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.

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***[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.]

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.

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[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. . .."

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[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.

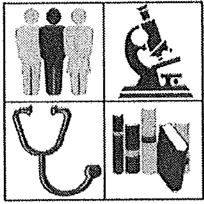
I request that the IDSA hold an individual vote on whether each of the recommendations in the 2006 Lyme disease guidelines is medically/scientifically justified in light of all of the evidence and information provided, and to have that vote memorialized with particularity for the record, reported by 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
Infectious Diseases Society of America

2008-2009
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July 9, 2009

To: IDSA Lyme Disease Guideline Review Panel

From: Jennifer J. Padberg, MPH

Re: To revisit the Panels' overall purpose and goals

Sent via e-mail

Dear Review Panel Members:

We are quickly approaching the July 30-31, hearing and panel meeting and as we discussed during our conference call in June, a reiteration of the purpose and goals of this effort may be helpful to you as we move into the events taking place in just a few short weeks. I have discussed these purposes and goals with the Connecticut Attorney General's Office. We agree that under the Action Plan, a copy of which is attached hereto for your review, the Review Panel must do the following:

- Objectively review and consider all the relevant evidence, including the information gathered (literature, public input) and presented (at the public hearing);
  - Evidence published after the publication of the 2006 guidelines should also be considered.
- The principle function of the Review Panel shall be to make an individual determination whether each of the recommendations in the IDSA's 2006 Lyme disease guidelines is medically/scientifically justified in light of all of the evidence and information provided.
  - Each Panel member must vote on each recommendation within the 2006 Guidelines
  - Upon completion of voting on the individual recommendations in the 2006 guidelines, 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 revision(s) should be made, OR
    - Complete re-writing is needed
  - All votes require supermajority support (75% or more). Hence 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.
    - All voting will be recorded by the Chaiperson and presented to the ombudsman.
- The Panel's overall recommendation and any proposed revisions must be submitted to the IDSA.
- A final report will be developed and made publically available.

We thank you for your committement of time and effort to this important process and for your anticipated objectivity in reviewing the evidence presented. If you have any questions about this information, please let me know (phone: 703/299-0162; e-mail: jpadberg@idsociety.org).

Sincerely,

Jennifer J. Padberg, MPH
Vice President of Clinical Affairs

cc: Richard Blumenthal, Attorney General, State of Connecticut
Howard Brody, MD, Ombudsman
Thomas Ryan, Assistant Attorney General, CT Office of the Attorney General

attachment

EXHIBIT 1

Action Plan

Infectious Diseases Society of America
Action Plan Requirements

I. The Infectious Diseases Society of America ("IDSA") shall convene a Review Panel whose task shall be to determine whether or not its 2006 Lyme disease guidelines, titled "The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America," (hereinafter, "2006 Lyme disease guidelines") should be revised or updated based on a review of all relevant evidence, including any evidence submitted through this review process. A Review Panel of not less than eight but not more than twelve members, none of whom served on the 2006 Lyme disease guideline panel, shall be convened for this review. The Office of the Connecticut Attorney General ("CTOAG") and the IDSA shall jointly select an Ombudsman whose duties are set forth in this Action Plan.

The Review Panel will be formed and conduct its responsibilities as follows:

A. Review Panel Chairperson Selection:

1. Selection of the Review Panel Chairperson shall be made by the IDSA's Standards and Practice Guidelines Committee ("SPGC") through an open application process.
2. Applicants shall disclose all financial relationships and competing interests via the Applicant Statement of Interests that is attached hereto as Appendix 1. Following said disclosure, the SPGC shall select a Chairperson that it and the Ombudsman have determined to be without any beneficial or financial interest related to Lyme disease, any financial relationship with an entity that has an interest in Lyme disease, and any conflict of interest.[1]
3. In selecting a Chairperson for the Review Panel, the SPGC shall use the following criteria:

   a. Must be trained in infectious diseases.

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[1] A conflict of interest exists when anyone involved in the guideline process has a financial or other beneficial interest in the products or concepts addressed in the guidelines or in competing products or concepts that might bias his or her judgment. For guidance purposes, if the combined financial or beneficial interests in the products or concepts addressed in the guidelines exceed $10,000, those interests may be considered to bias a participant's judgment.

b. Must not have previously published a particular viewpoint regarding Lyme disease diagnosis or treatment.

c. Must be knowledgeable about the subject of Lyme disease, but not necessarily an expert.

d. Must have experience in the review and interpretation of the medical/scientific literature.

e. Must have known abilities to:

i. Complete tasks in a timely manner.

ii. Consider varying points of view.

iii. Bring groups of individuals to consensus.

f. Must not have served on any Lyme disease guideline panel.

B. Review Panelist Selection: A Review Panel of no fewer than eight but no more than twelve panelists (including the Chairperson, who shall be a full member of the Review Panel) shall be selected by the SPGC and the Chairperson.

1. Review Panelist applicants shall be solicited by a fair and open application process.

a. Applicants for Chairperson may be considered for inclusion in the Review Panel.

b. IDSA shall post an announcement on the IDSA website encouraging interested clinicians and/or scientists to apply.

c. Applications from representatives of other relevant specialties may also be solicited by the IDSA.

2. Applicants shall disclose all financial relationships and competing interests via the Applicant Statement of Interests that is attached hereto as Appendix 1. Following such disclosure, the SPGC and the Chairperson shall select Review Panelist applicants that the SPGC Chair and the Ombudsman have determined to be without any conflicts of interest.

3. The SPGC shall select Review Panelists who, as a group, reflect a balanced variety of perspectives and experience across a broad range of relevant disciplines, ranging from clinical experience in treating patients with Lyme disease to experience in investigating the best methods to diagnose and treat Lyme disease or other infectious diseases.

4. The Review Panel shall include at least one physician with clinical experience in treating Lyme disease patients.

5. Review Panelists need not be members of the IDSA.

6. The SPGC shall give fair consideration to all reasonable applicants.

7. Review Panelists shall not have previously served on any Lyme disease guideline panel.

C. Review Panel Operation:

1. Data Collection

   a. Under the direction of the Review Panel, IDSA Staff shall conduct a comprehensive search and retrieval of the medical/scientific literature, which shall be considered by the Review Panel along with other literature submitted through the hearing or input collection mechanisms identified in subsections 1.b and 2.b of this section.

   b. IDSA Staff shall post a conspicuous announcement of its intention to collect medical/scientific evidence related to Lyme disease on the IDSA website and shall develop an online mechanism, which shall include a dedicated e-mail address, to collect input from individuals and organizations that shall be disseminated to and considered by the Review Panel.

   c. Input period shall be open for at least 60 days. Such period shall precede the Review Panel's commencement of its assessment of the 2006 Lyme disease guidelines.

2. Meetings

   a. The Review Panel shall meet at least once in person and as needed via teleconference to consider all relevant evidence and all input submitted, as indicated above.

   b. An open public hearing shall be held in conjunction with an in-person Review Panel meeting to offer a forum for the presentation of relevant written or oral data/information on the topic of Lyme disease. All public stakeholders may apply to make an oral presentation; however, clinicians and researchers shall be given preference. The Review Panel shall work with the Ombudsman and the CTOAG to finalize a list of presenters and shall reserve presentation time for divergent opinions. The presenters shall include a minimum of two members of the 2006 IDSA Lyme disease guideline panel. Individuals making presentations at the hearing shall disclose all conflicts of interest to the Review Panel by submitting a certified statement. A conflict of interest shall not be grounds for denial of the opportunity to present.

      i. The IDSA shall conduct a live video broadcast of the hearing for public viewing on its website. All oral statements made during the

hearing shall be recorded in the official transcript. Such transcript and copies of all written information provided by the individuals making presentations shall be made part of the Review Panel record and shall be made available to the public.

3. Weighing the Evidence

   a. The principle function of the Review Panel shall be 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.

   b. In evaluating the need for a revision or update, the Panel may consider the following questions (Shenkelle, *et al.*[2]):

      i. Has information about the magnitude of benefits and harms rendered the pre-existing guidelines invalid?

      ii. Has evidence identified important outcomes that need to be added to or considered by the guidelines (e.g., quality of life)?

      iii. Are there preventive, diagnostic, or treatment interventions to complement or supersede the interventions in the pre-existing guidelines?

      iv. Does the evidence show that current practice is optimal and the guidelines are no longer needed?

      v. Have there been changes in the values placed on outcomes?

      vi. Have there been changes in the resources available in healthcare (e.g., availability of less expensive (generic) drugs)?

4. Voting

   a. The Review Panel shall strive to achieve consensus.

   b. It is the responsibility of the Review Panel Chairperson to manage any vote on any key finding or recommendation and report such vote to the Ombudsman. The name and vote of each Review Panel member must be maintained for the record, but will not be made public, though the overall vote of the Review Panel on the final recommendation(s) shall be made public.

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2 Shenkelle P, Eccles MP, Grimshaw JM, Woolf SH: When should clinical guidelines be updated? BMJ 2001;323;155-157.4

c. Panel determinations/recommendations shall require a supermajority vote of 75% or more of the total voting members.

5. Recommendation

a. Based on its weighing of evidence, the Review Panel shall recommend one of the following three options:

i. That no changes to the 2006 Lyme disease guidelines are necessary.

ii. That there is a need for sectional revision of the 2006 Lyme disease guideline. In this instance the Review Panel shall make proposals for those revisions, which shall be considered and implemented by the SPGC.

iii. That a complete rewriting of the 2006 Lyme disease guideline is required. If the Review Panel determines that such a rewriting of the Lyme disease guideline is warranted, the IDSA shall convene a guideline panel consistent with the terms of this Action Plan and the and the IDSA's Handbook on Clinical Practice Guideline Development.

6. The recommendation(s) of the Review Panel shall be binding upon the IDSA.

D. Final Report:

1. The Final Report shall be certified by the Review Panel Chairperson and shall include the following:

a. The names of each Review Panelist.

b. Statements of 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.

c. A statement of the Review Panel's overall recommendation pursuant to subsection C.5 of this section, including any particular recommended revisions pursuant to C.5.a.ii.

2. The IDSA shall conspicuously place a link to the Final Report on its website's home page for one year following the release of the Final Report.[3] The IDSA shall also provide copies of the Final Report to any organization that endorsed

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[3] Should the Review Panel recommend a sectional revision or complete rewriting of the 2006 Lyme disease guideline pursuant to subsection C.5, then the IDSA shall continue to place a link on its website's homepage until such time as such revision or rewrite is complete.

the 2006 Lyme disease guidelines, the National Guidelines Clearinghouse, and the CTOAG.

E. Records and Minutes of Meetings:

1. IDSA shall retain all records relating to the Review Panel's activities, including the selection of the Review Panel Chairperson and Review Panelists. All vote tallies shall be recorded.

2. Official minutes of all in-person and telephonic panel meetings shall be recorded and maintained.

3. The Ombudsman and CTOAG shall have access to all records and minutes of all Review Panel meetings. IDSA shall provide copies of all records and minutes of Review Panel meetings to the Ombudsman, who shall keep such records confidential with respect to persons who are not parties to this Agreement. In the event that the CTOAG requires access to such documents, IDSA shall make them available for inspection and review at its offices and the office of its legal counsel in Connecticut.

APPENDIX 1

Applicant Statement of Interests
(Financial, Equity, Intellectual Property, Research, Advocacy)

Name: Date of Statement: ____

Use and reference additional pages if necessary to complete this form.

1. PAST OR PRESENT FINANCIAL RELATIONSHIPS: Please list below all pharmaceutical, medical device, biotechnology, or medical consulting companies in which you or your immediate family member(s) have or have had financial, equity, or intellectual property interests, currently and in the 2 years prior to the date of this document.

Name of Company	Type of Relationship (Please check (√) if yours or write "FM" if family member, defined as spouse and minor children)		
	Financial*	Equity**	Intellectual Property
For interests ≤ $10,000			
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
For interests > $10,000 to $25,000			
1.			
2.			
3.			
For interests > $25,000			
1.			
2.			
3.			

*Fees for consulting, speaker's bureaus, advisory boards, or other committees. Include fees paid to you directly or indirectly to you through a University account that is under your control (e.g., discretionary account).
**Do NOT include mutual funds.

2. FUTURE STOCK OPTIONS/PATENT RIGHTS: Please list all stock options and/or patent rights that you or your family member(s) have in a pharmaceutical, medical device, or biotechnology company. Include pertinent patent numbers.

Name of Company	Type of INTEREST (Please check (√) if yours or write "FM" if family member)	
	Future Stock Options	Patent Rights
1.		
2.		
3.		
4.		
5.		
6.		
7		
8.		

3. List any grant or contract that either provides salary support paid to you through your institution or supports your research without salary support, currently and in the 2 years prior to the date of this document. Only include research that could reasonably be considered related to Lyme disease.

Name of Sponsor*	Brief Description of Research
1.	
2.	
3.	
4.	
5.	
6.	
7.	

*List Government (e.g., NIH, FDA, AHRQ), Foundation source, name of private company (e.g., pharmaceutical, medical device, biotechnology, or medical consulting company), name of individual, or name of partnership, trust, or any other entity.

4. List all medical contracts not disclosed above, excluding contracts for the direct provision of medical care to patients, but including insurance and medical consulting contracts.

Name of Contractor	Description of Contract
1.	
2.	
3.	
4.	
5.	
6.	
7.	

5. Estimate the percentage of your clinical practice that is devoted to the diagnoses and treatment of patients for Lyme disease.

_____%

Estimate the amount of revenue generated by your clinical services to diagnose and treat patients for Lyme disease.

☐ <$10,000

☐ >$10,000-$25, 000

☐ >$25,000

6. In the past 2 years, did you serve as an owner, officer, director, partner, manager, or employee of any pharmaceutical, medical device, or biotechnology company?
No ______ Yes ______ If yes, specify the company(s) and details of your role.

7. In the past 2 years, have you received payment for expert testimony in a legal proceeding on a topic that could reasonably be considered related to Lyme disease?
No ______ Yes ______ If yes, specify content area of your testimony.

8. In the past 2 years, have you received payment for an advocacy role in government or non-profit organization on a topic that could reasonably be considered related to Lyme disease?
No ______ Yes ______ If yes, specify advocacy role.

CERTIFICATION

State of ___________________)
)   ss:
County of _________________)

I ______________________________hereby certify that the information provided above is true, accurate and complete to the best of my knowledge and belief.

Dated: _________________, 20___

_______________________________   __________________________
Print Name   Signature

Subscribed to and sworn before me this _________________day of

__________________20___.

____
Notary Public

My commission expires _____________, 20____