



John E. Baldacci, Governor

Brenda M. Harvey, Commissioner

Department of Health and Human Services  
Maine Center for Disease Control and Prevention  
286 Water Street 8<sup>th</sup> Floor  
# 11 State House Station  
Augusta, Maine 04333-0011  
Tel: (207) 287-6582; Toll-Free: 1-800-821-5821  
Fax: (207) 287-6865; TTY: 1-800-606-0215

## Report to Maine Legislature Lyme Disease

February 2009

Kathleen F. Gensheimer, MD, MPH, State Epidemiologist  
Peter Smith, PhD, Director, Division of Infectious Disease  
Dora Anne, Mills, MD, MPH, Director, Maine Center for Disease Control and  
Prevention  
Amy Robbins, MPH, Epidemiologist, Division of Infectious Disease  
Sara Robinson, MPH, Epidemiologist, Division of Infectious Disease

## Executive Summary

During the first special session of the 123<sup>rd</sup> Legislature in 2008, hearings and discussion over proposed legislation regarding the reporting of Lyme disease led to Chapter 561 of the Session Laws. This law, An Act to Implement the Recommendations of the Joint Standing Committee on Insurance and Financial Services Regarding Reporting on Lyme Disease and Other Tick Borne Illnesses, directed the Maine Center for Disease Control to submit an annual report to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over health insurance matters. This report was to include recommendations for legislation to address public health programs for the prevention and treatment of Lyme disease and other tick borne illnesses in the State, as well as to address a review and evaluation of Lyme disease and other tick borne illnesses in Maine.

Chapter 561 of the Sessions Laws of the 123<sup>rd</sup> Maine Legislature, now incorporated into a statute governing the Maine Center for Disease Control and Prevention, directs the Maine CDC to report on:

- The incidence of Lyme disease and other tick-borne illness in Maine
- The treatment guidelines for Lyme disease recommended by the Maine Center for Disease Control and the federal Centers for Disease Control and Prevention
- A summary or bibliography of peer-reviewed medical literature and studies related to the medical management and the treatment of Lyme disease and other tick borne illnesses, including, but not limited to, the recognition of chronic Lyme disease and the use of long term antibiotic treatment
- The education, training and guidance provided by the Maine Center for Disease Control to health care professionals on the current methods of diagnosing and treating Lyme disease and other tick borne illnesses
- The education and public awareness activities conducted by the Maine Center for Disease Control for the prevention of Lyme disease and other tick borne illnesses; and
- A summary of the laws of other states enacted during the last year related to the diagnosis, treatment and insurance coverage for Lyme disease and other tick borne illnesses based on resources made available by the Centers for Disease Control and Prevention or other organizations.

This report addresses these elements.

## Tick Borne Disease Summary for 2008

- Lyme disease incidence in Maine continued to increase during 2008. A total of 878 confirmed and probable cases were reported among Maine residents last year, an increase of 66% from 2006 (529 cases) (Preliminary data as of January 11, 2009).
- Over half of cases occurred among residents of York (32%) and Cumberland (25%) counties. But increases in numbers occurred in many areas of the state, with the most significant increases\* occurring in Kennebec (146%), Knox (229%), and Androscoggin (67%) counties.
- Confirmed cases were reported among residents of each of Maine's 16 counties.
- 2008 Case numbers by DHHS District:

York: 279

Central: 122

Cumberland: 220

Downeast: 16

Midcoast: 166

Penquis: 12

Western: 59

Aroostook: 4

Comment: The Portland metropolitan region, the Midcoast, and the Kennebec River valley are our most prominent emerging areas over the past several years and we will be working to target these areas in any prevention work that we do.

- Most persons diagnosed with Lyme disease in Maine had a characteristic expanding rash (59%) as one of their symptoms. While a large percentage of persons presented with the rash illness as their only major symptom (46%), about one-third (264 persons) had joint swelling, and 9% (78) had Bells Palsy or other cranial neuritis.
- 35 persons (4% of reported cases) were hospitalized.
- 57% of cases had their onsets of illness in June, July, or August (date of onset is missing for 24% of cases).
- 54% of cases are male
- Lyme diseases cases were reported among persons of all ages in 2008, but as has been the case historically in Maine and nationally, age groups with the highest numbers of cases are school-age children (5-14) and middle age adults (40-64).
- Each year we see small numbers of two other diseases carried by deer ticks: Babesiosis (11 cases in 2008) and Anaplasmosis (17 cases in 2008).

\* 2007-2008 increases of >50% in counties reporting at least 20 cases for 2008

## Key Prevention Messages:

- Everyone needs to learn about “tick hygiene” wherever they live in Maine. Although deer tick populations are concentrated on the Maine coast and in the river valleys, there are scattered populations of deer ticks in other parts of the state.
- Potential deer tick habitat includes deciduous forest, overgrown fields, shrub layer, leaf litter, brushy and grassy places, and the edge areas between lawns and woods.
- Most cases of Lyme disease are acquired in the summer months. In Maine, the incidence begins to increase in May and peaks in July.
- Avoidance of deer tick habitat is recommended, when possible, especially when deer ticks are prevalent. Walking in the center of trails to avoid contact with overgrown grass, brush and leaf litter at trail edges can minimize risk of tick exposure.
- Ticks found on people and pets can be submitted to the Maine Medical Center Research Institute for identification.
- Use of repellents containing 20%-30% DEET on uncovered skin and clothing for older children and adults (10% DEET for kids > 2 months). Wearing long sleeves and long pants and tucking pant legs into socks may also keep ticks from attaching.
- “Tick-safe” landscaping can reduce the risk of getting tick bites in areas where people are working or engaging in recreation. Remove leaf litter, tall grass, and brush. Creating borders between woods and lawn, careful use of pesticides applied by a licensed applicator, and discouraging deer with physical barriers may all be useful. (See Maine CDC website for detailed information).
- Checking for ticks after being outside in deer tick habitat is important. Removing ticks with tweezers during the first 24 hours of attachment will prevent most cases of Lyme disease.
- Most persons with Lyme disease develop an expanding red rash at the site of a tick bite 3-30 days after the bite, though many people did not recognize the tick when it was attached. The rash usually persists and enlarges over several days (it does not have to look like a bullseye!). If one has an unexplained rash, or if one sustains an illness with fever after having been in tick habitat a health care provider should be consulted and informed of the potential exposure to ticks. Early treatment of Lyme disease prevents most complications
- The great majority of Lyme disease cases can be treated very effectively with oral antibiotics for 10 days to a few weeks. IV antibiotics for up to 28 days may be needed for some cases of Lyme disease which affect the nervous system, joints, or heart.

## ***I. The Incidence of Lyme disease and other tick borne illness in Maine***

### ***Lyme disease***

Lyme disease is caused by a bacterium, *Borrelia burgdorferi* that is transmitted to a person through the bite of an infected deer tick (*Ixodes scapularis*). Symptoms of Lyme disease include the formation of a characteristic expanding rash (erythema migrans) at the site of a tick bite 3-30 days after exposure. This rash occurs in 80% of patients. Fever, headache, joint and muscle pains, and fatigue are also common during the first several weeks. Later features of Lyme disease can include arthritis in one or more joints (often the knee), Bell's palsy and other cranial nerve palsies, meningitis, and carditis (AV block). Lyme disease is rarely, if ever, fatal.

In the United States, highest rates of Lyme disease occur across the eastern seaboard (Maryland to Maine) and in the upper Midwest (northern Wisconsin and southern Minnesota), with the onset of most cases occurring during the summer months. In endemic areas, deer ticks are most abundant in wooded, grassy, and brushy areas ("tick habitat"), especially where deer populations are large.

The first documented case of Maine-acquired Lyme disease was diagnosed in 1986. Since 2003, when 175 cases were confirmed, the numbers of reported cases have increased each year, doubling between 2005 and 2007. During the 1990's the great majority of Lyme disease cases were residents of south coastal Maine, principally in York County. In recent years, however, disease incidence has increased steadily in the Midcoast, and in the Kennebec and Androscoggin river valleys.

In 2008 (preliminary data as of January 11, 2009) 878 confirmed and probable cases of Lyme disease were reported among Maine residents (67.4 per 100,000 persons). This is the greatest number of cases ever reported in Maine and represents a 66% increase over the 529 cases confirmed for 2007. Over half of the cases were reported among residents from York County (32%) and Cumberland County (25%). Numbers of cases continue to increase in other parts of the state, including Kennebec (145.7% increase from 2007), Knox (228.6% increase from 2007) and Androscoggin (66.6% increase from 2007) counties.

Fifty four percent of cases were male and 46% were female. The median age of cases in 2008 was 45 years of age (average age of 40), which is consistent with the median age for the previous 3 years. The age range was from 1-92 years of age. Just over half (56.6%) of cases had onset during June, July, or August (date of onset is missing for 23.5% of cases). Thirty five persons (4% of all cases) were reported to have been hospitalized with Lyme disease. For further information of Lyme Disease in Maine please see Appendix 1.

### ***Other Tick Borne Diseases in Maine***

In 2008 three other tick borne diseases were reported in Maine. Preliminary data as of February 23, 2009 showed 6 confirmed and 11 probable cases of anaplasmosis, 11 confirmed cases of babesiosis, and 1 confirmed and 17 probable cases of ehrlichiosis. The majority of these cases were reported from York county (64.71%, 63.64% and 33.33% respectively).

## ***II. Treatment Guidelines for Lyme disease recommended by the Maine Center for Disease Control and the federal Centers for Disease Control and Prevention***

Within the Maine Center for Disease Control, we continue to adhere to the strongest science based source of information for the diagnosis and treatment for any infectious disease of public health significance. At the national level, the Infectious Disease Society of America (IDSA) continues to provide leadership in setting the standard for clinical practice guidelines on Lyme disease and other tick borne illnesses: <http://www.idsociety.org/content.aspx?id=4432#ld> We continue to refer the medical community to this document.

Further, the Public Health Infectious Disease work group, comprised of infectious disease physicians from throughout the State, meets bi-monthly to discuss emerging infectious disease issues of potential public health significance. Vectorborne disease including Lyme disease and other tick borne illnesses have been in focus at many of these meetings. Discussions include an update on the surveillance, diagnostics and treatment for these disease entities.

***III. A Summary or bibliography of peer reviewed medical literature and studies related to the medical management and the treatment of Lyme disease and other tick borne illnesses, including, but not limited to, the recognition of chronic Lyme diseases and the use of long term antibiotic treatment.***

At the national level, the Infectious Disease Society of America (IDSA) continues to provide leadership in setting the standard for clinical practice guidelines on Lyme disease.

<http://www.idsociety.org/content.aspx?id=4432#ld>. Attached are correspondence and peer reviewed journal articles published in 2008 as related to these clinical guidelines, which were considered controversial by persons who felt the IDSA clinical guidance precluded long term antibiotic therapy.

In summary; In November 2006, the Attorney General of Connecticut launched an antitrust investigation of the Society's clinical practice guidelines on Lyme disease. The investigation reflected the controversy surrounding long-term antibiotic therapy, which IDSA did not recommend for this condition. IDSA reached an agreement with the Connecticut Attorney General that ended the investigation of the Society and its volunteer physician members and reaffirmed the ability of IDSA to develop practice guidelines based on the best available evidence and widely accepted standards of care. By reaching this agreement with the Attorney General, IDSA also reaffirmed that issues related to the prevention, diagnosis and treatment of Lyme disease should remain in a medical forum where they belong, and out of the courtroom. This agreement called for a special review of the guidelines, which will hopefully quell the unfortunate controversy around the treatment of Lyme disease and ensure that patients receive advice and treatment based on the best available medical evidence. IDSA will be convening a special review panel in 2009 to conduct a comprehensive and up to date evaluation of the scientific literature to determine whether the 2006 guidelines should be revised and updated. The Maine CDC will closely monitor the recommendation of this special review panel.

***IV. Education, Training and Guidance provided by the Maine Center for Disease to health care professionals on the current methods of diagnosing and treating Lyme disease and other tick borne illnesses***

The Maine CDC performs several functions related to the prevention and control of Lyme disease. Surveillance for tick borne diseases, including Lyme disease, is performed by the Division of Infectious Disease, as Lyme disease is a notifiable disease entity by both medical practitioners and clinical laboratories. The Maine CDC field epidemiologists provided consultation to the medical community on tick borne diseases, offering educational and preventive information as needed. Maine CDC field epidemiologists present educational seminars on tickborne disease prevention in statewide meetings of school health educators and school nurses throughout the year.

The Maine CDC promotes ongoing educational outreach activities targeting the medical community. Specific educational forums in 2008 included the annual infectious disease conference, October 29, 2008, which included a session on tick borne diseases: Ecological Considerations, presented by Dr. Robert Smith, an internationally recognized expert in Lyme disease.

Ongoing educational initiatives are featured on the Maine CDC web site:

[http://www.maine.gov/dhhs/boh/ddc/lyme\\_disease.htm](http://www.maine.gov/dhhs/boh/ddc/lyme_disease.htm) Lyme disease resources for Physicians on the web site include: Lyme Disease Update for 2005-2006; Case Report Form; Laboratory Testing for Lyme Disease; Treatment Guidelines for Health Care Providers and Post-exposure Prophylaxis. Since there is no state general funding support for our educational and outreach efforts, we attempt to direct the medical community to our web site, to download any and all materials that are specific to their individual needs

#### ***V. Education and Public Awareness activities conducted by the Maine Center for Disease Control for the Prevention of Lyme disease and other tick borne illnesses***

The Maine CDC performs several functions related to the prevention and control of Lyme disease and promotes ongoing educational outreach activities targeting the public and Maine municipalities. Surveillance for tick borne diseases, including Lyme disease, is performed by the Division of Infectious Disease, as Lyme disease is a notifiable disease entity by both medical practitioners and clinical laboratories. The Maine CDC field epidemiologists provided consultation to the public on tick borne diseases, offering educational and preventive information as needed.

The State Epidemiologist chairs the State Vector Borne Work group, a group comprised of both state agencies and private entities, which meets on a bimonthly basis to proactively address surveillance, prevention and control strategies. Members of this group include: Maine Department of Human Services, Maine Department of Conservation, Maine Department of Agriculture, Maine Department of Inland Fisheries and Wildlife, Maine Department of Education and Cultural Services, Maine Humane Society, Maine Veterinary Association, Acadia National Park, Maine Municipal Association, University of Maine Cooperative Extension Services, United States Department of Agriculture, Animal Control Officers, Attorney General's Office, Maine State Police, Maine Department of Public Safety.

The Maine CDC Vectorborne Working Group has developed a draft curriculum for 5<sup>th</sup> graders on Lyme disease prevention that was piloted in three York county schools in 2008 with plans to expand to other school districts in 2009. This endeavor is being undertaken in close partnership with the Maine Department of Education.

A forum on Community Prevention and Tickborne Disease, targeting municipalities was held on April 9 at Chewonki Center in Wiscasset and on April 16 at Laudhold Farms in Wells. Attendees heard presentations on epidemiology, tick biology, personal protection, landscape management, deer herd control, and safe pesticides use presented by experts from Maine Medical Center Research Institute, tick and mosquito management contracting companies, Maine CDC, Maine Department of Inland Fisheries and Wildlife, and the Maine Department of Agriculture. These forums have been convened annually by the State Vectorborne Work Group to target the informational and prevention needs for town officials in southern and coastal Maine.

The Maine CDC tickborne disease website is continually updated to provide information to the public and to health professionals about Lyme disease in Maine. Ongoing educational initiatives featured on the Maine CDC web site: [http://www.maine.gov/dhhs/boh/ddc/lyme\\_disease.htm](http://www.maine.gov/dhhs/boh/ddc/lyme_disease.htm) include: Lyme disease resources for Maine citizens on the website include: Tick Identification; Distribution of Deer Ticks in Maine; Proper Use of Insect Repellents (Q & A); Prevention of Tick-borne Diseases; History of Lyme Disease; Other Tick-borne Diseases; Powassan, Babesiosis, Ehrlichiosis; 2006 Lyme Disease Surveillance Report and the 2005 Lyme Disease Surveillance Report. Since there is no state general funding support for our educational and outreach efforts, we attempt to direct the public to our web site, to download any and all materials that are specific to their individual needs.

However, not all persons have web access, and specific requests for Lyme disease educational materials to the Maine CDC in 2008, resulted in requests for the following materials: 1,129 Lyme disease DVD;s; 1,409 Lyme disease brochures and 187 Lyme disease fact sheets. Maine CDC received a small grant from the federal CDC to produce and distribute 20,000 laminated wallet cards that provide information on tick identification and Lyme disease prevention measures. Work with members of the Vector-borne Disease Working Group assisted Maine CDC in distributing this resource as widely as possible throughout the State.

The Maine CDC releases Health Alerts on disease concerns of public health significance, including tick borne diseases. The Maine CDC also responds to numerous press inquiries and releases press statements as appropriate (<http://www.maine.gov/dhhs/boh/newhan.shtml>).

Our main prevention message is that currently, there is no human vaccine for Lyme disease. Personal protective measures include avoiding tick habitat, use of DEET-containing tick repellents, wearing long sleeves and pants, and daily tick checks and tick removal after being in tick habitat (ticks must be attached > 36 hours to transmit Lyme disease). Persons who have been in tick habitat should consult a medical provider if they have unexplained rashes, fever, or other unusual illnesses during the first several months after exposure. Possible community approaches to prevent Lyme disease include landscape management and control of deer herd populations..

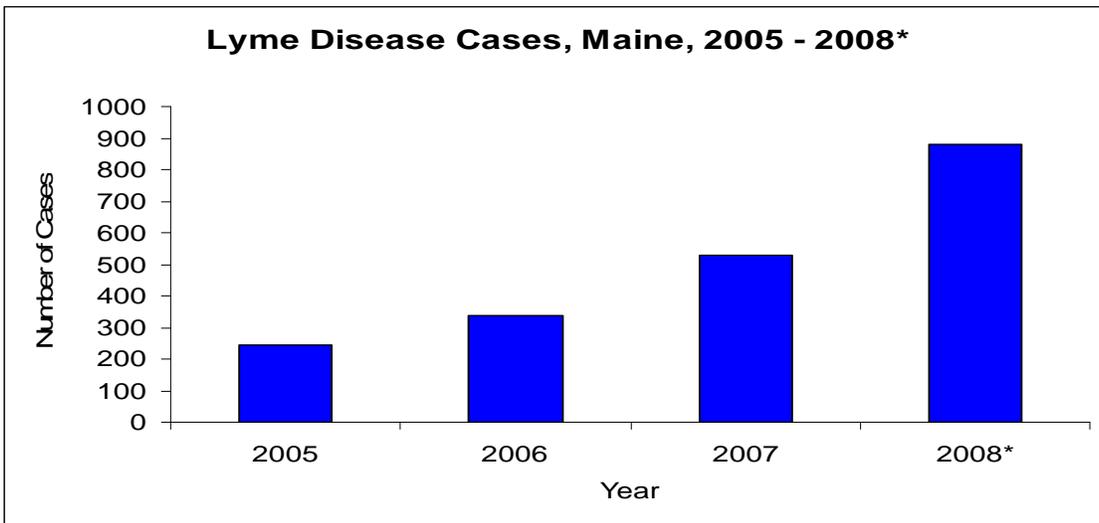
#### ***VI. Summary of Laws of Other states Enacted During the Past Year Related to the Diagnosis, Treatment and Insurance Coverage for Lyme disease and other Tick Borne Illnesses based on resources made available by the federal Centers for Disease Control and Prevention or Other Organizations***

Maine CDC did a search of state ad federal legislation and found no evidence of significant federal or state legislation passing during 2008. A bill to require insurance companies to cover Lyme disease treatments, including long-term antibiotic therapy, was introduced in West Virginia and was not passed.

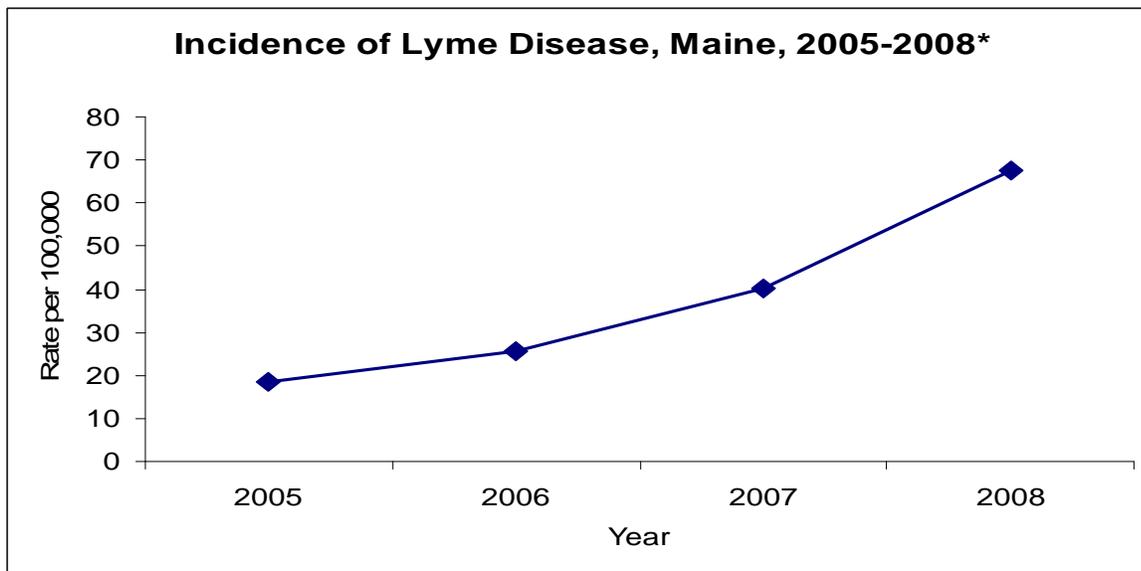
Number and Incidence Rate per 100,000 persons of Lyme Disease Cases by County of Residence, Maine, 2005-2008\*.

County	2005		2006		2007		2008*	
	Number	Rate	Number	Rate	Number	Rate	Number*	Rate
Androscoggin	5	4.7	10	9.3	21	19.7	35	32.8
Aroostook	2	2.7	0	0.0	2	2.8	4	5.6
Cumberland	70	25.5	96	35.0	165	59.9	220	79.9
Franklin	0	0.0	5	16.7	1	3.3	4	13.4
Hancock	7	13.1	6	11.2	14	26.3	13	24.4
Kennebec	12	9.9	22	18.2	46	38.1	113	93.5
Knox	16	38.9	17	41.4	21	51.5	69	169.2
Lincoln	18	51.1	19	53.9	26	74.7	39	112.1
Oxford	3	5.3	1	1.8	6	10.6	20	35.3
Penobscot	6	4.1	5	3.4	7	4.7	11	7.4
Piscataquis	0	0.0	0	0.0	0	0	1	5.8
Sagadahoc	7	19.1	13	35.3	33	90.7	40	109.9
Somerset	1	1.9	3	5.7	3	5.8	9	17.4
Waldo	1	2.6	8	20.7	12	31.2	18	46.7
Washington	0	0.0	0	0.0	0	0	3	9.2
York	97	48.0	133	65.8	172	85.4	279	138.6
Maine	245	18.6	338	25.6	529	40.2	878	67.4

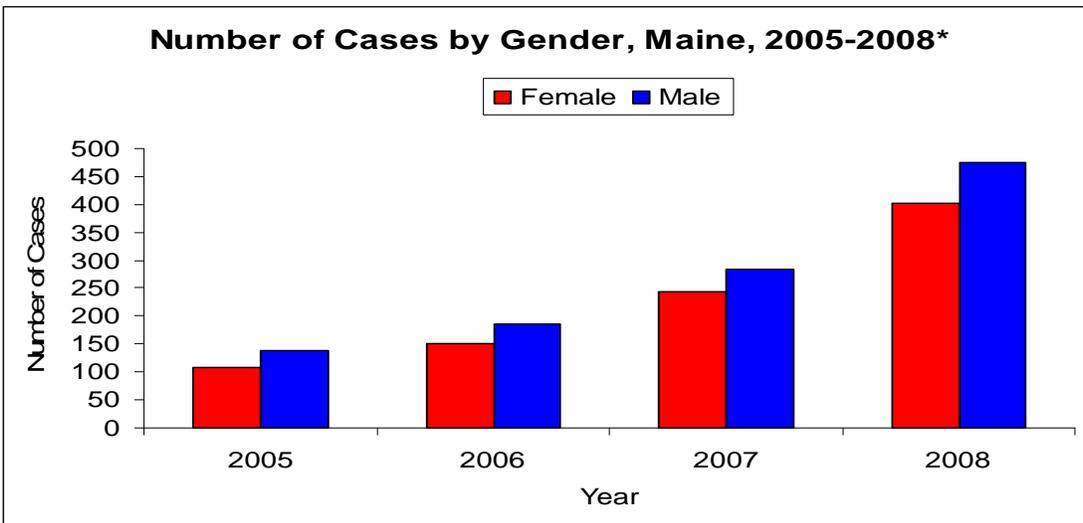
\*2008 data is preliminary as of 1/11/09



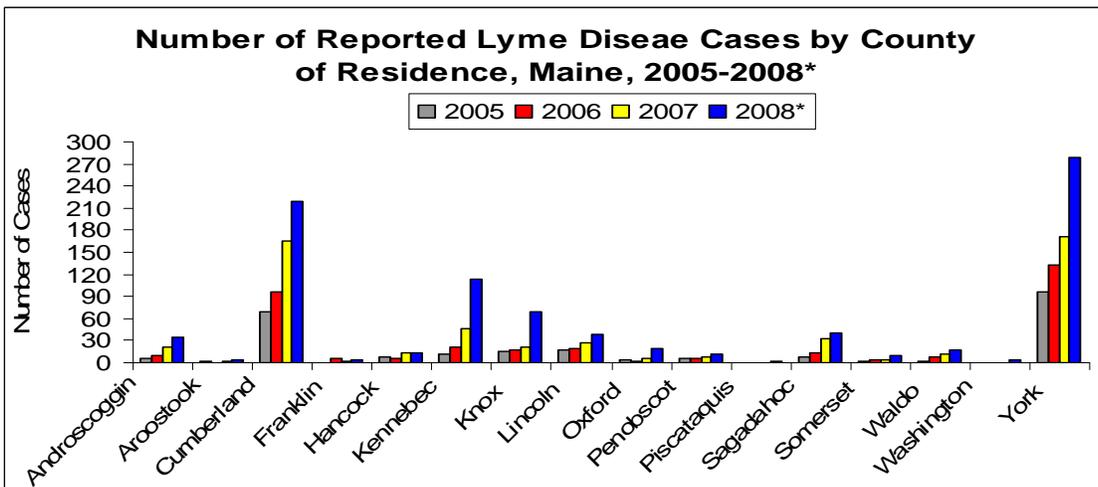
\*All 2008 data are preliminary as of 1/11/09



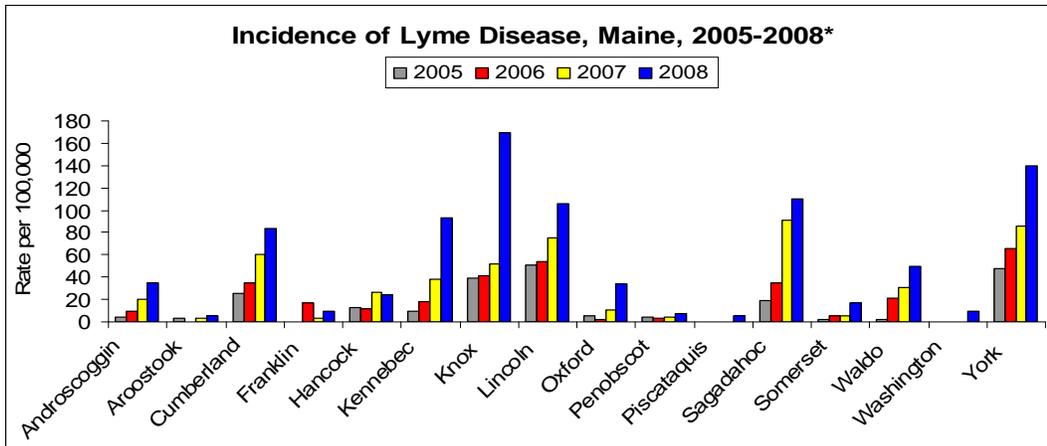
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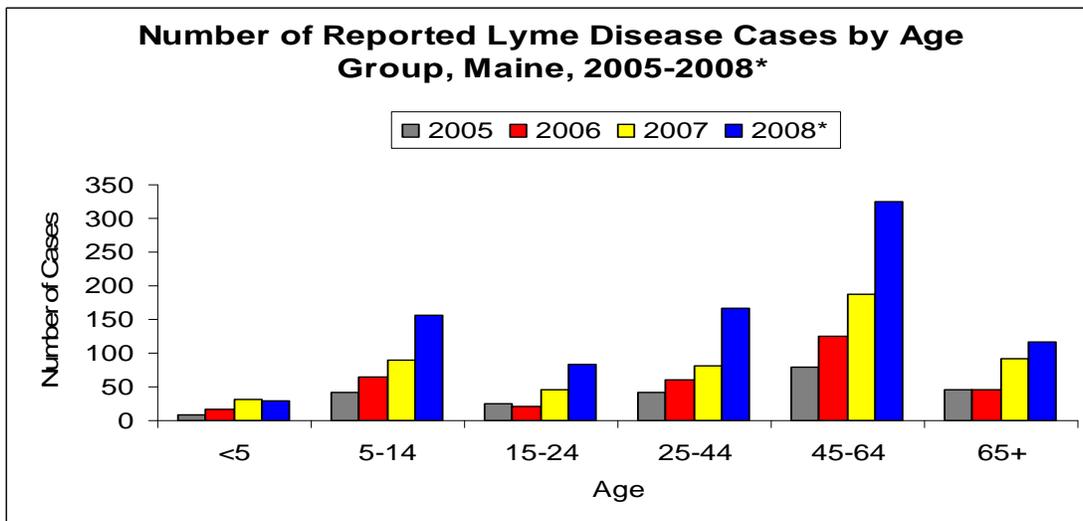
\*All 2008 data are preliminary as of 1/11/09



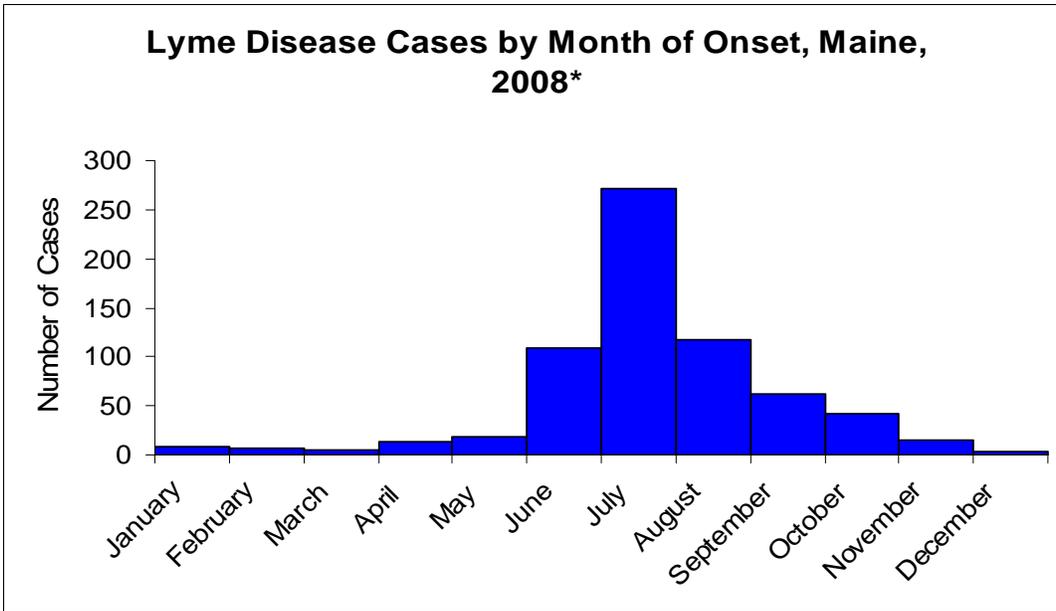
\*All 2008 data are preliminary as of 1/11/09



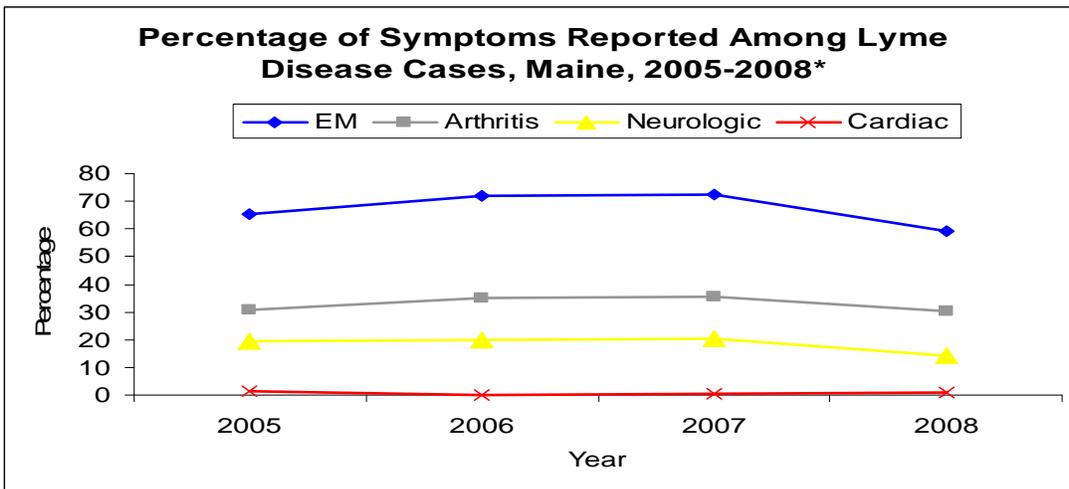
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Infectious Diseases Society of America

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### IDSAs Headquarters

1300 Wilson Boulevard  
Suite 300

Arlington, VA 22201

TEL: (703) 299-0200

FAX: (703) 295-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

May 1, 2008

Dear IDSAs Member:

As you may know, in November 2006 the Attorney General of Connecticut launched an antitrust investigation of the Society's clinical practice guidelines on Lyme disease. The investigation reflects the controversy surrounding long-term antibiotic therapy, which IDSAs does not recommend for this condition. We are pleased to inform you that IDSAs has reached an agreement with the Connecticut Attorney General that ends the investigation of the Society and its volunteer panel members and reaffirms the ability of IDSAs to develop practice guidelines based on the best available evidence and widely accepted standards of care. Our guidelines remain in place and continue to represent the best that science currently has to offer patients.

By reaching this agreement with the Attorney General, IDSAs keeps issues related to the prevention, diagnosis, and treatment of Lyme disease in a medical forum where they belong, and out of a courtroom. The agreement calls for a special review of the guidelines, detailed below, which we hope will quell the unfortunate controversy around the treatment of Lyme disease and ensure that patients receive advice and treatment based on the best available medical evidence.

IDSAs entered into the agreement in good faith. Unfortunately, the Attorney General is using the announcement of the agreement to grandstand for his own political purposes on the backs of suffering patients. We anticipate some negative press coverage in the short term. We are responding forcefully, in particular to his false and misleading claims about the panel's conflicts of interest and exclusion of alternate viewpoints. (Our press release is available online at [www.idsociety.org/lymedisease.htm](http://www.idsociety.org/lymedisease.htm)) In the long run, we expect this will blow over. Even though the Attorney General has attacked us and we were forced to respond in kind, we firmly believe it is in the best interests of the Society, its volunteer panel members, and our patients to have this protracted, distracting, and expensive investigation behind us.

Despite all the sound and fury instigated by the Attorney General, the agreement itself is very favorable to IDSAs. Under the terms of the agreement, IDSAs will convene a special review panel to conduct a comprehensive and up-to-date evaluation of the scientific literature, in order to determine whether the 2006 guidelines should be revised or updated. As part of the review process, interested individuals will be invited to submit relevant information, and a public hearing will be held to receive additional information. The review panel will consider all the evidence and make recommendations regarding whether the Lyme disease guidelines should be revised. If the panel recommends revisions, they will be carried out in accordance with our normal procedures overseen by

*PAGE TWO*

the IDSA Standards and Practice Guidelines Committee. The agreement does not set a precedent for future guidelines.

From a medical perspective, we are confident that the 2006 guidelines are sound. The Connecticut Attorney General's investigation of our guidelines questioned our process but never questioned the medical evidence. Like many medical associations, IDSA is continuously working to improve the process by which we develop guidelines. The panel members had no relevant conflicts of interest. Recognizing the controversy surrounding Lyme disease, the panel carefully considered all information provided by other organizations and individuals. Furthermore, the guidelines (like all IDSA guidelines) were subjected to a rigorous, multi-level review and approval process. We stand by our 2006 guidelines panel, and we believe they reached the right conclusions.

While we were prepared to defend in court any claim that the Connecticut Attorney General might bring and were confident that we ultimately would have prevailed, we concluded that ending the investigation at this stage is in the best interests of IDSA, our members, and our patients. The agreement recognizes that there was no legal wrongdoing. It protects the Society and the volunteer members of the guidelines panel from the burdens of a protracted legal proceeding. It avoids the uncertainty and expense of a continued investigation, which would likely cost IDSA hundreds of thousands of dollars more than the considerable resources already expended. The Connecticut Attorney General is not imposing any fines or penalties and does not have a role in IDSA guidelines panels, on Lyme disease or any other topic. Moreover, those who seek to undermine the credibility of our guidelines will no longer be able to use the stigmatizing phrase, "under investigation."

It is important to note that IDSA's current guidelines remain in place and our advice to physicians and patients remains the same. We are confident that this special review will serve as a further endorsement of our evidence-based process to determine the best treatment for those who suffer from Lyme disease. We sincerely hope it will bring a degree of closure to this controversy for our patients as well as for the Society, although we will be prepared to continue our education and advocacy efforts in this area.

We will weather whatever media storm may break over the announcement of the agreement. In the end, our mission is to make patients well and help them avoid ineffective and potentially harmful treatments. IDSA's guidelines on Lyme disease represent the best advice that medicine currently has to offer.

Please feel free to contact IDSA with any questions or concerns at [info@idsociety.org](mailto:info@idsociety.org).

Sincerely yours,

Donald Poretz, MD, FIDSA  
President, Infectious Diseases Society of America

## Danger Ahead: Politics Intrude in Infectious Diseases Society of America Guideline for Lyme Disease

Jerome O. Klein

Division of Pediatric Infectious Diseases, Boston Medical Center, Boston University School of Medicine, Maxwell Finland Laboratory for Infectious Diseases, Boston, Massachusetts

(See the editorial commentary by Poretz on page 1200)

In the fall of 2006, the Infectious Diseases Society of America (IDSA) received a subpoena from the Attorney General (AG) of Connecticut, Richard Blumenthal. The society was commanded to submit documents to the AG that were relevant to preparation of the 2006 guidelines for management of Lyme disease [1]. The initial communication stated that "the AG has reason to believe that a person has engaged in a contract, combination, or conspiracy which is in restraint of trade or commerce... or has the effect of lessening competition in the provision of health care services for Lyme disease by refusing to deal or inducing third parties to refuse to deal with others in the sale of such services... or has engaged in conduct which constitutes an abuse of monopoly power in violation of the General Statutes of Connecticut" [2]. During the next year and a half, lawyers for the IDSA and representatives of the AG held discussions that lead to an agreement that ended the investigation. The specifics of the agreement were presented to IDSA members in

an e-mail from the President of the IDSA, Donald Poretz, on 1 May 2008. The agreement requires the IDSA to select a new panel to review the 2006 guideline and judge the validity of the recommendations, to provide a public forum that will permit statements by stakeholders with alternative views, and to appoint an ombudsman who will oversee the review process. The purpose of this article is to (1) summarize the relevant documents, (2) discuss the decision of the officers of the IDSA to enter into an agreement with the AG, and (3) raise concerns about the intrusion of state or federal officials into the preparation and content of guidelines prepared by the IDSA and other scientific groups.

### ABOUT PRACTICE GUIDELINES

Practice guidelines and statements developed and/or endorsed by the IDSA are prepared to assist practitioners in making decisions about appropriate diagnosis and management of specific clinical conditions. Recent clinical guidelines have included topics such as appropriate antimicrobial agent use, infections of organ systems, and infections due to specific organisms, as well as general topics of importance (e.g., prevention and management of catheter-related infections, opportunistic infections in stem cell transplant recipients, and travel medicine). As

new information becomes available, guidelines are updated to provide the most useful and current recommendations. The 2006 practice guidelines for management of Lyme disease [1] replaced a 2000 guideline [3]. The authors are chosen by a guideline committee on the basis of expertise in the subject. The content is evidence based, and recommendations are graded with use of criteria for strength of recommendation and quality of evidence.

### WHY DID THE AG CHALLENGE THE LYME DISEASE GUIDELINE?

The AG acts as the chief law enforcement officer of the state and has the authority to enforce the Connecticut Antitrust Act. The motivation of the AG in bringing this action against the IDSA appears to be a response to the concerns of Lyme disease advocacy groups in Connecticut that the IDSA guideline raised doubts about the diagnosis of "chronic Lyme disease" and discouraged long-term antibiotic therapy. A press release from the office of the AG noted that 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 (>90 days) antibiotic treatment or other medical care and also strongly influence physician treatment decisions.... The guidelines are also widely quoted for

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Reprints or correspondence: Dr. Jerome Klein, Div. of Pediatric Infectious Diseases, Boston Medical Center, Boston University School of Medicine, Maxwell Finland Laboratory for Infectious Diseases, 670 Albany St., Boston, MA 02118 (jerome.klein@bmc.org).

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conclusions that chronic Lyme disease is nonexistent" [4]. The statement from the office of the AG was correct; the guideline concluded that "There is no convincing biologic evidence for the existence of symptomatic chronic *Borrelia burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (>6 months) subjective symptoms after recommended treatment regimens for Lyme disease" [1, p. 1094].

### RESPONSE OF THE OFFICERS OF THE IDSA TO THE REQUIREMENTS OF THE AG

The officers of the society responded to the subpoena and provided the appropriate documents. Legal counsel was provided to the officers and to the authors of the guideline. By the spring of 2008, the society had incurred more than \$250,000 in legal fees, and there was no certainty that continued defense of the guideline would be upheld in a state court (D. Porretz, personal communication). Rather than continue to spend time and money to defend the guideline, the officers of the society entered into an agreement that ended the Lyme disease investigation by the Connecticut AG.

### AN AGREEMENT BETWEEN THE IDSA AND THE AG

The agreement on 30 April 2008 between the AG and the IDSA noted that the AG had conducted an antitrust investigation of the IDSA relating to its development and promulgation of clinical practice guidelines for the treatment of Lyme disease. The AG contended that his investigation had uncovered certain significant procedural deficiencies related to the IDSA's development of its 2006 guideline. In response, the IDSA contended that it developed the 2006 Lyme disease guidelines on the basis of a proper review of the medical and scientific evidence by a

panel of experts in the prevention, diagnosis, and treatment of Lyme disease.

The IDSA agreed to an action plan, including recruiting a review panel whose task will be to determine whether the 2006 Lyme disease guideline should be revised or updated. The IDSA will select a chairperson of the review panel who "must not have previously published a particular viewpoint regarding Lyme disease diagnosis or treatment" and "must be knowledgeable about the subject of Lyme disease but not necessarily an expert" [5, p. 2]. The review panel of 8–12 panelists who were uninvolved with prior Lyme disease guidelines will conduct a comprehensive search and retrieval of the medical and scientific literature. The review panel will conduct an open public hearing to offer a forum for the presentation of relevant written or oral data on the topic of Lyme disease. All public stakeholders may apply to make an oral presentation. The office of the AG and the IDSA will jointly select an ombudsman whose duties will include reviewing the chairperson selection, determining that applicants for the review committee have no conflicts of interest, working with the review panel to determine presenters at the open public hearing, and having a role in the vote of the committee. The last responsibility of the ombudsman is vague: "the review panel chairperson is to manage any vote on any key finding or recommendation and report such vote to the ombudsman" [5, p. 4].

In accordance with the agreement, the review panel "shall be to make an individual determination whether each of the recommendations in the 2006 guideline is medically/scientifically justified in light of all of the evidence and information provided" [5, p. 4]. The review panel may choose 1 of the 3 following options: (1) no changes in the 2006 guidelines are necessary; (2) there is need for sectional revision, in which case, the panel will propose revisions; or (3) a complete rewriting of the 2006 guideline is required. The rec-

ommendations of the review panel are binding on the IDSA.

### DANGER AHEAD

The intrusion of an officer of the state into the business of a professional society is cause for concern. The AG is not only protector of the rights and needs of citizens of Connecticut but is also a politician and elected official who responds to the interests of constituents and advocacy groups. In the press release related to the agreement, Blumenthal stated, "This agreement vindicates my investigation—finding undisclosed financial interests and forcing a reassessment of IDSA guidelines" [4]. No specific information was provided about the financial interests or the nature of the purported bias. The public has become wary of associations of medical consultants and the pharmaceutical or vaccine industries, and the use of vague terms such as "undisclosed financial interests" may be accepted as valid without evidence of bias. In recent months, pharmaceutical companies and scientists have been criticized for increasing the frequency of use and extending the duration of drug therapy; in contrast, the Lyme disease guideline recommended restricting duration of treatment. The AG's press release stated, "The IDSA's Lyme guideline process lacked important procedural safeguards. The panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease" [4]. This statement is incorrect. The guideline carefully reviewed evidence for the diagnosis of "chronic Lyme disease" and concluded that the diagnosis was frequently made for patients with vague symptoms. We know that there are and will always be "alternative medical opinions," and the purpose of a guideline is to weigh the evidence for validity, reliability, and reproducibility and to provide the best opinion.

The action of the AG against the IDSA should raise concern for all medical and scientific groups that issue practice recommendations or guidelines. The door is

open to any constituency that feels it was not adequately represented in the process of developing the recommendations. If an AG can undermine evidence-based guidelines on the basis of dissenting views of medical and nonmedical advocacy groups, then every guideline for management of a disease or condition presented by any medical organization is at risk of challenge. For example, an antivaccine group could request action by federal or state officials to bring an action against organizations that provide guidelines for pediatricians or family physicians or even against the Advisory Committee on Immunization Practices. The threat of suit may have a chilling effect on the recruitment of experts to participate in guidelines that are likely to be controversial.

The agreement included additional areas of concern, including the perception that the 2006 guidelines were deficient in the selection of authors and that review of the recommendations is warranted, that a public forum is necessary to provide alternative views of management, and that an ombudsman should have a role in the review process. First, the agreement requires a panel of general infectious diseases physicians or other specialists to review the guideline prepared by experts who have devoted all or much of their clinical and investigative careers to the study of Lyme disease. Second, a public forum to provide opportunity for presentation of alternative viewpoints may be a reasonable step to take at the time of the initial development of selected guidelines but not after the guideline has been published and concern has been raised among advocacy groups. The Institute of Medicine holds public hearings at the initiation of reviews [6], and such a hearing should be considered by the IDSA for possible use

in development of future guidelines. Third, the requirement that an individual—the ombudsman—who is not a member of the IDSA and who is without infectious diseases expertise should review the process established by the society appears to be an intrusion into the business and responsibility of the IDSA. An ombudsman has been chosen by the AG and agreed to by the IDSA: Dr. Howard Brody, Professor of Family Medicine and Director of the Institute for the Medical Humanities at the University of Texas Medical Branch. Dr. Brody is a member of the Institute of Medicine and is the author of articles on medical ethics and the philosophy of medicine; he recently published a text on the ethical and political implications of the relationship between the medical profession and the pharmaceutical industry [7].

#### **DID THE OFFICERS OF THE IDSA ACT APPROPRIATELY IN AGREEING TO THE ACTION PLAN?**

The IDSA does not have deep pockets. Prolonged litigation would be costly without certainty of the outcome. Although the features of the agreement may be questioned and concern may be raised about accommodating the intrusion of a public official into the responsibilities of a professional society, the agreement has been solidified, and there is little value in carp-ing about the decision of the officers of the IDSA to end the litigation. None of the features imposed by the action plan detract from the responsibility of the IDSA to develop practice guidelines prepared by the most knowledgeable experts weighing the most complete evidence available and providing recommendations for health care workers that guide optimal diagnosis

and management for the benefit of patients. It is possible that the agreement sets a precedent for politicians representing the views of aggrieved constituents to challenge the recommendations and guidelines of professional societies. The action plan must be considered as a work in progress, and the proceedings must be monitored to assure that the process and the science are not subverted by advocacy groups or their political representatives.

#### **Acknowledgments**

*Potential conflicts of interest.* J.O.K.: no conflicts.

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## Clarification of the Agreement between the Infectious Diseases Society of America and the Attorney General of Connecticut

**Donald M. Poretz**

President, Infectious Diseases Society of America, Arlington, Virginia

(See the viewpoint by Klein on pages 1197–9)

Dr. Klein [1] fairly and thoughtfully summarizes many of the crucial issues that the Infectious Diseases Society of America (IDSA) Board of Directors grappled with during the IDSA's negotiations with the Connecticut attorney general's office concerning its investigation of the IDSA guidelines on Lyme disease. Two points are worth clarifying.

First, the ombudsman will have a limited role that will focus on screening potential conflicts of interest. The ombudsman will not be involved in the operation

of the review panel.

Second, the expanded review process detailed in our agreement with the Attorney General is pertinent to this unique case only. The IDSA has not agreed to use it as a model for other IDSA guidelines, nor do we urge other medical organizations and societies to use it.

We share Dr. Klein's [1] concern about the potential intrusion of politics into the scientific process. This is why we believe that an agreement that brings this discussion back into a medical and scientific fo-

rum (rather than a courtroom) is the best outcome.

### Acknowledgments

*Potential conflicts of interest.* D.M.P.: no conflicts.

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Reprints or correspondence: Dr. Donald M. Poretz, Infectious Diseases Society of America, 1300 Wilson Blvd., Ste. 300, Arlington, VA, 22209 (info@idsociety.org).

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# Science, Politics, and Values

## The Politicization of Professional Practice Guidelines

John D. Kraemer, JD, MPH

Lawrence O. Gostin, JD

**T**HE INFECTIOUS DISEASES SOCIETY OF AMERICA (IDSA) issued updated clinical practice guidelines in 2006 for the diagnosis and treatment of Lyme disease.<sup>1</sup> Within days, the Connecticut attorney general launched an investigation, alleging IDSA had violated state antitrust law by recommending against the use of long-term antibiotics to treat "chronic Lyme disease (CLD)," a label applied by advocates to a variety of nonspecific symptoms for which frequently no evidence suggests the etiologic agent of Lyme disease is responsible. The IDSA was forced to settle the claim to avoid exorbitant litigation costs, even though the society's guidelines were based on sound science. The case exemplifies the politicization of health policy, with elected officials advocating for health policies against the weight of scientific evidence.

### The Antitrust Investigation of IDSA

Although untreated or inadequately treated Lyme disease can progress to cause neurological complications and arthritis, there is no evidence the disease has a chronic form (except perhaps as sequelae) in the absence of objective clinical or serological evidence of active infection.<sup>2</sup> Nevertheless, some patient groups and a small minority of physicians contend *Borrelia burgdorferi*, the causative agent of Lyme disease, commonly persists in patients after standard antibiotic treatments. They maintain that a constellation of

nonspecific symptoms such as fatigue, myalgia, headaches, and chest pain are evidence of chronic infection, and that standard diagnostics are inaccurate.<sup>3</sup> Furthermore, some recommend using long-term, high-dose antibiotics—frequently administered intravenously—to treat patients with nonspecific symptoms and no objective evidence of infection.<sup>3</sup>

The IDSA treatment guidelines strongly disagreed and instead labeled the constellation of symptoms "post-Lyme syndrome"—either sequelae without ongoing infection or unrelated to *B burgdorferi*. The guidelines state, "There is no convincing biologic evidence for the existence of symptomatic chronic *B burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic ( $\geq 6$  months) subjective symptoms after recommended treatment regimens for Lyme disease."<sup>4</sup> The IDSA guidelines also rejected the use of a variety of alternative diagnostic tests deemed unvalidated by the Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration.

IDSA's guidelines were based on the biological implausibility of *B burgdorferi* persistence after proper treatment in the absence of objective indications of treatment failure; the high background rates of the subjective symptoms of

**Author Affiliations:** O'Neill Institute for National and Global Health Law, Georgetown University, Washington, DC.

**Corresponding Author:** Lawrence O. Gostin, JD, O'Neill Institute for National and Global Health Law, Georgetown University, 600 New Jersey Ave NW, Washington, DC 20001 (gostin@law.georgetown.edu).

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ten attributed to chronic Lyme infection; and the absence of benefit from, and the serious adverse effects of, long-term treatment. The CDC<sup>4</sup> and National Institutes of Health<sup>5</sup> concurred in the judgment that long-term antibiotic use is not justified: "despite extensive study, no clear evidence has emerged to support the contention that CLD results from a past or persistent Lyme disease infection."<sup>6</sup> American Academy of Neurology treatment guidelines for Lyme disease affecting the nervous system reached the same conclusion.<sup>6</sup>

The International Lyme and Associated Diseases Society (ILADS), a CLD advocacy group, immediately protested and asserted the superiority of its alternative guidelines,<sup>3</sup> which others have suggested were based on substandard review methods.<sup>7</sup> Shortly after, Connecticut Attorney General Richard Blumenthal launched an investigation of IDSA's guideline writing process, alleging it violated state antitrust laws by excluding differing viewpoints from its guideline creation process and including members who had financial interests in, or ties to, Lyme diagnostic and treatment makers.<sup>8</sup> IDSA did disclose its panel members' potential conflicts of interest in its published guidelines, even though there is no evidence that any conflicts altered the guidelines' content. Meanwhile, the committee that created the ILADS guidelines included the president of a company that manufactures an alternative Lyme disease diagnostic test<sup>9</sup> and multiple physicians whose practices are listed with a CLD advocacy group's patient referral service<sup>10</sup>—but ILADS did not disclose the conflicts in its guideline document.<sup>3</sup>

Antitrust laws are designed to ensure legitimate commercial competition and protect against predatory corporate practices due to inappropriate restraints on trade. Professional organizations, such as IDSA, can violate antitrust laws if their standard-setting is an unreasonable attempt to advance their members' economic interests by suppressing competition.<sup>11</sup> Applying the antitrust "rule of reason," a challenger must show that the professional organization both possesses substantial market power and that the anticompetitive effects of its standards outweigh patient benefits.<sup>12</sup> Even assuming IDSA wielded sufficient market power through its nonbinding guidelines to meet the first part (which is questionable considering that insurers and clinicians can independently choose which treatments to cover and prescribe), the second part of the rule of reason cannot be met because IDSA guidelines substantially advanced patients' interests.

The courts should defer to professional medical associations when standards are set on the basis of valid science aimed at protecting patient health or safety. A precisely on-point federal case (though one that does not bind Connecticut courts interpreting the state antitrust law) upheld the American Academy of Ophthalmology guidelines attaching the label "experimental" to radial keratotomy, a surgical procedure for correcting nearsightedness.<sup>13</sup> "Antitrust law is about consumers' welfare," said the court, so ultimately professional guidelines are a "medical not a legal question."<sup>13</sup> That truism should decide antitrust cases, so that

when a professional organization bases its work on the weight of science there can be no improper restraint of trade.

After spending more than a quarter of a million dollars on legal expenses, IDSA agreed to settle with the attorney general (without admitting any fault), assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines.<sup>14</sup> While it is unlikely IDSA's guidelines will change due to the investigation, the daunting potential for litigation by those unhappy with the outcomes of treatment guidelines may well chill the willingness of medical associations to make appropriate scientific evaluations of controversial topics—a development that would significantly threaten patient care and increase medical costs.

### Science, Values, and Politics

At the heart of this controversy is the conflict between the positive nature of science and the normative function of value systems and political thought. Science is, and can only be, descriptive and explanatory. Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and whether that finding is replicable. The scientific process is not democratic—no amount of desire for different results can establish them—and inconsistent findings create true controversy only when their methods are of comparable validity.

At the same time, the sciences cannot be normative. They can establish context and a factual base for normative discourse, but scientific findings cannot entail any particular normative conclusion without reference to outside systems of thought. Science, for example, cannot resolve the never-ending debate over abortion in the United States. Medical science can describe the maternal health risks of pregnancy, elucidate fetal development, and establish risks of birth defects and complications. Nothing, however, inherently follows from any of these; rather, policy makers must look outside science, to moral, religious, ethical, and legal norms—eg, when aggregated cells become human life or what the relationship between citizens and their government should be. Medical science can, and should, inform these discussions, and in a vibrant and healthy society, such value questions will be vigorously debated.

However, all too often, the normative and positive blend into one another. Positive assertions are presented in a normative light—for example, that the cost of treating a condition surpasses a benchmark of cost-effectiveness, hence it should not be used. This really consists of 3 separate assertions: the cost of treatment equals a particular amount (a positive claim); treatments costing more than a certain amount are not cost-effective; and cost-effectiveness should guide the allocation of health care resources. All these claims may be justifiable, but only the first can be established through scientific methods.

The converse—when normative views are passed off as positive assertions—is even more problematic, such as the well-documented issue of abortion and breast cancer in the

Bush administration. Multiple adequately powered and well-designed and analyzed studies investigated the putative association between abortion and breast cancer and found no evidence of its existence. However, from 2002 to 2003, information was placed on the National Cancer Institute Web site suggesting a link between abortion and breast cancer, based largely on older epidemiologic studies that failed to sufficiently control for recall bias.<sup>13</sup>

The Connecticut attorney general's action against IDSA falls into this latter category. The CLD advocacy community understandably seeks answers for the symptoms attributed to Lyme disease. But when high-quality research repeatedly was inconsistent with the group's hypotheses, the community should have sought other answers. Instead, many advocacy organizations—and the attorney general—insisted (against the weight of evidence) on a link between the symptoms and chronic infection and continued to call for long-term antibiotic treatments. Even this was perhaps defensible—after all, medical studies cannot prove the non-existence of a phenomenon—although physicians in the CLD community should treat their patients based on the best-available evidence. But when political leaders using the force of law sued IDSA for its appropriate scientific conclusions that differed with the results they desired, they abused the public good.

A wall of separation is needed between science, norms, and politics. Science should inform normative discussions and provide the evidentiary base for political choices. Likewise, values will always be important in deciding how science is applied for human benefit. But neither should be permitted to distort the other—limits on the outer boundaries of what questions each can answer must be respected when making public policy. Medical science, and the health of patients who depend on it, are too important to be subjected to political ideologies.

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# Community Prevention of Lyme Disease

*Sponsored by:*  
*Maine Center for Disease Control and Prevention*  
*Maine Medical Center Vector Borne Disease Laboratory*  
*Maine Vector-borne Disease Working Group*

Wiscasset, 9<sup>th</sup> of April 2008  
Chewonki Center, Wiscasset, ME  
9:00 AM – 1:00 PM

Wells, 16<sup>th</sup> April 2008  
Laudholm Farm, Wells, ME  
9:00 AM – 1:00 PM

09:00-09:05	Introduction and Overview – Kathleen F. Gensheimer, MD, MPH, Maine Center for Disease Control and Prevention (Maine CDC)
09:05-09:20	Lyme Disease in Maine – Geoff Beckett, PA-C., MPH, Maine CDC
09:20-09:30	Ticks: Biology and Personal Protection – Leif D. Deyrup, PhD, Maine CDC
09:30-10:00	Ecology of Ticks – Charles Lubelczyk, Maine Medical Center Vector Borne Disease Laboratory
10:00-10:20	Tick Management Regulation– Gary Fish, Maine Board of Pesticides Control
10:20-11:10	Tick Integrated Pest Management: Landscape and Pesticide Control of Ticks – Gary Fish and Michael Morrison, BS, Municipal Pest Management
11:10-11:30	Break
11:30-12:00	Deer Management in Maine "Addressing the public's interest: Challenges, options and opportunities." Lee Kantar, State Deer Biologist, Maine Department of Inland Fisheries and Wildlife
12:00-12:15	Tick and Lyme Curricula Development – Sherrie Juris, Atlantic Pest Solutions
12:15-13:00	Panel Discussion and Questions – Presenters

**Objectives:** To inform and encourage local action for community prevention of Lyme disease

**Target Audience:** Community leaders, administrators and the general public, including: Conservation Commission members, local land trusts, small woodlot owners, members of the Maine Veterinary Medical Association, Maine school nurses, pest management specialists and concerned citizens



# Emerging Infectious Diseases in Maine

## THE PUBLIC HEALTH RESPONSE

October 29, 2008  
Augusta Civic Center - Augusta, Maine

# Agenda

- 8am Registration**
- 8:45 Welcome**  
*Kathleen F. Gensheimer, MD, MPH*
- 8:50 Disease Control in Maine: 2008**  
*Kathleen F. Gensheimer, MD, MPH*
- 9:00 New Trends with MSM and the Internet and an Update on HIV Testing**  
*Mary Kate Appicelli, MPH, Jamie Cotnoir, MPH, Genevive Meredith, MPH, OTR*
- 10:00 Break**
- 10:20 Clinical Management of Drug Resistant Organisms**  
*August J. Valenti, MD, FACP, FSHEA, FIDSA*
- 10:50 Panel Discussion: Challenges in the Control of Drug Resistant Organisms**  
*Panel Moderator- Joshua Cutler, MD, Tammy Beaulieu Fuller, RN, CIC, Carol Cole, RN, D., Sheri Dirrigl, RN, CIC, Billie Porter, PharmD*
- 11:50 Refugee Health: A Different World**  
*Panel Moderator- Mike Rowland, MD, MPH, Pam Harpine, RN, Lorna Seybolt, MD, MPH, Susan Talbot, MD*
- 12:30 Epidemiology Recognition Awards / Viral Tones**  
*Kathleen F. Gensheimer, MD, MPH*
- 12:40 Lunch**
- 1:40 Case Presentations**  
*Moderator - Andrew R. Pelletier, MD, MPH, Mary Kate Appicelli, MPH, Jennah Godo, MS, Jon Eric Tongren, PhD, MSPH*
- 2:40 The Reemergence of Measles: Confronting Myths and Affirming Truths**  
*Imad Durra, MD, Peter Smith, PhD*
- 3:40 Tick borne diseases - Ecological Considerations**  
*Robert P. Smith, MD, MPH*
- 4:30 Adjourn**



Department of Health and Human Services  
Maine Center for Disease Control and Prevention  
286 Water Street 8<sup>th</sup> Floor  
# 11 State House Station  
Augusta, Maine 04333-0011  
Tel: (207) 287-6582; Toll-Free: 1-800-821-5821  
Fax: (207) 287-6865; TTY: 1-800-606-0215

Dear Health Care Provider:

The individual named on the attached Lyme Disease Case Report Form has been reported to the Maine Center for Disease Control and Prevention as having Lyme Disease. In order to track Lyme disease in Maine, we are following up on all disease reports to obtain additional information.

Please complete the attached case report form, including patient demographic information and diagnosis information. The case report form and copies of Lyme disease laboratory tests on this patient should be returned in the enclosed postage paid envelope or faxed to 207-287-6865.

Case report forms without clinical information and laboratory reports (with the exception of patient's with erythema migrans) will be considered incomplete and not be counted. Your cooperation is necessary to help enhance our surveillance efforts.

If you have any questions please contact the Infectious Disease Epidemiology Program at 1-800-821-5821 and ask for the epidemiologist-on-call. Thank you for your cooperation.

For current information on the clinical assessment, treatment and prevention of Lyme disease and other tick borne diseases, consult the Infectious Disease Society of America's Clinical Practice Guidelines available at: <http://www.idsociety.org/content.aspx?id=4432#ld>.

Sincerely,

Kathleen F. Gensheimer, M.D., M.P.H.

State Epidemiologist



# Maine Center for Disease Control and Prevention Lyme Disease Case Report Form 1/09

Patient's Last Name: \_\_\_\_\_ First name: \_\_\_\_\_

Street Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_

PLEASE FILL IN

PLEASE FILL IN

DOB: \_\_\_\_\_ Race:  White Ethnicity:  Hispanic  
 Black  Non Hispanic  
 Amer. Indian/Eskimo  Other  
 Asian/Pacific Isl.  
 Unknown

Gender:  Male  
 Female  
 Unknown

### Symptoms and Signs of Current Episode: Please answer each question.

Dermatologic			
Erythema migrans (physician diagnosed EM at least 5 cm in diameter).....	Yes	No	Unknown
Rheumatologic			
Arthritis characterized by brief attacks of joint swelling.....	Yes	No	Unknown
Neurologic			
Bell's palsy or other cranial neuritis.....	Yes	No	Unknown
Radiculoneuropathy.....	Yes	No	Unknown
Lymphocytic meningitis .....	Yes	No	Unknown
Encephalitis/Encephalomyelitis .....	Yes	No	Unknown
CSF tested for antibodies to B. burgdorferi .....	Yes	No	Unknown
Antibody to B. burgdorferi higher in CSF than serum .....	Yes	No	Unknown
Cardiologic			
2 <sup>nd</sup> or 3 <sup>rd</sup> degree atrioventricular block .....	Yes	No	Unknown

Other clinical: \_\_\_\_\_

Date of onset of first symptoms: \_\_\_/\_\_\_/\_\_\_ Date of diagnosis: \_\_\_/\_\_\_/\_\_\_

Was the patient hospitalized? Yes No Unknown If yes, hospital; \_\_\_\_\_

Name of antibiotic used: \_\_\_\_\_ Duration in days: \_\_\_\_\_

Was the patient pregnant at the time of diagnosis? Yes No Unknown

Where was the patient most likely exposed? County: \_\_\_\_\_ State: \_\_\_\_\_

### Laboratory Findings: Please send a copy of all Lyme disease testing

#### Diagnosis (please circle one option):

1. Yes, this patient has been diagnosed with Lyme disease.
2. This patient is still undergoing evaluation, a diagnosis of Lyme disease has not been made. Please contact me again in \_\_\_ days
3. I do not believe this patient has Lyme disease
4. Please contact the following health care provider to obtain information about this patient:

Other Provider Name: \_\_\_\_\_

Physician's Name: \_\_\_\_\_ Telephone No.: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_

Person completing form; \_\_\_\_\_ Telephone (if different): \_\_\_\_\_

# MAINE PUBLIC HEALTH ALERT NETWORK SYSTEM

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Maine Department of Health and Human Services  
Maine Center for Disease Control and Prevention (Maine CDC)  
(Formerly Bureau of Health)  
11 State House Station  
Augusta, Maine 04333-0011  
Phone 1-800-821-5821 / Fax 207-287-7443

**\*\*UPDATE – Important Information\*\***

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2007PHUPD001

**TO:** Hospital List; School Based Health Centers; School Nurses; Me Primary Care  
; Infection Control Practitioners; Public Health (PHN)

**FROM:** Dora Anne Mills, M.D., M.P.H., Public Health Director

**SUBJECT:** Lyme Disease in Maine:

**DATE:** September 12, 2007

**TIME:** 6:30 AM

**PAGES:** 5

**PRIORITY:** Review

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**Lyme Disease in Maine:**  
**Answers to Frequently-Asked Questions from Health Professionals**

**Background:** Although the Maine Center for Disease Control and Prevention does not provide clinical consultation on the management of individual cases of Lyme disease, the Medical Epidemiology Section in the Division of Infectious Disease receives frequent requests from health professionals for Lyme disease-related information to assist in patient assessment and care. This Health Advisory includes answers to some of the more frequently asked questions that we receive, and is not intended in any way to be comprehensive.

**Summary:** Maine has the 12<sup>th</sup> highest rate of Lyme disease among the U.S. states and its incidence has been increasing steadily since the late 1990's. While the majority of cases occur among residents of southern coastal Maine, medical providers should be aware that the range of deer ticks in Maine has expanded gradually in recent years and that exposure to deer ticks and Lyme disease can occur in other areas of the state as well. Authoritative guidelines for the clinical diagnosis and management of Lyme disease and other tickborne diseases have been recently updated by the *Infectious Diseases Society of America*, and links are available at the Maine CDC website:  
[http://www.maine.gov/dhhs/boh/ddc/lyme/lyme\\_1.htm](http://www.maine.gov/dhhs/boh/ddc/lyme/lyme_1.htm)

**FAQ: Lyme Disease in Maine**

***EPIDEMIOLOGY and ECOLOGY***

**1. Is the incidence of Lyme disease increasing in Maine?**

In Maine, the incidence of Lyme disease has increased steadily since the late 1990's. In 2006, 338 reported cases were confirmed among state residents, an increase of 37% from 2005. While improvements in diagnosis and reporting may contribute to some degree, researchers and epidemiologists believe that there has been a real increase in disease incidence. Similar increases were seen in some other New England states during the same period.

**2. What is the seasonality of Lyme disease in Maine?**

The great majority of cases of early Lyme disease have the onset of their symptoms during the summer months (June – August). A second, much smaller peak occurs in the fall (September – November), when adult deer ticks are active. Very small numbers of cases are seen during the winter and early spring (December – May).

**3. Where are the highest incidence rates in Maine?**

About two-thirds of reported Lyme disease cases in Maine are reported among residents of York and Cumberland Counties, with the highest rates in southeastern York County. Over the past decade the numbers of cases have also been increasing steadily in areas of the midcoast (Sagadahoc, Knox, and Lincoln Counties) and in the lower Kennebec river valley. The numbers of cases are generally much lower in the western mountains and in northern Maine. This distribution is consistent with ecological research on the distribution of deer ticks in Maine.

**4. In what types of outdoor environments are deer ticks likely to be found?**

“Potential tick habitat” is a term used to describe the type of environment preferred by deer ticks, and it includes woody or brushy areas and terrain with high grass and lots of leaf litter.

**5. Should I consider Lyme disease in the differential diagnosis of a person with compatible signs and symptoms (e.g., erythema migrans-like rash) whose only recent outdoor activities have been in a “low incidence” area of Maine, such as Aroostook County?**

Yes. Even in areas where deer ticks are relatively uncommon and the numbers of Lyme disease cases are low, small foci of tick populations may present some risk of Lyme disease exposure to humans. By the same token, there are many areas of “potential tick habitat” in generally high incidence regions - such as coastal York County - where ticks are absent or sparsely distributed. It is reasonable to assume that there is at least some risk of Lyme disease exposure for persons who engage in outdoor activities in any “potential tick habitat” in Maine, especially during the summer and fall.

#### OTHER TICK-RELATED ISSUES

##### **6. Do deer ticks in Maine carry infections other than Lyme disease?**

Yes. While Lyme disease is by far and away the most common tickborne disease, deer ticks in Maine can also occasionally transmit *babesiosis* and *human granulocytic anaplasmosis* (HGA). These are described in the IDSA Guidelines (reference in the summary section, above) and also on other areas of the Maine CDC website section on tickborne infections. A close relative of the deer tick (*Ixodes cookei*, also known as the “woodchuck tick”) can also transmit *Powassan encephalitis*, a rare viral infection closely related to West Nile virus. Four cases of Powassan encephalitis were documented here between 2000 and 2004.

##### **7. Do dog ticks in Maine transmit any diseases to humans?**

In other areas of the country, dog ticks (*Dermacentor variabli*) can transmit *rocky mountain spotted fever* (RMSF). In Maine, however, neither RMSF or any other significant human diseases have been documented to be associated with exposure to dog ticks.

##### **8. Where in Maine can I send a tick to be identified?**

The Maine Medical Center Research Institute (MMCRI) Vector borne Disease Laboratory in South Portland will identify the species of submitted ticks found on humans or pets. This is done free-of-charge. Ticks should be placed in alcohol in a leak proof container and sent to MMCRI per instructions that can be found at: (<http://www.mmcri.org/lyme/submit.html>).

#### DIAGNOSIS AND MANAGEMENT

##### **9. Is laboratory testing necessary to support a clinical diagnosis of erythema migrans (EM)?**

No. Serological testing during the first 2 weeks of infection is too insensitive to rule out Lyme disease. *Erythema migrans* – the expanding rash that occurs within 3-30 days of tick removal or detachment in about 70%-80% of Lyme disease cases – often occurs *before* a serological response has occurred. Thus, treatment decisions should be made on the basis of a clinical diagnosis based on physical examination and history (see the 2006 IDSA Guidelines referenced above, for an excellent and well-illustrated overview of *EM*) and should not depend on laboratory testing for confirmation. Laboratory testing, however, is a critical and necessary component of the evaluation of persons with possible Lyme disease-associated signs and symptoms other than *erythema migrans*.

##### **10. What diagnostic tests are currently recommended for use in Lyme disease diagnosis?**

In the absence of *erythema migrans*, both the Federal CDC and the *Infectious Diseases Society of America* recommend the use of two-tier serological testing, that includes a sensitive screening test (ELISA or IFA) followed by IgM and IgG Western Blot testing, if the screening assay is positive. Clinicians should be wary of non-validated test methods used by some commercial laboratories, including polymerase chain reaction (PCR) testing of blood, urine antigen tests, and lymphocyte transformation tests. Some laboratories also interpret Western blot tests using criteria that have not

been validated and published in peer-reviewed scientific literature (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5405a6.htm>).

### **11. Where can I find reliable guidance on current approaches to Lyme disease diagnosis and management?**

The *Infectious Diseases Society of America* (IDSA) released its detailed update of clinical practice guidelines for Lyme disease and other tickborne infections in late 2006. These can be downloaded from the Maine CDC website ([www.mainepublichealth.gov](http://www.mainepublichealth.gov)).

## PREVENTION

### **12. Does early tick removal effectively prevent Lyme disease?**

Yes. The removal of an infected deer tick within 36 hours of its attachment will prevent transmission in most cases. Perhaps the most important component of Lyme disease prevention is performing daily tick checks after spending time in potential tick habitat, and removing any ticks that may have become attached.

### **13. What are the current recommendations for the use of tick repellents?**

For application to uncovered skin, the federal CDC currently recommends the use of insect repellents containing a 20%-50% concentration of **DEET** for the prevention of tick bites. The American Academy of Pediatrics recommends that repellents containing up to 30% DEET can be used on children > 2 months of age. DEET concentrations in this range will provide protection for 5-8 hours against both ticks and mosquitoes. Data on the tick prevention effectiveness of **picaridin**, an effective alternative to DEET for prevention of mosquito bites, is currently limited. **Permethrin**, which is sold in spray and liquid forms, can be applied to shoes, socks and outer clothing (but not directly to skin), and kills ticks on contact. After an application, it will remain effective through several washings. It is also effective in preventing mosquito bites.

### **14. How do I report a case of Lyme disease to Maine CDC?**

Lyme disease case reporting forms can be downloaded from the Maine CDC website and faxed or mailed to our office. Remember that it is especially important to report cases of clinically-diagnosed erythema migrans (EM), and that laboratory testing is not required to confirm a case of EM.

### **15. What is Maine CDC doing to increase public awareness about Lyme disease prevention?**

Although there is currently no dedicated federal or state government funding for Lyme disease education and prevention, Maine CDC has worked with community partners for several years doing this work within existing resources, including developing and disseminating educational materials, assuring that information on Lyme Disease is presented at some annual medical and public health meetings, and maintaining a website dedicated to tick borne diseases in Maine. Maine CDC recommends that health education efforts utilize a “universal tick hygiene” approach that includes recognition of typical EM rashes, the proper use of insect repellents, and an emphasis on the importance of tick checks and early tick removal after work or recreation in tick habitat (whether or not it is in a high incidence area of the state). Existing materials can be found and downloaded at [www.mainepublichealth.gov](http://www.mainepublichealth.gov).

## Directions to the Municipal Forums

**Directions to the York Library:** The York Public Library is in the middle of the village, at 15 Long Sands Rd. Take Exit 7 from I-95 to Rt 1, go south 1/10 mile, turn left on 1-A. Go 8/10 mile, bear left at the statue, and turn right into the parking lot of the library.

**Directions to Governor Baxter School for the Deaf:**

From the South: Take the Maine Turnpike (Hwy 95 to Exit 44, "Hwy 295 North" to Exit 9 Falmouth/Foreside and continue across the Martin's Point Bridge. Watch for a blue and white sign for MECDHH and Andrews

Avenue on your right. Turn right onto Andrews Avenue. Drive through the row of houses and across the causeway to the guardhouse.

From the North: Take Hwy 295 to Falmouth Exit 10, "Bucknam Road". At the end of the ramp, take a left onto Bucknam Road and take Bucknam Road to the light at Route 1. Turn right. Continue south on Route 1 approximately two miles past several shopping centers. Watch for a blue and white sign for GBSD and Andrews Avenue on your left. Turn left onto Andrews Avenue. Drive through the row of houses and across the causeway to the guardhouse

**Directions to Burton Cross Building:**

I-95N or I-95S take exit 109 toward Augusta. Turn right onto Armory Street, turn left onto Capitol Street, turn right onto Sewall Street. End at 111 Sewall Street Augusta.

## 2009 Maine Vector-borne Disease Seminar for Municipal Officers

**May 7, 2009**

**York Library (Live Forum)**

15 Long Sands Road  
York, Maine 03909

**Governor Baxter School for the Deaf  
(Satellite hookup)**

Mackworth Island  
Falmouth, Maine 04105

**Burton Cross Office Building  
(Satellite hookup)**

Room 105  
111 Sewall Street  
Augusta, Maine

**Sponsored by Maine Municipal Association and**



*Maine Center for Disease  
Control and Prevention*

*An Office of the  
Department of Health and Human Services*

*John E. Baldacci, Governor*

*Brenda M. Harvey, Commissioner*

## Registration

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Business Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone: \_\_\_\_\_

Email Address: \_\_\_\_\_

There is no registration fee, however due to limited capacity (60 seats), registration is required and will be accepted on a first come, first serve basis.

Submit your completed registration form by April 2009 to:

Tammy Duguay  
Maine CDC/Infectious Disease  
286 Water Street 8<sup>th</sup> Floor  
Augusta, ME 04333

Phone: 287-7396 Fax: 287-6865

Email: [tammy.l.duguay@maine.gov](mailto:tammy.l.duguay@maine.gov)

## Agenda

**8:00 AM Registration**

**8:30 AM Welcome and Introductions:** *Kathleen F. Gensheimer, MD, MPH, State Epidemiologist, Maine CDC*

**8:45 AM Mosquito and Tick-borne Diseases in Maine:** *Eric Tongren, PhD, MSPH, EIS Officer, Maine CDC*

**9:00 AM Ecology of Maine Mosquitos:** *Michael Morrison, Mosquito Entomologist, Municipal Pest Management, and Ted St Amand, Atlantic Pest Solutions*

**9:45 AM Ticks: Biology and Ecology:** *Charles Lubelczyk, Field Biologist, Maine Medical Center Research Institution*

**10:15 AM Break**

**10:30 AM Regulatory Concerns-Tick and Mosquito:** *Gary Fish, Environmental Specialist, Department of Agriculture and Robert Stratton, Environmental Specialist, Department of Environmental Protection*

**11:15 AM Deer Management in Maine Addressing the Public Interest:** *Lee Kantar, Biologist, Inland Fisheries and Wildlife*

**11:45 AM Community Response to EEE:** *Rob Yandow, Town Manager, York and Jon Carter, Town Manager, Kittery*

**12:20 PM Tick and Lyme:** *Sherrie Juris, Atlantic Pest Solutions and Special Guest: Doug Rafferty, WGME*

**12:30 PM Expert Panel: Questions and Answers**

**1:00 PM Adjourn**