Attention Lyme Researchers: CDMRP PreAnnouncement for Lyme Research Monies

The Department of Defense Congressionally Directed Medical Research Program (CDMRP) is alerting Lyme & other tick-borne diseases researchers to the potential for anticipated FY17 monies that might become available through the program so that researchers can plan for possible grant submissions. The Lyme Disease Association is providing the link to the CDMRP program. All questions should be addressed to the CDMRP program.


Researchers: Lyme Monies
Available from CDMRP

The Congressionally Directed Medical Research Program (CDMRP) has announced funding opportunities under the auspices of the Tick-Borne Diseases Programmatic Panel. $5 million has been appropriated for tick-borne diseases research through the Department of Defense budget for the 2016 (FY16) CDMRP program. Research specifically involving the following areas is being sought:

Pathogenesis:

- Host-pathogen interactions
- Human immune response
- Mechanisms of persistence of Lyme disease
- New research tools to support studies of pathogenesis

Prevention:

- Interrupting the natural cycle
- Personal protection measures
- Targeted vaccines
- Post-exposure prophylaxis

Diagnosis:

- Direct detection of tick-borne pathogens or their products in humans
- Biomarkers for diagnosis

Treatment:

- Innovative approaches to treatment
- Basic studies aimed at safe and effective treatments for the cause of persistent symptoms in Lyme disease
- Biomarkers of effective prognosis, therapy and cure

Applications addressing persistence and direct detection of Lyme borreliae are highly encouraged.
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<tr>
<th>Award Mechanism</th>
<th>Eligibility</th>
<th>Key Mechanism Elements</th>
<th>Funding</th>
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<tr>
<td>Idea Award (IA)</td>
<td>Independent investigators at or above the level of Assistant Professor (or equivalent)</td>
<td>• Preproposal is required; full application submission is by invitation only.</td>
<td>• Anticipated maximum funding of $250,000 for direct costs (plus indirect costs).</td>
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<td>• Fund conceptually innovative, high-risk/potentially high-reward research in the early stages of development that could ultimately lead to critical discoveries and/or improvements in patient care and/or quality of life.</td>
<td>• Maximum period of performance is 2 years.</td>
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<td>• Preliminary data that are relevant to the proposed research project should be included.</td>
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<td>• Clinical trials are not allowed.</td>
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<td>Investigator-Initiated Research Award (IIIRA)</td>
<td>Independent investigators at or above the level of Assistant Professor (or equivalent)</td>
<td>• Preproposal is required; full application submission is by invitation only.</td>
<td>• Anticipated maximum funding of $700,000 for direct costs (plus indirect costs).</td>
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<td>• Fund highly rigorous, high-impact research with the potential to make an important contribution to research and/or patient care.</td>
<td>• Maximum period of performance is 3 years.</td>
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<td>• Preliminary or published data is required.</td>
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<td>• Clinical trials are not allowed, however human studies/clinical research are permitted.</td>
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For further information go to the CDMRP website:


For CDMRP press release on the funding go to:

A detailed description of the funding opportunity, evaluation criteria, and submission requirements can be found in the Program Announcements. The Program Announcements are available electronically for downloading from the Grants.gov website, the CDMRP website (http://cdmrp.army.mil/funding/prgdefault.shtml) and the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org). All CDMRP funding opportunities, both recently and previously released, are available on the CDMRP website. Listing of all open CDMRP funding opportunities can be obtained on the Grants.gov website by performing a basic search using CFDA Number 12.420.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov. Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

For an overview of the submission process, go to: http://cdmrp.army.mil/funding/apply.shtml

For questions: Researchers contact trained staff at the Electronic Biomedical Research Applications Portal (eBRAP) help desk, available Monday through Friday (except Holidays). Standard hours are 8:00 a.m. – 5:00 p.m. eastern standard time (ET).

• E-mail: Help@eBRAP.org
• Phone: (301) 682-550

In addition, PIs may want to visit the eBRAP website: https://ebrap.org/ for additional information, such as:

- Frequently Asked Questions
- Commonly Made Mistakes
Attention Lyme Groups: Take Action Now!

Signons from Lyme Group Leaders on FDA Test Takeover

The Lyme Disease Association, Inc. (LDA) has formulated a response to FDA to be included in its comment period on its testing Guidance which will affect specialty lab Lyme tests. Therefore, groups who want to support the position taken by the LDA may join in on the letter. LINK TO HISTORY OF FDA GUIDANCE ACTIVITY

- Please post and/or distribute this information widely to groups or provide link to LDA website www.LymeDiseaseAssociation.org for this information.

- Only the one Lyme group leader authorized by the group can sign onto the letter and must provide valid contact information. All groups welcome. No individuals, sorry. (Individuals see below Group Signon)

- Read full letter here. LDA LETTER TO FDA WITH 73 GROUPS SIGNED ON

- Signons to the response letter need to be entered on the LDA website form by 12M ET, January 27, 2015.

GROUP SIGNON HERE

All fields below are required, but the letter will contain name of group, contact name, and email only.

Letter was submitted with 73 groups signed on.
INDIVIDUALS READ THIS
Any individual who has not yet taken the Lymedisease.org survey on FDA testing takeover, can do so by clicking here.

BRIEF HISTORY: FDA is moving forward in the process of finalizing its new Laboratory Developed Test (LDT) Guidance proposal. The proposal would move LDTs from under the jurisdiction of Clinical Laboratory Improvement Amendment (CLIA) regulated by Medicare & Medicaid Services to under the jurisdiction of the Food & Drug Administration (FDA). The FDA now regulates non-LDT lab tests under “medical devices,” and “approves” or “clears” tests. Non LDTs are tests which are sold to other laboratories while LDTs are generally tests which are developed and used in one lab, commonly called specialty labs.

FDA Moves to Regulate All Lyme Tests

FDA is moving forward in the process of finalizing its new Laboratory Developed Test (LDT) Guidance proposal. The proposal would move LDTs from under the jurisdiction of Clinical Laboratory Improvement Amendment (CLIA) regulated by Medicare & Medicaid Services to under the jurisdiction of the Food & Drug Administration (FDA). The FDA now regulates non-LDT lab tests under “medical devices,” and “approves” or “clears” tests. Non LDTs are tests which are sold to other laboratories while LDTs are generally tests which are developed and used in one lab, commonly called specialty labs.

For the last several months, the LDA has been working a parallel track with other Lyme leaders and on its own to try to understand the implications of such a move for patient access and try to ameliorate any downsides to patients on moving Lyme test under this Guidance.
To that end, the LDA has been on 2 phone calls with FDA officials and other advocates. LDA also contacted a number of Lyme specialty labs about the issue. The LDA made a slide presentation to the FDA’s public workshop on the Guidance on Jan 8-9, 2015, and had a representative available at the 2 day workshop. All presentations at the workshop to the FDA panels were limited to 4 timed minutes and had a category restriction. The LDA and LDo cooperated to present different categories since the speaking time was so limited. CLICK HERE FOR LDA SLIDES Two representatives of IGenex Labs, CA, also presented at the workshop.

The LDA also contacted the offices of Congressman Christopher Smith (NJ), House Lyme Caucus Chair, and Senator Richard Blumenthal (CT), both of whom have worked with LDA on Lyme issues before. Congressman Smith’s office held a meeting with FDA officials to discuss concerns we had raised and continues to follow-up on unsettled issues. Senator Blumenthal wrote a letter to FDA expressing concerns LDA and LDo had voiced on the guidance.

The LDA has also submitted input to the US House of Representatives Energy & Commerce Committee’s 21st Century Cures initiative, specifically “21st Century Cures – A Modernized Framework for Innovative Diagnostic Tests.” CLICK HERE FOR LDA LETTER TO ENERGY & COMMERCE COMMITTEE

Concerns the LDA has are that

1. the peer review process which will be used to categorize tests and risks could be biased. This concern is based on the prior use of “experts” in Lyme disease.

2. the process used for collecting adverse events (MAUDE) currently used by FDA for approved/cleared tests is already flawed—FDA cannot determine which test kits are being reported. Yet under the proposed Guidance, the LDTs would be dumped into the same flawed MAUDE system. That action could
put the newly cleared LDTs at a disadvantage, because the LDTs put into the MAUDE system would be subject to greater scrutiny, since FDA would have the ability to more readily act upon the complaints.

3. government agencies have touted that all Lyme tests should be FDA approved, and through our analysis of FDA’s process, we discovered that FDA cannot point to any “approved” Lyme tests; they are all “cleared” which means substantially equivalent to a predicate test—to what test exactly, no one knows, since they cannot point to any original predicate test for Lyme that was not itself also based on substantial equivalence.

4. specialty lab tests will be removed from the market during the review process, citing safety reasons, which can be, e.g., too many positives.

CLICK HERE FOR LDA LETTER TO FDA WITH 73 GROUPS SIGNED ON

2016 UPDATE FROM FDA

FDA DELAYS FINALIZATION OF LAB-DEVELOPED TEST DRAFT GUIDANCE
The FDA announced in November 2016 that it would wait for the new administration and halt the finalization of guidance that would have changed the way laboratory-developed tests are regulated.

Important Survey: Proposed Lyme Test Regs

**Time Sensitive Survey:** The Food & Drug Administration (FDA) is poised to develop new regulations which may affect access to existing tests for Lyme and other tick-borne diseases. Please click on the link to complete a survey being done by LymeDisease.org, an affiliate of the Lyme Disease Association. The information is needed for upcoming meetings with FDA, an immediate response is required. This is very important information needed to help the Lyme Community. Thank you.

[Click here to take Survey](#)
[Click here for link to more information on the testing issue](#)

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From 2013 LDA Conf. to 2014 Peer Review: Ticks in Upper Midwest

At the LDA’s 14th annual Lyme & Tick-Borne Diseases 2013 conference held in St. Paul Minnesota, Ellen Stromdahl, Entomologist, US Army Public Health Command Entomological Sciences Program at Aberdeen Proving Grounds in Maryland, presented US Army Findings in Ticks from the Upper Midwest. Now, the paper of that talk has been published in the peer reviewed journal *Parasites & Vectors*.

[http://www.parasitesandvectors.com/content/7/1/553/abstract](http://www.parasitesandvectors.com/content/7/1/553/abstract)
The Environmental Protection Agency’s (EPA) Pesticide Environmental Stewardship Program (PESP), of which the Lyme Disease Association (LDA) is a long time member, features LDA in its Fall 2014 newsletter. PESP is designed to reduce pests, in this case, ticks, and reduce the exposure to ticks with minimal use of pesticides — how Integrated Pest Management (IPM) can be applied to reduce the incidence of potentially debilitating Lyme and other tick-borne diseases. Read about it below.

Click below for pdf of PESPWire Newsletter
Happy Trails, Candy!

We'd like to say goodbye and send well wishes to Candace "Candy" Brassard, who retired from EPA's Office of Pesticide Programs on August 23rd. Candy, a biologist with 35 years of federal service, spent much of her career with EPA. She devoted her final two years to the Environmental Stewardship Branch in support of PESP and our IPM efforts.

In her early career, she focused on ecological risk assessments and ecological monitoring. Candy later shifted to efforts to evaluate prevention and control methods for vectors that pose risks to public health, including tick-borne diseases.

An especially notable accomplishment of Candy's impressive career was the 2014 Federal Initiative: Tick-Borne Disease Integrated Pest Management White Paper. The document was the result of a two-year collaboration by the Federal Tick-Borne Disease IPM Workgroup, a group comprised of 14 agencies including EPA, Centers for Disease Control and Prevention, Department of Agriculture, Geological Survey, National Science Foundation, Department of Defense, National Institutes of Health, and National Park Service. Candy was instrumental in marshalling the production of this important document.

Candy was a leader and incredibly dynamic force in promoting IPM tactics to reduce the risk from ticks and tick-borne diseases. She was unique in that her work intersected with her personal passion. We'll dearly miss her ever-present optimism and support for IPM!

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Featured Member: The Lyme Disease Association

We sat down with Pat Smith, President of the Lyme Disease Association, Inc. (LDA), to discuss her organization's work preventing Lyme disease and how Integrated Pest Management (IPM) can be applied to reduce the incidence of this potentially debilitating disease. LDA is a longstanding Silver-level member of the Pesticide Environmental Stewardship Program.

Can you give us some background on your organization's history and goals?

LDA's mission is to promote awareness of and control the spread of Lyme and other tick-borne diseases (TBDs) through education of health care professionals, the public, and government officials; raising and distributing funds for cutting-edge research, external education initiatives, and other innovative projects; and assisting underprivileged patients.

LDA is a 501(c)(3) non-profit focused on research, education, prevention and patient support. LDA began as the Lyme Disease Association of Central Jersey in 1991, then became the Lyme Disease Association of New Jersey in 1993. Formed by patients and doctors who saw the need to organize to fund research and educate people on the many complex issues, by 1997, it had influence far beyond NJ borders. In 2000, it became the Lyme Disease Association, Inc. with a broader mission: LDA is volunteer-run and utilizes consultants for specific expertise as needed.

Continued on page 3...
The Lyme Disease Association

LDA presents fully accredited annual scientific/medical conferences, funds research nationally, provides monies for children without insurance coverage for Lyme, provides free literature, has a free information line, hosts a free online discussion referral and holds LDAmeet, an association of 41 organizations that work together on national issues.

LDA collaborates with EPA on a federal/public tick IPM workshop to reduce the risk from ticks and the pesticides associated with their prevention and control. To that end, LDA contributed to EPA's 2011 Promoting Community IPM for Preventing Tick-Borne Disease conference by providing speakers and co-hosting a session with the Centers for Disease Control (CDC). Pat Smith co-authored the article, You Can Make a Difference to a Child by Reducing the Risk of Lyme Disease in the May 2010 issue of the National Association of School Nurses (NASN) in conjunction with the Network to Reduce Lyme Disease in School-Aged Children developed with EPA, CDC, NASN, and LDA.

In its search for preventative measures and a cure for chronic Lyme disease, LDA has funded dozens of research projects, through some 95 grants, coast-to-coast. Much LDA-funded research has been featured in 35 peer-reviewed publications. A joint effort by LDA, Columbia University, and the Lyme Research Alliance, led to the 2007 opening of the endowed Lyme and Tick-Borne Diseases Research Center at Columbia University, the first in the world devoted to the study of chronic Lyme disease.

The LDA has presented 15 accredited scientific conferences for researchers, doctors, and health care providers, featuring international speakers on TBD; most jointly sponsored by Columbia University. LDA has also educated through public, school, corporate, and government seminars. Annually, LDA awards education grants to Lyme groups, universities, and other organizations to further their TBD mission. To date, 94 such grants have been awarded.

Since children are at the highest risk of acquiring Lyme disease, in 2004 LDA created LymeAid4Kids, a fund to help uninsured children initiated in conjunction with author Amy Tan LymeAid4Kids has awarded almost $250,000 in grants.

LDA's website features a Lyme: Kids & Schools section with free information for teachers, parents, and the public. In addition to material directed at children, LDA also offers for free (after postage) the Lyme Primer brochure, Tickmark, and Tick Card, downloadable and printable copies of National Case Map, Case Number graphs, Personal & Property Prevention Posters, Symptoms Lists; and at cost materials including conference DVDs, and books. The site also houses an extensive collection of tick and rash pictures and tick-borne microbes. Finding doctors who are experienced in treating tick-borne diseases is difficult, thus LDA created an automatic doctor referral system to help people worldwide.

LDA representatives have testified in many state legislatures and participated in press conferences with congresspersons, governors and other elected officials. LDA had led the charge on the introduction and passage of federal and state Lyme-related legislation. The LDA President testified before the US House of Representatives Foreign Affairs Global Health & Human Rights Subcommittee (2012) and Energy & Commerce Health Subcommittee (2013).

What is your organization's role in promoting IPM to help prevent Lyme disease?

One of the goals of the LDA is to reduce the number of people exposed to ticks, thereby reducing the risk of the diseases they carry. LDA has always incorporated information about personal, domestic animals, and property protection related to ticks and TBDs into its educational seminars, presentations, published literature, and research agenda.

LDA does not advocate for the use of products, but rather, presents strategies for reducing TBDs, such as the avoidance of tick habitats, proper clothing, property maintenance, and, perhaps most importantly, tick checks. The realities of increasing tick populations, however, create a need for individuals to be aware of products that can be used on clothing, skin, and property to kill or repel ticks. Therefore, LDA has incorporated into its programs information on the availability of such products, their differing purposes, the need to know and comply with manufacturers' directions/recommendations, the risks/benefits of such uses, and where they can find more information on these types of products, such as EPA's website.

Additionally, LDA has presented information on IPM tactics such as deer feeder stations to control ticks on large properties, bait boxes to control ticks on small mammals, and biological controls for ticks such as fungi and nematodes. It is LDA's philosophy that they have a responsibility to inform people of all prevention options, but that people are ultimately responsible for their choices.

What techniques and messages have you found to be the most effective in preventing exposure to ticks?

The most effective message in preventing exposure to ticks is immersion - saturating people with the facts about the diseases ticks cause.

continued on page 4
These facts include that: (1) Lyme disease is now found in 80 countries worldwide, (2) 15+ TBDs now affect people in the US, (3) one tick bite can transmit many diseases, (4) TBD diagnosis and treatment is challenging, (5) there is a lack of awareness of and medical knowledge about TBDs among physicians, and (6) children are at the highest risk. LDA has done hundreds of presentations over the years, and the feedback from audience members has been consistent - that they had no idea of the magnitude of the problem. LDA's awareness building has led people to take precautions and further spread the message directly and through support/advocacy groups.

Tell us about a major success in using IPM to prevent Lyme disease.

LDA's development and dissemination of free print materials on Lyme disease and its prevention has been a major success. These materials include the LymeR Primer (with information on 15 TBDs), tick identification and removal cards and bookmarks, and the ABCs of Lyme Disease pamphlet for parents and educators. To date, more than 2.2 million pieces of literature have been distributed to doctors, hospitals, health departments, government officials, military installations, veterinarians, parks, businesses, schools, Lyme groups, and the public. LDA has been fortunate to secure corporate sponsors, several of whom are involved with TBD prevention, to underwrite the production of these materials.

What are your goals in the next five years?

In the next several years, LDA hopes to be able to expand its research efforts. We also intend to work with other groups and federal agencies for a focused federal research agenda that will include developing a gold standard Lyme diagnostic test, developing safe and effective treatments for Lyme, and identifying effective approaches to reduce the size and spread of tick populations thereby reducing disease transmission.
LDA Presents Lyme & TBDs to EPA

On September 18, 2014, Lyme Disease Association President Pat Smith presented a 1.5 hour PowerPoint presentation entitled Lyme & Other Tick-Borne Diseases: A National Overview & The Role of LDA to the Environmental Protection Agency Biopesticides & Pollution Prevention Division in Arlington, VA. The presentation was done in person, and through a webinar and call in. Question and answer followed, and education materials were distributed by LDA Board member Richard Smith.

Ms. Smith discussed her organization’s role in Lyme disease prevention and provided an overview of Lyme and other tick-borne diseases with an emphasis on research and prevention. The LDA has been a long time partner in the EPA’s Pesticide Environmental Stewardship Program (PESP)—a program designed to reduce risks from pests, in particular, ticks, thereby reducing risks of tick-borne diseases with minimal use of pesticides. This goal is to be achieved by developing tools to be used in schools and for people who have access to public lands for outdoor uses.

LDA helped in the PESP to form the Network to Reduce LD in Children & High Risk Groups. LDA also helped to plan and organize the EPA Conference in 2011 in Virginia, Promoting Community Integrated Pest Management (IPM) to Prevent Tick-Borne Diseases. Pat also co-chaired with CDC, a conference session: Public Outreach Strategies to Reach Targeted Populations. Ms. Smith also co-authored the article from the Network which appeared in the National Association of School Nurses (NASN) March 2010 Journal, You Can Make a Difference to a Child by Reducing Risk of Lyme Disease.
LDA Speaks Out: CDC/Advocates Meeting & “No Lyme In The South”

I think it is time to clarify some of the issues surrounding both the Lyme advocate meeting held at CDC in Ft. Collins CO, June 2013 and the “no Lyme disease in the South” controversy. In early 2013, I wrote to the Centers for Disease Control & Prevention (CDC) and presented the objections of the Lyme Disease Association (LDA) to the CDC’s website statement that Lyme does not occur nationwide. I asked for all the pertinent data used to support that statement. The goals of LDA in this context are that threats of disease be realistically assessed and that patients not be condemned to unnecessary suffering because they are denied the opportunity for early diagnosis and safe and efficacious treatments. I am sure everyone agrees that patients and physicians have the right to the best, most up-to-date data and science.
CDC’s initial response included this rationale: (1) the distribution information on the tick vectors of Lyme disease and specifically that Ixodes scapularis is limited in distribution to the eastern and upper mid-western regions of the U.S. and Ix. pacificus to the west coast, (2) that it is well-established from the literature that Ix. scapularis ticks in the southern U.S. [GA, FL, AL, MS, etc] do not typically bite humans, especially the nymphal stages that are most important for transmission of B. burgdorferi and (3) the relatively small numbers of Lyme disease cases reported from states where Ix. scapularis and/or Ix. pacificus are not present can almost entirely be shown to be travel-related cases that were not acquired locally, hence the use of the term “does not occur” nationwide.

CDC said that LDA could have an opportunity to further discuss this issue if we disagreed, which we did. In conjunction with CDC’s “no Lyme in areas such as the South and central states,” I suggested that the flawed surveillance system is heavily weighted against disease even being reported there: “I think discussions on the failures of Lyme surveillance and how that impacts upon patient diagnosis and treatment, research dollars, health care spending, need to happen, and since I like to assume we are all working for the same goal, I would like to propose that we do what it takes to begin that discussion in an open and transparent way, with all at the table to provide and review available evidence. Many lives & dollars could be saved by such a move.”

LDA then requested all supportive documentation from CDC showing that reported cases in other states were almost entirely travel related. CDC admitted they did not have that data nor could they direct us to any entity which had such information. They sent a box of peer-reviewed literature supporting the remainder of their “no Lyme in the South and central states position” such as geographic distribution of Ixodes ticks and the “ticks in the South rarely bite humans”
literature, which LDA then began to analyze.

In the meantime, CDC contacted LDA and suggested a meeting at CDC Ft. Collins with Lyme leaders from various geographic regions. Several groups were invited by the CDC and many of the Vector-Borne Disease Division personnel were at the table, as well as a representative from CDC Atlanta, when the meeting was convened on June 11, 2013. Seven groups including LDA attended, and 3 organizations did not attend in person but by speaker phone for a 2 hour portion of the all day event – unfortunately, they were only able to hear a small portion of the whole day’s proceedings— a day packed with meetings, discussions, lab tours, and an informal dinner with all attendees.

In the group presentation section, I gave the allowed 10 minute PowerPoint which provided factual data that placed the CDC “no Lyme in the South and Central states” argument in serious jeopardy. The papers which CDC cited contained very old data, some citing journals decades old, some of which did not even support what was touted, and many did not contain current statistics from states they place in the no/doubtful Lyme category, some used maps of projected deer tick populations that current research had long since proven were out of date. Notwithstanding claims to the contrary, according to researchers, physicians, and tick-bite victims in the South, deer ticks are certainly biting people. No one questioned my presentation then or in the subsequent 3+ months.

I have since read all the speculation on the net and in newspapers about what did or did not occur or what was/was not accomplished at this meeting. I am not sure anyone would be naïve enough to think that government Lyme policies would be immediately changed as a result of this one meeting, if so, they certainly set their expectations too high. Perhaps some people feel that there is not any reason to meet with CDC anyway, with the rationale that we can get what we want
without meeting with them. I have been involved now in Lyme work for almost 30 years as an advocate. As frustrating and absolutely exasperating as it has been and may continue to be, I can tell you that the major federal public health agencies need to be part of the solution in order to achieve more than very fragmented, partial successes in our battle against Lyme & other tick-borne diseases.

What needs to be recognized by all is that two agencies under the US Department of Health & Human Services (HHS), the CDC and the National Institutes of Health (NIH), are the ones designated by Congress with responsibility to oversee disease areas which most impact Lyme patients. They are the ones who set policies, receive grant funds to distribute, and in general, are “in charge of” diseases. To complicate the chain of command with Lyme, the CDC in Ft. Collins, CO is the home to the Vector-Borne Diseases Division which handles Lyme and other tick-borne diseases and which is under the direction of CDC Atlanta, GA, which is under US Department of Health & Human Services (HHS). Therefore, for something to be accomplished with Lyme, one chain goes from CDC in Colorado to CDC in Georgia, and, if it is perceived to possibly overlap another agency’s jurisdiction, on to HHS in DC. HHS is part of the executive branch and overseen by the Executive Office of the President. With any “non-political” disease, this process is not an easy one, but with one as complex as Lyme, in such a contentious climate, you can be sure substantive decision-making is going up the chain of command and changes to policy will be well vetted and time consuming.

This meeting was like the first meeting at a negotiations table, parties get to meet each other face-to-face. They get to hear positions discussed at the same table, and in our case, we had a lengthy session where each person could discuss what they did not like about what the “other side” was doing in the “Lyme wars.” That helped people to see real people behind the issues; it put a face on the disease. There was
passion, disagreement, and intelligent discussion of the science and of the lives affected. There was no shouting or disrespect. A list of attendee-suggested future actions was created— the CDC said it would set up some of the meetings we felt were most important, and it has since reiterated they will proceed with that agenda. We did have a late August conference call with CDC regarding the materials released by CDC at the Boston Lyme disease conference regarding confirmation that Lyme cases are indeed ten times more prevalent than reported surveillance case numbers indicate. That fact was not a surprise to any of us advocates who for many years have used a “Lyme is underreported by a factor of ten” qualifier based upon past CDC remarks that Lyme was that vastly underreported for surveillance purposes.

My position is that this CDC-advocates’ meeting was successful, as opposing parties met, talked, presented their programs and issues, interacted on a personal level, and CDC has committed to moving forward with some of the items placed on the “wish list” of the advocates. I know there are good people on both sides who would like to see the Lyme disease issue resolved. Like everywhere else in life, unfortunately, there are others who would like to keep the pot stirred and do not want the two sides to try to find common ground.

Speaking for LDA, we will try to continue to work with the agencies in government that have responsibility for dealing with Lyme, but we will also continue to speak out using science and statistics to promote policies which support the current realities of tick-borne diseases and to overturn policies supported by obsolete data and/or specious analyses which continue to hurt Lyme patients and physicians, e.g., CDC’s “no Lyme in the South,” a policy which delays diagnosis and treatment, skewers surveillance, and suppresses relevant research. Dr Kerry Clark’s recent research on southern Lyme, partially funded by LDA, is a step in that direction, and rather than “contradicting” other older research, I think it
shines new light on areas on which other researchers have feared to tread lest they be mired in the political morass of Lyme disease—where researchers may be told “don’t go there or you may never publish again.” Dr. Clark’s research postulates there may be additional factors besides those considered by CDC to explain the cases of Lyme in the South, factors that might help explain the fact that the FL Dept. of Health indicates that 30% of Lyme cases from 1999-2008 occurred in state, not from travel.

I am sure that many of you, like me, have been extremely frustrated by reading in countless studies from the ’80s through today recommendations for further studies to move the field forward—studies which far too often were not pursued. To facilitate forward progress, it would be productive and responsible for CDC and other agencies to refrain from reflexively repeating statements and positions based on fragmentary and often outdated data. It is time to formulate policies based on current and convincing data and support research using cutting edge techniques which can provide the answers we all need to stop the spread and devastation of Lyme disease, not only nationwide, but also worldwide.

Patricia V. Smith
LDA President