The War on Lyme Patients

Douglas W. Fearn
Lyme Disease Association of Southeastern Pennsylvania, Inc.

Who has declared war on Lyme patients?

Infectious Disease Society of America (IDSA)

Infectious Disease Society of American (IDSA)

-- A professional medical organization of 8000 infectious disease doctors founded in 1963

-- Writes expert guidelines on the diagnosis and treatment of infectious diseases

-- Its guidelines are adopted by the CDC, other medical specialties, and health insurers

New Guidelines in October 2006

IDSA Lyme Disease Guidelines

A positive Lyme disease diagnosis requires:
1. living in a Lyme-endemic area
2. a bite by a deer tick (doctor confirmed)
3. a positive blood test using the CDC two-tiered surveillance criteria

OR

a physician-observed bull’s eye rash that occurs within 30 days of the tick bite
The rash must be at least 2” in diameter

The tick must be attached for at least 36 hours

IDSA 2006 Lyme Disease Guidelines
IDSA 2006 Lyme Disease Guidelines

**Testing**

2-tiered test procedure designed for the CDC’s surveillance of Lyme disease

1. ELISA screening test  
2. if ELISA positive, Western Blot  

**IDSA 2006 Lyme Disease Guidelines**

**Testing**

NY Dept Health 1996: found CDC’s 2 tiered testing missed 82% of positive Lyme cases  
DeBuono, B. NY Dept of Health report to CDC April 15, 1996  

Johns Hopkins study 2005: found CDC 2-tiered testing missed 75% of positive Lyme cases  
Coulter, et al., J Clin Microbiol 2005; 43: 5080-5084

**IDSA 2006 Lyme Disease Guidelines**

**Treatment**

Doxycycline or amoxicillin for 10-21 days

**IDSA 2006 Lyme Disease Guidelines**

If you still have symptoms after treatment, the doctor may give you another 10-21 days of doxycycline or amoxicillin, after waiting at least a month.

“Treatment for 14-28 days has a 26-50% failure rate.”  
Wahlberg et al., J Infec 1994; 29(3): 255-261

**IDSA 2006 Lyme Disease Guidelines**

And that’s all, for the rest of your life, regardless of your symptoms
Antibiotics NOT recommended
(partial list):
• Bicillin
• Cipro or Levaquin
• Vancomycin
• Flagyl or Tinidazole
• Ketek
• Difflucan

Treatments NOT recommended
(partial list):
• More than two course of antibiotics
• Combinations of antibiotics
• Pulsed antibiotics
• Hyperbaric oxygen
• Cholestyramine
• Any treatment for Bartonella
• Vitamins or nutritional supplements

Who wrote these guidelines?
Gary P. Wormser Raymond J. Dattwyler
Eugene D. Shapiro John J. Halperin
Allen C. Steere Mark S. Klempner
Peter J. Krause Johan S. Bakken
Franc Strle Gerald Stanek
Linda Bockenstedt Durland Fish
J. Stephen Dumler Robert B. Nadelman

Where did they get their facts?
405 articles are cited
OUT OF OVER 19,000 ARTICLES PUBLISHED (less than 5%)

Do the authors believe what they say?
“We studied 17 patients who had presented with acute Lyme disease and received prompt treatment with oral antibiotics, but in whom chronic Lyme disease subsequently developed.”

Raymond Dattwyler, John Halperin,
New England Journal of Medicine, 1998 (319(22): 1441-6)
**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“... isolation of Borrelia burgdorferi from the blood of seven patients with Lyme disease four months after treatment …”

Gary Wormser, Robert Nadelman
American Journal of Medicine, 1990 (88:21-26)

**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“The relapses she repeatedly suffered despite initially successful antibiotic treatment could be related to the observation that Borrelia may possibly be able to remain dormant in certain tissue compartments, thus escaping bactericidal antibiotic activity.”

Gerold Stanek
British Journal of Dermatology, 2001 (144(2):387-392)

**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“Similarly [as in tertiary syphilis or tuberculoid leprosy], the antigenic stimulus in Lyme arthritis would appear to be a small number of live spirochetes, demonstrated here by monoclonal antibodies, which may persist in the synovial lesion for years.”

Allan Steere
American Journal of Medicine, 1995 (88:4A-448-51S)

**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“Lyme borreliosis is a chronic infectious disease caused by the spirochete Borrelia burgdorferi.”

Raymond Dattwyler
Reviews of Infectious Diseases, 1989 [11(6)S; S1494-8]

**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“...commercially available FDA-approved kits are only 36-70% sensitive, : the ELISA assay does not have adequate sensitivity to be part of a two tiered approach to diagnosis.”

Johan S. Bakken
Journal of Clinical Microbiology, 1997 [35(3): 537-543]

**IDSA 2006 Lyme Disease Guidelines**

**Do the authors believe what they say?**

“*Borrelia burgdorferi*, as well as other coinfections, can be transmitted from an infected mother to the fetus through the placenta during any stage of pregnancy.”

Steere et al.,
Do the authors believe what they say?

“In many instances continued infection appears to be essential for symptoms to persist, no matter how small the number of organisms, as antimicrobial therapy is generally followed by clinical improvement.”

John J. Halperin
Neurology, 1992 (42:43-50)

“57% of patients who had relapse were seronegative at the time of relapse.”

Dattwyler RJ et al., Annals of Internal Medicine 1996; 124(9):785-91

Do the authors believe what they say?

“Currently, Lyme Disease is treated with a range of antibiotics, e.g., tetracyclines, penicillin and cephalosporins. However, such treatment is not always successful in clearing the infection. Treatment is often delayed due to improper diagnosis with the deleterious effect that the infection proceeds to a chronic condition, where treatment with antibiotics is often not useful. One of the factors contributing to delayed treatment is the lack of effective diagnostic tools.”

Raymond J. Dattwyler
Patent application for Lyme vaccine 2007

IDSA 2006 Lyme Disease Guidelines

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ILADS

International Lyme and Associated Diseases Society

Doctors, other health-care professionals, and others involved in the issues of tick-borne diseases

Most of the 400 members are doctors who have devoted their practice to Lyme and other tick-borne diseases

ILADS has developed diagnostic and treatment guidelines based on their members' many years of experience in treating real patients

ILADS Guidelines

Published by the U.S. government as a standard of care for tick-borne diseases


IDSA vs. ILADS Guidelines

<table>
<thead>
<tr>
<th>IDSA Says</th>
<th>ILADS Says</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyme is rare and hard to catch</td>
<td>Lyme is common and easy to catch</td>
</tr>
<tr>
<td>10-24 days of a single antibiotic will cure all cases of Lyme</td>
<td>Treat the patient until all symptoms are gone</td>
</tr>
<tr>
<td>Lyme is easy to diagnose with a blood test</td>
<td>Blood tests for Lyme are very unreliable</td>
</tr>
<tr>
<td>Chronic Lyme disease does not exist</td>
<td>Lyme disease can be persistent</td>
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### IDSA vs. ILADS Guidelines

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<tr>
<td>Almost all patients get the bull's eye rash</td>
<td>Only 35-68% of patients ever have a rash</td>
</tr>
<tr>
<td>Neurological Lyme disease is rare</td>
<td>40% of Lyme patients have neurological involvement</td>
</tr>
<tr>
<td>No mention of psychiatric manifestations</td>
<td>Lyme can cause psychiatric symptoms</td>
</tr>
<tr>
<td>Blood tests are reliable</td>
<td>Over half of cases will have false-negative results</td>
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### IDSA vs. ILADS Guidelines

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<tr>
<td>The only clinical manifestation is the bull's-eye rash</td>
<td>Lyme disease requires a clinical diagnosis</td>
</tr>
<tr>
<td>The CDC surveillance criteria should be used for diagnosis</td>
<td>The CDC explicitly says that their surveillance criteria should not be used for diagnosis</td>
</tr>
<tr>
<td>Pregnant women should not worry about Lyme disease</td>
<td>Lyme can be transmitted from an infected mother to her baby</td>
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### WHAT WOULD THIS MEAN FOR LYME PATIENTS, PAST AND FUTURE?

Most new cases of Lyme disease will not be diagnosed
Most cases of Lyme will never be treated
The number of reported cases of Lyme will plummet

### WHAT WOULD THIS MEAN FOR LYME PATIENTS, PAST AND FUTURE?

Health insurance companies will deny payment for Lyme disease treatment

This is already happening

### IDSA is not alone

The Council of State and Territorial Epidemiologists

Has changed the way States and counties report Lyme disease to the CDC

### IDSA is not alone

The Council of State and Territorial Epidemiologists

They say that there are so many new Lyme disease cases reported that it is putting a burden on state and local health departments
**WHY?**

What would motivate doctors to contradict what they have said in the past and take a position that effectively eliminates Lyme disease?

Why would doctors take a position not to help sick patients?

**WHY?**

The Attorney General of Connecticut has investigated the IDSA for anti-trust violations

**Attorney General’s Findings**

Most of the IDSA panel members had conflict of interest in one or more areas

-- Patent holders on blood tests
-- Patent holders on Lyme vaccines
-- Consultants to drug companies
-- Consultants to insurance companies

**Attorney General’s Findings**

The chairman of the guidelines committee held a bias regarding the existence of chronic Lyme disease

The chairman handpicked other committee members with the same point of view

The IDSA blocked the appointments of others to the guidelines committee, telling them the panel was full

**Attorney General’s Findings**

The IDSA’s 2000 and 2006 committees refused to consider information regarding chronic Lyme disease

One member of the 2000 committee was removed in order to achieve “consensus”
Attorney General’s Findings

The IDSA portrayed another medical associations guidelines as corroborating their own ...

when the committees shared several of the same members, including the chairman of both committees

Attorney General’s Ruling

IDSA will create a review panel to scrutinize the 2006 guidelines, and update or revise them as necessary

Attorney General’s Ruling

They will:

Completely review the medical and scientific evidence

and recommend whether each point needs revision or updating

Attorney General’s Ruling

No member of the new panel can have a conflict of interest

Attorney General’s Action Plan

• A new review panel of 8 to 12 members
• None of the same members
• The IDSA must consider all applicants
• An ombudsman selected by the AG will ensure that the panel is free of conflicts of interest

Attorney General’s Action Plan

• The panel will conduct an open scientific hearing
• It will consider all scientific and medical presentations from interested parties
• It will be broadcast live on the IDSA Web site
**Attorney General’s Action Plan**

- The panel will vote on each recommendation in the IDSA 2006 guidelines based on whether it is supported by the scientific evidence.
- At least 75% of the new panel has to vote in favor to sustain each recommendation or it will be revised.

**Attorney General’s Action Plan**

They have three options:

1. make no changes to the guideline
2. modify the guideline
3. replace the guideline

**Attorney General’s Action Plan**

The new panel is now being formed.

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**WHAT CAN YOU DO?**

Help us to educate the public about the reality of Lyme disease.

If your doctor is not familiar with the ILADS guidelines, provide him with a copy.

Support state and federal legislation that will provide funds for education, research, and the development of improved tests.

**WHAT CAN YOU DO ABOUT IT!**

Sign the petition on the Lyme Disease Association’s web page: www.LymeDiseaseAssociation.org

Participate in upcoming Lyme rallies www.rally11-30-06.lymerights.org/
WHAT CAN YOU DO ABOUT IT!

Two Standards of Care

1. IDSA
2. ILADS

Both are recognized by the U.S. Government

Doctors should know that there is more than one acceptable way to diagnose and treat Lyme disease.

Thanks to the following for many of the facts and quotes for this presentation:

- ILADS
- Ann F. Corson, MD
- Lyme Disease Association
- Steven Phillips, MD
- CT Attorney General Richard Blumenthal

Resources

www.LymePa.org
www.LymeDiseaseAssociation.org
www.ilads.org
www.idsociety.org/
http://www.ct.gov/AG/