

*the*

# Lyme Times

NUMBER 30

*Education, Support, Advocacy, Research*

SPRING 2001

## New Lyme bill introduced in Washington

**Washington, DC** – On March 27, New Jersey congressman Christopher Smith introduced the Lyme Disease Initiative 2001 (H. R. 1254) into the House of Representatives. Joining Smith as co-sponsors were congressmen Pitts (PA), Maloney (CT), Gilman (NY), Morella (MD), Hinchey (NY), Delahunt (MA), Traficant (OH), Wolf (VA), Towns (NY), and Saxton (NJ). Smith has been a leader on Lyme issues since he held a 1993 Congressional meeting in his district and in DC, followed by the first federal Lyme bill in 1998. This year's Lyme Disease Initiative (LDI) is the same bill that was introduced in 1998 and, with some modifications, in 1999, and was backed by 65 Lyme patient advocates and support organizations.

### The Three Fives

The Lyme Disease Initiative 2001 is a comprehensive bill which provides \$125 million in funding to five federal agencies involved with

*See LDI on page 33*

## Inside...

**California DHS announces open meeting, page 25, and**

**Ray Stricker, MD, reports from ILADS conference, page 45**

## Warnings urged for Lyme vaccine

**Bethesda, Md.** - Patients claiming to have been seriously harmed by the Lyme disease vaccine urged a Federal Food and Drug Administration (FDA) committee to take the vaccine off the market or at least to put a warning on the label. The January 30 meeting was the culmination of over a year of growing concerns that SmithKline Beecham's LYMERix vaccine may cause irreversible autoimmune arthritis in some patients. The FDA has received 1,048 reports of LYMERix recipients suffering possible side effects. They are investigating 133 reports of severe arthritis-like symptoms. Over 440,000 people have been inoculated.

Patients claim that vaccine developers knew about the risks

beforehand since they required people who participated in the clinical trial to sign papers indicating a "theoretical possibility" existed that the vaccine might cause arthritis in certain genetically susceptible individuals. The FDA approved LYMERix in 1999.

SmithKline spokeswoman Carmel Hogan said the company wasn't trying to hide the theoretical link to arthritis. "It's been no secret," she said. "We knew this hypothesis was out there during clinical trials, and we presented it to monitoring boards and the FDA, and they concluded there was no clinical evidence [establishing a link]. There was no difference between those who took the placebo and those actually vaccinated."

*See FDA on page 30*

## NIAID's Chronic Lyme Disease studies terminated

On November 14, the Data and Safety Monitoring Board (DSMB), an independent monitoring group of doctors and researchers from around the country, reviewed a planned interim analysis of data from two placebo-controlled drug trials under this contract. The trials were testing the safety and efficacy of intensive antibiotic treatment in people with Lyme disease who had developed chronic symptoms despite earlier treatment with antibiotics. The study

compared treatment with 30 days of intravenous ceftriaxone followed by 60 days of oral doxycycline to treatment with intravenous placebo followed by oral placebo for the same duration.

After its review, the DSMB unanimously recommended that NIAID terminate the treatment component of both trials. Their preliminary analysis showed no

*See Study aborted on page 30*

NUMBER 30  
SPRING 2001



the

# Lyme Times<sup>©</sup>

Publication of the Lyme Disease Resource Center

## In this issue...

- 3 Editorial
- 4 Letters
- 6 Opinion
- 12 Front Lines
- 13 Beginners' Pages
- 15 Patient Story
- 17 Patient Support
- 21 In Memoriam
- 22 Regional News
- 28 News Briefs
- 35 Research
- 38 Abstracts
- 40 Conference Reports
- 47 Subscription Form
- 48 Calendar

## Features

- 6 Tick eradication efforts needed, by Jill Auerbach
- 10 Complex disease demands complex treatment protocol, by Harold Smith, MD
- 19 The truth about mild silver protein, by Rosemary Jacobs
- 32 Lyme Disease Association goes national
- 39 A million ticks, by Linda Finn

## From the Editor

Dear Readers -

LDRC extends congratulations to all the groups and individuals who have been working so hard for our Lyme community. Some of your success stories are contained in this issue and you all deserve credit and accolades. The torch is being passed to a new generation of actively involved Lyme disease patients. Suzanne Smith (in her review of the LDRC conference on page 40) aptly points to the irony of all this work being done by disabled people on shoestring budgets. It's not easy, however there is no doubt that our voices are being listened to and that we have a real chance of affecting change which will benefit patients in the long run. Please keep me informed about all your accomplishments so the Lyme Times can continue to be a source of inspiration and encouragement to all.

On a more serious note, two of our long-time Lyme workers are currently undergoing treatment for cancer. Some of you might like to send cards or wishes to Nancy Brown of the LDRC or Betty Gross of the Westchester County Lyme Disease Support Group. Nancy's address is in the first column on the next page; we

## Erratum

The Lyme Times apologizes to photographer Kathy Townsend for the erroneous attribution of her picture of Mis-Tick in front of the Capitol in Washington, DC, in the Lyme Times #29.

will forward any letters to Betty if you do not have her address. Betty and Nancy have each been dedicated Lyme educators for more than a decade.

We appreciate your tolerance of our unpredictable publishing schedule, and are working to remedy the situation. We are asking people who are already expending considerable effort on our behalf to work a little harder and become regional reporters or section editors for the Lyme Times. If you are not already involved beyond your capabilities, please volunteer and share the burden with those who are already doing so much. Writing ability is not essential although it helps. Contact me by email or phone 707-462-7745, after dark Pacific time zone or take your chances any other time.

Last but not least, please support the Lyme Disease Initiative 2001 which was introduced in March. We have a real chance at getting this legislation passed this session. The bill has already earned support in the House and Senate. Write to your legislator and encourage him/her to co-sponsor HR 1254.

Finally, if you are not on the Lyme Times mailing list, and are wondering why you received this issue, please thank the Lyme Disease Association.

Phyllis Mervine, Editor

*The Lyme Disease Resource Center was founded in 1990 as a nonprofit education and communications center for the public, for Lyme disease patients, for physicians, and other interested people. The goals of the LDRC are to educate the public about Lyme and other tickborne diseases, including risk factors and prevention; to provide services for Lyme disease patients and their families and friends; to provide a forum for physicians and health care professionals for the exchange of ideas and information about symptoms, diagnosis, and treatment of Lyme disease; to be a communications center for individuals and groups who are working to help patients with Lyme disease; and to encourage Lyme disease research. The LDRC gratefully accepts tax-deductible contributions to assist its efforts.*

**the Lyme Times**

Spring, 2001

**Publisher**

Lyme Disease Resource Center

**the Lyme Times Staff**Editor: *Phyllis Mervine*Associate Editor: *Jean Hubbard*Contributing Reporters: *J. Der Bedrosian, Virginia Sherr, Harold Smith*Contributors: *Sandy Berenbaum, Jill Auerbach, Jon Strong, Henry Oster, Rita Stanley, Martin Atkinson-Barr, Gillian Reese, Jo Johnson, Rosemary Jacobs, Kathleen Dickson, Cathy Morrissey, Sarah Weiss, Brian Fallon, Linda Finn, Suzanne Smith, Ray Stricker*

The Lyme Times (Library of Congress card no.92-595999) is published four times a year by the Lyme Disease Resource Center, PO Box 1423 Ukiah CA 95482

Address correspondence to:

Phyllis Mervine, Editor  
the Lyme Times  
PO Box 1423  
Ukiah CA 95482

or email at &lt;pcm@pacific.net&gt;

Individual subscription rates 1 year (4 issues): domestic \$25; Canada & Mexico \$35; Foreign \$40. Institutional/Library rates \$50. US funds only, please. Send check to LDRC, PO Box 707, Weaverville CA 96093

**Send address changes to:**

Nancy Brown, Secretary, LDRC, PO Box 707, Weaverville CA 96093

or email LDRCsec@snowcrest.net

Include both old and new addresses, including zip code.

The articles in the Lyme Times are not intended as medical advice regarding the treatment of any symptoms or disease. Medical advice of your personal physician should be obtained before pursuing any course of treatment. The Lyme Times makes no express or implied warranties as to the efficacy or safety of any treatment in its articles or letters and disclaims all liability for any use of any such treatment. Opinions expressed in articles are those of the authors alone and are not necessarily those of the Editor or the LDRC.

Republication of any portion of the Lyme Times without written permission is prohibited. Please contact the Editor if you wish to duplicate articles. To submit articles, please send electronic files to <pcm@pacific.net>. Original articles are preferred. Published uncopyrighted articles become the property of the Lyme Disease Resource Center.

© Copyright 2001LDRC

**Editorial**

# Freedom of choice in medical care - the real issue

by **Sandy Berenbaum, CSW-R, BCD**

As we educate ourselves about Lyme disease, as we engage in honest dialogue with our colleagues, if we are part of the medical and mental health community, as we face the challenges that the politics of Lyme have created, we have to keep focused on the bottom line: the right of a physician to make medical decisions in concert with his/her patient, in support of the healing process.

Seven or eight years ago, in a support group meeting here in upstate New York, two patients (out of about 20 in attendance) reported that they were denied antibiotics by their insurance companies BECAUSE there were lesions on their brain MRIs. Thus the insurance carriers defined them as having MS, and not Lyme. Soon after that, as apart of my own treatment, I refused a brain MRI, fearing that my own IV would be stopped if there were lesions.

Anything and everything can be used as evidence against us, in undermining our treatment needs, if the insurance companies do not deem these treatments cost-effective. When the conclusion is reached first, then the building blocks are put in place to support that conclusion, the entire line of reasoning is faulty.

We need to be very, very careful to remain focused on the clear fact that the patient and doctor should be making these decisions, and not the insurance company. This is not bargaining for a dress on the lower East Side of New York. Our lives and the lives of our patients are at stake here.

Our doctors are medically licensed, most board certified. Those

who are Lyme-literate are very well-read, often treating thousands of Lyme patients, keeping good records of what works and what doesn't. They engage in scientific discussion with their peers, remaining open to hearing what other practitioners have to offer from their broad experience base. Our doctors attend conference after conference, presenting at many, spending days and days preparing for these presentations. They publish articles in peer-reviewed journals. They take on the responsibility of teaching others what they have learned, both formally and informally.

Where is the list of credentials, the hours of continuing medical education focused on Lyme, that the insurance doctors have accumulated? Where, indeed, is their objectivity, working in an atmosphere where success is measured by cost-effectiveness, in the short term, and not by restoring health to the patient?

We need to stick with our bottom line - I chose my doctor because he knows Lyme. He chose the testing means, ancillary treatments, and primary medical treatment because he knows me, the history of my illness, and how it affects me TODAY.

*Ms. Berenbaum works at Family Connections Center for Counseling in New York State. In an afterword she wrote: "Many people, even those who have options to be in Fee for Service plans, don't understand how the HMO review process really works. I've heard, 'My HMO says they treat Lyme disease. I called them and asked them specifically.' Until your need for treatment has been rejected, you don't know how bad it can get."*

## Letters

*We do not recommend any of the doctors or treatments which may be mentioned here by writers. Patients should discuss any treatment options with their physicians. Signed letters of general interest may be printed.*

### Patients need to fight health insurance denials

I recently appealed Oxford's denial of IV antibiotics for treating my Lyme disease. When that failed, I filed an appeal with the State of NY Insurance Dept., who farmed out my records to a corporation known as "IPRO." IPRO had a rheumatologist review them and decided that I had "No symptoms of Lyme Disease." These records included a positive LUAT, positive Ehrlichiosis, positive Babesiosis and equivocal WB (by CDC standards...*only* 4 bands) positive SPECT scan, and every symptom of Lyme disease except tender testicles!

IPRO's position? That Lyme disease is OVERdiagnosed, the risk of IV antibiotics causing infection is too great, and that I DO NOT HAVE LYME DISEASE.

They never examined me, and they disputed the findings of two LLMDs [Lyme-literate MDs].

Now, more than ever, we need to make a lot noise...we and our precious doctors are being discriminated against.

It will only get worse if allowed to continue.

**Joan Starkman**  
Bohemia, New York

### Did vaccine activate hidden Lyme disease?

Dr. Parenti's talk at the 2000 LDF Conference was billed as an update on the SmithKline-Beecham vaccine, but instead he gave a very interesting talk on EM rashes and how 30% of patients with biopsy-proven EM have negative serology! Then, when questioned by Dr. [Leslie] Fein, he

denied any vaccine-related adverse reactions.

Was I the only one puzzled by Dr. Parenti's talk? But I think I get it now. Here's what I'm wondering (and I've wondered this for a long time):

If the studies of the vaccine relied on serology to determine pre-existing Lyme and the researchers thereby missed 30% of cases, then isn't it likely that many of the people with adverse reactions, including Lyme-like arthritis, actually had previously undetected Lyme which was somehow activated by the vaccine?

In light of all the uproar over adverse events and the potential liability of SKB, is it possible that Dr. Parenti's talk was a clever move to shift the liability onto the researchers?

**Deborah Solomon, MD**  
North Kingston, Rhode Island

### What is counted as an adverse reaction to LYMERix?

I've heard Dennis Parenti, of SmithKline Beecham, speak at several LDF conferences regarding the vaccine. I have found him to be a good speaker who stuck to the topic and was crystal clear, easily understood by those of us who do not have a strong medical/scientific background.

The last time I heard him, after the

legal action against SKB began, I looked forward to his making some sense of the controversy, and expected him to speak to the topic. I was, however, disappointed.

Focusing, for the most part, on the EM rash, his presentation answered no questions for me. He did not address the misunderstandings in the medical community regarding how to diagnose Lyme in patients who had had the vaccine, nor did he address the incidence of adverse reactions.

The confusion among doctors is rampant. When a vaccinated patient goes to the doctor with symptoms of Lyme disease, they may be told, "You can't have Lyme. You've had the vaccine," or, "Even though you have several positive bands on the western blot, you don't have Lyme."

Dutchess County, NY, the home of the clinical trials for the vaccine, is highly endemic. I don't believe that anyone can say they don't have Lyme! I've spoken with people who've taken the vaccine who are loaded with what could be Lyme symptoms. It is absolutely frightening. How to screen, before giving the vaccine, was not addressed by Parenti.

One interesting comment, at the end of Parenti's presentation. I was sitting in the back when Parenti was asked about adverse reactions. There was a very strong, shocked reaction from the audience when he said there were no reported cases of severe adverse reactions. A woman turned to me and said, "I can't believe he said that. I am one of the people with a severe adverse reaction."

I responded, "Maybe he only counts death as an adverse reaction."

Those who brought us this vaccine should offer explanations and clarity, and not side-step the issues that are out there.

**Sandy Berenbaum, MSW**  
New York

**Send your letter to the  
Editor at PO Box 1423,  
Ukiah, CA 95482, or  
email pcm@pacific.net.**

## Health insurance industry may limit patient options

I have Lyme Disease. Not the “small red rash, achy knee” kind the press often describes as Lyme Disease. No, I have the scary kind of Lyme Disease that is being ignored and swept under the rug. I have the kind of Lyme Disease that insurance companies are trying to deny exists.

I have the kind of Lyme Disease that you don’t hear about in the press. You hear about it from your next door neighbor who suddenly can’t work anymore or care for her children. I have the kind of Lyme Disease that can land patients in emergency rooms, psychiatric hospitals, pain clinics and yes, sometimes even morgues. It has been called Late Stage Lyme Disease or Central Nervous System Lyme Disease or Chronic Neurological Lyme Disease or Lyme Encephalopathy.

You don’t want to get this kind of Lyme Disease. This kind of Lyme Disease will make you lose your career, your social life, your friends, your family, and your sanity. This is the kind of Lyme Disease that Dr. Joseph Burrascano has been trying to cure for decades.

Without Dr. Burrascano’s knowledge, experience, research, courage, and most importantly, his right to treat patients with Lyme Disease until they are cured, you may very well get this kind of debilitating kind of Lyme Disease and there won’t be any doctors who can treat you if the OPMC [Office of Professional Medical Conduct] prevails.

Investigate the OPMC and ask them why they are trying to stop Dr. Burrascano’s treatment protocols. You may find the health insurance industry in their back pocket.

**Donna Cenerizio**  
**Trumbull, Connecticut**

*Ms. Cenerizio is affiliated with the Wilton [Conn.] Lyme Disease Task Force. She wrote this letter as a*

*press release at the December rally supporting Dr. Burrascano outside the OPMC offices in New York City.*

## If we persist, the truth about Lyme will come out

I hope to be here when the day comes that we finally get to stop explaining ourselves and our illness. I want to see the assistance that so many other illness receive, be given to those with LYME.

I also dream that we will have some sort of apology from those who took our money, our health, and our lives and left us for dead, lied to us about what we are living with, and told the world we just complain too much.

OK, it’s just a dream, but I do think if we are persistent and don’t quit, the truth of Lyme Disease will come out.

I also wish there were “someone else,” but since there isn’t, I won’t quit and will do all I can until it’s finally finished.

**Regina Wrenn**  
**New York, New York**

## Defense Funds

Funds have been established for the legal defense of Dr. J. Burrascano and Dr. R. Horowitz, both currently under investigation by the Office of Professional Medical Conduct, New York State Dept. of Health. To make a donation, send your check or money order to:

**Horowitz Legal Defense Fund**

and/or

**Burrascano Legal Defense Fund**

c/o Monica Miller

PO Box 410

Kinderhook, NY 12106

## Protect us from harm!

The New York State Office of Professional Medical Conduct (OPMC) proceedings against Dr. Burrascano, of Long Island, NY, constitute nothing less than a modern day version of the “Darwin Monkey Trial.”

Currently, theoretical biology and medical research recognize chronic relapsing infection as the etiologic agent, or a major component, in many disease syndromes. However, the OPMC faults, to the point of censure, a prominent physician who incorporates these and other advanced concepts into the daily practice of medicine. Should he, instead follow the insurance-friendly standard of mediocrity?

Such a standard, tarnished by the power and profits gleaned from advances in medical technology and the inadequacies of managed care, fails to adhere to traditional medical ethics. To accept this reduced standard is to allow special interest groups and bureaucracies to undermine the physician-patient relationship to the detriment of all.

It is crucial that we unite to protect the integrity of our health care system. We all value freedom, particularly at a time of illness and increased vulnerability. Doctors who prioritize innovation, judgment, individualized care, and ethics should not be intimidated into deferring to a lesser standard. We urge you to spread this message by asking other physicians, researchers, health care providers, and educators to sign onto the “Medical Community Petition to Support Dr Burrascano” at: <http://www.angelfire.com/or2/burrally/petition.html>

Thank you for supporting Dr. Burrascano, and his struggle to promote honesty, ethics, and fairness in medicine.

**Robert Bransfield, MD**  
**Red Bank, New Jersey**

## Opinion

# Better tick-eradication efforts needed to curb Lyme epidemic

by Jill Auerbach

Dutchess County [NY] has the highest per-capita incidence of Lyme disease in New York state and is second in the country. What some of us do not know is that many of the ticks are also infected with other very serious diseases such as Ehrlichiosis and Babesiosis, etc. The Lyme vaccine will not protect you against any of these other diseases. Dutchess County had a \$5.1 million budget surplus this year. \$1.5 million profit was from the LYMERix vaccine study. More than \$1 million has been allotted to avert the West Nile virus, which is a threat. Yet, though a raging Lyme disease epidemic already exists here, none of the Lyme vaccine profit is being used for tick control research. The Millbrook-based Institute of Ecosystem Studies, a renowned ecological research institution, is a perfect place for the county to fund safe ecological tick-control research.

\* In 1999, a 3-year-old girl had 23 ticks pulled off her body during a bath the evening after visiting a park in Dutchess County. \* In a survey by Richard Falco, PhD, (medical entomologist) of residents in areas heavily infected with Lyme disease, 26 percent of households had at least one member who had contracted Lyme disease.

\* Lyme disease, like syphilis, is caused by a spirochete (a type of bacteria). The two varieties of spirochete go through the same stages, including dormancy, and share many of the same symptoms. This should demonstrate the seriousness of Lyme, the fastest-growing infectious disease after AIDS.

We have Lyme disease, we have co-infections, we have an epidemic. What's the common denominator

here? It's simple; it's the ticks. There is much exciting and promising research under way, but public awareness and funding are sorely needed. Every one of the researchers whom I've spoken with has expressed frustration with the lack of funding.

Nematodes, which are microscopic worms, are sold to citrus growers to protect their crops, yet the US Department of Agriculture researcher who is trying to provide them for the protection of people cannot get sufficient funding to complete her studies. (In her field study, nematodes killed 100 percent of the ticks just before they laid their 3,000-3,500 eggs). Some species can be purchased for control of Japanese beetle larvae and cutworms in your lawn.

Pheromones - chemicals secreted by insects to convey information - control certain tick activities such as assembly, attachment, sex, etc. So if researchers could identify and reproduce them, the possibilities are quite interesting.

Bait boxes for rodents are also of great interest, since mice are the Lyme spirochete's biggest disseminator, carrying as many as 100 ticks on their bodies. A rodent goes into the bait box to feed, is dusted with a non-systemic mild insecticide, and voila, it comes out clean, no ticks.

### Huge increases

Tick numbers have been increasing like wildfire during this past generation. Money should be spent to support research to reduce the number of ticks in the environment, which could virtually eliminate Lyme and other tick-borne diseases. This research is ignored and received a pittance of funding, while Lyme and other tick-borne diseases spread, infecting, re-infecting and co-infecting our children and ourselves. Scientists have found solutions for agricultural pests; now it's time to protect humans by turning this neglected field of science into an effective tick control program.

Dutchess County should take the lead, supporting and funding research, and sponsoring pilot programs such as are being done in other communities. Children should be able to play in their yards!

*Jill Auerbach is coordinator of the Hudson Valley Committee for Lyme Disease Patient Advocacy.*

---

## Lyme Disease Politics - X-Files paranoia or the real thing?

by Jonathan Strong

When I make new acquaintances, I find that I have recently become hesitant to get into more than a superficial discussion about Lyme disease lest I appear to be some kind of paranoid conspiracy nut. Insurance reimbursement denials? Doctors treating you as a psychiatric case? Government funded researchers abusing their responsibility and power? Nationally recognized

specialists refusing to consider research results that prove the existence of your chronic debilitating but serologically negative illness?

More often than not, when I start to relate this to somebody unfamiliar with Lyme disease, I soon see the skeptical frown start to appear. "Why," they ask, "would doctors and government employees do something like this? How could the insurance

companies get away with this?"

Even as I tell what many of us have learned the hard way, it barely sounds plausible to me.

The threads are tenuous, but if you start to pull them together, it is possible to start to see very real reasons behind the kind of behavior and situations that have stunned so many Lyme disease patients.

#### **Motivation for Insurance companies**

The motivation here is to minimize the cost of testing and treatment protocols for Lyme disease patients. As it stands now, if an insurance company can stand by the "common wisdom" that states that an illness is only Lyme disease if it meets criteria that have already been proven to be inadequate (e.g., "positive" antibody tests), they can instead insist that the illness is Fibromyalgia, Chronic Fatigue Syndrome or possibly even something psychogenic. The costs accruing to these "syndrome" illnesses are relatively trivial, and might include a few visits to a chiropractor, some pain management medication and perhaps a prescription for an antidepressant.

Reading recent statements by some of the doctors who think that Lyme disease is "over-diagnosed and over-treated", you will find that they don't even recommend *doing* extensive testing unless the patient meets certain predefined arbitrary criteria. This perspective fits the Salem witch trials rationale better than it does modern medicine.

#### **Consider that testing for Lyme disease could include:**

- Antibody serologies, which run approximately \$150 to \$200
- PCR serology, in the range of \$400 to \$600
- LUAT series, which is approximately \$240 for a set of 3
- MRI of the brain, which typically costs \$1,100 to \$1,300
- SPECT scan of the brain, which averages about \$1,400

- Lumbar puncture, which costs a couple of hundred dollars for the procedure, as well as the costs for any related serological testing on the cerebrospinal fluid.

#### **Consider the treatment for Lyme disease:**

Even for early disseminated Lyme disease, proper treatment could be months of expensive third-generation cephalosporins or macrolides, costing approximately \$10 per capsule and totaling anywhere from \$300 to \$1000 a month.

For late disseminated Lyme disease or neuroborreliosis, you will likely need IV medication, the cost of which ranges from \$250 to \$300 per day. The experiences of dozens of doctors and thousands of patients suggest that you may need months, a year or perhaps several years of such treatment to get the infection under control. If you add doctor visits to this, the actual cost to treat advanced Lyme disease could easily come to \$110,000 per year per patient. Periodic retesting adds approximately another \$2,000 to \$4,000 to this. Many patients wind up needing *at least* one year of treatment, and perhaps a few courses of such treatment over several years.

#### **Consider the numbers**

Now we must consider how many cases of Lyme disease are probably "out there". The CDC even acknowledges that their figures are based on narrowly defined "case surveillance criteria". It is generally accepted that they probably under-report the incidence of the illness by a factor of at least 10. Since we know that Lyme disease can be subclinical for long periods and often winds up being dismissed as something like "growing pains", "summer flu", seasonal allergies, depression, FMS, CFS, etc., it is conceivable that the real number is still another order of magnitude higher. Most doctors just do not know anything about the illness. If you don't know what something looks like, you'll never recognize it even when it's right in front of you.

The CDC has noted that reported cases that even meet their admittedly narrow criteria jumped something like 40% from 1995 to 1996, and they attributed this to an increase in the tick population and the incidence of infected ticks - and not to earlier under-reporting. As of a year ago, they acknowledged more than 17,000 cases that both met their criteria and were reported.

It has been my experience that, in almost ANY social or business gathering, at least one person in the room either was diagnosed with Lyme disease or knows someone who was diagnosed. What are the odds that the 17,000 people are all part of my little social circle in the northeast? By the CDC's own admission, the number is likely to be at least 170,000 in one year alone. By some estimates, it's quite possible the real number is over a million. Even if we only assume 170,000 cases each year, just a few years of this means that over a million people are infected. Since most are never diagnosed, the majority will be untreated while the illness may progress to a fully disseminated and intractable state.

The basis for the politics becomes obvious and compelling when we work through the numbers. If we allow for the possibility of one million people with an advanced infection, each costing the insurance industry \$150,000, simple calculations yield at least \$150 billion in potential treatment cost. This is over and above the costs that are borne today by the insurance industry for this illness.

Then the really big costs become apparent. Eventually, it will become common knowledge that infections like Lyme disease may be resistant to long-term antibiotic treatment, and yet the patient continues to benefit from such treatment. Lyme literate doctors have been publishing papers to this effect for many years. It will likely be possible to demonstrate that insurance company denials of payment for such treatment constituted legally actionable misdeeds. In other words,

people whose lives were compromised, ruined, or lost because their insurance company wouldn't authorize proper treatment will now have the basis for massive lawsuits.

To the extent that it can be shown that the decisions were made to save the insurance companies money while knowing full well that the patient would benefit from the denied treatment, these lawsuits have the potential to become comparable to the recent tobacco industry lawsuits. These settlements are in the hundreds of billions of dollars.

Combined, the treatment and litigation costs could conceivably bankrupt and destroy an already dysfunctional United States health-care insurance industry. This is not a big stretch, nor are the numbers science fiction.

The costs accruing to the proper diagnosis and treatment of the illness provide insurance companies with overwhelming reasons to deny the existence of chronic intractable Lyme disease.

#### **Motivation for the CDC**

If we allow ourselves a moment of speculation, what would the US government position on this be if our calculations were accepted? If our struggling healthcare system is faced with imminent bankruptcy, who will pump in the extra trillion dollars to keep it going? Who takes the fall for the mess? Who is held responsible for having allowed this cover-up to continue for so long? Who takes on the challenge of completely restructuring health care in the US?

I don't want to become or sound like a conspiracy theorist. But it does appear that the CDC may have good reason for being very cautious in publicly speculating about the extent of the illness and the possibility that realistic and appropriate treatment is lengthy and expensive.

**Motivation for doctors and researchers** who continue to state that Lyme disease is over-diagnosed and over-treated. There are at least two

components to this.

1) Good intentions gone bad: Some may have initially come forth with the "over-diagnosed and over-treated" viewpoint because they assumed that the American public was merely indulging in hysterics as it so often does. As with many industries, the medical establishment tends to be skeptical of news that challenges its cherished beliefs. Bolstered by each other's published papers on the subject, these doctors wound up directly impacting the diagnostic and treatment protocols applied to tens of thousands of patients. Many of these patients have become incapacitated - their quality of lives compromised, their families destroyed, their financial futures wiped out. A number of patients have died. At least one source lists more than 15 patients in the past year alone in the US that have Lyme disease listed as the official cause of death on their death certificates.

The doctors of the "over-diagnosed and over-treated school" now enjoy prominence in their fields and incomes in the top percentile of US earnings. If nothing else, they would be professionally disgraced if it were publicly demonstrated that their perspective was incorrect and unsupportable for the past several years, and that they routinely ignored the published findings of Lyme literate doctors who disagreed with them.

If the disabled and the families of the dead were to now have solid unassailable legal ground on which to sue them, these doctors would also be financially ruined.

These doctors have essentially gone down a path from which there is no safe return.

2) Professional network: We must speculate about why certain university research groups and at least one nonprofit "foundation" continue to push the "over-diagnosed and over-treated" position. They likely jumped on the bandwagon originally because their prominent associates took the

lead. The risk of now being proven to be lax, unprofessional and inexcusably wrong would certainly motivate many to continue to insist that the world is, indeed, flat while they search for a graceful way to back out of that perspective without being held culpable.

3) Direct interest in profits: As an example, consider that one of the more prominent doctors who claim that Lyme disease is "over-diagnosed and over-treated" owns a significant interest in one of the Lyme disease vaccines. If, in the course of the class action suit against Smith-Kline Beecham, it can be shown that people like this doctor were fully aware of the risks but still publicly recommended that all people, and now all school-children, take the vaccine, this doctor (and others) would be publicly disgraced, massively sued, and probably ruined altogether. So the alternatives for him to consider would seem to be: massive income if everybody goes along with the vaccine, and potential ruin if the whole thing is exposed as disingenuous. This is compelling enough to make an otherwise reasonable person look for reasons to believe his own position.

Another connection is the patents on the outer surface protein DNA used in the test kits. Such patents directly translate to royalties. It is conceivable that 30 million Lyme disease test kits might be processed in the US in one year - especially as word of the "second fastest growing epidemic in the nation" gets out. Even if this only means a \$5 royalty per test kit to the patent holders, \$150 million in royalties would be a pretty good motivation for many people to want to believe in their own business interests.

**Motivation to discredit non-two-step tests** such as Schutzer and Coyle's antibody complexes, Mattman's L-form imaging and the IGenEX LUAT: All of the new tests are purported to be more sensitive and specific than the two-step antibody tests. Official

acceptance of any of them pretty much destroys a multi-hundred-million dollar business for a few people. Additionally, if it could ever be shown that the attempt to suppress the new tests had an illegal component to it (e.g., conspiracy, libel, etc.), it is likely that massive lawsuits would follow.

**Turning the tide:** The motivations that we have speculated about are compelling. They are, in fact, far more compelling than the reasons for which many crimes against humanity have been committed in the past. Lyme disease issues are really political and business issues, and they will only be resolved when we acknowledge what this means. We are in the midst of a long uphill battle that will only be won as the public, our politicians and our doctors learn and acknowledge the truth about Lyme disease. To the

extent that we are capable, we all need to become activists. We need to share accurate information with others when we are able. We must write to our representatives in Congress and the Senate. We must continue to try to interest the news media in the situation. It is a difficult process, especially as so many of us already find “normal” activities to be a challenge, but it is crucial.

I am looking forward to the day when I can discuss Lyme disease with friends and business acquaintances and be taken seriously. Even more, I am looking forward to one day being able to talk about Lyme disease as something that *used* to be a national problem, but was finally resolved.

*Mr. Strong is a Lyme patient and president of The Strong Group, Inc.*

scientific methods, while quoting the same scientific data in support of their (unscientific) contentions. There is a tendency to cast blame, which goes as far as the originator of and prominent researcher in the field of Lyme disease.

My concern in this regard is twofold. First, I fear that by placing too much credence in desperation, we are permitting a revival of pseudo-science which is reminiscent of the romanticism of the 19th century. The AMA and other professional organizations, working with government, spent decades setting the record straight to protect the unsuspecting public from scam artists and “snake oil” salesmen. Now the stage is set for this work to be undone, this time with government financial support of health care.

Second, I fear that government, by acquiescing to anecdotal or frivolous claims and other demands by such special interest groups, will alienate the rest of society, which until now has retained confidence in it.

I believe that individuals with these special interests should receive the same counseling from government that I give my patients. First, that it is unreasonable to expect that there will be widespread support for unproven or anecdotal treatment regimens. This is not to say that there is denial of freedom to pursue them, but simply put, the price of “snake oil,” should not be an entitlement (or “covered expense”), until it is of proven benefit.

Second, let’s all work on raising the next generation of Americans to have reasonable expectations from their health care system, and for that matter, their government. Let’s work on realities: with chronic diseases, compassion and understanding will go further than promoting the search for the perpetual “fountain of youth.” It is useless to blame anyone for one’s chronic illness, least of all the teams which will be responsible for future solutions.

*Dr. Oster practices medicine in Ventura, California..*

## Physician fears revival of pseudo-science

*Background: U.S. Senator Arlen Specter (R. PA) has been supportive of the efforts of the Gettysburg Lyme Support Group and has asked for increased funding for the NIH. He has also expressed support for the “dedicated doctors” who continue to provide “aggressive treatment in the face of sometimes considerable obstacles.” Patients have been writing to Sen. Specter, who is Chairman of the Senate Appropriations Subcommittee on Labor, Health, and Human Services and Education, and his colleague, Sen. Rick Santorum, to complain about the intense scrutiny these doctors are facing from State Medical Boards. In the following letter, Dr. Oster expresses another point of view.*

**by Henry A. Oster, MD, FACP**

Dear Senator:

I am writing because of your particular interest in difficult aspects of health care delivery, particularly with reference to Lyme disease. I am a Lyme disease treating physician.

I fear you and I will, unfortunately, continue to receive tales of woe concerning what is perceived as a failure on the part of physicians and other professionals to adequately deal with this disease. These types of complaints are engendered as well by

chronic fatigue, HIV, and a host of other ailments, not yet completely understood by the scientific community. Much criticism, largely undeserved, has been levelled at the world’s best, including the CDC, for perceived inadequacies in dealing with the HIV epidemic, by groups who fail to provide any meaningful alternative recommendations.

Those most vocal often demonstrate a lack of regard for results of

# Complex disease demands complex treatment protocol

by Harold Smith, MD

As a physician who continues to recover from severe disseminated tick borne diseases, I can personally attest to the effectiveness of Dr. Burrascano's treatment protocols. These protocols match what is now known about three critical areas:

1. the microbiology of *Borrelia burgdorferi*.
2. the overwhelming evidence of persistence of infection in many patients
3. the direct evidence of the failure of short term monotherapy to eradicate this persistent infection.

First, *Borrelia burgdorferi* is a spirochete belonging to the family of spirochetes including syphilis and leptospirosis. All of these microbes are known for long term infections with difficulty in eradicating persistence and resurfacing of the infections even years later.

In addition, *Borrelia* is microaerophilic and is constantly modulating its outer surface proteins. Thus it hides deep in low oxygen tissue niches such as cartilage and ligaments distant from macrophage attack and continuously evades immune defense by changing its outer surface proteins (of which there are at least 150).

In addition, *Borrelia* hides inside our own cells at the same time evading killer cells that attack infected cells. Intracellular existence confers tremendous longevity to microbes.

Two additional forms of *Borrelia* in a complex life cycle also exist. One is a cyst form. Preac Mursic and Brorson have both published extensive evidence that *Borrelia*, especially when attacked by the very monotherapy some experts claim to be effective, can survive the antibiotics by shedding outer walls, curling upon itself and evading immune attack by

simple membrane enclosure.

Inside the membrane, electron microscopy reveals not a random degenerative granular form, but an active well developed system for DNA replication and association with flagellar protein and then timely release as motile spirochetes when conditions are right.

Cyst forms are neither new concepts nor confined to *Borrelia*. All the spirochetes share this adaptation. As early as 1911, Dr. MacDonald described their presence in spirochete infections of fowl. In 1932, Dr. Ingraham published an extensive summary of the worldwide knowledge and differing opinions about cyst forms.

A disturbing property revealed by Dr. Dorward of the NIH is for *Borrelia* to attach to our own cell outer membranes, tear away part of the membrane and cloak itself in our own clothes. Such wall deficient forms are a very reasonable hypothesis explaining why so many Lyme disease patients have low grade autoimmunity titers in many tissue studies.

There are innumerable studies documenting the persistence of infection and the failure of short term therapy. Three that are emblematic are Dr. Straubinger's work at Cornell with dogs infected by *Borrelia*-carrying ticks, Dr. Oksi's work with direct testing of patients in Finland, and Dr. Donta's work with a series of 270 patients given long term treatment.

In Dr. Straubinger's work, all the dogs received a 30-day plan for appropriate treatment. Two years later all the dogs were still infected, determined by direct testing.

Dr. Oksi utilized PCR DNA testing of patients after the 30-day treatment plan and found that many had relapsed and at the same time had

converted back to positive direct evidence of *Borrelia* in the blood stream. When these patients were treated extensively again, they improved and the absence of *Borrelia* DNA now corresponded with their improved clinical state.

Dr. Donta's study demonstrated that from the patient's perspective using diary recording, some patients started improving at 3 months, others 6 months, and many required treatment out to 18 months to stay in remission.

As noted, these studies are just a few examples of the world wide literature.

Dr. Straubinger has already done the work that couldn't be done today in humans, that is to infect and then autopsy after treatment and on-treatment to study the effects of treatment.

The rhesus monkey is a faithful model of human tick borne diseases; It would require only 12 months and much less money than the NIH study to give the direct evidence needed to shed light on the debate of short versus long term treatment.

Chronic tick borne disease victims are often not free of germs by direct testing evidence until well past 3 months. Such need for long term treatment is well known and accepted in other chronic infections such as tuberculosis and syphilis. Both are followed diligently to confirm remission, to prevent serious sequelae and control spread of infection.

Persistent infection certainly is a very demonstrable model for many patients who relapse after treatment.

The history of medicine regarding infectious diseases is a history marred by tremendous errors in thinking and an amazing ability to ignore evidence in front of a physician's own nose. Childbirth fever, syphilis, gonorrhea, papillomavirus, malaria and helicobacter induced ulcers are all examples of the ineptitude of medical practice to recognize the obvious

over many years. Even with acute onsets of infections, medicine was still unable to recognize microbial origins. Now add the situation of chronic infections, often presenting distant from the original time of host entry, and the setting is perfect for continuing the tragedies of failing to recognize the major role of infectious agents in human diseases.

The short-treatment advocates do not appear to appreciate the significance of being vector borne by a tick. This allows the carried microbes to adapt to a multitude of naturally vaccinated hosts from mouse, to deer, to horse, to cat and man. These microbes must survive tremendous temperature changes, the attack of a multitude of specific antibodies and activated macrophages with each

feeding and yet at the same time have the ability to remain dormant even for a year until the next feeding induces changes enabling the spirochete to infect another host. Much can be gained by simply looking at how *Borrelia* helps a tick and how the tick helps *Borrelia* (and the other coinfections) while at the same time realizing that this is an ecosystem designed for persistence.

Finally, we need to remember George Orwell's dictum: "To see what is in front of one's nose needs a constant struggle." Hopefully, we can move beyond the oversimplified 30-days-and-you're-cured treatment protocol.

*Dr. Smith lives in Danville, Pennsylvania.*

*Dr. Stanley is a director of the Lyme Alliance and founder of a patient support group in Portland, Oregon..*

## Understanding cyst or L-forms of *Borrelia burgdorferi*

*Reprinted from Biography of a Germ by Arno Karlen Hardcover - 176 pages 1 Ed edition (May 30, 2000) Schocken Books; ISBN: 0375401997*

*Borrelia burgdorferi* (Bb) can change more than its length and the number of tightness of its coils. Like many spirochetes, it can switch its shape from a spiral to a filament, cyst, granule, hooked rod or elbow. These variants are called L-Forms, a reference not to their shape, but to the Lister Institute in London, where they were first studied. They are also called cell-wall deficient bacteria; they take these nonspiral shapes when they have lost much of their cell wall. In harsh environments, many microbes do what large creatures do in famine or foul weather: they hunker down, reduce their activity, and try to get by on stored energy. This can be seen in lab cultures of Bb, when the germ first thrives but then falls victim to its own success. Over crowding sets in, nutrients dwindle, and toxic wastes accumulate. Many of the microbes die, but others survive at smaller sizes, expending little of their energy on maintaining a wall. In such circumstances, Bb may turn into a minute granule; put in fresh growth medium, it turns back into a cork-screw.

Many L-forms (cysts) keep their normal abilities. Even when not overcrowded, Bb in a lab culture

## The Truth will not win by itself

by Rita Stanley, PhD

I have heard ad nauseam that "truth will win out"; like some magical force of its own, truth, if just given enough exposure through retelling tales of woe, "awareness" and "education" and pounds of research, somehow the powers that be will get the idea and all will be fine in the end.

Not even close. This is politics. The powers that be have everything to lose (power, prestige, grants, consulting money, etc.) if the truth is allowed out any further; and those who actively and selflessly promulgate it like Dr. Burrascano and Dr. Horowitz and my doctor (who lost his battle for truth 7 years ago) have got to go.

So, a favorite quote of mine:

"The most casual student of history knows that as a matter of fact, truth does NOT necessarily vanquish. What is more, truth can NEVER win unless it is promulgated. Truth does not carry within itself an antitoxin to falsehood. The cause of truth must be championed, and it must be champi-

oned dynamically." - William F. Buckley, Jr., "God and Man at Yale"

So, in the ongoing struggle to hang onto our health and physicians, if you can find the fight in you to stand up and let the pols know you KNOW what is going on and that this has to be stopped NOW, go and DO IT. Don't talk about it, don't tell each other "truth will win out," don't think that another article in the newspapers about how sick you are will really do anything to end the silencing of your physicians; that's been going on for years. It's not just how sick you are, but how sick the power structure is that has allowed you to be backed up against the wall so that soon who may be there to treat you?

Hey, I know. I lost my doctor 7 years ago. I know what that game is all about. And I know that it is going to take a continual showing of force to put the breaks on this. Lobby Day [in Albany, NY] is another step toward forcing the truth to be acknowledged.

sometimes becomes a filament or cyst, and in these shapes it can still reproduce. The small, granular form of Bb can also infect hosts and cause disease; this may help explain why Lyme disease sometimes resists antibiotics, many of which work by attacking microbes' cell walls. The deficient walls of L-forms may deprive these drugs of a target. If all this is true, the L-form is a truly remarkable survival tactic.

L-forms are a recondite aspect of microbiology, but they are strong evidence of Bb's versatility at

infecting hosts and surviving inside them. Bb's L-form should know that it is not a term that refers to its shape but its power of metamorphosis.

Sometimes it develops large cystlike bodies in which small spirochetes develop, which are then released. Or buds may form along Bb's length; each one eventually becomes a cyst from which new spirochetes emerge. Sometimes Bb sprouts branchlike filaments, each of which becomes an independent spirochete. Even Bb's odd little L-forms can reproduce.

task of counting them.

I remember the first time after 1991 when Dad died that I thought about the All-overish-ness Syndrome again. I had been sure that the new mattress that my husband and I had purchased was defective. It was so firm, I thought, that it made my hips ache. But when the aching spread to my hands and to my ankles, it became more difficult to blame the mattress.

Soon after that, as I hurried to get my purse to pay a delivery man, I suddenly collapsed on the steps leading upstairs. The doctor who I consulted then for weakness and joint pains tried to reassure me that my lab work generally was OK and I looked just fine for my age. I thought, "I have heard this somewhere before and I know this drill!" But I never knew another name for it until an additional 6 years had come and gone. That was when my new family doctor recognized the symptoms and applied a scientific label to my version of Dad's excellent clinical description, "the All-overish-ness". Of course, that syndrome was in him more than likely the same syndrome that later developed in me.

My doctor identified it as chronic Lyme, co-infective with other tick-borne diseases, verified many months into treatment with positive borrelia and babesia DNA testing.

Dr. John Drulle wrote in 1991: "Polymyalgia rheumatica (PMR) is a common disease of elderly people characterized by pain and stiffness in the muscles of the upper arms and legs, fevers, malaise and weight loss... In classic form, the cause of the condition is unknown... I have personally seen three cases of Lyme-induced PMR, ...".

Polymyalgia rheumatica sounds a lot like "chronic Lyme All-overish-ness" to me. However, I may rename it for myself. It could just as well be called chronic "Overall-ish-ness"—tyrant that it is.

*Dr. Sherr practices medicine in Holland, Pennsylvania.*

## Front Lines

# All-overish-ness

by Virginia Sherr, MD

Dad lay in bed or was propped up in a chair. He walked in great pain, feebly, and only with assistance. Everyone said that's what happens when you get to be 99 years old. But I could not understand it. For 90 of those years, he was vital, vigorous—a determined biologist and active gardener. I thought that surely something specific must account for his symptoms and his suddenly appearing to have given up.

Not depressed a day of his very zestful life, the change in him impelled me to search for an unrecognized melancholia. He wouldn't have any of it:

"It's the All-overish-ness, Virginia, the All-overish-ness."

A cadre of medical specialists thought his might be a case of polymyalgia rheumatica but the usual blood work was normal. With a sense of finality he insisted that I be satisfied with his version of a diagnosis whenever I asked him what was wrong. He always spoke as if I, a physician, certainly should understand as meaningful, this obvious, accurate label. At that time I could not; 10 years later I believe I do

understand because I have experienced the All-overish-ness, myself.

Checked out again by a battery of medical specialists as he approached the century mark, there were no logical answers to the question of Dad's diagnosis. He was pronounced a remarkably healthy male with normal blood pressure, no major cardiac problems and looking especially good for his age. He made it to the century mark and beyond by nearly a year. Those last 10 years were a nightmare for him, however, because of pains that relentlessly incapacitated him.

A man who was raised never to acknowledge any discomfort, he eventually screamed with pain at every attempt to move or to be moved. It also was heart rendering to his family and to his attendants.

Ticks are a part of the way of life for people who live on the rural Eastern Shore of Maryland. And he was a biologist; ticks are considered by biologists and birders there to be common occupational nuisances. He picked them off himself without a thought. One dog belonging to the family had a known total of 300 ticks on him when my sister undertook the

## Beginners' Pages

# X-rated: The Bazaar and the Cathedral

*This is a speech given in Los Angeles at the Democratic National Convention. Patient activists obtained a permit for a half-hour presentation on the outdoor stage.*

by **Martin Atkinson-Barr, PhD**

Firstly this is the right place to acknowledge Congressman Brad Sherman, Democratic Congressman for the 24th District, that covers much of the San Fernando Valley and Calabasas – wherein lies my home. Congressman Sherman, in a very short time, has won the hearts of his constituents and I hope, one day, that we will see him as part of the Democratic ticket.

Now to my subject – Lyme Disease. I make no apologies for the somewhat sensational title of my address which is X-rated: The Bazaar and the Cathedral.

First to the X-rated portion which I know you have been waiting for. This is Lyme Disease. Lyme Disease is passed to humans through the bite of an infected tick.

A tick lands on its victim. It may be a juvenile or an adult. As a juvenile, they are called nymphs and are smaller than the period on the page, almost invisible. It gnaws a pit into the skin and having made its feeding trough it cements its head to the edge. As the victim exudes fluids to repair the pit it feeds on those fluids for days, until gorged, and then drops. If the tick is infected with disease, of which there are several dangerous to the human, it is passed during the feeding process.

Lyme is the most common of these tick diseases. It is a corkscrew shaped bacterium. Some days or weeks after the bite a round rash appears at the site in perhaps two-thirds of cases. At this time the corkscrew bacterium is just finding its

way through the lower layers of skin. Some weeks later, as the bacterium penetrates deep into the body, the victim goes through an intense flu-like illness as his immune system struggles in vain to fight the invader. The victim never fully recovers and remains malaised, fatigued and curiously without motivation.

As the corkscrew bacterium encounters the victim's immune cells instead of succumbing to their attack it instead, like AIDS, attacks and takes over the immune cell.

But the corkscrew's progress is not yet at an end, it is only just beginning. Over months and years it drives its way into the heart, the lungs, the liver, the spine and the joints, in fact every organ and part of the body. In the joints, especially the knees, it causes pain and sometimes inflammation. In the heart it attacks the valves and gives rise to irregular heartbeats. In the lungs it produces brown phlegm and associated breathlessness. In the liver it makes the victim sweat, especially at night. In the spine it makes the back ache.

Yet the worst is yet to come as it attacks the brain. The Lyme infected brain creates violent rage, anxiety, hallucinations, vivid dreams, wild thoughts, memory loss and cognitive difficulties. The victim is limited in his ability to work, finds everyday chores a major undertaking, cannot relax and enjoy even a simple TV show, and restful sleep comes only with difficulty.

Lyme is indeed a horror worthy of an X-rating.

And it is not uncommon. The CDC reports 300,000 diagnosed cases. Thanks to the difficulty in diagnosis the number of infected persons is no doubt three times greater – a million people in the United States. One in every three hundred or so.

It takes your child, your A-student, and they come home from school with Cs. It turns that bright delight of your life into a mere shadow. It infects more people than the polio epidemics of the 1950s.

It is The Crippler of our generation. Instead of lines of pathetic iron lungs we have thousands, even tens of thousands, of children confined to bedrooms – some even unable to walk.

It robs them of their future, like the once 20 year old Boston Pops singer who traveled worldwide, infected now for 20 years who has trouble leaving her small apartment. Sometimes, like the 18 year old girl last month it simply kills.

And you get it very easily, like Dr Smith and his whole family who only sat on a seemingly innocuous grassy bank during a hike.

And what of treatment. Physicians experienced in late-stage Lyme prescribe large quantities of antibiotics for long periods, sometimes years. Yet not every Lyme patient has easy access to doctors who know about Lyme, many go from doctor to doctor seeking more and more antibiotics.

Some physicians and researchers have claimed that the infection can be cured in a few weeks with simple antibiotics and that any residual effects are the consequence of irreversible damage. This is wrong. There is ample evidence those long term effects are the result of ongoing infection and short courses of antibiotics do not eliminate the disease.

That is my X-rated part.

Now how do we go about finding a cure? What role does our political

process have in solving the problem of Lyme disease?

First let us clear up a great misunderstanding related to costs. In recent years it has become normal to speak of disease costs in terms of health care. One of the major issues before this Convention is referred to under the heading "health care." The costs associated with a disease are not the same as the costs of treating it.

We use the cost of health care as a gauge because it is relatively easy to measure. The true costs of disease are different, much greater and more difficult to quantify.

It is not that the health care industry costs are a subset of the total costs of disease. Modern health care is, in some sense disconnected from the goal of universal good health.

This contradiction between health care and disease cost was brought into stark contrast with the discovery of stomach ulcer causing bacteria by the Australian physician Dr Barry Marshall in the late 1980s. His results proved that stomach ulcers could be cured with a simple two week course of antibiotics rather than a lifetime of acid-blocking drugs. This unexpected discovery by something of a maverick doctor from Western Australia threw a sector of our health care system into turmoil and now, ten years later, still only about one half of physicians treat and cure stomach ulcers with antibiotics. In this instance the health care industry resisted the newly discovered cure.

Our common purpose as individuals, that is to be healthy, is frustrated by the economic drivers of our system. To put it coldly it is more economically viable to have more customers, that is people with health problems, receive more treatment over a longer period of time.

Medical research is not looking for cures, it is looking for either vaccines that can be given to the largest number of recipients or for

drugs that must be taken continually. There is no economic reward for a rapid cure be it for Lyme, AIDS, breast cancer or heart disease. We will not cure these diseases until we face these economic realities.

And so to the second part of my title: The Bazaar and the Cathedral.

People outside of medicine and medical research misunderstand the role of the medical doctor and the role of science. The practice of medicine has nothing to do with science, it is based upon clinical experience. The doctor who examines you and prescribes you tablets for what ails

---

### ***Most breakthroughs have not come from the established centers but from the mavericks....***

---

you are rarely, if ever, looking to solve some disease. So who is?

This great country pours billions of dollars into medical research through the National Institutes of Health and the Centers for Disease Control. This money is distributed as grants to Universities, institutes and individuals through a process we call peer review, that is the lengthy proposal in the form of a PHS-398 form is distributed to other scientists to determine whether the research should be funded with the people's money. Those reviewers approve the allocation of funds according to their beliefs, research money flows to support their own view of the issues.

Similarly the charities use peer review to judge who should be the beneficiary of their donated funds.

Lastly the medical journals use peer review to determine whose research should be published.

The status quo controls every aspect of the research process. As

we pour more money into medical research in this way we only serve to build more walls to ensure that the current situation will not be changed. And in the past fifty years our progress in curing diseases has been woeful. Most breakthroughs have not come from the established centers but from the mavericks like Dr Barry Marshall. Advances in medicine have been revolutionary rather than evolutionary since the time of Pasteur.

So finally to explain the Bazaar and the Cathedral. The quote is "on the whole I prefer the Bazaar to the Cathedral". It is a recognition that the babble of voices in the marketplace makes more sense than the priesthood. It is the essence of our democratic process, the reason we are here this week. It is the fundamental underpinnings of this country and the way in which it is governed

I say that medical research is a priesthood and is the poorer for it.

Let those who are sick and their families play a role in determining how government dollars should be spent, not through charities or organizations but by their individual voices

Thanks to the efforts of our current Vice-President and soon to be President those who are sick have a voice, they are connected electronically across this Country and around the World. We call it the Internet. Health issues have become the ebb and flow of this digital world. There is a great opportunity here to make the most of this.

Lyme is a terrible disease that threatens all of us and our families, it is growing rapidly. It affects whole communities. It is one of many diseases we should be making better progress on but progress is mired in the cathedral and the solution is not one for the laboratory bench, it is one for the political arena.

## Patient Story

# Mystery illness baffles doctors

by Gillian Reese

I am a biologist who has suffered from the British Medical Profession's total ignorance of Lyme disease for the past 2 1/2 years.

I have been familiar with ticks all my life from my home life in the farming world and my days as a zoology student. I also have friends who are retired vets. Never in all my 50 years have I heard any mention that ticks in this country carried a dangerous disease. They were something of a nuisance to be removed from the skin of our dogs, and nothing more.

That was until September 1997 when one of our dogs came home after a days rabbiting covered in thousands of the tiniest ticks I have ever seen. We washed her in insecticidal shampoo, to no avail. So eventually I resorted to scraping them off her skin with the finger nails of my left hand, to relieve her discomfort.

In those days I led a most extraordinary busy life, and to begin with I didn't notice this dull headache creeping upon me. I am normally a very healthy person, with no time to indulge in illnesses! But I soon was aware that this headache was keeping me awake at night and even an exhilarating gallop on my horse didn't relieve it. After a month I visited my GP who immediately diagnosed STRESS. I was a bit taken aback, because 8 months before we had moved house into a wonderful area, and everything was better than it ever had been. He told me to get some strong painkillers. With hind sight I realise that, at the same time, my left arm was getting weaker and the muscles wasting away. This was the hand that had removed the ticks.

A few days later the headache was really bothering me. I went to

work and hoped to bump into one of our pathologists to ask his opinion. Unfortunately I didn't see one that day. That evening I took some of the recommended paracetamol and codeine tablets. My husband was asleep in front of the telly, my son doing homework and my daughter in the bath. I was watching our tropical fish. Everything was as serene as possible!

---

***During my sleepless nights I was questioned about problems at home. This puzzled me as there were none that I was aware of!***

---

I got up and felt very strange inside as if I was fading away, and summoned help. By this time I was having a rigor - every muscle was trembling independently inside me. We called an ambulance, as we are miles away from medical help. My own doctor also arrived from the opposite direction and after a quick examination took my husband out of the room and left the ambulance men in the hall. I thought I was going to die alone. Eventually they came back in the room and told me that nothing was the matter. I asked to go to hospital, because I knew that there was something severely wrong, and I naively thought that another doctor would immediately know what it was.

I had one night under observation, then was sidelined into as Gastro ward, which wasn't very pleasant. As

the week went on I was getting worse and worse. I was unable to sleep, had a burning pain in the nape of my neck and though I hadn't a fever I was sweating profusely and having to urinate every half hour, (though I didn't have a UTI). During my sleepless nights I was questioned about problems at home. This puzzled me as there were none that I was aware of!

Nobody had a clue as to the cause of all these symptoms, and after 5 days I just wanted to get home to my children and animals if nothing serious could be found.

Back home pains became more intense so that I couldn't get out of bed. Muscles were twitching all over my body. My doctor said he hadn't a clue and pursued the domestic problem line and began to blame sweating on the menopause. I was given acupuncture to help with the pains, and forced against my will to have HRT! All to no avail. I was now wearing a collar to support my neck. I wasn't able to sleep, would shiver at night, my heart palpitated so hard that it almost bounced the bed, and my intercostal muscles got so tender that I could barely breath. I could hardly get out of bed now, but nobody would visit me at home. They still thought it was a mental problem.

I really thought that I was going to die and my departmental Pathologists would end up doing my PM, before I got a true diagnosis. I keep a diary and kept going back to the week I removed the ticks from the dog. Up till then I was well. I mentioned this to my doctor who immediately dismissed it. Oh! How I wish he had taken this clue more seriously. I kept on with this story and one day my parents sent me an article about a man who got a disease from ticks. To my husband's amazement he too worked at Hull University. Allan went to see Ken Spencer and found that my symptoms were identical to his. He had fallen very ill and a blood test had revealed that he had Lyme disease. It all made sense to me now. I JUST had

to tell my doctors!

You can imagine the disbelief when a patient returns armed with lots of information from the internet about a strange disease that she claims she now has. I was made to feel a fool, and a very sick one at that. I now knew that immediate treatment was necessary, but I had to wait weeks to see an Infectious Disease Specialist, who knew less about Lyme than I did now. I was meant to wait even longer for the return of my blood tests before I could start treatment. But eventually I bullied my GP into giving me some antibiotic, as my health was deteriorating still further.

The Specialist told me to record my temperature regularly. I found that it was always below 37C and when I had a very bad attack it would plummet to nearly 35C. I phoned my doctors and was told 'there I told you you didn't have an infection'. Now I know that Lyme depresses your temperature, but doctors don't seem to know this fact yet.

I was having constant neck pain and panic attacks so a Neurologist saw me in April 1998. He told me that the burning pain in the nape of my neck was a whiplash injury. I believed him and he stopped my antibiotics. Over the summer I became a little more mobile, but I developed more strange symptoms. A cough, a 'burnt' tongue, a feeling the insects were walking over my face, loud tinnitus, painful lumps on my fingers, a feeling that my legs were cold, days of nausea, bouts of tachycardia, a terrible feeling in my back between my shoulder blades, a phobia about some smells, vibrations and sudden noises upset me, I was dyslexic and very forgetful and many more subtle things. MRI and CT scans and lumbar puncture showed nothing.

By now I was learning much more about Lyme disease, both off the internet and also from copies of British Medical Journal (BMJ) and Lancet borrowed from the university library. I learned more about its strange symptoms which could be

rather like those of syphilis, as indeed the bacterium is, and that it could be very difficult to cure if not caught early and later cases needed to be hit long and hard with antibiotics.

In September 1998 I returned to my GP, this time as an 'expert' of Lyme., and demanded large doses of antibiotic. He tried to give me less, but he could see by now I was confident and knew more than him. I had to promise to tell my Neurologist when next I saw him. A few months later when I did see him I was beginning to dramatically improve. The lumps on my fingers were going, the cough stopped, and all the other symptoms lessening by the month. My Neurologist was impressed and told me to stay on the treatment till he saw me in another 6 months time.

I continue to see him 6-monthly and am still on high antibiotics and very gradually my symptoms are diminishing. Recently my mind has felt more 'clear' and my memory is still improving. This has been one hell of an illness, made much worse by the total lack of support and understanding by all the doctors I have seen. Had it not been for my own determination to solve my own medical mystery I don't think I would be here now.

Recently I have been well enough for my children to teach me how to use the internet myself. This has opened up a whole new world to me. By writing various pieces for such things as the electronic BMJ I have become known to many more sufferers of this horrendous disease. Now I realise that I am the fortunate one, and that all these (rapidly growing) others have met arrogant and ignorant doctors who totally refuse to listen to their patients who have the brains and determination to solve their own medical mysteries.

I am dealing with people who, after years of suffering this disease and had every test under the sun, finally find out what has ruined their life and the lives of their families. They are given a mere 3 weeks low

dose antibiotic therapy. They are no better at the end of the course, then the doctor tells them that he was right and they DIDN'T have Lyme after all! Then they hear of me, and when I hear their catalogue of weird symptoms they have endured all these years I understand their language, perhaps the first person to have done so for many years! To date I'm helping 3 who have had Lyme symptoms for 15 years and nearly 20 others who have had it for less time. Many have presented with an easily recognisable EM rash, only to be given some steroid cream. One was told that the rash would go away on its own. Yes it did, they ALL DO whether treated or not, but his Lyme symptoms unfortunately didn't!

Some have positive Lyme tests and are told 'it's a false positive'. Others have a fleeting positive and are then told that the Lyme must have gone as they are negative now, and very many like myself have never shown a positive. Lyme specialists in the States say that the blood test is only about 50% reliable and that each patient must be diagnosed by the symptoms first and the lab test is a bonus. Here there is 100% reliance on a flawed test.

Americans apologise to me and tell me we are 20 years behind them in all aspects of Lyme. They have been trying to help British Lyme sufferers for years now. Here the same old spiel has been used for years to describe the symptoms of Lyme and its treatment. It is never updated. More worryingly new doctors coming out of medical school now, know no more about it than ones near to retirement - usually nothing!

I think there are probably thousands of infected people who remain undiagnosed for the rest of their miserable lives, and the ones that reach me are only the tip of the iceberg.

*Mrs. Reese lives in East Yorkshire, England. She may be contacted by email at*  
<gilly848@netscapeonline.co.uk>

## Patient Support

# Fitness and exercise program help to restore health

by Jo Johnson

I want to announce that I've been able to stay off of all antibiotics since April and have been on a fitness program. I'm feeling about 80% of what I did prior to Lyme and am nearly down to pre-Lyme, top-shape weight, when I was an athlete (about 137). The 30 extra pounds are nearly gone - 4 more to go. I'm wearing my size 8 and 10 again (thank God I didn't give up and give them away). I was having to wear 14 and 16.

My beloved horse and companion of 18 years passed away in June - a few months after my beloved Sister passed away in February. I replaced Waffie with Imogene, another purebred Arabian mare, a little over a week ago - she was used in a children's handicapped riding program in Flagstaff and they were kind enough to offer her to me when they heard I'd lost Waffie.

Imogene is now carrying me safely and gently back to health. I'm having to use both sides of my body and brain to do this and in just a week, I've noticed that my balance and coordination are improving and I'm not stumbling so much. We're just doing walk and trot - nothing earth-shaking - but I ride nearly every day even if it's just the mile to the mailbox. I'm also accepting the death of my Sister in February more and more.

I am feeling very happy and content with life as it is - I've accepted Lyme, HGE and RMSF, and have accepted the fact that if I'm to recover any more than this, I'm going to have to work my tail off to do it. I am feeling stronger every day.

I finally got a BowFlex machine and I love it. I use that to restore my legs and left arm. It ain't easy... want

to tell ya'll that. I use it daily, too, even if it's only for 5 minutes. I got an Aerobic video which I do about 4 days a week in front of the boob tube. I am doing sit ups, leg lifts and lifting 10 pound weights with my arms (left one took it in the shorts and is still numb along with legs, neck, chest and face, but what the heck, I'm alive).

I am walking about 5 miles a day - sometimes I go twice a day on the route.

I went river rafting, canoeing and kayaking in Jackson, Wyoming, a few weeks ago and had a blast, also ate myself sick at Bubba's BarBQ. There can be life with Lyme if we push for

it... and I'm determined to do that. I had NO life for 6 years. Now, I want one back and am willing and ready to work very hard for it.

Pain? Yes. Tired? Certainly, but there are power naps. Brain still feel "fried"? Yes, but my friends help with that elusive word or remind me what was going on in conversation, and that's OK. I'm finished with being embarrassed -can't help the brain damage I'm stuck with.

I rode for 2 hours today - Imogene carried me all over my tiny New Mexico village this afternoon, through dump trucks, construction, noisy and horse-eater irrigation channels, cars, dogs, sheep, goats - you name it! And it was FUN! I did get a little disoriented at one point but I let Imogene go where she wanted and she got me back into familiar territory on the way back home. Now it's nap time.

I want everyone to know that I think this is part of the answer...



pushing through the pain, fatigue and really sweating it out. I still get sick feeling after really working myself but I just take a shower and go to bed then do it again the next day.

It's time for me to encourage everyone who may need it the best I can. I want to help others now--I had a horrible time of it and there are probably going to be more horrible times, but I'm convinced that if I can keep myself in good condition it may not hit me as hard the next time around.

After all, I was in great condition when LD, HGE and RMSF got me and I did survive all that to many doctors' surprise. I had it bad, folks, for 6 years -this can be done. I'm living proof.

Everyone please hang in there - I

encourage everyone to force themselves to do some heavy-duty sweating. I'm seriously thinking of offering my New Mexico home, horses, equipment and encouragement to anyone who may want to come here and spend two weeks with me to get started on their own road to physical fitness/ recovery... if anyone is interested in joining me, e-mail me. I have two horses and can push hard if necessary. I'm really doing the best I have in 6 years right now and I owe it to forcing myself working through the awful stuff. I have done it alone, too.

*Jo "Denim" Johnson lives in Corrales, New Mexico. Her email is DenimLD@aol.com.*

The brochures, which are free to the public, provide patients with helpful information on how managed care works, the pitfalls of managed care, questions to ask before choosing health insurance, and how to fight back when patients have a problem with their health plan.

Our outreach programs provide patients with the tools and information they need to speak out and make a difference in the health care debate. Our toll-free hotline, quarterly newsletter, legislative actions alerts, award-winning homepage on the internet ([www.patientadvocacy.org](http://www.patientadvocacy.org)), and easy to understand information about the legislative process and proposals moving through Congress are just a few of the services and resources available from the Center. By offering these types of resources and services, the Center helps to empower patients with the decisions affecting their health care and gives them the ability to effectively deliver their message to Congress.

There perhaps is no better example of this than the enactment of the Newborns' and Mothers' Health Protection Act, landmark maternity stay legislation passed during the 104th Congress. During that debate, the Center was responsible for activating more than 100,000 Americans nationwide to contact Congress and demand that the legislation be passed. And through these efforts, the Center was able to craft a bipartisan coalition of Members of Congress in support of the bill. In fact, the grassroots support generated by the Center was praised by the legislation's sponsors as a major reason it became law.

The accomplishments the Center for Patient Advocacy has achieved in our short history are, indeed, exciting. However, the Center's success has only been possible because of strong and solid support from thousands of patients across the country. As individuals, our efforts to fight for patient rights seem insignificant compared to the agendas of the

## Center advocates fight for patient health care rights

The Center for Patient Advocacy is at the forefront of the battle to ensure that patients have timely access to the highest quality health care in the world. Fueled by the strength of a diverse, nationwide, grassroots coalition that is constantly growing, the Center has established a strong grassroots presence on Capitol Hill to advocate for the rights of patients.

Prior to the Center's founding in 1995, no single organization truly brought the patient's perspective to the health care debate in Washington. However, the Center has filled that void. We have established a new type of consumer organization. One that not only brings the real-life concerns of patients to the attention of the nation's lawmakers, the media and the public, but also educates patients about the health care system and assists them with the problems they experience. But what makes the Center truly unique, is that we motivate patients to become "citizen lobbyists" for health care reform and

encourage them to play a more proactive role in the legislative process that can help to ensure patients have access to quality health care.

While the Center encourages patients to take part in the health care debate, we also provide assistance to patients who are experiencing problems in the nation's managed health care system. Patients can call our toll-free hotline (800-846-7444) to receive advice from patient advocates. In addition, the Center has published several educational brochures to help patients navigate through the maze of managed care.

### Thank you, Cathy!

LDRC Board member Barbara Barsocchini would like to acknowledge Cathy Doyle, who is donating a portion of her work time in her office without pay, to help Barbara enter Lyme data in the computer, among other things. Plus, she is educating her doctors.

managed care industry and other organizations who have enormous corporate resources. But, working together to form a single grassroots coalition of hundreds of thousands of voices, there is no politician, corporation or government agency — no matter how large or powerful — who can ignore us.

Every day the Center articulates patient concerns to Members of Congress, the Administration and the media. During the 105th Congress alone, the Center and our members have testified before Congress 10 times and we have participated in numerous “town hall” meetings, press events and field hearings held by Members of Congress and the President. The Center also is a regular source from which the media seeks information and comment. We have been featured in countless newspapers, magazines, and television programs, including: CNN, PBS, ABC, NBC and CBS; The Washington Post, The Miami Herald and the San Francisco Chronicle; Time Magazine, U.S. News & World Report and Good Housekeeping... and the list goes on.

The Center’s unique ability to activate the public and inspire them to participate in the legislative process has been and will continue to be the key to our success. And as health care needs and issues change over the coming years, the Center for Patient Advocacy will remain a strong constant — fighting on the side of patients to ensure that Americans have timely access to the highest quality health care in the world.

If you or your organization would like to join us in our continued fight for quality patient care, please contact the Center or visit our homepage on the internet, [www.patientadvocacy.org](http://www.patientadvocacy.org). As a grassroots coalition of patients and patient advocates working together, we can make a difference in the lives and health of millions of American patients.

*Reprinted from the Center for Patient Advocacy website at [www.patientadvocacy.org](http://www.patientadvocacy.org).*  
**Number 30**

# The Truth about Mild Silver Protein

by Rosemary Jacobs

Mild Silver Protein (MSP) was very popular in the early part of the last century. The best known brand was Argyrol. Some of you or your parents may remember it. Alfred Barnes of Philadelphia introduced it to commerce in 1902 and it was fraudulently advertised as being nontoxic and effective for decades. It was sold in the US until at least 1996. (Fung & Bowen)

I’ve been searching medical journals for about 30 years gathering information on silver drugs and argyria – gray skin caused by ingesting silver – and have never found anything by any reputable author reporting benefits. I did find articles from the early 1900s by Henry Crookes and his cronies promoting colloidal silver which he manufactured in England then. I also found articles in medical journals calling him and his business partners quacks (JAMA 1919). I also found many articles warning doctors and pharmacists about the fraudulent ads for MSP. Argyrol was repeatedly singled out as one of the worst culprits. Not only was it not an effective antibiotic, it was toxic. There are many documented cases of argyria caused by Argyrol. (Mack, Gaul & Staud, Hill & Phillipsbury)

How is it, you ask, that I’ve spent so much time reading old medical journals and researching silver drugs? It’s because I have argyria. I’ve had it for about 40 years. And where are my citations, you ask? On my webpage. If the subject interests you, be sure to look at my story, FAQs and links. You will find the full citations for the authors given above in my bibliographies.

I have read M. Paul Farber’s book, *THE MICRO SILVER BULLET*, which some people think tells the Truth about colloidal silver. It’s hilarious.

My favorite part is p. 328. Next to a photo of Einstein Farber has a caption stating that he prays that the Theory of Relativity will become easily understood by the average layperson reading his book. Honest. That’s what he says. On p. 102 in the chapter on “The Most Effective HolisticNatural Supportive Treatments” he includes “Colonic Irrigations.” Give me a break! Enemas and

---

***“Ingesting silver is dangerous and there is no evidence of benefits from drinking it.”***

---

**Rosemary Jacobs  
argyria patient**

---

silver drugs didn’t work for my grandparents or yours. That’s why they were discarded.

The medical and scientific community, the FDA and alternative medicine guru Andrew Weil all share my views on silver. Ingesting it in any form, amount or particle size is at best useless and at worst harmful. It causes argyria, gray skin. Ionic silver is as small as it comes. It has caused argyria. Silver does not get “lodged” in body parts. It forms very strong chemical bonds with many of the tissues in human bodies having an especially strong affinity for that around the sweat glands in the skin. It is a result of its binding there that the skin appears gray.

Go to your medical library and read the letter to JAMA from Fung, Bowen, & Weintraub, October 18, 1995 Vol. 274, No. 15 p. 1196-7. Every

hospital should have copies of JAMA. There shouldn't be a fee for reading it. Every hospital in the US has a medical library. The librarian will order the article for you if s/he does not have a copy of the journal. There may be a fee.

It says that there is no reason to ingest silver in any form. It is dangerous. You still get it in your diet. This is the closing paragraph:

"Moreover, indiscriminate use of silver can lead to irreversible toxicity and silver in drug products can add to silver exposure from environmental sources such as food and water. Silver is deposited in many organs including neurons. Argyria, the most commonly reported adverse event, results from accumulation of silver deposits in the skin below the epidermis. We conclude that the risk exceeds the unsubstantiated benefit for OTC [over the counter] silver-containing products. Consequently, there are no FDA approved CSP products available OTC."

I met Dr. Bowen and Dr. Michael Weintraub in person at their office at the FDA in Maryland and have spoken at length with Dr. Fung. Fung and I did interviews with CNN. He was no longer with the FDA at the time. Bowen did a phone interview with an AP reporter who wrote a story about me. I always understood them to think that all the evidence indicates that ingesting silver is dangerous and that there is no evidence of benefits from drinking it.

*Rosemary Jacobs developed argyria from her use of colloidal silver. She has a webpage on silver drugs at <http://homepages.together.net/~rjstan/rose3.html> and may be contacted by email at [rjstan@together.net](mailto:rjstan@together.net)*

Some doctors claim if a month of antibiotics doesn't cure you of Lyme then the initial diagnosis was wrong. This is as ridiculous as saying that if the chemotherapy did not cure you, then you didn't have cancer in the first place.

anonymous

## Colloidal silver products neither safe nor effective

Although some patient groups still promote colloidal silver, the Food and Drug Administration (FDA) issued a final rule effective September 16, 1999, establishing that all over-the-counter (OTC) drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective and are misbranded. FDA took this step because many OTC drug products containing colloidal silver ingredients or silver salts were being marketed for numerous serious disease conditions and FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients or silver salts for these disease conditions.

Colloidal silver is a suspension of silver particles in a colloidal base. In recent years, colloidal silver preparations of unknown formulation have been appearing in retail outlets,

labeled for numerous disease conditions, many of which are serious diseases. The dosage form of these colloidal silver products is usually oral, but product labeling also contains directions for topical and, occasionally, intravenous use. Adequate safety and effectiveness data have not been provided to establish general recognition of the safety and effectiveness of colloidal silver or silver salt ingredients for any OTC drug uses. Ingestion of colloidal silver can cause a condition known as argyria [see story on page 19].

For further information contact the Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0063.

---

## Lyme is really no big deal

by Kathleen Dickson

You can't have Lyme unless you have a blown out knee. Then if you have been given three weeks of antibiotics and still have this problem, you have no longer have Lyme but a symptom set that is not more severe than that which is suffered by the general population, suffering simply as a result of the aging process.

If you have neurological symptoms, they are subtle or mild and therefore of no consequence.

So, if you have Lyme disease, you really don't, no matter what happens. What's so hard to understand or accept about that? It's the anxiety about being sick that is the most detrimental to the patient.

Similarly, patients who have neurosyphilis, AIDS, tuberculosis, polio, smallpox, etc., no longer have these diseases once they have been treated for three weeks, as that is all it takes to cure the infection.

Yet the anxiety caused by the fear of these diseases is what consumes health care resources. So, if given a vaccine, people will have less anxiety.

And as we all know, people who suffered and died during the Black Plague, during the Middle Ages, or the Spanish flu, in the early part of the 20th century, before vaccines were available, died of fright.

## In Memoriam

**Beverly "Country Girl" Stanton**, age 53, died Feb 14, 2000. She was a member of the internet MGH Lyme Chat room. Friends teased her about "opening and closing down Lyme Chat" on a daily basis. She gave advice and helped many.

Pat Sprague, who authors Lyme Matters newsletter and Pat's Tips & Tricks (for internet help), built a memorial site in Bev's honor. It is open for those who want to stop by, to visit or read remarks left by others at <http://lymebev.homestead.com/bevlyme.html>.

Her friend Debbie Allen Harris writes: "Love, support and encouragement is what life is about when all else seems to have been taken away. It has kept me willing to persevere beyond all obstacles placed in front of me thus far. I know sometimes we want to give up; remembering how Beverly touched the lives of many challenges me to remain busy and available, positive and strong."

**David**, age 18, of Tinton Falls, NJ died May 15, 2000, at home following a long battle with Lyme disease. He was a student at Monmouth Regional High School, Tinton Falls, and a member of the varsity swim team. He was a member of the First Baptist Church of Red Bank.

Donations in David's name may be made to the Lyme Disease Association, Box 1438, Jackson, NJ 08257.

**John Stanzcyk** of Easton, CT, died in February, 2001. According to his friend Dolly Parton, John was the owner of a prize-winning garden and raspberry farm. He became gravely ill several years ago with Babesiosis, a tickborne disease which can be very serious in the elderly and the very young. He went to the hospital for about 10 days where they luckily made this diagnosis and John recovered to do several more gorgeous gardens. He had also been treated all summer for the Lyme

infection which he was continually battling because he was bitten so many times.

"Tragically," Dolly writes, "this year when he became ill with cancer and his heart had previously had several surgeries, he left us. I am very saddened. There won't be anymore beautiful, heavenly late sunset nights picking berries at Stanzcyk's Farm. No more sips of chilled raspberry brandy which was reserved for special guests. I don't know how I will enjoy the summer without this enchanting place to go and spend quiet serene time...picking berries."

**Bill Nicols**, died April 12, 2000. His friends Roger and Marilyn Grismore of Arroyo Grande, CA, write: "Bill Nichols was a good man, a true friend, and a fine scientist who had suffered from Lyme disease for 12 years before taking his own life.

"Bill was desperately ill from the complications of the disease, which was in his spinal column and his brain. For the past two years he had

to struggle to get out of bed, often became disoriented, and was unable to drive a car. He was also losing his eyesight and his ability to walk.

"Unable to continue with his research, Bill found that he no longer had the energy to concentrate and was terrified of losing his faculties. He suffered from terrible headaches, debilitating tremors, skin lesions, cough, and eyesight problems which kept recurring despite massive doses of antibiotics.

"But he struggled bravely and was kind and gentle to the end, always trying to help others in any way he could. It is with deep pain and sorrow that I write these words for a very special friend who will live in our hearts forever."

**Ron Ferris**, age 55, of Calgary, Alberta, Canada, died in November, 2000, after a brief illness. Ferris had been active in the patient support community and is memorialized on a website at <http://www.cadvision.com/lwdahl>.

## Tick-Borne Illness Memorial Page

<http://www.angelfire.com/punk/lymedisease/memorial.html>

These pages are dedicated to those who have died of Tick-Borne Illness: Lyme, Tularemia, Babesiosis, Ehrlichiosis, Relapsing Fever, Colorado Tick Fever, Tick-Borne Encephalitis and Rocky Mountain Spotted Fever.

If you have a loved one who has died of a tick-borne illness and you would like to see them on this page, you are more than welcome. Please email [AramSarah@cs.com](mailto:AramSarah@cs.com). Please provide as much information as possible and any page preferences. This site also links to Memorial Pages made by people's families or friends. Even, if reading a newspaper, you find an article or Obituary about someone who has died of a Tick-Borne Illness, please email the contact person so they may be included.

Most, but not all of the people on this site have a Tick-Borne Illness on their death certificate as Cause of Death.

There are, in the Lyme pages, suicides as well. Dr. Brian Fallon of Columbia University has stated his belief that Lyme disease patients are much more prone to depression and generalized anxiety than other patients with similar chronic diseases such as lupus, thus he believes there is a physiological basis to these disease traits. A disease can affect the will to live in the same way it affects joints, tendons, hearts and eyes. On this basis of reasoning are Lyme suicides included.

## Regional News

# Wilton Task Force raises funds for research and fellowship

by Cathy Morrissey

The Wilton Task Force (WTF) raised over \$210,000 (and still counting!) for Lyme disease research at its second fundraiser on March 3. A total of \$375,000 has been raised by this group in just under one year. The overwhelming majority of the proceeds benefit Lyme Disease Research Programs, both current use and endowment accounts, that WTF established at Columbia University as part of a focused initiative last year. Columbia is helping to coordinate research projects for researchers in and outside Columbia.

A highlight of "Dance the Lyme Away" was the announcement of the establishment of the Dr. Charles Ray Jones Endowed Student Fellowship, a \$75,000 Columbia project that will name a medical student every year in perpetuity to study Lyme disease with community doctors. There will be an emphasis on pediatric Lyme. The fellowship will begin this summer. Dr. Jones was honored by several of his young patients during a very special presentation during the event.

This year's benefit had the support of an extraordinary honorary committee, including local celebrities and federal and state politicians.

The entire US Congressional delegation from Connecticut endorsed the event. Many of them attended or publicly endorsed the fundraiser. The celebrities donated items for the auction or spoke to the media about their interest in Lyme disease research. Some of these can be viewed on our website. (see below)

CT Attorney General Richard Blumenthal spoke at the dance. He said, "Part of what we do in these events is to give abstract concepts a human face and educate people,

raising awareness about the tremendous toll this dreaded disease takes and how it impacts all of us eventually.... how it touches lives in a way that is searing and irreparable. ....I can't think of any work that I have done that has been more meaningful to me because of that human quality that involves doctors who have the courage and conviction to stand up to the HMOs.... The people in the medical community who have stood up on this issue really have demonstrated what is best about medicine."

Blumenthal also said "It's very meaningful for me because I've seen the bravery of parents and victims, most particularly children, who are not only victims, but also leaders. And this is an area where truly our children, in many instances, have shown us the way."

Erin Morrissey, now 16, was presented with a citation from his office. On recounting his initial meeting with Erin, then 14 and visibly quite ill, Mr. Blumenthal said, "I have no real words to tell you how it affected me, but as an inspiration, as someone who for me was the physical embodiment of why spiritually, politically and in every other way possible, we ought to commit ourselves to a cure for this disease. She was it.... She was probably as important as any single person in reforming the laws that relate to HMO coverage, insurance coverage of this disease.... Simply because she came with a kind of credibility and integrity that spoke thousands of words to anyone who heard her."

Lyme patient Dolly Curtis of Easton said that when Erin Morrissey spoke briefly about the 18 months of school she missed and the hospitals

she visited and the doctors who wouldn't treat her because they were scared by her mysterious disease, the audience was completely quiet.

US Congressman Jim Maloney also spoke and pledged his support at the national level.

Dr. Fallon told the audience, "Your efforts, either on the Dance floor or in the auctions, will have a nationwide impact on Lyme disease. The pilot funds - \$5,000 or 10,000 or 25,000 - raised here tonight will allow researchers from around the country to try out new ideas that more established institutions like the NIH might not yet fund.... These pilot funds are key to the financing of novel, pioneering projects that will lead to the next breakthroughs in our battle against Lyme Disease.

"This is an extraordinary evening - a celebration of life - a celebration fueled by an explosion of support from people all over Connecticut. This is an evening wrought from the hard work of many folk, some quite ill, who persisted despite having little energy, diminished cognitive skills, and bodies crippled by pain. This evening was forged by the fire of love - love of one's children and of one's neighbors - and by a determination that the suffering and debilitation caused by Lyme Disease must stop."

See our website for more information at <http://www.lymetaskforce.org>.

## Patients at rally offer scientific information to conference goers

Patients rallied in Philadelphia on November 1, 2000, at the American College of Rheumatologists, where Allen Steere, MD, was presenting a seminar on Lyme disease. The rally

was designated a "Teach Out" by its sponsors, a Tri-State coalition of Lyme disease patients, because one of the goals was to present science-based Lyme information to the rheumatologists at their conference. The other goal was to simply protest Steere's appearance in Philadelphia and to demonstrate with good numbers of protesters that we in the Delaware Valley Area "say no" to Steere, his theories, research, and his adherents.

The rally took the form of an old fashioned street protest at the Philadelphia Convention Center, site of the College of Rheumatologists' conclave. Many of the the rheumatologists were supportive, and listened to our dialogue, as they visited with protesters outside the entrance to the Convention Center. An array of posters and educational information lined almost half a city block, with the theme, "Science Shows A Different Point of View On Lyme Disease." Thousands of pieces of literature were distributed. MSNBC issued a most positive news story the following day.

According to an MSNBC article the following day, Steere has become more reclusive as the patient groups have become increasingly vocal. Outside the meeting, patients talked about why they were targeting Steere in particular.

"He has been the most public," said Susan MacNamee, 43, of Perkasio, PA. "He's the most well known. He even discovered it. So doctors believe what he says."

Others suggested that Steere's vocal opposition to long-term antibiotics have led insurance companies to refuse payment for these treatments.

"When he stands up and says we all are cured after four weeks of antibiotics, we can't get treatment," says Gail Wallin, 50, of Holland, PA.

MSNBC continued that some physicians, like Dr. H. Paul Lasky, who stopped to spar with the

protestors, attempted to convince them that Steere's analysis of the disease is right. Lasky, a physician in private practice in Cornwall, N.Y., believes that the patients who believe they have chronic Lyme disease have simply been duped by the companies selling intravenous therapy.

But a Swiss doctor who stopped to talk was perplexed by all the furor.

There is no controversy over Lyme disease in Europe, said Dr. Fritz Hasler, a physician in private practice in Chur, Switzerland. Doctors simply treat patients with antibiotics until they get better, Hasler said.

*Mark Delmerico, a member of the Delaware Lyme Disease Support Group, contributed to this report..*

## Patients lobby NY legislators in support of key doctors

**Albany, NY, March 27** - A patient activist group, Voices of Lyme, and the Foundation for the Advancement of Innovative Medicine (FAIM) organized a lobby day at the state capitol to protest what they say is a misuse of the state's professional discipline system is being used to suppress scientific debate and punish dissenting physicians. Two hundred patient protesters from New York and many other states formed a silent billboard decrying the chilling effect of New York's misguided actions

against doctors on whom their own doctors rely for guidance. They later kept appointments with key legislators.

The New York State Department of Health, Office of Professional Medical Conduct (OPMC) has brought charges of misconduct against Joseph Burrascano, MD and Richard Horowitz MD. Burrascano is the author of a protocol which sets forth guidelines for the treatment of Lyme disease in situations where the

NY Assemblywoman Nettie Meyerson, left, shown here with LDA president Pat Smith (right) at Albany Lobby Day, is on the NY State Legislature Health Committee. Meyerson has been a key advocate for patient interests with her colleagues.



illness has not responded to short-term antibiotic therapy. A synopsis of this protocol was published in 1997 in the mainstream peer-reviewed medical publication *Conn's Current Therapies*. Dr. Horowitz is a leading advocate of the theory that tick-borne Babesiosis and Ehrlichiosis pose as serious a threat to New Yorkers as Lyme disease.

Also at issue is the accuracy of diagnosing these diseases because no currently available single test is totally accurate in affirming infection in all cases, nor confirming cure. Lyme disease is a growing epidemic fostered by the recent warm winters, and the geographic spread of the deer-tick population. With no single scientifically validated method for diagnosis or treatment, FAIM and

Lyme patients nationwide question why any state health department would enforce select practice methods to the exclusion of other viable options. They claim that scientific debate should be settled in the scientific community but not by OPMC.

A press conference was led by Pat Smith, President of the Lyme Disease Association, a national research and support organization; Dr. Howard Hindin, a board member of FAIM; and Dr. Steve Phillips, a Connecticut physician and developer of a test for Lyme disease.

A legal fund has been formed to support the two doctors charged. Donations are urgently needed. See details on page 5.

lobbying her legislators right along everyone else. The New York Times Magazine reporter David Grann interviewed quite a few people at length, as did Nightline reporters.

People who had come from out-of-state showed solidarity with their New York Lyme brethren in a Silent Vigil. The line stretched from one wall of the huge room to the other. Each person wore a green sash with the abbreviation for their state in white upon it. Fifteen states were represented. Vigil organizer Mark Delmerico represented Delaware. Representing South Carolina was Sue Fox, a woman with Lyme whose mother has Lyme as well. There were three people from California, a couple from Virginia, and others from Connecticut, Rhode Island, Maine, Florida, Washington and many Mid-Atlantic and New England States. Lynn Olivier, editor of the newsletter TickTalk, came all the way from Minnesota on a bus. The Washington State representative was not feeling well, but she was there. Many people were not feeling well, but they were there.

There was an intensity in the vast room that hummed in the crowd, a combination of anticipation and desperation. When the patients from out-of-state gathered at the front, there was a cacophony of clapping and cheers. The whole row of people from out-of-state held up signs which spelled out in big black letters,

**THE NATION IS WATCHING THE  
NY OPMC BIAS ON LYME**

Lyme Disease Association president Pat Smith gave the keynote speech. Nightline filmed her next to a US Army poster depicting a male soldier in camouflage holding a gun. Next to the soldier stood a woman, clearly his wife, a little girl and a friendly looking dog. The caption in big letters read: **LYME IS A FAMILY DISEASE.**

Smith detailed the extreme measures the US Army is undertaking in its own battle against tick-borne

---

## Report from Albany - a patient's first-hand account

by Sarah Weiss

There were weeks of preparation, mostly done by desperate patients of the doctors under fire. New York State Lyme patient activists Ellen Lubarsky, Regina Wrenn, Sue Schriber and Joan Green spent weeks of intense effort organizing, coordinating everything with Monica Miller, lobbyist of Foundation for the Advancement of Innovative Medicine (FAIM), the group helping the doctors under investigation.

The goal of Lobby Day was for New York State constituents to ask New York State legislators to investigate the OPMC Lyme disease treatment bias- and to halt the investigation against Dr. Burrascano until that is thoroughly done.

In the last year, Dr. Joseph Burrascano, who holds a special place in Lyme disease diagnosis and treatment as his guidelines are followed by many Lyme doctors throughout the world, has been

facing charges of physician malpractice by the New York State Health Department Office of Professional Medical Conduct (OPMC). Dr. Richard Horowitz, best known for his dedicated work with the Lyme coinfection Babesiosis, has been notified that he is also facing investigation.

"Lyme patients believe that failing to stop the unjust prosecution of these physicians will endanger the rights of physicians throughout the country to treat persistent Lyme disease infection," stated organizer Wrenn. "This [OPMC censure] would end patients' rights to such treatment."

There was a flurry of excitement as people began to gather. The crowd swelled over two hundred strong as the day progressed. Buses arrived with loads of patient passengers, poignantly including Mrs. Richard Horowitz herself, who spent the day

disease. She spoke of the Global Positioning Satellite scans of the entire earth, the mapping of patterns which indicate environments for tick viability and the headgear worn by commanders in which this data could be displayed into the field at a moment's notice, so that the troops could be moved up one hill or down the next, to avoid ticks. She detailed the Army Research and Development efforts which had created a small box in which a field officer could test a tick immediately after a soldier was potentially infected. The US Army clearly views Lyme and other tick-borne disease as a very serious health threat. Smith continued with an overview of Lyme disease in the United States and particularly in New York State, the leader in numbers of cases. She stressed the prevalence of disease and the paucity of physicians willing to diagnose and treat in such an atmosphere of political threat. She was emphatic in stating that persistent infection is no longer a question, but a reality based on a multitude of medical abstracts.

Dr. Phillips was the sole LLMD (Lyme-literate MD) who showed up to speak to the crowd. The word came that there were meant to be more LLMDs to speak than simply he, but that at the last moment others had withdrawn. When this was said there was a brief hush over the crowd, a whisper of fear, a public awareness of the reason we all were there. Many people thanked Phillips especially after he had spoken, as everyone present knew it was an act of courage.

A FAIM representative spoke about the persecution of doctors for treating chronic Lyme disease with long-term antibiotics, and about the inequity evident to FAIM in OPMC investigations, when doctors who treat in nontraditional ways are more likely to be investigated and subsequently censured.

The actual lobbying of legislators generally went well. I was privileged to sit in on one session and was surprised to find a legislative aide

fully cognizant of Lyme disease and the infamous controversy. At times when people spoke, tears welled in their eyes. Telling of the hardship this journey was for so many to make, one young constituent who was to speak in this session instead had to leave, as the long walks down corridors in the legislative building had exhausted her. She was sick. She was sick, but she had come, to this sterile, massive civic building, to speak on behalf of herself and her doctor. Instead, she gave papers she had brought to a fellow patient and left to go home and recover. All who were there knew that they stood for countless others who were much too sick to ever consider attendance.

While those in-state lobbied their legislators, those out-of-state people who had come for the Silent Vigil paraded around the legislative building en masse.

"Considering the distance traveled and the time commitment for the day — plus the time involved 'on stage' at the press conference — the people coming to Albany for the Silent Vigil showed a very significant

focus and determination for their role in Lobby Day," concluded Delmerico.

As the hours passed, the Terrace Room remained full of patients, some sitting quietly, some obviously fatigued, some ebulliently conversing with one another. As time went on, as more lobbying sessions carried on and passed, the crowd began to disperse. There were hugs and such warmth in good-byes. One after another, and another, until there were only a few organizers left, worn-out, exhausted- and satisfied that they and everyone who attended had done their very best.

"It was an incredibly emotional day for me," stated New Jersey patient Sue Massie. "Not only because I woke at 4:30 am, drove 4 1/2 hours there and met some of the most loving, wonderful internet buddies, but there were such incredible electrical vibes in the air all day! We did accomplish alot and I thank everyone who made it possible."

*Sarah Weiss is a Lyme patient activist from Santa Cruz, California.*

---

## Public invited to California LD Advisory Committee Meeting

The August 7, 2001 meeting of California's Lyme Disease Advisory Committee (LDAC) will be open to Lyme patients and other interested Californians, the state's Department of Health Services (DHS) told the Lyme Times this week.

The meeting is tentatively scheduled for 10 am to 2 pm on Friday, August 7 in the Lillian Gish Conference Room in the Office of AIDS in the Continental Plaza of the DHS offices at 601 North Seventh Street in Sacramento. As soon as the time is definitely set, DHS will mail announcements to patient support group leaders and other interested parties.

Slated for discussion at this

meeting, the Committee's fourth, are recommendations for the new DHS Lyme brochure and for a questionnaire to assess current physician knowledge about the disease. A document generated by the state's LD support group leaders, entitled "High Hopes from CA Lyme Disease Support Groups," will also be discussed.

People interested in attending can obtain more up-to-date information in late July from support group leaders in their area or by calling Anne Kjemtrup, LDAC Coordinator, at 916-324-3738. Minutes of LDAC's earlier meetings are also available through support group leaders or Dr. Kjemtrup.

# Patients hold press conference protesting OPMC policy

**New York City, November 9** - A group of doctors who treat Lyme and about 400 patients with the disease rallied in New York City on November 9 to protest what they term systematic persecution of doctors who treat Lyme disease with long-term antibiotics. They accuse state medical boards of violating doctors' right to treat patients according to their own judgment, based on clinical experience and scientific information. The demonstrators pointed to the most recent case of two New York physicians, Dr. Joseph Burrascano and Dr. Richard Horowitz, who are currently being tried by the Office of Professional Medical Conduct (OPMC), the medical licensing arm of the New York State Department of Health. Both doctors are at risk of losing their licenses to practice medicine, essentially because of their willingness to offer aggressive treatment to chronic Lyme disease patients, the demonstrators claim. The OPMC has stated in writing that they believe that Lyme disease is almost always cured by 3 weeks of antibiotics.

According to a report in the New York Times (Nov. 10) Michael Schoppmann, a lawyer from Lake Success, NY, said he had represented more than 40 doctors in board hearings in New York, New Jersey and Pennsylvania. He cautioned that because of the hearings' rules of confidentiality, the public would never know how many doctors are currently in this same predicament or had faced it in the past.

"If a doctor begins to treat patients with Lyme disease in any significant percentage of their total practice," Schoppmann said, "they are guaranteed to face investigations - either private or governmental or both - by managed care, insurance companies and state licensing agencies. The treatment of Lyme disease and its financial implications

are the insurance industry's worst nightmare. No one dies from Lyme disease, no one is cured, and many patients require years of expensive treatment."

About 50 physicians in other states, including New Jersey, Connecticut, Michigan, Oregon, Rhode Island and Texas have been investigated, disciplined, or have had their licenses removed, the demonstrators said. If the OPMC is permitted to go ahead with these trials and take or restrict these doctors' licenses, they fear it will have a chilling effect on the medical climate throughout the country, with most Lyme patients losing their access to effective care.

The charges against Burrascano are said to have been based on the medical charts of nine patients, five of whom were at the rally and were irate that their charts had been used without their knowledge or consent. All told the New York Times reporter that Burrascano had brought them back to health or had improved their conditions after long periods of

suffering.

Among the speeches and statements, Lyme Disease Association president Pat Smith of New Jersey captured the crowd with her promise that Lyme patients "would not go away."

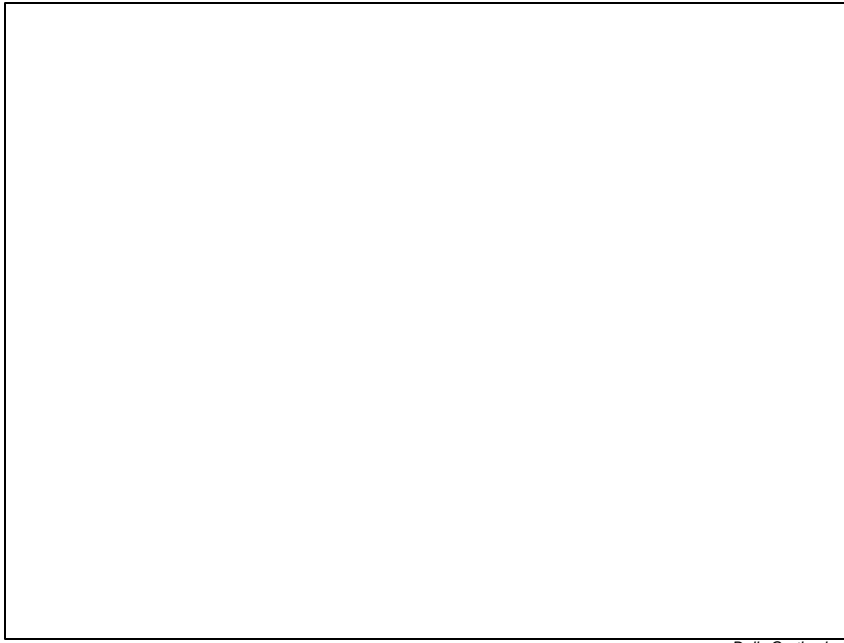
"The roars from the crowd were so loud, I believe all of New York could hear. And she surely spoke for all of us," said NJ patient Jean Der Bedrosian. "Then the Maryland/Virginia/Washington D.C. bus people, who had chanted and cheered the whole way up, could not be contained any longer, and started up behind their large green banner, coming to the forefront of the crowd with matching caps and chanting, 'O-P-M-C, Stop Harassing Dr. B!' Well, that did it," Der Bedrosian continued. "The crowd went wild and would not stop. The news cameras rolled, reporters frantically dialed their editors, the sound crew swung the mike booms around to catch the full sound, newspeople scribbled furiously, the chanting went on.....and on.....and on.....and nobody wanted to stop."

Peter Klapak presented NY Senator Kemp Hannon with a

Patients from two states and Washington, DC, gather to protest doctor persecutions.

*Dolly Curtis photo*





Dolly Curtis photo

Connecticut patients (L-R) Donna Cenerizio, Dolly Curtis, and Eileen Wade hold posters which state, "Investigate the OPMC, Not Dr. B.," "Lyme Disease: A National Health Crisis," and "Dr. Joe B. saved my child's life (and my life) from Lyme Disease."

notarized copy of his wife Cathy's death certificate, which lists one of the causes of her death as "Tertiary Lyme Disease." "I appealed to him and told him that I have already buried my wife, and I don't want to also have to bury my child," Klapak said. "My 21-year old daughter has Lyme which I believe my wife transmitted to her during her birth."

Evan White, a college student and former patient of Burrascano's who has recovered from Lyme disease spoke eloquently of his treatment and his admiration for Burrascano's abilities. Tom Forschner, of the Lyme Disease Foundation, spoke movingly of his long friendship and affiliation with Burrascano and gave tribute to his work.

The members of the International Lyme and Associated Disease Society (ILADS) statement in support of Burrascano's work was displayed, recognizing him as an international leader in the establishment of guidelines for the treatment of tick-borne illnesses, including Lyme disease. His frequently updated treatment guidelines have been the backbone of patient management

since their inception and have been found to be effective and successful in the treatment of patients with these complaints, they assert. ILADS also opposes rigid diagnostic treatment guidelines currently being advocated by certain academic centers and the Centers for Disease Control.

Donations are urgently needed. Legal expenses have already exceeded \$75,000.00, not including time lost from work, and are expected to rise to over \$120,000.00.

Please mail contributions to Dr. Horowitz's Legal Defense Fund to: Horowitz Legal Defense Fund c/o Monica Miller, PO Box 410, Kinderhook, NY 12106.

Contributions for Dr. Burrascano should be mailed to; Burrascano Legal Defense Fund c/o Monica Miller, PO Box 410, Kinderhook, NY 12106.

*Voices of Lyme, a grassroots organization of Lyme disease patients, contributed to this report.*

*Thanks to the generosity of several donors, the LDRC was able to sponsor 6 people to attend Lobby*

*Day. We wish to thank the following people for their generous donations to the travel fund:*

*Carolyn Cramoy  
Liz Missett  
Marylynn Barkley  
Douglas Dodge  
Lora Mermin  
Sarah Weiss  
Kerry and Ken Fordyce  
Sandy Stowe  
anonymous*

*One of the recipients, Deb Harris of Kentucky, wrote the following letter on being notified of her travel grant:*

*"I don't know the words to write to you that convey how I am feeling right now. I am in tears but they are in thankfulness. I feel so loved, appreciated and blessed by the Lyme community and special people whom I can't name because I don't know who has made this possible. I want to thank everyone. How can I give back what has been given to me? Next time I hope it will be me that says, "Yes, let me help. I can do it."*

*"You are far too busy to have spent time on this today but I suspect you did and others as well. I can't tell you how much I appreciate it. I'm just lost for words. I feel overwhelmed and am so very grateful."*

*In her thank-you letter, Myrna Vallejo of Calsbad, California, wrote that a reporter asked her if she spoke Spanish. She did, and so most of the interview "was for the benefit of those who do not speak English. I explained how you get it, the numerous symptoms of the disease, how difficult it is to diagnose, and more important, how often it is misdiagnosed and untreated."*

*"As people were disbanding, another reporter approached me and I expressed my concerns in both languages, this time not only for a microphone but also cameras. If a small percentage of our interviews are broadcast, we have accomplished something."*

# Benefit raises funds to help establish Lyme research center

## News Briefs

**Stamford, CT** - On April 28th, silver stars and hope filled the air of the Westin Hotel as The Greenwich Lyme Disease Task Force (GLDTF) held its first Time for Lyme gala benefit. Over five hundred people attended the black-tie event, and nearly \$750,000 was raised to help to establish the Columbia Lyme Disease Research Center in New York City.

The stage was set for a successful evening with the music of celebrated pianist Rob Mathes and the breathtaking floral arrangements and gorgeous setting created by William Bainbridge Steele Floral Designs. Connecticut State Attorney General Richard Blumenthal and his wife Cynthia were the honorary benefit co-chairs. Connecticut Commissioner of Public Health Dr. Joxel Garcia, was a keynote speaker. He expressed his commitment to helping the children of Connecticut by allocating the resources of his department to finding answers to the issues surrounding tick-borne illness.

Dr. Brian Fallon of Columbia Presbyterian Medical Center in New York City was a guest speaker. He spoke of the courage and dedication of the members of the GLDTF: "For those of you who don't know this community well, behind every person committed to this cause there is a heart-wrenching story." Dr. Fallon and Columbia have joined forces with the GLDTF and the Lyme Disease Association (LDA) to make the Columbia Lyme Disease Research Center a reality. Now they are closer to that reality thanks to the huge efforts of the Task Force and the generosity of Time For Lyme supporters.

Jay Thomas was the gracious and humorous emcee for the benefit, and the evening also featured a tremendous silent and live auction, with such hot ticket items as a barge trip

for six people in France, an exclusive day on the New York Stock Exchange, and numerous travel packages complete with airfare.

Children were involved in the evening as well, and mingled with guests while selling silver wishing stars that were attached to balloons and released in the ballroom. By the end of the evening, the ballroom was turned into a beautiful starry night with hundreds of balloons.

The Greenwich Lyme Disease Task Force would like to thank corporate sponsors: Columbia Presbyterian Medical Center, the Isabelle and Leonard Goldenson Association, Inc.; Greenwich Capital Markets, Hoenig Group, Inc., Grey Goose Vodka, Sotheby's International Realty, William Bainbridge Steele-Floral Design, Tiffany & Company, and UBS Warburg for making Time For Lyme a tremendous success.

Lyme disease affects so many people in the Tri-State area and beyond, and Time for Lyme marks the beginning of the road to unraveling the mysteries of Lyme disease and hopes to help the many people who are touched by this insidious disease. As an affiliate of the LDA you are part of a network of groups and individuals striving to bring vitally needed attention to the devastating effects of Lyme Disease, states Connecticut Senator Joseph Lieberman. The LDA plans to continue this effort by conducting a national fundraising campaign to contribute to the Columbia Lyme Research Center.

*The GLDTF is a registered nonprofit organization and an affiliate of the Lyme Disease Association. For more information on the Columbia Lyme Disease Research Center or the Greenwich Lyme Disease Task Force, please contact the GLDTF, Inc. at (203) 531-5090.*

The February 15, 2001, the New York Times reported that two groups representing 7,000 **Connecticut** doctors filed a battery of lawsuits today against six large health maintenance organizations, claiming that the companies "systematically harmed" patients by arbitrarily denying crucial medical treatment and illegally withholding millions of dollars in payments they owe doctors. The American Medical Association said it supported today's legal action, and expressed hope that doctors' groups in other states would join the suit. The suits' basic contention is that the companies place profit above patient welfare.

A Yale study published in April, 2000 shows that ehrlichiosis is now the second most common tick-transmitted ailment in southeastern **Connecticut**. Ehrlichiosis causes headache, fever and muscle aches, but unlike Lyme disease, it does not produce a telltale expanding skin rash. A three-year surveillance study found annual rates of illness ranging from 24 cases to 51 cases of ehrlichiosis per 100,000 inhabitants per year. In comparison, the annual rate of Lyme disease in the same area is about 275 cases per 100,000 persons.

In March, 2000, the **Florida** Supreme Court ruled that people whose insurance companies require them to submit to a medical second opinion have a right to bring along an attorney and even to videotape the exam, according to an article in the Tallahassee Democrat.

The **Illinois** legislature has passed a law mandating the Health Department to start tracking reports of Lyme cases that fall outside of the CDC surveillance criteria. Over 100 such cases reported in 1999 but were not added to the Illinois count.

The **Michigan** Lyme Disease Association is conducting an informal survey to find an accurate count of those diagnosed and/or treated for

Lyme Disease, Ehrlichiosis, Babesiosis throughout the state. MLDA officials are asking those diagnosed or treated for Lyme Disease to complete a confidential survey. To do so, call 1-888-784-5963.

According to Tom Grier, past president of the **Minnesota** Lyme Disease Coalition, nymphal ticks have been collected from dogs in Minnesota in late summer, although over 90% of nymphs feed in the spring. According to a chart of reported tick bites and reported symptoms at the Minnesota Health Department, statistics for the past ten years show that tick bites have been reported in every month of the year with symptoms hitting a peak in July.

The Las Vegas Sun reported in September that a Clark County man is the first ever confirmed case of Lyme disease in **Nevada**. The middle-aged man had lived for several months in the Lee Canyon area of Mount Charleston, Clark County Health District epidemiologist Rose Bell said.

In August, the **New York City** Department of Health was investigating 3 cases of babesiosis in New York City residents who deny travel to known endemic areas. The only common travel history in these individuals was to northern Westchester County, an area not previously considered to be endemic for *Babesia microti*. Health care providers are being encouraged to consider babesiosis during the late spring to early fall in patients with fever and a compatible clinical syndrome, especially in those patients at higher risk for severe disease.

Also in **New York**, Dutchess County Health Commissioner Dr. Michael Caldwell has been criticized by patient advocates for owning stock in and getting paid by SmithKline Beecham, manufacturer of the controversial Lyme disease vaccine. Caldwell was instrumental in setting up the clinical trials for the vaccine in Dutchess County. Caldwell and other county officials deny any

conflict of interest. As a trial host, the health department has brought some \$3 million into Dutchess to provide staffing for the trials. Some 800 adults and 250 children in Dutchess County have participated in trials of LYMERix.

Angry dentists in **Ohio** have mounted an offensive against the agency that regulates them, convincing the legislature to look at whether the Ohio State Dental Board has violated dentists' right to due process. According to the Columbus Plain Dealer, critics alleged the board had been overzealous in prosecuting violations of the Dental Practice Act. Dentists accused of mistreating or misdiagnosing patients were upset because they never learned the identities of their alleged victims due to patient-confidentiality regulations. Among those cases that went to hearings, the prosecutions, later upheld on appeals, were based on the witness testimony of third parties. Most of the board's critics are dentists the board has disciplined.

**Pennsylvania** has recently started The Attorney General's Health Care Unit (HCU) to investigate, mediate and take legal action where appropriate on behalf of consumers against entities that engage in unfair or deceptive acts or practices in the delivery of health care. The HCU will cover the problems that physicians are facing with their insurance providers as well. Complaint forms can be obtained by calling 1-877-888-4877 or from the website [www.attorneygeneral.gov](http://www.attorneygeneral.gov). If you would like further information on the HCU or would like to know more about implementing this unit in your own state, contact Lyme Disease Society director Mary Halinski at [LymeSociety@aol.com](mailto:LymeSociety@aol.com).

The **Texas** legislature held hearings last year and Lt. Gov. Rick Perry directed the Senate Administration Committee to review Lyme and other tick-transmitted diseases, including Rocky Mountain spotted fever, because of many complaints from Lyme disease patients. The

Houston Chronicle reported that the committee is chaired by state Sen. Chris Harris, a Republican whose Lyme disease went undiagnosed for years because doctors did not know what was causing his severe pain and the damage to his heart. It wasn't until Harris' dog died of Lyme that the vet figured out what was ailing the senator.

For years, patients in **Texas** have complained they were misdiagnosed, mistreated and turned away by doctors who know little about Lyme. The committee concluded that **Texas** patients are not receiving adequate care.

Harris' committee is recommending that the state beef up education efforts, encourage medical schools to teach diagnosis of the ailment and develop a research and diagnostic center at the University of North **Texas** Health Science Center.

In the article Lyme Disease Surveillance in **England** and **Wales**, 1986-1998, Robert Smith, et al. state that improved surveillance indicates that Lyme borreliosis has increased from 0.06/100,000 during 1986-1992 to 0.32/100,000 since 1996. Case reports peaked in the third quarter of each year. Several high-incidence localities were identified. Erythema migrans was reported in 41% of patients; arthritis in 4%; musculoskeletal symptoms in 18%; and neuroborreliosis in 15%. The report was published in the Review of Medical Entomology 1991;79:323-33.

In **Scotland**, doctors have discovered that the sheep tick is responsible for passing a rare but deadly form of skin cancer to humans. Researchers at Raigmore Hospital in Inverness have identified a link between a B-cell lymphoma skin cancer and *Borrelia burgdorferi*. Although the Scottish Highlands has one of the highest rates of Lyme disease in Northern Europe with 16 cases per 100,000 people each year, the disease is not reportable.

# FDA considers warnings on Lyme vaccine

continued from page 1

SmithKline was instructed to conduct followup safety studies of 25,000 more people after the vaccine was released for sale, but has so far enrolled only 3,600, not enough to draw any firm conclusions.

A leading Lyme disease researcher, Allen Steere of Tufts University, who helped run SmithKline's clinical trials, shortly afterward published a scientific paper in which he noted the genetic link "is an issue of concern . . . ongoing surveillance will be important," according to an interview he subsequently gave to the journal *Science*.

Some patients in the vaccine trials accuse study doctors of trivializing their complaints and failing to document side effects they reported, although federal research rules require it. A class action lawsuit has been filed against SmithKline by a Philadelphia law firm representing patients who developed severe arthritis after getting the vaccine. The suit alleges that LYMERix triggers degenerative autoimmune disease in HLA-DR4-positive patients and that SmithKline knew of the association before its vaccine was approved but failed to warn doctors.

Patient groups have expressed reservations about the vaccine since before the clinical trials. The well-regarded website LymeNet has a comprehensive paper listing numerous concerns based on scientific research. The New Jersey based Lyme Disease Association advised that people inform themselves before accepting the vaccine, and publicized a list of potential problems. Another advocacy group was widely criticized by patients for accepting a matching grant from SmithKline and for appearing to endorse the vaccine on their website.

SmithKline claims an efficacy of 80% for the vaccine series given in the clinical trials, but patient advocates question their conclusions, because of the serological standard used. Kathleen Dickson, an analytical chemist from Southeastern Connecticut told the committee that rather than preventing infection, the vaccine may actually be triggering asymptomatic Lyme disease. Dickson told the committee that the specific immune response in Lyme disease is known to evolve over time, and the strict serologic standard used in the clinical trial may have missed many subclinical cases.

According to an article in PHARMACY TODAY (Jan 2001) a handful of rheumatologists is already refusing to give the vaccine to their patients, among them Andrea Gaito, MD, president of the International Lyme and Associated Diseases Society (ILADS). Gaito has treated 22 patients who developed severe, crippling rheumatologic disorders following vaccination. A colleague of hers at Yale has treated 40 such patients.

"The rheumatology community was suspicious of this vaccine to begin with," Gaito said. "Before it was ever approved, there were reports published of autoimmune reactions in rats, mice, and other lab animals. It

doesn't seem limited to DR4 positive patients. There is such a clear-cut problem here that this (product) needs to come off the market."

Charlene DeMarco, a New Jersey physician and emerging-diseases specialist also wants a moratorium. "You have healthy, young people getting the vaccine and then getting sick," she said. "It's impossible that the vaccine didn't have anything to do with those reactions."

Although the FDA scientific advisors expressed dissatisfaction with the failure of SmithKline Beecham to address safety concerns which were raised at the original approval hearing, the committee did not move to restrict the sale of the vaccine or to require any warning on the label. They did say they would investigate all cases of vaccine-associated arthritis, a step that indicates heightened concern. A New York Times article stated that until now, the government was actively investigating illnesses that broke out after vaccination only if they were officially classified as serious - defined as life-threatening, persistent and long-term or requiring hospitalization. Lyme disease and arthritis were not generally regarded as meeting those criteria.

The vaccine company is currently seeking approval to market LYMERix for use in children.

*Ed Silverman of the New Jersey Star Ledger contributed to this report.*

---

## Study aborted, LUAT criticized

from page 1

significant difference in the percentage of the patients who felt their symptoms had improved, gotten worse, or stayed the same between the antibiotic treatment and placebo groups in either trial.

The DSMB's review suggested

there was only a slight chance a difference between the two groups would be found even with continued accrual of another 131 patients, the number needed to reach full enrollment. Therefore, the DSMB recommended that the treatment component

of the studies stop enrolling new patients and that those currently receiving treatment discontinue that therapy. The DSMB further recommended that the investigators continue to follow the study patients to monitor their longer-term safety and to obtain additional information that may have value in determining the underlying basis of chronic Lyme disease.

NIAID concurred with the DSMB and study investigators have been notifying participants of the board's recommendations. Future directions of the study will be decided once these preliminary results are evaluated further.

The independent DSMB plays a crucial role in ensuring the safety and welfare of patients enrolled in randomized, comparative clinical trials. All DSMB members must confirm that they have no financial interest or other conflict of interest in the outcome of the study.

#### **Claims LUAT gave inconsistent results**

In a related story, Mark Klempner, MD, of New England Medical Center, principal investigator in the clinical studies, and his scientific collaborators reported their findings about the reliability of two Lyme disease tests in the February 15 issue of the *American Journal of Medicine*. They used an IgG Western blot, a licensed test used to screen blood samples for antibodies to the Lyme bacterium, *Borrelia burgdorferi*, and the LUAT, a proprietary antigen test manufactured by IGeneX Reference Laboratory in Palo Alto, California. The LUAT detects proteins derived from the bacterium in urine samples. The Advisory Committee had pushed for inclusion of the LUAT in the hope that the study would afford an opportunity to evaluate this test.

To perform the IgG Western blot, the investigators collected blood samples from 21 patients who met the CDC case definition of Lyme disease. All patients had been treated for acute Lyme disease symptoms with

recommended antibiotics, but they had continued to suffer symptoms of fatigue, muscle and joint pains, or neurocognitive problems for at least six months thereafter. These 21 blood samples were analyzed and compared with those from 10 healthy volunteers who had no history or symptoms of Lyme disease.

Testing was performed at NEMC, a laboratory recognized by CDC as qualified to do so. In accordance with current recommendations, the IgG test was considered positive if it revealed 5 or more of the 10 bands (indicative of antibodies) deemed significant for Lyme disease.

Duplicate fractions of blood from the 21 patients with chronic Lyme disease symptoms were tested at separate times. The laboratory performing the test was not aware of the results from the previous test.

On initial testing, two-thirds (14/21) of the patient samples tested positive for Lyme disease by standard IgG Western blot criteria; the remainder tested negative. The same results were obtained when the duplicate fractions of the same 21 samples were tested. All samples from the same 10 healthy volunteers tested negative.

The LUAT was performed by the test's manufacturer (IGeneX, Palo Alto, CA) on urine samples taken from 10 healthy volunteers who had no history or symptoms of Lyme disease. Each urine sample was divided into five equal fractions, or replicates, so that a total of 50 individual LUATs were performed.

The LUAT results, unlike the highly reproducible IgG Western blot results, varied markedly. At least one urine fraction from each of the 10 samples examined tested positive. Two urine samples consistently showed positive results. Replicates for the eight remaining samples examined were a mixture of positive and negative values, making it impossible to conclude that they were positive or negative. Klempner et al conclude that the LUAT is not a reliable test or evaluating patients

with active or suspected Lyme disease.

#### **IGeneX disavows test results**

Nick Harris, PhD, president of IGeneX, claims that the urine samples were improperly handled, and therefore the conclusions are not valid.

When they received the samples in late 1998 or early '99, IGeneX scientists sensed that the samples had been improperly handled.

"Negative controls on the LUAT normally test negative 99.9% of the time," Harris told the *Lyme Times*. "It is very unusual to get a mix of such high and low results as we saw with these samples."

When Harris called NEMC and shared his suspicion that the specimens were substandard, the laboratory supervisor confirmed that the samples had not been kept frozen but were refrigerated for many months. This was contrary to the written requirements for the study were that samples must be frozen after collection in a 70C freezer and remain frozen prior to testing to test accurately.

"I called and informed the laboratory manager at NEMC that I would not release the results due to the improper handling of the samples," Harris states. "He informed me that I must send the results anyway because NEMC had paid for them under an NIH grant."

Harris sent NEMC the results along with a letter to Dr. Klempner clearly stating that the results could not be considered valid due to improper storage and possible contamination.

Subsequently, Klempner presented the results of this study at the International Lyme Conference in Munich, without mentioning the contamination, and without giving prior notice to Harris that he would present the report. When questioned, Klempner told the *Lyme Times* that the IGeneX protocol allowed for lengthy storage in a refrigerator, and that different specimens - not the

refrigerated ones - had been used for the published study.

IGeneX then offered to pay for a repeat study involving an independent third party evaluator. Klemperer declined the offer and reported the matter to his Medical Officer at the NIAID. Harris personally made the same offer to Phil Baker, NIH Lyme Program Director. All refused the offer.

### **IGeneX passes rigorous inspection**

IGeneX has recently been vindicated by agencies investigating the sensitivity and specificity of several tests. The tests were suspended while the New York State Department of Health, the State of California as a State agency, and the State of California as a Federal Agency for Health Care Financing Administration that administers CLIA (The Federal Clinical Guidelines), performed a rigorous review which lasted several months. They finally determined that the LUAT, the *B. burgdorferi* PCR and the Babesia PCR can be performed on clinical specimens for diagnostic purposes.

The agencies also accepted that the clinical data provided supported the laboratory's claims about analytical sensitivity and specificity and clinical utility.

Harris told the Lyme Times that the FDA does not and has never approved a laboratory test unless it is made into a kit by a manufacturer and sold to other laboratories. IGeneX tests are not kits and are not FDA-approved, he said.

The LUAT, any non-HIV and -Hepatitis PCR and Stony Brooks' Lyme Western Blot all fall into the same category as a non-FDA approved laboratory test. Most large or specialty laboratories perform a significant number of CLIA approved, but non-FDA-approved laboratory assays.

IGeneX has recently retired the LUAT in favor of a new, more sensitive immunoblot assay for antigen, the Lyme Dot Assay (LDA).

## **Lyme Disease Association goes national, seeks affiliations with other Lyme groups**

The Lyme Disease Association of New Jersey has a new focus and a new name. It is now Lyme Disease Association, Inc. (LDA) and the focus is national. President Pat Smith says that the move increases LDA's ability to procure more money for Lyme disease research.

In 2000, LDA awarded over \$93,000.00 in research grants. Ninety-five cents of every dollar income goes toward Lyme disease research and education.

LDA already has one chapter - Pennsylvania - and will seek alliances with other regional groups. The Lyme & Associated Diseases of the Brandywine Valley, Pennsylvania, (LADBV), which held its first meeting in November, has just affiliated with LDA. The Lyme Disease Resource Center of California is considering joining, as are other groups.

A copy of the basic contract may be obtained by contacting LDA at PO Box 1438, Jackson, NJ 08527.

"We have always felt cooperation will lead to a cure," said Smith.

LDA has also revamped their voicemail system and instituted a toll free number which allows round-the-clock access to Lyme disease information. The LDA website is at <http://ldanj.tripod.com>.

LDA is planning a new membership drive. Only \$12.00 buys a two-year membership and entitles members to monthly mailings of LDA meeting minutes and announcements. Checks may be sent to the address above. Everyone on the mailing list, member or not, also receives a free copy of the LDA newsletter "Tiny Ticktales."

LDA president Pat Smith, second from left, meets with LADBV co-directors Lori Levesque and Jerri Lynn Wier (L-R) and Larry Linford, LADBV fundraising chair to announce a \$30,000.00 donation from the Teddy Foundation for Lyme disease awareness and research. Linford is also president of the Pennsylvania chapter of the LDA. Wier is a member of the PA Chapter. For information about LADBV, write PO Box 551, Unionville, PA 19375, or call 610-347-1329.

# LDI 2001

## from page 1

Lyme for five specific prioritized public health goals to be accomplished over a five-year period.

According to Lyme Disease Association president Pat Smith, no bill is perfect, and the patients, clinicians and legislative aides who worked on LDI tried to strike a balance which would allow the bill to be passed. It was important to avoid antagonizing powerful lobbies in Washington which might easily derail the bill on its way through committee hearings.

“We need the support of agencies as well as private citizens to get this passed,” stated Pat Smith. “Treatment is not the focus of this bill, but we must get recognition, or we will continue to linger in the shadows as a ‘politically incorrect’ disease with little funding or understanding.”

Some of the wording is designed to bring the clinical reality of patient suffering to the attention of legislators, for instance there are references to “chronic” Lyme disease.

“This will help us give credibility to a concept we know exists but which must get mainstreamed into the national consciousness before it will be accepted as valid,” explained Smith.

The Lyme community has responded to this bill by mounting a letter writing campaign to congressmen urging them to support LDI [see sample letter below]. Smith says getting the bill passed is the hardest part of the job, but thinks it is possible because LDI has already earned the support of many legislators in the past, and the LDA has been getting commitments from several unions and lobby groups to support the bill. The text of the bill and its sponsors may be found on the government website [www.house.gov](http://www.house.gov), and addresses of representatives may also be found on that site, or in local

## Lyme Disease Initiative 2001

### Overall

- 5 year plan, 125M
- Carefully delineated goals
- Prioritized goals
- Task force to oversee secretaries establishing goals/distributing monies
- Collaboration of secretaries delineated
- Broad-based, to provide education, monies, tools to all federal agencies involved with Lyme: CDC, NIH, DoD, DoA, DoI
- Allows for agency segmentation & negotiated reductions if necessary

### 1<sup>st</sup> goal

- Direct detection test - Clearly defines distinguishing features: determination of acute/chronic Lyme, active infection, distinguish LD from other TBDs, measure responsiveness to treatment

### 2<sup>nd</sup> goal

- Improved surveillance & reporting system - Includes assessment of medical, social, economic burden: review of surveillance & reporting system & determination of whether & in what manner system can be improved To carry out, consult with states, physicians, patients, patient organizations, consider uniform reporting system, consider maintaining record of non-CDC definition physician diagnosed cases

### 3<sup>rd</sup> goal

- Lyme disease prevention: development of indicators - Establish baseline incidence in 10 highest states, encourage use of natural & non-pesticidal tick control where appropriate, reduce risks on federal lands (assessment of human cases, capable & infected vectors, public awareness programs on federal lands, habitat management & integrated pest control measures)

### 4<sup>th</sup> goal

- Prevention of other TBDs - Implement adequate surveillance, improved diagnosis, prevention & control strategies for other TBDs

### 5<sup>th</sup> goal

- Improved public & physician education - Improve knowledge of prevention, diagnosis, treatment for public, physicians

### Task Force

- Public & agency member
- Clearly establishes their input into achieving the delineated goals, i.e. prioritization/distribution of monies

phone directories.

National Lyme leaders collaborated on writing the letter below

which will be used to promote the bill. People who wish to sign on should contact the Lyme Times or the LDA.

*continued on following page*

*Dear Congressman, We, the undersigned united leaders of the Lyme disease patient advocacy community, have amassed a total of over 125 person years of volunteer service in helping victims of this complex disease. We are committed to working together, and some of us have already become affiliates of the newly formed Lyme Disease Association (LDA), formerly Lyme Disease Association of New Jersey. Others are in the process of affiliating with LDA or are supporting LDA's efforts in Washington.*

*In 1998, we and representatives of over 65 patient advocacy groups supported the Lyme Disease Initiative 1998, which was introduced by NJ Congressman Christopher Smith after many months of discussion with Lyme disease patient advocates, physicians, and legislative advisors. We continue to support this year's version of that bill, HR 1254, Lyme Disease Initiative 2001, and are urging our constituents to support this bill and to contact their legislators and ask them to sign on as co-sponsors. We appreciate all the work and thought that went into the Lyme Disease Initiative, and now more than ever, when our doctors are under attack and treatment is difficult to obtain, we want to see it passed. We are committed to working together to make that passage happen.*

*The Lyme Disease Initiative 2001 is comprehensive. It enumerates five detailed and specific public health goals to be accomplished over a five-year period. It provides measurable outcomes and accountability. It establishes a task force with representatives from the patient and professional community, as well as government departments. The purpose of the task force is to ensure that representatives of government departments and members of the public communicate and provide input into accomplishing the stated goals within the specified time period and funding level. Importantly, HR 1254 is structured to*

*permit amendments, should they be deemed desirable.*

*The Lyme Disease Association, their affiliated Lyme advocacy groups and other Lyme advocates whose principals have signed below, believe that the Lyme Disease Initiative 2001 will serve the needs of the Lyme community. We support all efforts to move the Lyme Disease Initiative 2001 through the committee stage to a vote on the House floor. We appreciate the efforts of many of our representatives to promote the welfare of the Lyme disease patient community by signing as co-sponsors onto this bill. We ask you to do the same.*

The letter is signed by Patricia Smith, President, Lyme Disease Association, New Jersey; Diane Blanchard and Debbie Siciliano, Greenwich (Connecticut) Lyme Disease Task Force Co-Presidents; Lisa Johnson, Co-President, Texas

Lyme Coalition; Sharon Smith, President, Lyme Alliance, Michigan; Phyllis Mervine, President, Lyme Disease Resource Center, California; Jerri-Lynn Wier, Co-President, Lyme and the Associated Diseases of the Brandywine Valley, Pennsylvania; Marvin Lodge, President, Florida Lyme Disease Network; Lee Lull, Marin County (California) Lyme Disease Support Group, Member of the CA Lyme Disease Advisory Committee; Donna Robertson, Support Leader New Jersey Tick-Talk; Larry Linford, Co-Director, Pennsylvania Chapter, Lyme Disease Association; Edina Gibb, President, South Jersey Lyme Disease Coalition; Jill Auerbach, Coordinator, Hudson Valley Committee for Lyme Disease Patient Advocacy, New York; Sue Huesken, Coordinator, Lyme Disease Information Group of Burlington County, New Jersey; Kenneth W. Zieber, Co-Facilitator, Lyme Coalition Group of Quarryville, Pennsylvania.

## Sample Letter to Congress

The Honorable Congressman  
US House of Representatives  
Washington CC 20515

Dear Representative \_\_\_\_\_:

I am writing to ask you to co-sponsor the Lyme Disease Initiative 2001 introduced in the House on March 27, 2001 by Congressman Christopher H. Smith (NJ) for himself and Congressmen (women) Pitts, Maloney, Gilman, Morella, Hinchey, Delahunt, Traficant, Wolf, Towns, and Saxton.

This bill will provide \$125 million over five years through a number of federal agencies for research into and education about Lyme disease and related tick-borne illnesses. As you may know, estimates place the cost of Lyme disease to society at \$1 to 2 billion per year. The number of cases reported is, in actuality, about one-tenth the actual cases, since cases are reported according to a "surveillance" only definition, and do not include all diagnosed cases.

The goals of the bill in priority are:

- Detection test
- Improved surveillance and reporting system
- Lyme disease prevention, development of indicators (10 highest endemic states)
- Prevention of tick-borne diseases other than Lyme
- Improved public and physician education.

*(Personal story here if desired, and attach photo of victim if possible)*

For further information on this bill, please contact Congressman Christopher Smith, C/O Katie Hogan, Legislative Assistant, 202-225-3765

Thank you for your consideration.

## Research

# Entry criteria for Columbia-NIH clinical study are relaxed

## *Patients from any state will be considered*

by Brian Fallon, MD

Because enrollment into the Columbia Brain Imaging and Treatment Study of Chronic Lyme Disease has been slower than expected, the National Institute of Health's Review Committee has recommended that we modify the entry criteria slightly — so that entry is made easier while at the same time keeping the very strict standards for documenting the diagnosis of Lyme Disease.

- First, we will accept patients into the study from any of the contiguous 48 states as long as the patient is willing to travel to Columbia for at least 5 visits over the course of one year. We will screen patients over the telephone and conduct the blood testing for Lyme from a distance. Should patients need assistance with travel costs, we will pay for reasonable air travel costs.

- Second, we now require only 4 weeks of prior IV antibiotic therapy - not 8 weeks as in the original set of criteria.

- Third, while we continue to require a current IgG Western blot or PCR for entry into the study, for historical confirmation of disease in patients without a physician-documented Lyme rash, we now require only one reactive test in the past (ELISA/IFA or Western blot) - not both. For patients with good documentation of erythema migrans, we do not require any past test results.

- Fourth, we are seeking approval from the appropriate regulatory agencies to provide patients who have had gall bladder problems in the past with an alternative to IV ceftriaxone. Specifically, we would like to be able to provide IV Cefotaxime to

these patients as that is an antibiotic known to be effective for neurologic Lyme Disease and it is not known to cause gall bladder sludging. We expect that these changes will provide many more patients with the opportunity to participate in this valuable study.

To learn more about this study, please go to Columbia NIH Lyme Study <http://www.columbia-lyme.org/dept/nyspi/flatp/NIHstud-n.html>. If you'd like to be screened for the study, please complete the screening form at the bottom of that page.

If you or someone you know meets the following criteria, please have that person send us an email at [CULyme@aol.com](mailto:CULyme@aol.com) or call us at 212-543-6510. Please also direct them to our web site at [www.columbia-lyme.org](http://www.columbia-lyme.org) for more information about the study.

### Who may be eligible to participate?

The key criteria are: 1) persistent memory, verbal fluency, or attention problems despite past treatment with at least 4 weeks of IV antibiotics; 2) current IgG positivity or current PCR positivity; 3) past seropositive results: either a) IgG or IgM; or b) ELISA or IFA. d) good documentation in a doctor's chart of the classic clinical symptoms of Lyme disease (e.g., erythema migrans rash, swollen joints, Bell's palsy, meningitis, radicular pains, cardiac conduction abnormalities, or other typical features); e) age 18-60.

Excluded from participation are people with other major medical or neurologic problems, people who smoke more than 10 cigarettes/day, people with uncontrolled high blood

pressure, and people who have a history of marked cocaine abuse. We are also seeking 20 healthy controls.

If each doctor refers one patient into the study, we would be more than able to accomplish our goals.

The goals of the study are:

1) to determine whether the brain abnormalities in Lyme Disease are primarily due to blood vessel inflammation or a nerve metabolism problem

2) to determine whether 10 weeks of IV antibiotics result in further improvement among patients who have already received more than the standard amount of treatment.

3) to identify clinical or biological markers that might be associated with treatment response.

### The study design

For each patient, this is a 24 week treatment study that will evaluate response to treatment using neuropsychological testing and state-of-the-art brain imaging. There is no financial charge for participation in this study. The brain tests include neuropsychological testing of memory and attention, brain imaging (MRI and PET scans) to look at blood flow in the brain and nerve cell structure and metabolism, a neurological exam, and studies of the fluid that surrounds the brain (.the cerebrospinal fluid ).

The treatment involves 10 weeks of either intravenous antibiotic (Ceftriaxone aka "Rocephin") or intravenous placebo (inactive substance). There is a 2 out of 3 chance of getting the real medicine and a 1 out of 3 chance of getting the placebo. (At the end of the 24 weeks, patients who got placebo will be given the option of getting 6 weeks of the actual medicine at no cost). After the first visit, the remaining treatments will be done in the patient's home.

Patients will be screened over the phone and in person to confirm study eligibility. The neuropsychological tests will be done 4 times (screening, baseline, week 12 and 24) and the

brain imaging (MRI and PET scans) and physical exam will be done 3 times (baseline, week 12, week 24). From the patient's home, blood tests and self-report ratings will be done more frequently. A lumbar puncture will be done once at the start of the study in order to study the cerebrospinal fluid to look for markers of infection. There is also a 6 month follow-up at the end of the study at which time neuropsychological testing will be repeated. Therefore, over the first 6 months, the patient will visit Columbia at least 4 times, followed by an additional visit 6 months later. The patient's physician will receive a report at the end of the

study summarizing the results for his/her patient. Additional studies addressing infectious and immunologic markers in the serum and CSF have been funded by the Wilton Lyme Disease Task Force.

#### How to contact us

Call the treatment clinic between 9-5 pm EST to make an appointment or call our study coordinator, Dr. Kathy Corbera, at 212-543-6508.

You can also fax us a copy of the screening questionnaire or send it to us by computer transmission. You may also email us at [CULyme@aol.com](mailto:CULyme@aol.com).

which was funded in part by a grant from LDANJ, served as the background to support the NIH award to Dr. Fallon to conduct a placebo-controlled treatment study of persistent Lyme Disease. The full text of this article can be found at [www.medscape.com](http://www.medscape.com).

---

## ***Borrelia burgdorferi* recovered from infected mammal cells**

In the March 2001 issue of *Infection and Immunity* Dorward and Larson demonstrate that Bb spirochetes can adhere to mouse lymphocytes and that Bb spirochetes with affinity for mouse lymphocytes can establish disseminated infections in mice. This is the first study to demonstrate the attraction of Bb to mammalian lymphocytes in vivo.

The recovery of viable spirochetes in this study from mouse B and T cells indicates that the spirochetes and the lymphocytic cells are in intimate contact with one another in the mammal. While previous work demonstrated that Bb spirochetes could target, adhere to, and invade primary human B and T lymphocytes in vitro, the exact nature of the in vivo spirochete-lymphocyte interactions could not be demonstrated by electron microscopy in this study; the same lymphocyte preparations from the spleen and blood of infected mice did however produce active spirochetal cultures.

The authors speculate that visualization may not have been possible due to a low number of spirochetes per ml. This study supports the suggestion that cellular tropism and lymphocytic-Bb interactions may be mechanisms of persistent infection and disease pathogenesis in the mammalian host.

---

## **Persistent Lyme responds to additional antibiotic therapy**

Dr. Brian Fallon and colleagues of Columbia University reported in the Fall 1999 issue of the *Journal of Spirochetal and Tick Borne Diseases* that a repeated course of intravenous antibiotic therapy results in marked improvement in memory, attention, and overall functioning.

Enrolled in the uncontrolled study were 23 patients with complaints of persistent memory problems who had previously received 4-16 weeks of intravenous antibiotic therapy for Lyme disease. Patients were tested at baseline and 4 months later. During this interval, the private physician determined treatment (intravenous, intramuscular, oral, or none). Assessments included standardized measures of cognition, depression, anxiety, and functional status.

Between times 1 and 2, 5 patients were given no antibiotics and 18 were given additional antibiotics: 7 intravenously, 4 intramuscularly, and 7 orally. At time 1, there were no statistically significant group differences in cognition, depression, or anxiety between those who later received antibiotics and those who didn't. At time 1, the 23 patients were also quite functionally disabled, far

more disabled in fact than patients in other studies with congestive heart failure, type 1 diabetes mellitus, and major depression. At time 2, compared to patients who received no antibiotics and compared to patients who received a continuation of oral antibiotics, patients given intravenous antibiotics showed the greatest functional improvement (pain, physical functioning, energy) and the most cognitive improvement, even when controlling for differences in cognition at baseline between the groups.

Of considerable interest was that patients who did not have a positive Western blot result currently or historically were just as likely to benefit from the repeated course of antibiotic therapy as patients who had fully reactive IgM or IgG Western blot results. This uncontrolled study suggested that repeated antibiotic treatment can be beneficial, even among patients who have been previously treated and even among patients who currently have negative Western blot test results, with the intravenous route of treatment being the most effective.

The pilot data from this study,

# A million ticks

by Linda Finn

Imagine a million ticks in one place. A frightening thought, isn't it? The place is the National Tick Collection in Statesboro, Georgia. Happily, these ticks are bottled in alcohol and being used for study purposes. A 1996 article in *American Entomologist* calls the collection a national treasure.

"As a resource for identification purposes, systematics research, and the investigation of tick-related problems of humans and animals, this tick collection is unrivaled."

It contains most of the world's approximately 850 described tick species and more than 300 types. This collection is believed to be larger than all other world tick collections combined. People with Lyme disease will be most interested in their work on Lyme vectors and hosts; it is important work indeed!

Here are just a few examples of research in which the staff of the collection has participated. The first isolation and cultivation of the Lyme spirochete in Missouri was obtained. Before this study, controversy swirled around clinically-diagnosed cases of the disease in the state. They were being called "Lyme disease-like" but not Lyme itself because the spirochete had not been documented in ticks there. Researchers sampled ticks and tick hosts for a three-year period and showed that borrelia infected several species of ticks.

Other aspects of interest in the study included bridge vectors, rabbits as host vertebrate, and novel genetic strains in the spirochete. (*J Parasitol* 36(1): 1-5. 1998.) Wild birds were sampled and tested in Georgia and South Carolina. Some harbored borrelia spirochetes, suggesting that birds may be reservoir hosts. Migrating birds can carry sub-adult ticks to new locations. (*J Parasitol* 83(6): 1178-1182. 1997)

Antibodies to *B. burgdorferi* were found in 14 species of mammals in coastal Virginia and Maryland. Several tick species infested these animals, but *I. scapularis* had the broadest range. (*J Med Entomol* 36(5): 578-587. 1999)

Lyme borreliosis in the southern U.S. was reviewed in an article: "New data show that *B. burgdorferi* is widely distributed in the South and that strains are genetically more varied than in the north. Moreover, Bb enzootic cycles [in animals] appear

926-935. 1996)

Patients with EM lesions at a Georgia clinic were found to have genetically variant spirochetal DNA poorly detected by existing laboratory tests (70% tested negative). Another case of the test failing the people instead of the people failing the test. (*Archives of Dermatology* 135:1317-1326. 1999)

And providing more evidence that the work of the national tick collection scientists should be cheered on enthusiastically by the Lyme community, another journal article describes the importance of systematics to public health. It notes that the complex patterns of ticks, microbes, disease, and host animals cannot be fully understood without accurate identification, involving complicated taxonomic considerations. One of the reasons that Lyme disease in other parts of the country was not recognized as early as in the NE had to do with tick taxonomy. This situation changed when *I. dammini*, described as the vector in the NE, turned out to be the same species as *I. scapularis* in the South. Scientists at the tick collection carried out breeding experiments, chromosome analysis, and studied life cycles and morphology to make this determination.

All too often Lyme cases are doubted by the medical and health establishment unless the vector and the spirochete are known to inhabit the area. Clinical diagnosis of cases is apparently not enough on its own. First you have to prove a vector exists, then that Bb is in animals and vector species, and it also helps to know the infection rates of ticks. Enter scientists such as those at the National Tick Collection to sort this out and help to confirm that Lyme cases are possible.

Their work in systematics is more than naming of species. It includes relationships between species and genera as well as attempting to trace the evolution of the group.

The people of the tick collection, a

---

## **Patients with EM lesions at a Georgia clinic were found to have genetically variant spirochetal DNA poorly detected by existing laboratory tests (70% tested negative).**

---

to be more complex and more tick species are identified as vectors of the spirochete in the southern states."

Note that not all tick species carrying Bb bite humans.

The greater genetic variation of the tick *I. scapularis* in the South is thought to indicate a southern origin, with northward migration, rather than the reverse. The infection rate of ticks appears to be lower than in northeastern states, but more data is needed. The lower number of LD cases reported in the South might be caused by: poor surveillance; lack of testing reliability; symptoms not being recognized by patients or doctors; differing infectivity of strains of the disease; differing population density between the SE and the NE; complexities of the enzootic cycle; and human residential patterns. Lots of room here for more research! (*J Parasitol* 82(6):

part of the Institute of Arthropodology and Parasitology at Georgia Southern University, include Dr. James Oliver, director; Dr. James Keirans, curator; and Dr. Lance Durden, assistant curator.

Dr. Oliver worries about the future of systematics, pointing out that fewer new specialists are being trained, particularly for arthropods of medical and veterinary importance. He would like to see more of these doctoral students in university entomology departments. He explains, "Without a clear understanding of the causative agents, it isn't possible to develop a rational plan to deal with diseases." This makes systematics a "foundation" science.

The unique history of the collection deserves a few words too. It was started when scientists surveyed Montana in the early part of this century to collect ticks that carried Rocky Mountain spotted fever. A Montana scientist added African ticks to this nucleus. After moving to the Rocky Mountain Lab, this same man added tremendously to the collection. Scientists in overseas service during World War II made field collections and maintained cooperative research programs around the world after the war. Other notable collections were acquired or donated. In 1983 the by-now very large collection was donated to the Smithsonian. Because of lack of space and funding, the Smithsonian in 1990 transferred it under a long-term loan to GSU.

The institute, with its scientists studying a variety of arthropods and parasites, is now a world-class research and service facility. The library contains 50,000 articles on file. Foreign scientists visit to study the collection and the library. Although the research function is primary, the institute's faculty members also teach, organize symposia, and serve on editorial boards. Research activities have traditionally been supported extensively by external funding sources.

## Adie pupil - a sign of Lyme?

In a letter in the March issue of *The Lancet*, Raphael B Stricker, MD, of the California Pacific Medical Center in San Francisco, and Edward E Winger of Immunodiagnostic Laboratories in San Leandro, California, report on three Lyme patients who presented with tonic pupil and areflexia, or Holmes-Adie syndrome. The syndrome has occasionally been linked to early syphilis, parvovirus B19, and herpes simplex virus infections.

All three patients had significant neuropsychiatric and cognitive defects, hyporeflexia, and facial dysaesthesia without anhidrosis. All

had a history of tick bite, an erythema migrans rash and positive serology for the spirochaete *Borrelia burgdorferi*. Two patients had abnormal brain magnetic resonance imaging with white-matter lesions consistent with neurological Lyme disease.

Neurological Lyme disease has been associated with various cranial nerve, meningeal, and neuropsychiatric abnormalities. The authors suggest that Holmes-Adie syndrome might represent an early and unrecognised manifestation of Lyme disease.

### Abstracts

## *Borrelia burgdorferi* prefer meninges and connective tissues

Cadavid D; O'Neill T; Schaefer H; Pachner AR. Localization of *Borrelia burgdorferi* in the nervous system and other organs in a nonhuman primate model of lyme disease. *Lab Invest* 2000 Jul;80(7):1043-54

Lyme borreliosis is caused by infection with the spirochete *Borrelia burgdorferi*. Nonhuman primates inoculated with the N40 strain of *B. burgdorferi* develop infection of multiple tissues, including the central (CNS) and peripheral nervous system. In immunocompetent nonhuman primates, spirochetes are present in low numbers in tissues. For this reason, it has been difficult to study their localization and changes in expression of surface proteins.

To further investigate this, we inoculated four immunosuppressed adult *Macaca mulatta* with 1 million spirochetes of the N40 strain of *B. burgdorferi*, and compared them with three infected immunocompetent animals and two uninfected controls. The brain, spinal cord, peripheral nerves, skeletal muscle, heart, and

bladder were obtained at necropsy 4 months later. The spirochetal tissue load was first studied by polymerase chain reaction (PCR)-ELISA of the outer surface protein A (ospA) gene. Immunohistochemistry was used to study the localization and numbers of spirochetes in tissues and the expression of spirochetal proteins and to characterize the inflammatory response. Hematoxylin and eosin and trichrome stains were used to study inflammation and tissue injury.

The results showed that the number of spirochetes was significantly higher in immunosuppressed animals. *B. burgdorferi* in the CNS localized to the leptomeninges, nerve roots, and dorsal root ganglia, but not to the parenchyma. Outside of the CNS, *B. burgdorferi* localized to endoneurium and to connective

tissues of peripheral nerves, skeletal muscle, heart, aorta, and bladder. Although ospA, ospB, ospC, and flagellin were present at the time of inoculation, only flagellin was expressed by spirochetes in tissues 4 months later.

Significant inflammation occurred only in the heart, and only immunosuppressed animals had cardiac fiber degeneration and necrosis. Plasma cells were abundant in inflammatory foci of steroid-treated animals. We concluded that *B. burgdorferi* has a tropism for the meninges in the CNS and for connective tissues elsewhere in the body.

## Antibiotics may help patients with CFIDS and positive titers

Treib J, Grauer MT, Haass A, Langenbach J, Holzer G, Woessner R. Chronic Fatigue Syndrome in Patients with Lyme Borreliosis. *Eur Neurol* 2000 Feb;43(2):107-109

Several authors have reported a chronic fatigue-like syndrome in patients that have suffered from Lyme borreliosis in the past. To further investigate this suspicion of an association without sample bias, we carried out a prospective, double-blind study and tested 1,156 healthy young males for *Borrelia* antibodies. Seropositive subjects who had never suffered from clinically manifest Lyme borreliosis or neuroborreliosis showed significantly more often chronic fatigue ( $p = 0.02$ ) and malaise ( $p = 0.01$ ) than seronegative recruits. Therefore we believe it is worth examining whether an antibiotic therapy should be considered in patients with chronic fatigue syndrome and positive *Borrelia* serology.

## Apparent brain lymphoma is neurolyme

Kieslich M, Fiedler A, Driever PH, et al. Lyme borreliosis mimicking central nervous system malignancy: the diagnostic pitfall of cerebrospinal fluid cytology. *Brain & Development* 22: (6) 403-406 SEP 2000.

We report two children with acute loss of neurological functions and signs of an increased intracranial pressure. Imaging techniques ruled out space occupying lesions, whereas CSF cytology indicated CNS involvement of a non-Hodgkin lymphoma in the form of abnormal lymphocytic pleocytosis with malignancy criteria fulfilling lymphoid cells. CSF protein electrophoresis and *Borrelia burgdorferi* serology revealed neuroborreliosis which was successfully treated with antibiotic therapy.

The malignancy mimicking cytology is based on a blastoid transformation

of B- and T-lymphocytes due to the antigenic stimulus of *B. burgdorferi* infection. Lymphoid cells in the CSF of a patient with acute or chronic neurological symptoms raise the differential diagnosis of inflammatory etiology versus CNS lymphoma. Monomorphism and higher quantity of the lymphoid cells point to CNS lymphoma. A lower quantity and polyclonal pattern of lymphoid cells associated with an elevated protein fraction caused by intrathecal immunoglobulin synthesis: suggest an inflammatory etiology.

## Strain variation can cause false negative serology

Kaiser R. False-negative serology in patients with neuroborreliosis and the value of employing of different borrelial strains in serological assays. *J Med Microbiol* 2000 Oct;49(10):911-5

The risk of obtaining false-negative results in serological assays in serum and CSF specimens with only one strain of *Borrelia burgdorferi sensu lato* as antigen was investigated in 79 patients with neuroborreliosis with specimens obtained at initial presentation. Serum antibodies were assessed by immunoblotting; the criteria of Hauser et al. were used to evaluate the test. The intrathecal synthesis of borrelial-specific IgM and IgG antibodies was examined by enzyme immunoassay (EIA). Strains of *B. burgdorferi sensu stricto* (BbZ160), *B. garinii* (Bbii50) and *B. afzelii* (PKO) served as sources of antigen in both assays. All patients produced either a positive IgM or IgG test in serum with at least one strain of *B. burgdorferi sensu*

*lato*. Reactivity of IgM or IgG antibodies, or both, with antigens of all three strains was demonstrated in 67 (85%) of 79 sera.

The correlation of results of immunoblotting with different strains was significantly better for IgG (85%) than for IgM antibodies (54%). The variability of positive IgM reactions in 18 specimens was mainly due to the fact that the antibodies were directed to the relevant variable outer-surface protein C (p23). Intrathecal synthesis of IgG antibodies was demonstrated in 58 patients (81%) of 72 and of IgM antibodies in 25 of 58 patients. No patient had isolated intrathecal synthesis of IgM antibodies. The majority of CSF samples (56 of 58) were assessed as IgG antibody-positive, independent of the borrelial

strain used as antigen in EIA, whereas only 10 of 25 IgM antibody-positive CSF specimens reacted with all three strains. All patients in the study had intrathecal antibody synthesis demonstrable at 6-week follow-up. From this study it is concluded that there is a small, but

real, risk of false-negative serological findings at the time of initial clinical presentation in patients with typical symptoms of neuroborreliosis. In these patients a negative serological result with one strain should prompt the repetition of the test with other strains of *B. burgdorferi sensu lato*.

where he was speaking with Dr. Walter Prehn, a treating physician from Sonoma. Dr. Prehn welcomed the audience. Following introductory remarks by Phyllis Mervine of the Lyme Disease Resource Center and *the Lyme Times*, the speakers began.

### The Big Picture - Lyme in the State

The first presenter was Lucia Hui, a slightly built Asian woman with a pleasant manner, welcoming smile, and a black belt in statistics. Her job title: California State Senior Public Health Biologist, Department of Health Services, Vector-borne Disease Section, is about as big as she is if you stack the letters side to side. Her command of her field is authoritative and unquestionable. She profiled the recent history of tick-borne diseases (TBDs) in California from 1989-1999. Interestingly, there was a sharp decline in reported cases that correlated directly with the illness and subsequent death of Dr. Lavoie in 1993-1994. 350 cases of Lyme disease were reported in 1990 while only 68 were in 1994. The obvious question in my mind was: "Is this the 'Lavoie effect,' that result seen when the doctor who reported a great majority of the cases dies, so the entire State of California is miraculously cured of a politically sensitive and very expensive disease?" It makes one wonder.

Ms. Hui went on to discuss the state's rather complex reporting criteria. This is a 4-level process whereby the doctor is asked to fill out 2 sets of paper work that swim up stream like dying salmon, through the County Health Department, the California Department of Health Services, and finally gasps its last breath in the polluted headwaters of the Centers for Disease Control (CDC). Lyme disease is "cured" like a piece of jerky smoked over the bonfire of political debate every step of this process. The CDC criteria are responsible for the large attrition rate of clinical cases that never live to make it upstream.

The other part of the number

## Conferences

# Fallon addresses day-long meeting in San Francisco

by Suzanne Smith

*This meeting was organized by Karen Chew and supported by the Mid-Peninsula Lyme Disease Support Group and the Lyme Disease Resource Center. Ray Stricker MD also helped with the arrangements.*

**November 11** –When I first heard that this conference was to be held at The California Pacific Medical Center in San Francisco, I couldn't help remembering that day, 14 years ago, when Dr. Paul Lavoie finally told me my "mystery illness" was Lyme disease.

At first, I didn't believe him. We debated over many months of treatment; a treatment that made me sicker for two years before it began to make me better. How could one disease account for over 30 years of suffering? How could it effect so many different organ systems? Why was I getting worse, not better? Paul spent hours training me about my disease, and in turn, expected me to reach out to help others.

Now, 45 years after the tick bite, 14 years into treatment, hundreds of hours of patient interviews later, and 12 years of attending medical seminars, I finally can acknowledge — Dr. Lavoie was right. Unfortunately, he is no longer here to thank. He passed away from pancreatic cancer in January of 1994. Some of our hopes and dreams for finding a cure for Lyme disease died with Paul Lavoie. It has taken years for the Lyme disease community in California to recover.

Undeniably, it will never be the same. He was one of the most clinically knowledgeable treating physicians in the USA.

Walking into the new wing of the California Pacific Medical Center Hospital, I wondered if anybody else would remember the fact that Dr. Paul Lavoie's office had been here. I quickly found the conference room and began setting up the recording gear. I soon caught myself scanning the room, fully expecting to see a tall gangly man with silver-gray hair, steel blue eyes, and Cheshire-cat smile. Dr. Lavoie would not have missed a conference like this on his own turf. These were his patients. This was his hospital, and his cause *celebre*. Being there without Paul brought back a familiar pain in the pit of my stomach, tightness in my chest, the loneliness, fatigue and sense of futility that I had battled for the past 44 years.

I ducked into a corner and took a private moment to say a prayer of thanks for the life of Dr. Paul Lavoie.

The familiar voice of Dr. Robert Lane of University of California at Berkeley, Department Entomology snapped me back to the moment and focused my attention on the podium

problem comes from unreported and under-reported cases, which has to do with most physicians' inbred dislike for the secretarial duties of paperwork. Maybe if we could have them mumble into a voice-activated hand-held reporting system to be transcribed by others, we might have a snowball's chance in Hell of getting actual numbers of Lyme disease casualties.

Ms. Hui outlined the county-by-county breakdown of reported cases of Lyme disease. Sonoma County ranked first, followed by my home county, Mendocino, on the lovely northern California coastline. Tourism accounts for a great deal of this county's revenue stream with bed tax and wine production being two of the big ticket items. Mendocino alone hosts well over one million tourists a year. That is a population of 1,000,000 people who have potential to be bitten by ticks and then go home to other cities, states, and countries. The "HOMING PIGEON FACTOR" provides another seed for under-reporting because, as Ms Hui pointed out, cases will be reported in the county where the person LIVES, not in the county where they contracted the disease. Money for research will, unfortunately, follow the victim home never to be seen by the county with perhaps the largest tick exposure problem.

The next data presented dealt with counties that have NO REPORTED CASES in 1999, i.e., Alpine, Colusa, Inyo, Modoc, San Benito, and Sierra. It would be interesting to do a survey of doctors in those counties to see if they could pass a basic Lyme disease 101 exam (Introduction to Lyme Disease). One cannot help wondering if the lack of reported cases is because there ARE no cases, or is it because patients are going undiagnosed? Interestingly, two of the counties listed, Modoc and Alpine, do not even have any records on the distribution of *I. pacificus* ticks, the primary implicated vector of Lyme disease in California. This cannot be construed to mean that the tick is not

present in these counties, but merely indicates a lack of records.

We often hear the argument that California and Oregon have a low infection rate for *Borrelia burgdorferi* (Bb). That is tempered by the fact that California residents 'enjoy' a longer exposure period (over 9 months of the year, due to a milder climate). Parts of the state report 41% of the nymphal ticks tested were positive for Bb. That is higher than the adult tick infection rate for Lyme, Connecticut!

Ms. Hui's personal account of her own exposure to Lyme disease is a familiar one, and brings humanity, understanding, honesty and wisdom to a field fraught with problems. She made us laugh and cry as she described her continuing battle with this disease. Maybe, just maybe, when Ms. Hui's colleagues see Lyme played out in one of their own scientists, with their own eyes, the state and Public Health officials will take a deeper look at TBDs as a major health problem.

State Senate Bill #1115, sponsored by Wes Chesboro, asks for funding for a Lyme disease specialist and a nine-member Lyme Disease Advisory Committee to be formed. There is enough evidence already on the table showing that Bb is not the only problem the state faces. TBDs in California include Ehrlichiosis, Babesiosis and other unnamed pathogens or strains.

#### **Dr. Robert Lane**

Dr. Lane is a tick man with an understated Berkeley style. Dressed in a warm sweater, casual slacks, and suede boots, one would hardly guess that Bob Lane is a world renowned scientist. His bashful, unassuming, polite manner comes with an easy smile and self-deprecating sense of humor.

One thing that I have always admired about Dr. Lane is his ability to remember and credit his co-workers, both past and present. His thank-you list stretched on for several minutes, clearly leaving one with the

impression, 'We are tall only because we have been lifted upon the shoulders of giants.' (That means you, Willy Burgdorfer, wherever you are!)

Dr. Lane tapped in the fact that "85% of cases of vector-borne diseases reported to the state of California are Lyme disease." 85% for God's sake! I mean, Rocky Mountain Spotted who?

He follows that with a chaser: the fact that it is the NYMPHAL, NOT THE ADULT STAGE of the tick, that is the PRIMARY VECTOR of Bb to humans.

#### **Testing issues**

Jumping in to describe the art of testing for TBDs was Dr. Jyotsna Shah, a petite woman with flashing eyes and matter-of-fact manner, vice president of research and development at IGeneX Laboratory in Palo Alto. She patiently explained that there are two methods for testing; either direct or indirect. Direct testing methods include biopsy, culture, PCR (polymerase chain reaction), or antigen capture. All four direct methods use some part of the infecting organism.

Indirect methods include IFA, (immunofluorescent assay) ELISA, and Western Blot. The three indirect methods search for the body's response to the presence of a pathogen. The big "IF" is—IF A PERSON'S IMMUNE SYSTEM IS CAPABLE ENOUGH TO REACT. Only 60-70% of people produce antibodies. That means there are 30-40% of people for whom indirect methods of testing will NOT necessarily be indicative of their infection. The Western Blot appears to be the most agreed-upon testing method.

The next question is—what are we looking for? Antibody proteins have specific weights and, like athletes at a track and field event, the heavier ones don't run as fast or as far. Some stop at the 23 kilodalton line, some at 31, 34, 39, 41, etc. And it is that "yard line" which earns them the number on their shirt.

During the IgG match, the Centers for Disease Control states that only players #18, 23, 24, 25, 28, 39, 41, 45 and 58 are legitimate contenders in Lyme disease diagnosis. IGeneX names players #31, 34, and 93 as other contenders and does not recognize players 18, 28, 45 or 58. So we have a problem of disagreement among the game's organizers about Western Blots and which players will be allowed to play in the Lyme diagnosis game.

Meanwhile back on the soccer field, we have another match going on called the ELISA test. This used to be the game of choice for diagnosing Lyme disease, but has fallen out of favor, due to a lack of sensitivity and specificity. Similarly, a third match, a squash game called IFA, is no longer utilized for the diagnosis of Lyme disease. We are now all playing football and Western Blot is the name of the diagnosis game.

Dr. Shah ran down the playing field of diagnostic tests. The biopsy method of detection is difficult because—“Where do you punch out the biopsy?” (a piece of skin taken from a patient for the purpose of determining the presence of the Lyme organism *Borrelia burgdorferi*.) Culture methods are notoriously difficult to do, antigen capture testing has yielded positive results when the patient's blood was negative, PCR is expensive, LUATs (urine tests) can't be done when there is a concurrent urinary tract infection, etc. And these are the problems with testing for Lyme disease only! Adding to the confusion is the fact that patients can have other tick-borne illnesses like babesiosis, Human granulocytic ehrlichiosis (HGE) or Human monocytic ehrlichiosis (HME).

### Babesiosis

When I first heard the term “babesiosis” it sounded to me like a disease of chimpanzees. In reality it turned out to be a malaria-like illness found in man. Symptoms include: high fever, malaise, muscle aches, bone pain, chills and fever. Unfortu-

nately, the vector is the same tick that causes Lyme disease. (translation—you can get a multitude of illnesses from just one tick bite.)

*Babesia microti* (Bm), the causative agent of babesiosis, is a parasite that lives within the erythrocytes. In trying to diagnosis this illness, physicians have relied upon actually finding the organism inside the erythrocytes in blood smears. Historically the diagnosis has been made either by Giemsa-stained thin blood smear techniques or IFA testing methods. Both of these lack specificity and sensitivity. Generally, isolation and culture techniques are not in use with *Babesia microti*.

The disease occurs in stages and there may only be a small number of organisms present during some periods. Detection relies upon the experience and skill of the person using the microscope and plenty of old fashioned luck. Hamsters were originally used as incubators for this disease. Patient blood was injected into these little fur balls and could take up to 6 weeks for the parasite to “amplify”. Because of the long lead time to diagnose in this manner, IFA soon became the testing method of choice. The IFA techniques brought back the problem with indirect detection methods, and lack of antibody responsiveness in many individuals. In addition, was the fact that antibodies can persist for years even after symptoms are gone. (i.e. a positive result only meant that the patient had been exposed and did not necessarily mean they were symptomatic.) The test lacked specificity, and the situation was further compounded by the fact that a negative test did NOT rule out the disease.

IGeneX has developed a PCR test for Bm using DNA extracted from whole blood. Using whole blood samples, they go through a three step process I refer to as “SAD”:

S-for SELECTION of the part of the DNA they wish to test for,

A-for AMPLIFICATION of those DNA,

D- for DETECTION of the target DNA.

Of the 137 samples from patients with a babesiosis-like illness, 35.7% tested positive for Bm by PCR methods. None of the control group was positive. The researchers contrasted these results to 97 samples tested by IFA techniques. 64 of those samples tested positive by IFA. 3 of the positives were from the control group! Because the PCR testing method does NOT rely upon an immune response it facilitates earlier detection of the infection.

The PCR shows much more sensitivity. It reveals even biochemically unusual strains, is a direct method of testing for the organism itself, and does not rely on the patient's immune system remembering to leave its ‘calling card’ antibodies. With direct testing, the physician can actually learn if an antibiotic is working to decrease the number of parasites. The PCR-based testing for Bm can find the pathogen even in skin, a tissue that is normally low in antibody titers. We have all heard the years of teeth gnashing and complaints around the problems of testing for Lyme disease. At least with Babesiosis it appears that we may have a very good chance of accurate detection.

### Myths about Lyme disease

Dr. Sticker started out his lecture with a David Letterman type top 10 list of myths about Lyme Disease.

10- There is no Lyme disease in California

9- Only Deer ticks carry *Borrelia*, the cause of Lyme disease

8- All patients with Lyme disease have a skin rash

7- Arthritis is the only symptom of Lyme

6- A negative ELISA test rules out Lyme disease

5- Men and women react the same on Lyme Western Blots

4- All Laboratories do a good job

with Lyme Disease testing

3- Two weeks of antibiotic therapy cures all Lyme disease

2- The neurological symptoms of Lyme disease are easy to treat

1- There is no such thing as Lyme disease

He chronicled for the doctors present the “acute” vs. the “chronic” stages of LD. He mentioned heel pain and myoclonus (muscle twitching) Oh yes and the “adie pupil” and “musical hallucinations” (commonly referred to by patients as ‘Name that Tune’) He beat the audience over the head with the problems of testing, slashed the ELISA and IFA to ribbons and even brought in some negatives about the Western Blot. For example, did you know that men and woman may react differently with the Western Blot?

Sticker seemed to like the PCR but lists it as “expensive.” LUAT he favored for monitoring, but was unsure of its diagnostic role. His discussion of C6-Peptide ELISA escaped me. The CD57 lymphocyte subset was his darling of the day and he provided a copy of his abstract published in the FASEB Journal 4/20/2000 V14 No.6.

Stricker claims that immunologic abnormalities appear to have a role in Lyme disease. The longest ‘chronic’ LD patient in the study had been infected for approximately 15 years. Of the 25 patients studied 72% evidenced decreased total CD57 lymphocytes. Patients with neurological symptoms showed lower counts than those with musculoskeletal symptoms and CD57 levels were observed to rebound after treatment. Conclusion—C57 lymphocytes MAY be an important marker of chronic Lyme disease. He will be monitoring their response to therapy.

#### Case studies of neurolyme

If you thought you were crazy with Lyme disease before, you have absolutely no idea how crazy you could get. Dr. Brian Fallon, a slightly built man with dark hair and beard whose credentials read like a Nobel

laureate took the podium. He began by bringing out the guns and flashing his ammunition belts by accurately describing the ongoing meltdown of a Lyme disease patients’ personality, intellectual, motor, and neurological functions. His talk focused on three case histories.

#### Case 1

The first was a 7 year old female who was having problems in school and had been diagnosed as having a “probable attention deficit disorder” (ADD). This child’s ADD resolved with treatment for her Lyme disease. As long as she was kept on antibiotics, she did well but when she was taken off antibiotics, she relapsed. Her teachers reported that the child had problems with consistency and was sloppy, careless, scattered, forgetful, late and disorganized. (Does this sound like anybody you know?) Bottom line—encephalopathy secondary to Lyme disease.

#### Case 2

The second case was a 16 year old boy with depression who said he stopped dating a girl after 2 weeks because he felt “too tired and not smart enough.” The symptoms were: problems with concentration, sleepi-

ness, short term memory, headaches, stiff neck, sudden sweating, sort throats, testicular pain. Brain SPECT revealed a moderate to severe diffuse and heterogeneous DECREASED PERFUSION. After treatment the boy was no longer depressed, his school performance improved markedly and his IQ jumped 22 full scale points.

#### Case 3

The third case present was that of a 45 year old male with a recent diagnosis of Multiple Sclerosis (MS) and a history of seronegative Lyme disease 6 years previous. His treatment had consisted of a 2 week course of intramuscular ceftriaxone followed by 4 weeks of oral doxycycline. He was then given oral prednisone. Over the next 5 years he was improved but symptomatic. Chief complaints were: ankle pain, headaches, night sweats, paresthesia below the waist, insomnia, testicular pain, and fasciculations .

One year previous to his visit, his symptoms worsened and new symptoms appeared; slurred speech, facial tingling, double vision, poor coordination, problems with balance and light-headedness. The neurological evaluation noted decreased pain and temperature sensation and a

## A Lyme Moment

by Sarah Weiss

Dr. Fallon had just spoken about psychiatric manifestations of Lyme disease and I went to say hello to my friend Jane at the break. We were sitting on two chairs and across the aisle from us, about a foot away, was a doctor who had come to the meeting. Anyway, we were talking for a couple of minutes and suddenly I realized I had forgotten whatever question I was just about to ask Jane! So I said, “Oh Jane, I completely forgot what I was going to ASK you!” I said, “I can’t even remember what we’re talking about! WHAT are we talking about?” Jane: “What ARE we talking about? I don’t KNOW!” ME: “Wow, I have no idea!” Jane: “I can’t remember EITHER!” ME: (Here the doctor cocks his head, listening.) “We WERE talking!” Jane: “We WERE!” Me: “I wonder what we were talking about...” Jane: “I don’t know!”

Here the doctor got this incredibly satisfied expression on his face and nodded, like he had just thought to himself, “Ahhh, so THAT’S what Dr. Fallon meant!” It was funny! But I still couldn’t remember either my question or our topic and neither did Jane!

delayed left corneal reflex. MRI showed multiple focal white matter from brain stem to parieto-occipital lobe. Eye examination suggested optic nerve or severe retinal disease and axonal optic nerve dysfunction. Again the man was treated with prednisone. Fallon did a blood test on him which showed a positive IgG, reactivity for Bb, but other tests were "normal". Brain SPECT uncovered decreased perfusion throughout the cortex, white matter and basal ganglia on both sides of his brain. The patient was off all steroids and treated with high doses of oral cefuroxime and minocycline. The MRI was then repeated and showed that the brain stem demyelination was even worse. The doctors then blasted him with ceftriaxone IV plus clarithromycin and have kept him on this treatment. Happily, recent MRI scans documented that his white matter lesions are reducing in size. Both his neurologist and infectious disease doctors have now changed their diagnosis from MS to Lyme encephalomyelitis. This is a lucky, lucky, lucky man with an excellent team of doctors who are confident enough in their skills as physicians not to be afraid to change their minds when contrary facts are presented.

The question remains, what is it going to take to chip away at the ice block of denial still so prevalent today? Who knows? Clearly we have made some progress. Clearly, to patients who are suffering, it is never fast enough.

It is ironic that Lyme disease conferences are still being organized, conducted and staffed largely by unpaid volunteers working with shoe string budgets who themselves are having trouble with attention, poor mental tracking, fatigue, and mood disorders. The patient motto is "We are not lazy we are sick." The Lyme physicians, motto is "We are exhausted." This situation truly is a case of the sick leading the exhausted till we find a cure for TBDs. We can not cure AIDS, Syphilis, Lyme or other TBDs with bake sales. Clearly

the gloves are going to have to come off and the Government must get serious about addressing the issues.

Enough of the microbiology is now known to structure effective treatment protocols. We don't need to wait for a cure we can control the symptoms and make tremendous progress with the drugs we currently have on hand. (I went from being an invalid to a fully functioning real estate broker and head of my own active buyers brokerage firm) The problem with Lyme disease treatment is NOT as much scientific as it is political.

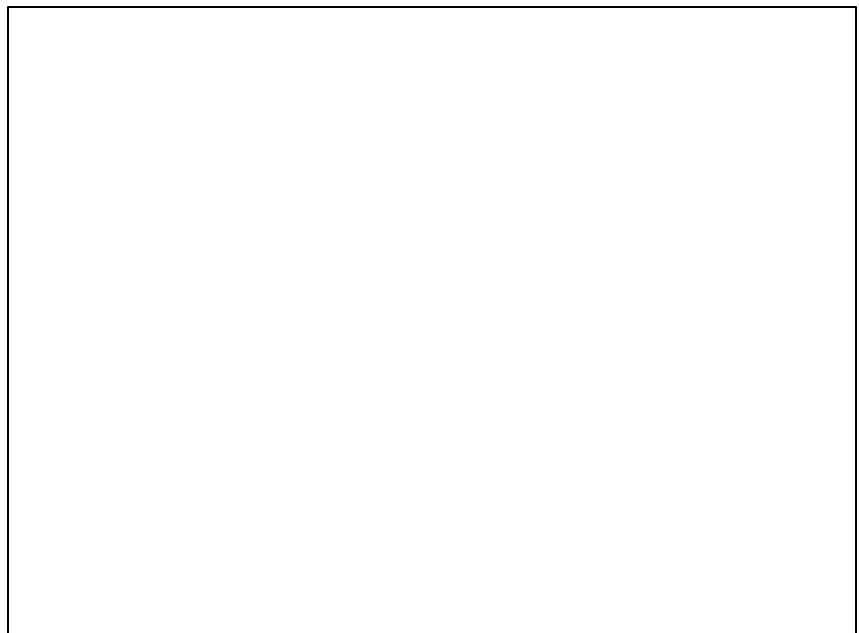
Clearly absent from the San Francisco Conference was a discussion of bacteria static vs. bacteriocidal effects of drugs on Bb. The conference jumped from ticks to treatment. Missing were the microbiologists, endocrinologists, cytologists, and pathologists that draw the pieces of the puzzle together and connect the dots into a consistent whole. Where are the Paul Durays, and Alan MacDonalds to weave together the TBD pathogens with the action of the human cell? This Conference was a "fly by" in a missing man formation. It was like trying to solve a murder without a

detective. Nobody is doing the ground work—the whole field of Lyme disease research has become a no man's land, a mine field strewn with body parts of the sick and dead. What can I say but "We had an epidemic and nobody came."

I am nearly 50 years old now. I contracted Lyme 45 years ago at a public park near Lyme, Connecticut. It took 30 years to diagnose my condition—30 years to begin treatment. I intend to live long enough to see this thing cured if not for myself, certainly for others. Unfortunately, we can not cure what we can not see or admit even exists.

What is everyone SO AFRAID of? I hear the muttering at conferences "It could bankrupt the insurance or health care system in the USA." "It could disrupt the blood supply" "It could result in lawsuits." What would have happened if the US Government had turned its back like this on malaria or AIDS? At some point, the land of the brave and the free has got to find enough back bone to confront the epidemic of TBDs and make them a national priority, by declaring a public health emergency, assemble a task force and get down to business.

Keynote speaker Brian Fallon flanked (L-R) by Phyllis Mervine, LDRC secretary Nancy Brown, and conference organizer Karen Chew.



I am living proof of Fallon's conclusion "even among patient who have had LD undetected for long periods, antibiotic treatment can be helpful although not curative." Yet every month, I have had to beg for antibiotics. The same antibiotics that are freely given to chickens, cattle, pigs, and given for years to people with aches, or irritable bowel syndrome or rheumatic fever. These same antibiotics that can be bought for pennies on the dollar over the counter in Mexico or Canada.

There is a movement afoot in the USA to come down hard on doctors who prescribe repeated doses of antibiotics to their patients. This movement cites the fact that microbes are fast becoming antibiotic resistant. On the surface this seems to be a legitimate concern. But, if you scratch the coating of the argument, you will find big money interests. Most of these oral antibiotics are out of patent and there is little money to be made on them as compared to newer more expensive designer drugs. Old standby drugs, like Amoxicillin are critical to the cattle, dairy, and poultry industries, interests with large lobbying groups on Capitol Hill.

Somebody missed the point that unless they intend to close down these businesses and the border of the USA to all imported products, refugees, and migrating birds we will still have a problem with antibiotic resistance in the USA. Don't look now but antibiotic resistance is a GLOBAL PROBLEM and will need a GLOBAL SOLUTION. The problem will not be solved by taking away my oral Amoxicillin!

So where do we stand? Amazingly, I believe that we stand on the edge of finding a cure for TBDs:

- What makes Bb grow?
- What triggers it to go dormant?
- How does it enter the cell?
- How does it react with hormones and light?
- How does it reach and enter immune

privileged sites such as the brain and eye?

- What is the role of co-infections?

Until we have a cure for all TBDs there is much work still to be done.

The conference ended with a question and answer period followed by the slow dismantling of the tables, chairs and donated food. By the time we closed the doors and turned off the lights it was evening. As I walked down the darkened empty corridors towards the parking structure, I flashed back on a line from a song "...I be here in sunshine or in shadow...."

*O Danny Boy* was Paul's favorite

song. Clearly, his presence is still felt. I know that he would be very, very proud of the people that made this Conference possible. This ragged motley crew, patients, doctors, scientists and volunteers are the front line in a different kind of war. There is a strange thing about people who are fighting for their freedom, for truth or for their lives. They never give up. They can't be defeated. Enemies may kill them and millions may fall. But I'll bet on the Bay horse any day.

*All Rights Reserved, Copyright, Suzanne M. Smith, 2000. Not for publication or distribution without the author's written consent.*

## ILADS meeting focuses on progress and controversy

by Raphael Stricker, M.D.

*Excitement, hope, fear and loathing.*

That was the gamut of sentiments expressed at the Second Annual Meeting of the International Lyme and Associated Diseases Society (ILADS). The all-day meeting was held on February 24, 2001, amidst the beautiful snow-covered but tick-infested wilds of Warren, New Jersey. About 50 conference attendees listened to talks covering tick sex, clinical conundrums, treatment treatises, Machiavellian Lyme politics and medicolegal *Borrelia* battles. Needless to say it was a stimulating day.

The meeting opened with a reading of the ILADS Mission Statement by Dr. Nick Harris, chief executive officer of IGenEX Laboratory in Palo Alto, California. The mission of ILADS is "to create an interdisciplinary forum for health science professionals to communicate their collective wealth of knowledge about the management of Lyme and associated diseases". The ultimate goal of ILADS is to provide successful treatment regimens for patients suffering from these diseases, and

thereby establish "new standards of excellence in medical care".

Meeting attendees were then treated to a rousing tick talk by Dr. Jim Occi, a microbiologist at Merck Pharmaceuticals who said that ticks were his "hobby". Dr. Occi covered the natural history of Lyme disease, stressing that birds and mice are becoming more important reservoirs for the *Borrelia* spirochete. These animals do not transmit Lyme disease directly, however, and a tick vector is needed for this purpose. He showed graphic photos of ticks having sex while riding on deer, which he described as "four-star bed and breakfasts" for their passengers. He also made points about ticks being active even in snow-covered winter landscapes such as nearby New Jersey state parks, and he provided visual proof that ticks can be the size of real poppy seeds. Dr. Occi closed with the alarming observation that transmigration birds can carry spirochetes between continents, setting up new possibilities for the spread of Lyme disease.

Jumping from the woods to the

workbench, Dr. Harris discussed the laboratory evaluation of the three most common tickborne diseases: Lyme disease, Babesiosis and Ehrlichiosis. He stressed that no single test may be sufficient to make a Lyme disease diagnosis. Rather, a battery of tests including the Lyme Urine Antigen Test (LUAT), as well as blood and urine molecular testing for the *Borrelia* spirochete using the polymerase chain reaction (PCR), may be necessary to confirm the presence of the disease. He revealed the exciting news that two new Lyme tests should be available shortly from IGeneX: the Lyme Antigen Dot (LAD) and Lyme Reverse Western Blot (LRW). These new tests should provide much-needed help in making the diagnosis of Lyme disease.

Moving from the laboratory to the bedside, Dr. Richard Horowitz discussed problems with coinfections in Lyme disease patients. He stressed that drenching sweats (both day and night) combined with flushing are the hallmarks of Babesiosis, another tickborne pathogen similar to the malaria parasite that can be transmitted along with the *Borrelia* spirochete. Treatment of Babesiosis is still in evolution, with the older regimen of Mepron and Zithromax giving way slowly to Lariam and Doxycycline. Dr. Horowitz presented two difficult cases from his practice, stressing the complexity of coinfections and the clinical challenges to physicians who try to care for these chronically ill patients. He also made one of the most important points of the meeting, stating that antibiotics may not be a sufficient means of treatment in some cases and that immune-boosting therapy combined with antibiotics would be superior, if only we knew how to do this. Ironically or fortuitously, his thoughts echo much of the current thinking about the treatment of AIDS, another challenging and complex disease.

Next, Dr. Eric Lerner presented an alternative practitioner's view of Lyme disease. After wading through the concepts of Yin and Hue Chi and

dissecting Yang, Dampness and Spleen, he described Lyme disease as a "Knobby Disease" with many layers according to the emotional/spiritual/physical dynamic of Chinese medicine. He discussed the use of herbs such as Cordyceps and milk thistle, and he said that he obtained his herbal compounds from only three companies in order to assure purity and lack of adulterants. He defined a Herxheimer reaction, the die-off of spirochetes with Lyme treatment, as a "healing crisis". Since as many as 75% of Lyme patients use herbal and alternative medications, Dr. Lerner's talk gave a valuable perspective on the theory behind these treatments.

Shifting back to Western medicine, Drs. Stephen Philips and Andrea Gaito discussed autoimmune aspects of Lyme disease. Dr. Philips presented a patient with a very high antinuclear antibody (ANA) blood level of 1:10,000 that usually accompanies a rheumatologic disease, systemic lupus. However the patient responded well to antibiotics for her Lyme disease, even though her ANA level remained elevated. Dr. Gaito made the point that in Lyme disease, joint fluid is often negative for spirochetes even by molecular testing with PCR. She referred to a recent article from the rheumatology literature showing that the inflammatory mediators in joint fluid from infectious, traumatic and osteoarthritic joints are very similar. This observation suggests that all joint inflammation may be mediated by a common pathway regardless of the cause of the joint disease. Another implication is that infection may be at the root of all forms of arthritis, as suggested for many years by a group called the Roadback Foundation that advocates long-term antibiotic therapy for arthritis (*See the Lyme Times, Spring 2000, p. 40*). Dr. Gaito suggested that the new anti-inflammatory drug Etanercept (Enbrel), which is only approved for rheumatoid arthritis, may be useful for Lyme arthritis as well.

## Lyme literacy a global problem

A bittersweet highlight of the meeting was a presentation by Dr. Laurence Meer about Lyme disease in Switzerland. Dr. Meer reviewed the various types of *Borrelia* species in Europe that tend to cause a different pattern of skin lesions and more neurologic disease than their American cousins. She pointed out that the diagnosis and treatment of Lyme disease in her country is plagued by the same problems as in the USA, including unreliable laboratory testing, poor treatment guidelines, and physician unfamiliarity with Lyme disease and its coinfections. She called for an international congress on Lyme disease to discuss these issues. Her colleague, Dr. Werner von Lorber, then gave a chilling account of a medical meeting in Switzerland at which one of the senior academicians, after listening to Dr. Meer's presentation on Lyme disease and Babesiosis, tried to discredit her work because "those diseases don't exist in Switzerland." Obviously Lyme literacy is a global problem.

In the afternoon session, Dr. Robert Bransfield led off with a discussion of neuropsychiatric aspects of Lyme disease. Dr. Bransfield, a psychiatrist who oversees an invaluable Internet discussion group on Lyme disease, pointed out the growing list of infectious agents that are linked to neuropsychiatric diseases, such as *Streptococcus*, Cocksackie virus and *Mycoplasma* in obsessive/compulsive disorder, Herpes simplex virus in Alzheimer's disease, and Epstein-Barr virus in chronic fatigue syndrome. He emphasized the importance of maintaining deep sleep at night in patients with Lyme disease by using older or newer antidepressants, and he touched on the role of stimulants in patients with profound fatigue. Another psychiatrist, Dr. Bernard Raxlen, presented the case of a six-year-old boy from Brooklyn who was diagnosed with acute schizophrenia. After failure of psychotropic medications, a diligent history revealed that

## Yes! I'd like to give a year of the Lyme Times...

Please begin a one year subscription of the Lyme Times for \$25\*...

- as a gift      • for myself      • Special Offer      • this is a renewal
- I enclose an extra \$10.00 for a packet of 5 back issues.
- I enclose \$\_\_\_\_\_ as a tax-deductible contribution to the LDRC.
- Enclosed is my check or money order for total amount of \_\_\_\_\_. *Please make your check payable to LDRC and mail with this form to LDRC, PO Box 707, Weaverville, CA 96093.*

**My  
Name**

**Gift  
For**

Please print

30

Street

Street

City

City

State

Zip Code

State

Zip Code

\* Annual rate for the US. Canada and Mexico add \$10.00, other foreign countries add \$15.00 for air mail. US funds only, please.

Take advantage of our special bulk rates for your rally or conference. Write LDRC, PO Box 707, Weaverville, CA 96093. Allow 2-3 weeks for delivery; more for large orders (over 100). Offer good while supplies last.

**Bulk  
Rates**

clip and mail

the family had vacationed on Block Island, where the tick population abounds. The boy's Lyme Western Blot test was negative by Centers for Disease Control (CDC) criteria, but his LUAT was positive. He was treated with antibiotics, and his psychiatric symptoms disappeared. Dr. Raxlen made the point that psychiatric disease in a very young patient should always trigger the suspicion of Lyme disease.

Another aspect of Lyme disease was presented by Dr. Ritchie Shoemaker, who views the disease as a neurotoxic illness induced by Borrelia toxins. These toxins cause an abnormality in a test called Visual Contrast Stimulation (VCS), which can be used to monitor treatment of the disease. Dr. Shoemaker advocates oral treatment with a resin called cholestyramine to flush out the Lyme

toxins. He pointed out that cholestyramine should only be used under three conditions: if there is proven Lyme disease, if the disease has already been treated with antibiotics, and if there is no coinfection with Babesiosis. The mechanism of toxin damage is thought to be due to alteration of circulating blood factors called cytokines, and cholestyramine may work by increasing one of these cytokines known as tumor necrosis factor. Studies of cholestyramine in Lyme disease are now in progress.

The remainder of the meeting focused on political and medicolegal aspects of Lyme disease. Pat Smith, director of the Lyme Disease Association, discussed the recent Food and Drug Administration hearing that questioned the safety of the current Lyme vaccine. She noted the difficul-

ties in passing legislation to improve Lyme testing and treatment because lawmakers are reluctant to challenge the CDC criteria that have shackled research on the disease for many years. Although the pattern of investigating practitioners who treat Lyme disease has continued over 10 years, Pat felt that lately the press has presented a more balanced view of the Lyme controversy and was more sympathetic to physicians like Dr. Joseph Burrascano, who is being investigated by the New York State Medical Board. She also pointed out that the military has been very concerned about tickborne diseases and now impregnates its uniforms with permethrin, a tick repellent. Extensive research on these diseases has apparently been carried out by the armed forces for years with little fanfare.

Dr. Burrascano was scheduled to speak at the meeting but was unable to attend. Instead, attorney Michael Schoppmann delivered an excellent talk on medicolegal investigations performed by the "two-legged ticks" that suck blood out of Lyme practitioners. The attorney noted the importance of documenting clinical problems and their progression or resolution while treating Lyme disease patients. He stressed the need to consider other diagnoses and to involve consultants in the care of these complex patients. All of these medicolegal factors are important in defending the Lyme practitioner against prosecution. Another attorney, Andy Schlafly, discussed harassment issues for physicians, including the staggering economic impact of a medical board investigation. As dusk descended and the temperature outside dropped below freezing, the attorneys reminded meeting attendees involved with Lyme disease that it really is a cold world out there.

In a sense, the ILADS meeting fulfilled Dr. Meer's call for an international conference on Lyme disease. The meeting brought together practitioners from around the world to share their experiences in treating tickborne diseases. A striking aspect of the meeting was the uncanny similarity of these worldwide experiences from Switzerland to Santee. For a disease whose very existence has been questioned, the meeting was a watershed of knowledge, encouragement and hope for the future. Sadly, both the morning and afternoon sessions ended with reminders of Lyme illiteracy around the world. Just as true illiteracy continues to be beaten back by education, Lyme illiteracy will hopefully give way to the ILADS goal of broader medical awareness and improved patient care in nations everywhere.

*ILADS kindly permitted Dr. Stricker to attend their conference as a reporter from the Lyme Times. For more information about ILADS, see their website at [www.ilads.org](http://www.ilads.org).*

## Calendar

### LYMEAID 2001

Gettysburg, Pennsylvania

10 am

Saturday, August 11

An outdoor country music Festival, "Country Fire On The Mountain," will take place on the slopes of Liberty Mountain outside of Gettysburg. The festival will open at 10 am with craft booths. Bands and country music singers will perform from noon until 8:00 pm. Nashville entertainers who will perform are: Chris Cagle; Marshall Dyllon Band; Tammy Cochran; T. Bubba-comedian and quest MC. Local talent includes-Borderline and Amanda Perko. Tickets go on sale 6/1/01 for \$20 at [www.ticketweb.com](http://www.ticketweb.com) (Key in PA, then LYME AID to order the tickets.) or call 1-866-468-7519.

T.O.F.U., INC. (Ticked Off and Fed Up, Inc.) is a nonprofit 501(c)(3) Charity organization for victims of Lyme disease. The T.O.F.U. mission includes grants, education and research. Send tax-deductible contributions to: T.O.F.U. Inc., 2389 Chambersburg Road, Biglerville, PA 17307. LYMEAID is a Country Music Festival to be held at Ski Liberty. 10,000 people are expected. The purpose is to raise money to help the victims of Lyme Disease and other worthwhile projects.

### TBD patients sought for Bartonella testing

University of California at Davis researcher Dr. Bruno Chomel is interested in testing patients infected with tick-borne diseases for Bartonella sp. Bartonella has been found in Ixodes ticks and a confirmed human case of Bartonella was reported from San Jose, California, recently. For more information or to participate in the Bartonella study, please contact Dr. Chomel at (530)752-2377.

## Tick-Borne Diseases Conference

University of Hull

East Yorkshire, England

Saturday/Sunday,

September 1-2

The Tick Borne Diseases Conference will take place at the University of Hull, Cottingham Road, Hull, East Yorkshire, England. It is Lymearduk's (Lyme And Related Diseases in the UK) first conference. Members are expected to come from Europe and the United States.

For more information, email Gill Reese at [gilly848@ntlworld.com](mailto:gilly848@ntlworld.com). More detail will be provided in the next Lyme Times.

*If you are not on the Lyme Times mailing list, this issue is being sent to you compliments of the Lyme Disease Association. Please help the fight against Lyme by subscribing. Use the form inside the back page.*

the Lyme Times  
Lyme Disease Resource Center  
P.O. Box 1423  
Ukiah CA 95482

Non-Profit Organization  
PRSRT STD  
US Postage Paid  
AutoZIP