifically justified in

light of all of the evidence and information provided.”¹ In other words, the Review Panel was assigned the task of determining whether the Lyme disease panel “got it right” in the first instance for each recommendation.

In order to ensure there were no misunderstandings in the interpretation of the AP, attorneys from my office participated in a telephone call with the IDSA’s attorneys on May 5, 2008, during which it was agreed that there were two voting elements in the agreement, each of which would require a supermajority confirmation. The first voting required, as part of the Review Panel’s “weighing of the evidence responsibility”, involves the “principal function” of the panel, which is “to make an individual determination whether each of the recommendations in the *2006 Lyme disease guidelines* is medically/scientifically justified in light of all of the evidence and information provided.”² As our attorneys discussed, the term “determination” was specifically used in this section to ensure that votes be held on this question for each recommendation and that a supermajority be required to find that a particular recommendation was “medically/scientifically justified in light of all of the evidence and information provided.” All “determinations/recommendations” require “a supermajority vote of 75% or more of total voting members.”³ Moreover, it was agreed that the Final Report requires disclosure of the outcome of this basic, yet fundamental voting element. In Section D.1(b), the AP requires that the report include “[s]tatements whether each recommendation in the 2006 Lyme disease guidelines was found by the Review Panel to be medically/scientifically justified in light of the evidence and information collected and provided” to demonstrate the outcome of this primary assessment. This primary voting was intended to elicit an affirmative yes/no results.

In anticipation of the Review Panel’s issuance of the Final Report, members of my staff recently visited the office of your local counsel to view minutes and records pertaining to the Review Panel’s voting. During this review my staff discovered that the Review Panel failed to conduct the principal voting required by the agreement and the AP on whether each recommendation in the 2006 Lyme disease guidelines was justified by the medical/scientific evidence. Instead of conducting this vote, it appears that the Review Panel, with your Vice President of Clinical Affairs present, voted on whether each recommendation warranted one of four actions: (a) no change was required, (b) no change was required with comment, (c) a revision was necessary or (d) a re-write was required. These voting parameters do not specifically appear anywhere in the AP, as even the secondary vote on what actions to take following the initial assessment of whether the evidence supported each recommendation does not permit a vote on whether to determine no change is warranted with the option to comment. Such an option actually diminishes the three permitted secondary voting options.

¹ See AP section IC3(a)

² Section IC3(a)

³ Section IC4

My staff has notified the IDSA's Vice President of Clinical Affairs and your counsel of the improper voting procedure, and I understand it is the IDSA's position that the vote conducted was in accordance with the agreement and the AP. Moreover, the IDSA maintains this position even after my office sent a copy of a July 9, 2009 IDSA directive to the Review Panel's Chairperson and panel members instructing them as to the AP's voting requirements. This directive was drafted on IDSA letterhead and commanded adherence to the very two-stage voting process that the IDSA currently is at risk of violating. The directive (a copy of which I have enclosed for your consideration), stated that:

“[e]ach Panel member must vote on each recommendation within the 2006 Guidelines” prior to a secondary vote in which “each Panel member must vote on an overall recommendation for the guidelines as follows: No changes are necessary, OR Sectional revision is needed; proposals for any such revisions should be made, OR Complete re-writing is needed.”

The directive further restates the requirement that all votes “require supermajority support (75% or more), and specifies that “a minimum of seven panel members must vote in favor of a recommendation in order for the panel to deem it supported by the evidence, just as a minimum of seven panel members must support one of the three options for the overall guideline evaluation in order to recommend that option to the IDSA.”⁴ This directive highlights three important facts: (a) The IDSA actually agrees that the AP requires two separate voting processes and that the first involves an individual evaluation by each Review Panelist as to whether the scientific and medical evidence supports each recommendation in the 2006 guidelines; (b) that the Review Panel and its Chairperson were informed of this position prior to the scientific hearing and any voting activities, and thus should have followed the directive and (c) that the IDSA's Vice President of Clinical Affairs failed to admonish the Review Panel to follow the AP and directive during the voting phase and instead established a paradigm for that voting that violated the terms of the AP.

My staff has concluded from its review of the voting that the first recommendation, which states in part that “[d]iagnostic testing performed in laboratories with excellent quality-control procedures is required for confirmation of extra-coetaneous Lyme disease, HGA and babesiosis,” received a vote to revise by four of the eight voting panelists on the Review Panel. The reasonable conclusion is that half of the eight panel members found that this provision was not supported by the medical/scientific evidence, such that it required revision and, consequently, that the requisite 75% supermajority could not be achieved in the primary votes to, in the IDSA's own words, “deem it supported by the evidence. . .”

⁴ At the time the directive was written there were nine panelists, meaning a supermajority of seven panelists was required. Since that time, one panelist resigned from the panel for personal reasons, such that currently a supermajority would consist of six votes.

Since the Final Report has not yet been issued, a cure to this apparent violation in the form of an individual vote on whether each recommendation in the 2006 Lyme disease guidelines is medically/scientifically justified in light of all of the evidence and information provided" is readily achievable, especially since the Review Panel has already reviewed and considered the evidence presented. To date, the IDSA has rejected this relatively simple remedy.

I request that the IDSA hold an individual vote on whether each of the recommendations in the 2006 Lyme disease guidelines is medically/scientifically justified in light of all of the evidence and information provided, and to have that vote memorialized with particularity for the record, reported by the Review Panel Chairperson to the Ombudsman, and ultimately reflected in the final report as required by the AP.

Thank you for your attention to this most important matter.

Sincerely,



RICHARD BLUMENTHAL

RB/pas

IDSA Violates Lyme Antitrust Settlement Agreement with Connecticut Attorney General

On Monday, February 1, 2010, the Connecticut Attorney General sent a letter to the IDSA expressing “concern” over “improper voting procedures” used by the IDSA in the Lyme guidelines review voting process. The IDSA may soon approve hearing determinations based on this improper voting procedure. The Attorney General requested that the IDSA redo the vote to comply with the Settlement Agreement.

<http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284>. The four-page Attorney General letter was released in response to a Freedom of Information Request made on behalf of patient groups for information regarding the IDSA’s compliance with the Settlement Agreement.

What happened? The IDSA used an “improper voting procedure,” based on a process of its own design, which blatantly violates the Settlement Agreement and undermines the integrity of the voting process. The IDSA consented to the voting procedure in the Settlement Agreement and confirmed its understanding of the required voting procedure in an internal memo from the IDSA to the panel before the panel met. The [Attorney General’s letter and the IDSA internal memo to the panel](#) are attached to this release.

What voting process was required and how was it violated? The Settlement Agreement requires a two step voting procedure, with each step requiring a supermajority vote (6 of 8 panelists). The first vote asks the question whether each of the contested guideline recommendations is “medically/ scientifically justified in light of all of the evidence and information provided.” This vote requires a supermajority of the panel (6 of 8) in order for a guideline recommendation to stand. In essence, it asks “did the panel that adopted the 2006 guidelines get it right”? The second vote, also by supermajority, determines whether the guidelines require no changes, partial revision or complete revision.

The IDSA’s flawed voting procedure combined the two voting steps into one. First, the panel failed to conduct the vote to determine whether the science was sufficient to support the guideline recommendations. Next, the panel substituted its own procedure for the second step in the voting and required a supermajority for any change. This process effectively flipped the supermajority requirement to favor no change to the guidelines.

From the get-go, two significant points stand out:

- The IDSA failed to voluntarily comply with the Settlement Agreement in good faith.
- Absent oversight by the AG pursuant to the Settlement Agreement, the IDSA would have carried out a corrupted process that blatantly violates the agreement—and it might never have been discovered.

Patient groups are appalled that so far the IDSA, which should conduct an honest review and assessment of the evidence supporting the IDSA recommendations, has chosen to manipulate the voting requirement to influence the outcome, in clear violation of the Settlement Agreement and the scientifically based review and voting process which it provides. This turns evidence-based medicine on its head.

Can the process be saved? Patient groups, along with the public at large, expected that the IDSA would comply with the Settlement Agreement in good faith. It is, after all, a settlement agreement with the Attorney General of the State of Connecticut. When the IDSA panel so deliberately violates the voting procedures, as expressly confirmed by the words of the IDSA's own internal memo, and refuses to comply with the Attorney General's request, there can be only one conclusion: The ability of the IDSA to run this process with integrity is extremely suspect and any outcome must be viewed critically.

Other examples of abuse by IDSA of settlement process: This is not the first time legitimate questions have been raised regarding the IDSA's willingness and reliability in performing its obligations with integrity under the settlement process. For instance, the IDSA was charged with selecting the panel and chose to exclude divergent viewpoints (including physicians who treat chronic Lyme disease). One panelist was removed by the panel after patients complained because he had served on another Lyme guidelines' panel— a direct violation of the settlement agreement. Another panelist had also served on a previous Lyme guidelines' panel, but despite patient complaints, was not removed.

Patient organizations call upon the IDSA to hold an individual vote on whether each of the guidelines' recommendations is medically/scientifically justified in light of all the evidence as requested by the Attorney General. If IDSA fails to do so in good faith, patients continue to rely upon the Attorney General to continue to enforce the Settlement Agreement.

[An example of the IDSA manipulation of the voting procedure.

The guidelines mandate that Lyme cannot be diagnosed without a confirming diagnostic test. The tests are known to be insensitive and flawed. Requiring a positive test means that many patients with Lyme disease will fail to be diagnosed. One panel vote described in the AG's letter was whether this recommendation should be revised. Four of the eight panel members voted for change, without the panel first having voted to determine whether the recommendation was supported by the science. As the AG's letter points out, this clearly means that had the panel voted in accordance with the Settlement Agreement, this recommendation would have failed as not properly supported by the medical/scientific evidence. Why? A vote to uphold this recommendation would have required 6 votes; however, the 4 votes calling for revision (even though predicated on a flawed procedure) plainly indicates insufficient evidence to support the recommendation. Thus, (a) the IDSA failed to vote to determine whether the science supported the recommendation, (b) substituted its own procedure regarding revision (requiring a supermajority vote to revise), and (c) thereby manipulated the voting requirements to achieve a result in its favor.]