

# **The War on Lyme Patients**

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## **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

## **IDSA Lyme Disease Guidelines**

**New Guidelines in October 2006**

## **IDSA 2006 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

## **IDSA 2006 Lyme Disease Guidelines**

**The tick must be attached for at least 36 hours**

**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

**MISSES 30-82% OF INFECTED PATIENTS**

**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.**

**IDSA 2006 Lyme Disease Guidelines**

And that's all, for the rest of your life, regardless of your symptoms

**IDSA 2006 Lyme Disease Guidelines**

**“Treatment for 14-28 days has a 26-50% failure rate.”**

Wahlberg et al., J Infect 1994; 29(3): 255-261

### **IDSA 2006 Lyme Disease Guidelines**

#### **Antibiotics NOT recommended**

(partial list):

- Bicillin
- Cipro or Levaquin
- Vancomycin
- Flagyl or Tinidazole
- Ketek
- Diffucan

### **IDSA 2006 Lyme Disease Guidelines**

#### **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

### **IDSA 2006 Lyme Disease Guidelines**

#### **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	Gerold Stanek
Linda Bockenstedt	Durland Fish
J. Stephen Dumler	Robert B. Nadelman

### **IDSA 2006 Lyme Disease Guidelines**

#### **Where did they get their facts?**

**405 articles are cited**

**OUT OF OVER 19,000 ARTICLES  
PUBLISHED (less than 5%)**

### **IDSA 2006 Lyme Disease Guidelines**

#### **Where did they get their facts?**

**Nearly 50% of the articles used to  
develop these guidelines were written  
by the guidelines' authors**

### **IDSA 2006 Lyme Disease Guidelines**

#### **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-44S-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)S6; 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.,  
Ann Intern Med 1985; 103(1): 67-8

### **IDSA 2006 Lyme Disease Guidelines**

#### **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)

### **IDSA 2006 Lyme Disease Guidelines**

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

**“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

### **IDSA 2006 Lyme Disease Guidelines**

#### **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

### **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

[www.guideline.gov/summary/summary.aspx?doc\\_id=4836&nbr=003481&string=lyme](http://www.guideline.gov/summary/summary.aspx?doc_id=4836&nbr=003481&string=lyme)

### **IDSA vs. ILADS Guidelines**

#### IDSA Says

#### ILADS Says

Lyme is rare and hard to catch	Lyme is common and easy to catch
10-24 days of a single antibiotic will cure all cases of Lyme	Treat the patient until all symptoms are gone
Lyme is easy to diagnose with a blood test	Blood tests for Lyme are very unreliable
Chronic Lyme disease does not exist	Lyme disease can be persistent

**IDSA vs. ILADS Guidelines**

IDSA Says

ILADS Says

Almost all patients get the bull's eye rash

Only 35-68% of patients ever have a rash

Neurological Lyme disease is rare

40% of Lyme patients have neurological involvement

No mention of psychiatric manifestations

Lyme can cause psychiatric symptoms

Blood tests are reliable

Over half of cases will have false-negative results

**IDSA vs. ILADS Guidelines**

IDSA Says

ILADS Says

The only clinical manifestation is the bull's-eye rash

Lyme disease requires a clinical diagnosis

The CDC surveillance criteria should be used for diagnosis

The CDC explicitly says that their surveillance criteria should not be used for diagnosis

Pregnant women should not worry about Lyme disease

Lyme can be transmitted an infected mother to her baby

**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?

## **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

## **WHAT CAN YOU DO?**

#### **WHAT CAN YOU DO ABOUT IT?**

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](http://www.LymeDiseaseAssociation.org)

Participate in upcoming Lyme rallies  
[www.rally11-30-06.lymerights.org/](http://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](http://www.LymePa.org)

[www.LymeDiseaseAssociation.org](http://www.LymeDiseaseAssociation.org)

[www.ilads.org](http://www.ilads.org)

[www.idsociety.org/](http://www.idsociety.org/)

<http://www.ct.gov/AG/>