

the Lyme Times

NUMBER 28

Education, Support, Advocacy, Research

SPRING 2000

Vaccine recipients needed for class action lawsuit

A class action lawsuit was filed on Dec. 14, 1999 by the Sheller, Ludwig & Bradey law firm of Philadelphia against SmithKline Beecham (SKB), the manufacturer of LYMERix, the first human vaccine against Lyme disease. They are seeking people who have experienced adverse reactions after receiving the vaccine to participate in the suit.

The plaintiffs allege that the vaccine may cause permanent, intractable, degenerative arthritis in the one-third of the population with the HLA-DR4+ gene. There is a simple, albeit expensive, blood test to detect the gene. SmithKline Beecham knew about the problem, litigants allege, but did not inform the doctors who were giving the vaccine. The vaccine may also trigger latent Lyme

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Inside...

Connecticut group organizes successful fundraiser for Lyme research

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Patient support needed to promote major Lyme Bill

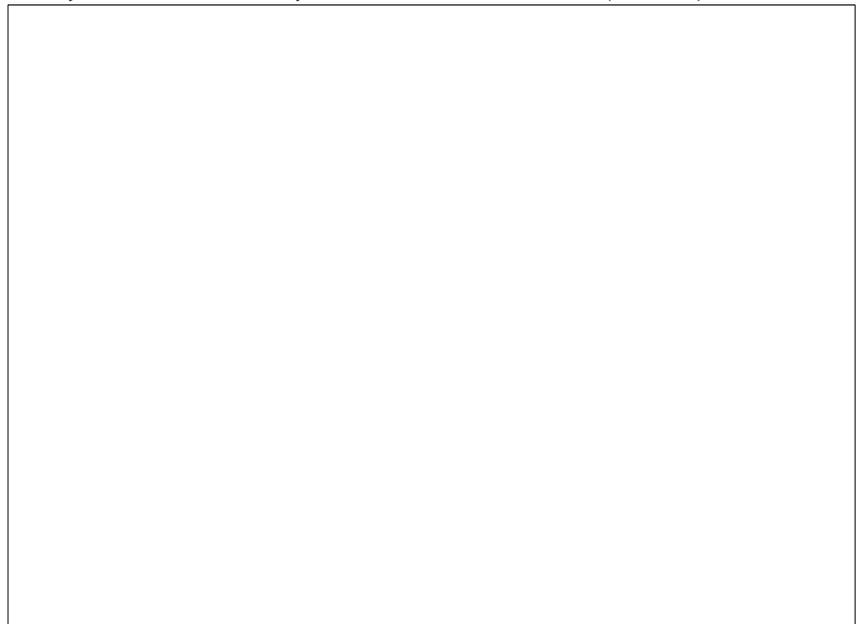
The Lyme Disease Initiative 1999 (HR-2790) is the product of several years of work by members of the New Jersey Lyme Disease Association (NJLDA), the Pennsylvania Chapter of NJLDA, and US Congressman Christopher Smith. A 1998 version was introduced, but without enough time left in the legislative session to pass it. The bill was revised and improved with input from both the Lyme disease community and federal

agencies and reintroduced in 1999. The Lyme Disease Resource Center and many other patient advocacy groups signed on in support of the bill. More congressional support is now needed to move it out of the House committee, and several more senators to move the Senate version (S-1905) which is sponsored by Pennsylvania Senator Rick Santorum.

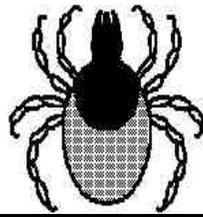
The legislation will provide \$125

See Lyme Bill on page 29

(L to R) US Senator Rick Santorum (Penn.), Patricia Smith, President of Lyme Disease Association of New Jersey, Mary Halinski, Director, PA Chapter LDANJ, US Congressman Joe Pitts (Penn.) met at a press conference in Pennsylvania to discuss the Lyme Disease Initiative 1999 Bill (HR 2790).



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From the Editor

Dear Readers,

This issue of the Lyme Times is particularly rich in its many contributors. In an effort to generate more interesting discussions about our favorite subject, we have included several sections to showcase the efforts of some thoughtful and intelligent individuals. We are delighted that at least one, Virginia Sherr, MD, wants to become a regular in the Lyme Times. She reports from the "Front Line" of her Pennsylvania psychiatry practice. We hope you enjoy the diversity of opinion.

We greatly appreciate the efforts of those who are working on many fronts to improve the situation for Lyme disease patients. While we may not all agree about the best way to proceed, everyone must utilize his or her own unique talents and opportunities in the way s/he deems best. People, especially volunteers, deserve our respect and our thanks for their efforts. Please remember to moderate your criticism and to thank someone who is trying his/her best to make your life easier.

Thanks to A. Lautin, MD, for the following excerpt, which seems to apply well to our current situation in Lyme disease.

When questioned about his pioneering surgical interventions in Parkinson's disease and related disorders, Irving Cooper (1922-1986) wrote: "I am somewhat puzzled by

your request for justification for alleviating the total incapacity of Mrs. M.... I am a doctor. It is my legal and moral responsibility to try to make sick people well. I have for many years refused to apologize for the therapeutic benefit of these operations simply because results could not be immediately explained by laboratory of clinical scientists on the basis of existing physiologic ideas — ideas which ultimately were demonstrably false. If I may quote a remark that Sir Peter Medawar made ... 'It is a doctor's job to do good. It is a scientist's job to explain the facts' I invite Professor Wall, as a scientist, to examine the unprecedented facts emerging from this experiment to explain them. If the facts do not fit his present concepts, then he will have to rethink the concepts because the facts will not change ... these are the facts. If we cannot entirely explain them now, they will, nevertheless, not go away. Eventually we will understand them, and they will teach us more about the brain. In the meantime they have made some sick people well — and that is the role of the doctor.'" (Irving Cooper, cited by Macdonald Critchley)

Phyllis Mervine, Editor

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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.

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Number 28**Guest Editorial****The new Lyme vaccine – is it for you?**by **Teresa Royer MacKnight, D.O.**

In January, 1999, TV news stations announced that Maine was the first state to approve the use of the recently FDA released vaccine LYMERix. The potential for Lyme disease to cause long term illness has been one of the major motivating factors in the vaccine development effort. SmithKline Beecham, a British pharmaceutical company which has its US base in Philadelphia, Penn. developed LYMERix. Pasteur Merrioux Connaught of Swiftwater, Penn. is a branch of a French company applying for licensure of a similar vaccine. The financial stakes for success are high with the estimated annual sales predicted to be over \$200 million.

The Lyme Disease Network, an Internet Lyme information and support organization, posts at their web site the following statement; “Although the FDA approval of a Lyme vaccine would obviously be welcome news, the recommendation for approval did not come easily and was accompanied by several important caveats.”

Dr. Patricia Ferrier of the University of Minnesota, who chaired the FDA committee said, “It’s rare that a vaccine be voted on with such ambivalence and a stack of provisos.” As with any new vaccine the big questions are, “Is it safe?” and, “Is it effective?” To begin to answer these questions one must understand how the vaccine works.

Both Lyme vaccines use a protein found on the outer surface covering of the Lyme bacteria called “OspA.” After the vaccine (OspA) is injected into a person, it causes the body to produce anti-OspA antibodies. When a tick bites a vaccinated person, these new antibodies enter the tick

when it takes in their blood. The antibodies attack the OspA protein on the Lyme bacteria while the germs are still inside the tick, *hopefully* killing them before they can be passed on to the person.

The vaccine’s success appears to be dependent on critically high levels of anti-OspA antibodies, as reported in the Jan. 1999 issue of the journal “Infection and Immunity” by Drs. Nowling and Philipp.

Disturbing news is that recent research has linked the development of severe arthritis in humans and animals to the vaccine’s OspA protein and the antibodies it induces.

Allen Steere, M.D., et.al., in the same journal mentioned above, reported that elevated anti-OspA antibodies were being found in patients with chronic Lyme arthritis. According to their research higher levels of the antibody correlated with more severe and prolonged cases of arthritis. Dr. Ron Schell, Ph.D. from the University of Wisconsin has been studying the effect of the OspA protein when given to animals. He has observed the development of degenerative arthritis in animals after receiving the vaccine. According to these studies, anything that boosts the level of OspA antibodies should be approached with extreme caution until more is known about its effect in humans.

Clouding the issue further is that previous research has shown that a specific subset of patients with the HLA-DR4 genetic marker are more likely to develop chronic arthritis when infected with Lyme disease. Thus concern has been raised that the vaccine could trigger arthritis in this unidentified genetically vulnerable

population, basically people who have this marker but don't know it.

Attorney Ira Maurer of New York has represented several individuals who claim to have been harmed by the vaccine. He states, "Not enough research has been conducted regarding the safety of administering the vaccine to persons who might have been exposed to the Lyme organism prior to vaccination." This particular issue is complicated further by the lack of a sensitive screening test to identify individuals who may unknowingly already be infected with the Lyme bacteria.

According to Dr. Denise Foley, a professor and researcher at Chapman University near Los Angeles, the vaccine does not offer protection against all strains of the Lyme bacteria found in the US. Strains from different geographic locations vary in their protein structure.

To sum things up, at this point researchers don't know how to accurately screen for those individuals who might be at risk for a potential adverse reaction to the vaccine. They don't know the level of antibody required to guarantee protection against Lyme disease. They don't know how many boosters will be required and whether they will be safe in the long run. Presently no boosters are approved by the FDA.

The Lyme Disease Network's "Vaccine Position Paper" on the Internet (www.lymenet.org) presents the dilemma patients will face when making the decision whether to get or not to get vaccinated for Lyme disease.

"Potential vaccine recipients will have to balance the vaccines 76% efficacy rate against its more nebulous safety picture."

Dr. MacKnight is the Executive Director of the Maine Lyme Awareness Project, an organization of Maine citizens concerned about Lyme disease. She may be reached at 207-392-1302.

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.

Fight for mandatory medical disclosure laws

Please share the concept of mandatory medical disclosure laws with your support groups and ask them to begin a letter writing campaign to their State and National congressmen and congresswomen to get some legislation proposed. I think it is high time we had access to the economic resume of our so called "neutral advisors." I sure want to know if my doctor is receiving undisclosed profit from the prescription he writes for me to take!

Realtors have disclosure laws, financial advisors have disclosure laws--why not doctors and researchers who are involved in deciding human health care standards and practices? I think it comes under a patients right to know. And too, any university that receives public or private funds for research related to human health care should be required to disclose on an annual basis the sources and amount of revenue received. Also, any so called professional publication which discusses issues related to human health care should be required to disclose the sources of their revenue. I mean if, for example, JAMA says some treatment is the greatest thing since sliced bread, is the Company that makes this wonder drug their primary source of advertising revenue? What exactly did Smith Kline or Pfizer or others contribute to JAMA's bottom line last year? I sure would like to know.

I am tired of being sold the Brooklyn bridge of Lyme treatments. Medical consumers need protection and we need it now! I believe that doctors and researchers should have a right to profit from their inventions but I also believe that patients have a right to know that their "neutral

advisors" may not be so neutral!

**Suzanne MacDonald Smith
Mendocino, California**

The Lyme Times is supported entirely by subscriptions. Our occasional advertisements are clearly marked.

Physician awed by patients' "cognitive rebirth"

I recently began treating a pilot (years ago an avid hunter and woodsman) who has been sick for a decade with what I now find is Lyme disease. He stopped flying shortly after becoming ill, and only a few years ago began to work again as a ground simulator instructor.

As I was unaware of *Borrelia* and its treatment until about 8 months ago, I was unprepared for what happened as this patient progressed with his antibiotic regimen (Amoxicillin and Probenecid). His personality literally changed form. His energy increased, as did his directness of communication and his involvement with others and events in his environment. To me, it was like seeing a "cognitive rebirth"; almost like a child seeing the world for the first time. There are just no good words to describe my reaction to seeing this man change so dramatically.

Encouraged, I have 9 people on the same simple regimen. All are responding in measurable ways, some physical, some cognitively. None are yet completely "well", including the pilot. But NOTHING has impressed me more than seeing personalities literally change in ways that must be somehow measurable. In these few months I've become a believer...first, that *Borrelia* must exist

in Chronic Lyme, and secondly, that it exists in the brain.

So, on we go. I plan to continue treating these people until I/we can find an end point without remission, if that's possible. I remain intensely grateful to physicians in the North-east from whom I've copied this protocol. And with this unbelievable metamorphosis I'm witnessing, I hold those physicians in highest regard. They had the courage to persist with long-term antibiotics in the face of intense criticism. Now I know why.

anonymous physician

Dosing schedule, medications must be individualized

Thanks for the excellent publication. Any time you can, I advise these Lyme victims, especially the chronic ones, to share their dosing ritual. In a recent issue I read a story about a 55-year old lady who had undiagnosed Lyme for five years. She finally mentioned the name of the IV medicine she went on and bless her heart she's back to normal. I have hope with similar but worse symptomatology.

**Silvia Jauchler
New Orleans, Louisiana**

While the Lyme Times may from time to time mention a particular person's treatment regimen, your own physician should be making these decisions based on your own individual situation. In the case of an inexperienced doctor, the Lyme Times has an extensive database and is willing to put such doctors in touch with Lyme specialists for detailed information on treatment.

Lyme has not done me any favors

I have had Lyme disease since 1991. It has pretty much wrecked my life. My beloved career as a school counselor is gone, my college professor husband wanted "an equal

partner, not a burden" and walked out for a healthier woman. I've gained 60 pounds and walk with a cane. My memory is very poor. I'm 56. My dad wants me in an institution or a nursing home. My mother's not living. My children are married and live far

away. It's not the life I had in mind by a long shot.

Thanks for listening. Keep up the good work.

**Lynda Lowney
Macon, Georgia**

Opinion

The Ostrich Mentality

by **B. Ziegler, M.D.**

One needn't be a prophet to be able to predict that in Germany, Lyme disease is declining.

This is no zoological phenomenon (perhaps through lower infection rate of ticks, or better protection against tick bites), nor a result of earlier recognition, nor thanks to the health authorities (perhaps through promotion of vaccination), nor because of statistical error. No, the decline is due plainly and simply to the July 1, 1999 laboratory reform decreed by the federal medical board of physicians, which states:

1. For members of health insurance plans, the immunoblot may only be used to confirm a positive EIA antibody test.
2. For members of health insurance plans, the PCR is not an acknowledged procedure for borreliosis.
3. Lab services will be charged to the person ordering the service (money for service). In other words, if you don't do anything, you get something, and if you do something, you don't get anything!

The one who orders the service (i.e. the treating physician) isn't going to give a damn if the patient receives a more sensitive test if s/he (the physician) has to pay for it! Without doing anything (as in the case of accepting a kickback), the physician is inclined to an action, in this case a NON-action, and his/her ethics are compromised. It is a perfect example of the view that in the context of

professional ethics one must always examine the personal materialistic vested interests of whoever is either ordering or NOT ordering services. In other fields of laboratory medicine, the NON-service is being similarly remunerated. The statistics will show this, naturally without explaining the true causes:

- Decrease in the number of cases of cancer - through limiting diagnostic tests to two;
- Decrease in cases of salmonella - by eliminating microbiological tests.

And responsibility for these successes will be claimed by various groups (federal medical board, health departments, statistical offices, employers' representatives, self-help groups, ...etc) as a supposed result of their own activities....

Meanwhile, the only thing that continues to rise is the rate of chronically ill people without a diagnosis, i.e., the "hypochondriacs" and the "death from unknown cause."

Three facts should not be forgotten:

1. Laboratory diagnostics is the decisive factor in 70% of diagnoses.
2. What you don't look for, you won't find.
3. There is only one enemy to ethics - materialistic self-interest.

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Commentary

Demonstrating the intracellularity of *Borrelia burgdorferi*

by Harold Smith, MD

“The theory that the organism becomes intracellular within a human has never been demonstrated.” Leonard Sigal, M.D. in a deposition 8/12/96.

Often the fact of intracellularity is discounted or dismissed by those who view borreliosis as a simple, easily cured infection. Intracytic existence is a fundamental concept in understanding the persistence of spirochetal infections in humans—syphilis, leptospirosis, borreliosis and spirillum infections. This goes back almost a hundred years to the observations of a Dr. Wilbur Winkler and more recently to Lida Mattman.

There is quite a bit of Russian and European literature on the subject of intracellularity. In the US, researchers interested in chronic Lyme disease went down the trail of immune incompetence and molecular mimicry and disregarded a wealth of information about spirochetes that dovetails in very well with chronic infection. Numerous studies have demonstrated that *Borrelia* have the equipment to invade intracellularly.

Although we lack the Sigal's exact definition of “demonstrated,” Webster’s Dictionary states that “to demonstrate” means “to prove or make clear by reasoning or evidence, to explain especially with many examples. We can therefore “demonstrate” that the Lyme organism does become intracellular.

1. *Borrelia burgdorferi* (Bb) possesses the capability to penetrate cell walls or junctions. Burgdorfer showed that borrelia, when faced with the incoming blood meal, leaves the tick gut endothelium by invading the tick’s gut wall and spreading via the hemolymph to the salivary apparatus. Linden reveals that Bb binds human

plasminogen to surface proteins. (Inf Immun 1995;Sept:3491) When this is converted to plasmin it provides the mechanism whereby Bb can digest the extracellular matrix and penetrate cell walls using the host’s own enzymes. It is obvious that Bb has the evolutionary practice and the equipment to penetrate.

2. Once in the skin, Bb are internalized into dendritic cells, both blood-borne and originating in the skin. Figueira et al disclosed by electron microscopy of a human skin biopsy that some are located “free “ in cytosols and others are in phagolysosomes, i.e. some are killed and some are not. (J Immun 1996;157: 2998-3005)

3. Ying Ma used human umbilical cord endothelial cells in culture to take up Bb into the cell bodies. Within 24 hours up to 25% of Bb was internalized. “Thus the *demonstration* [authors’ emphasis] of Bb within endothelial cells suggests that intracellular localization may be a potential mechanism by which the organism escapes from the immune response of the host and contributes to persistence of the organism during later stages of Lyme disease.” (Inf Immun 1991;Feb:671-78)

This is how we suspect Bb invades cells—first into the vessel lining and then into the tissue cells.

4. Dorward et al wrote: “We found that Bb actively attaches to, invades, and kills human B- and T-lymphocytes—significant killing began within 1 hour of mixing. The results

suggest that invasion and lysis of lymphocytes may constitute previously unrecognized factors in Lyme disease.” (Clin Inf Dis 1997;25 Suppl 1 S:2-8. Invasion and cytopathic killing of Human Lymphocytes by Spirochetes Causing Lyme Disease.)

I think that Dorward’s discovery of Bb attaching to lymphocyte surfaces and later releasing with a lymphocyte coating may be a more universal pattern of Bb behavior with other cells than those Dorward portrays-- i.e. borrelia enfolds in fibrocytes, macrophages, and synovial cells without always penetrating. Does this mechanism then stimulate low-grade autoimmunity as the host tries to recognize danger at the same time co-stimulated by an attached sequence of self antigens?

5. Although Bb often is not found with silver staining, when tissue is studied by DNA analysis, Bb is present. This is evidence that the Bb are intracellular and thus not seen with silver staining but found when tissue extracts are analyzed for Bb DNA. (Priem. Ann Rheum Dis 1998; Feb 57:118-21. Detection of Bb by PCR in synovial membrane, but not in synovial fluid from patients with persisting Lyme arthritis after antibiotic therapy.)

6. Nanagar and Duray used electron microscopy with immune features to localize spirochetal antigens within vacuoles of fibroblasts and cytophagosomes of mononuclear cells. They suggest sites at which spirochetes may elude host immune response and antibiotic treatment. (Human Pathol 1996; Oct 27:1025-34)

7. Dennis Grab et al provide fascinating evidence that when human fibrocytes are cultured with Bb, the Bb binds deeply into the cell membrane in a coiling fashion and thus is carried to sites of injury, while at the same time protected from attack by the immune system. (Molecular Medicine 1999; 5: 46-54)

8. This also may be why when

human foreskin fibroblasts were cultured with Bb and then ceftriaxone was added, the Bb survived for at least 14 days of exposure. When fibroblasts were absent, Bb did not survive. (Georgilis et al. JID 1992;166:440)

9. Next we have isolation of Bb from biopsy specimens taken from healthy looking skin of patients with Lyme borreliosis (Kuiper. J Clin Microbiol 1994 Mar;32:715-20) Six patients had Bb present from the healed site of EM up to 6 months later by culture and PCR but not by silver staining. Intracellularity would explain this discrepancy.

10. Likewise in PCR reaction for detection of Bb DNA in skin lesions of early and late Lyme borreliosis, von Stedingk found that over 60% of these skin biopsies had Bb DNA which were negative after antibiotic treatment, but staining could not demonstrate Bb. (Eur J Clin Microbiol Inf Dis Jan 1995;14:1-5)

Where were they?

11. Using electron microscopy of human ECM, Hulinska found vacuolated Langerhans cells releasing debris of Bb into lymphocyte infiltrates. (Int J Med Microbiol Virol Parasitol Infect Dis 1994 Jan;280:349-59)

12. Again with electron microscopy Hulinska showed that Bb spirochetes were discharged into human leukocyte's cytoplasm but were not surrounded by phagosomal membranes.

"This could be one of the possible mechanisms of persistence of Bb in the host organism." (JSTD 1995;2:82-86)

13. Rittig et al incubated human peripheral blood monocytes, leukocytes, and synovial macrophages with Bb. Then, with light and electron microscopy they found that the cells took up the spirochetes intracellularly with multiple abnormal patterns such as leaky lysosomes, invagination of large membrane areas and formation of giant cells and clusters with Bb inside.

"Moreover, these results may provide new insights into the pathogenesis of other infectious diseases characterized similarly by microbial persistence." (J Pathol 1994 Jul;173(3)269-82)

14. Aberer et al used precise three dimensional video microscopy with immunohistochemical staining to demonstrate all the variant forms of Bb. In humans these forms have the same appearance as those seen in vitro cultures. At the same time Bb are seen intracellularly in macrophages and keratinocytes of the skin. (Amer J Derm 1996;18:571-579)

15. Klempner et al used human fibroblasts and electron microscopy to show Bb were attached to the cell surface of fibroblasts after 24 to 48 hours of incubation but were eliminated from the cell surface by 5 days of ceftriaxone. Yet Bb were still culture viable from the lysates of fibroblasts and found intracellularly in the perinuclear region within human fibroblasts by laser scanning confocal microscopy.

"These observations suggest that Bb can adhere to, penetrate, and invade human fibroblasts in organisms that remain viable." (J Infect Dis 1993;167: 1074-81)

16. Of course mice aren't human, but they are part of the chain of evidence from tick to mouse to tick to human—so we are allowed to apply logic in our "demonstration."

By scanning confocal microscopy at multiple times after infection, Malawista et al clearly demonstrated Bb spirochetes living within macrophages.

"Persistence of spirochetes within macrophages provides a possible pathogenetic mechanism for chronic or recurrent Lyme disease in man." (J Immunol 1993 Feb;150:909-15)

17. Wadstrom found that "glycosaminoglycan-binding microbial proteins may mediate adhesion of microbes to eukaryotic cells, which may be a primary mechanism in mucosal infections and are also

involved in secondary effects such as adhesion to cerebral endothelia in cerebral malaria or to synovial membranes in arthritis caused by *Borrelia burgdorferi*." (J Med Microbiol 1999 Mar;48(3):223-33)

This article provides more information about how Bb penetrates cells by attaching.

18. Girschick et al found that Bb persist in resident joint cells using human synovial cells compared to macrophages.

"*Borrelia burgdorferi* were found attached to the cell surface or rolled into the cell membrane of synovial cells analyzed by transmission electron and confocal laser scanning microscopy. In contrast to macrophages, morphologically intact Bb were found in the cytosol of synovial cells without engulfment by cell membrane folds or phagosomes. Treatment with ceftriaxone eradicated extracellular Bb but spirochetes were reisolated after lysis of the synovial cells. Bb persisted inside synovial cells for at least 8 weeks. (Rheumatol Int 1996;16(3):125-32.)

19. Girschick et al found "*Borrelia burgdorferi* downregulates ICAM-1 on human synovial cells in vitro."

Downregulation of ICAM-1 surface molecules results in less adhesion of mononuclear cells to the synovial cells and subsequently suppression of local immunosurveillance. This enables Bb to persist in joint cells of humans and partly explains the mechanism whereby intracellular Bb in synovial cells block immune recognition even though living within cytosols of the synovial cells. (Cell Adhes Commun 1999;7(2):73-83.)

20. One of the best summaries of intracellular concern is The Challenge of Intracellular Pathogens by Mahmoud in NEJM (March 1992;326;11:761-2) which outlines the dangers of intracellular replication.

And finally,

21. Roxithromycin: review of its

antimicrobial activity: "It also displays good activity against atypical pathogens, such as *Mycobacterium avium*, *Helicobacter* and *Borrelia spp.* It penetrates and accumulates within cells, such as macrophages and polymorphonuclear neutrophils where it is distributed between the cytosol and cellular granules. Once inside the cells, it is active against intracellular pathogens such as chlamydia... and *Borrelia spp.* Like other macrolides, roxithromycin displays a significant post antibiotic effect." (Bryskier et al. J Antimicrob Chemother 1998 Mar; 41 Suppl B 1-21)

In summary, there is ample evidence demonstrating intracellular pathology involving humans and *Borrelia burgdorferi*. Science is only as good as its hypotheses—and it is time to hypothesize that a cure for borreliosis in humans must involve intracellular eradication.

The autoimmunity of chronic borreliosis (molecular mimicry) is itself evidence of intracellular location—when the organism is coated with the host's own cell structures (thyroglobulin, myelin, nuclear debris, cardiolipin, etc.) and then recognized as partly microbe and partly self structure, the basis is set for persistent immune attack due to intracellular location. This also explains the elevated antimyelin antibodies, anti thyroglobulin, anti DNA, anti cardiolipin etc. frequently found in patients with chronic Lyme disease.

Borrelia is well demonstrated to have intracellular life cycles in humans and these facts help explain its pathology and lend direction to effecting a cure. Molecular mimicry is likely just some of the smoke of the real cause—i.e. persistent infection—with membrane-sharing between microbe and host cell stimulating combined antibody attack as one contributing cause of disease. Intracyclic existence is a reasonable model to explain much of the persistence of *borrelia* and evasion of antibiotic attack.

How belief systems affect progress in scientific research

by A.J. Lumsdaine

In an article about Post-Polio Syndrome from April 1998 Scientific American, author Dr. Lauro Halstead explained the reason it took nearly 40 years for the medical profession to take the suffering of these patients seriously.

He wrote, "Because there was little in modern medical literature about delayed neurological changes in polio survivors, the initial response by many physicians was that the problems were not real. For a time they were dealing with a cluster of symptoms that had no name—and without a name there was, in essence, no disease. Having a name—even if imprecise and misleading as to causation—at least confers an element of credibility."

We in the Lyme community know that the latter portion of this explanation is an incorrect supposition, a poor excuse. The first sentence of this explanation is key: paraphrased, it says the when many physicians are confronted with a problem they do not know or do not understand, they assume that it is not real.

It would be to the benefit of both the medical profession and patients with many diseases, including Lyme, if this very common belief (which translates into some unfortunate but very common practices) were examined for its scientific basis. It would be beneficial, at the same time, to systematically examine the consequences of this belief to research and health care delivery.

For example, the above article mentions that there are currently as many as 250,000 persons suffering from post-polio syndrome. What consequence has this systematic disbelief by the medical profession had to their health and well-being in the 40 years their problems were deemed "not real"? What consequence has this systematic disbelief had to the progress of research, to the search for answers? Does it, for example, translate to delays or biases in the formulation or interpretation of scientific studies? What consequence has this systematic disbelief had to the accomplishments and reputation of the medical profession as a whole? What positive benefit to society or medicine from this disbelief justifies these negatives?

Beliefs and behavior that have such profound and far-reaching effects in our society should be examined. It would certainly be beneficial for persons with Lyme disease, and many other diseases with nontrivial clinical profiles, if physicians could see a scientific review of the effects of this belief system; it would hopefully lead to research into and establishment of better practices for physicians confronted by patients with these kinds of problems. Just think how this would have sped up research on Lyme.

This problem did not just crop up with Lyme disease. Herculean political efforts by patients and their doctors usually help move things along for specific disorders, but they have never changed the belief system that made such efforts necessary, they have never prevented the same suffering for the next group of patients. Until a genuine effort is made to examine this belief system scientifically, we are stuck with it.

German Internet support groups

<http://www.borreliose.de/forum/index.html> and <http://www.f2.parsimony.net/forum2958/>

Front Line

Mea (non) culpa

by Virginia Sherr, M.D.

This is the first of Dr. Sherr's regular columns for the Lyme Times. Dr. Sherr practices psychiatry in the Lyme-endemic state of Pennsylvania. The Lyme Times welcomes readers' responses to this, as well as other articles.

Now that my "index of suspicion" has been raised, I sometimes I feel anguish over missed cases of TBD, though I know full well I am not blameworthy. I think of the bewildered man whom I saw as an intern 40 years ago. Because of normal labwork he was accused by his attending of creating low grade fevers by heating the thermometer on a lightbulb.

I recall the child slowly going brain dead while I was instructed by my residency supervisors that she was schizophrenic because all her evaluations were otherwise normal. More recently, I recall the euphoric bird-watcher whose sexually uninhibited delusional mania and on-off paranoid dementia were misdiagnosed as Alzheimers over my protests as one neurologist after the other decried the possibility of the Lyme which by then I was able to recognize clinically. He died, as did most of the others.

I think of the young girl with severe Crohns, medicating herself with cocaine and heroin to quell the pain yet feeding a growing addiction. I didn't know much of the Lyme connection then. Most of all I think about the anguished family of a man who I had treated for a depression 10 years before. They begged me, after a gruesome event just several years ago, "Why would he do such a thing? What could make someone like my father commit a heinous act? There must be an answer!" Now I recall that he had excruciating pain in his shoulder which the specialists could not explain and other symptoms of TBD as did all of these patients.

I wonder, should I open this up

with any of these families? How can I? How can I not? Where does my responsibility lie? I have no proof and the world of experts is against me. On the other hand, I am the only one who

has any clue as to what the real culprit likely is. Is it fair for me to withhold ideas and information which may save the sanity of another generation or two who have found other reasons to explain these dire events, for example, blaming themselves? What do I owe them, what do I owe myself? There are legal aspects to these answers. Like Hamlet, I hesitate. Perhaps so do all the newly Lyme literate, focussing on the living and on those in need of immediate help.

It would be good to know there are other doctors wondering about these same things.

Beginners' Pages

Lyme disease testing update

The riskiest season for Lyme disease is springtime, when nymphal ticks are active. These poppy-seed-size eight-legged creatures are so tiny that they are not easily noticed when they crawl on your skin and painlessly insert their mouthparts to feed. They live under hardwood trees in the leaf litter. Researchers collect them by slowly dragging a fuzzy piece of white flannel over the leaves. You may unintentionally acquire them by cleaning up your garden, sitting under a tree, or jumping joyfully into piles of leaves.

Although Lyme disease is often considered an "East Coast" disease, scientific studies of ticks in parts of northern California show that the density of questing nymphal ticks infected with Lyme is comparable to some of the highest densities of infected nymphal ticks ever recorded in the United States. According to a study published in 1999, the nymphal tick infection rate in one community was 12% (range 4-41%). The unexpectedly high 41% in one location caused the researchers quite a shock. More studies of the area are under way to see whether the high levels are consistent from year to year or

whether they fluctuate, and to try to figure out why.

This type of basic scientific study is very important for Lyme patients, because diagnosis of any disease depends upon the level of suspicion among health care providers that the patient has been exposed. In 1996, the Michigan Lyme Disease Association funded a study to look for Lyme disease in blood samples submitted by vets. They found significantly higher levels than those published by the Michigan Health Department. If a significant risk of acquiring Lyme disease exists, and doctors know about it, then the chances for a correct diagnosis are enhanced.

Some experts think that less than half the infected people display the classic Lyme rash, and the tests are inaccurate. So is it worth even getting tested? The answer is, "Yes." Research has come a long way in the past few years, and although many questions still remain, the tests can tell us something.

There are a couple of good labs for Lyme tests: IGeneX Laboratories in Palo Alto (1-800-832-3200) and BBI in Connecticut (1-800-866-6254). Both offer tests for other TBDs (tick borne

diseases), ehrlichiosis and babesiosis, as well. IGeneX has a good website (www.igenex.com) which describes their tests and when to use them.

Direct Tests

There are two kinds of tests: indirect and direct. The indirect tests are the most common and focus on the your antibody production. When infection occurs, normal people make antibodies to attack the specific germ. Antibody tests measure this response.

Antibodies to Lyme disease rise gradually in the first 6-8 weeks of infection. Tests done before 6 weeks are likely to have a negative result. Even after this time, some individuals do not have antibodies to Bb in spite of being infected. There is true seronegative Lyme, although experts disagree about how common it is. No one really knows yet.

Other people may have antibodies at some point but the production drops off by the time of the test. This is particularly true in people who have coincidentally been treated with antibiotics for another illness. Some people have such rampant Lyme infection that all their antibodies are occupied fighting the germs and are bound up in immune complexes.

The **ELISA** is the most commonly used antibody test. Unfortunately, it is not very sensitive, and may fail to detect up to 30% of people with actual Lyme disease, especially those with neurologic rather than arthritic manifestations. The Centers for Disease Control and Prevention (CDC) requires this test on all cases of Lyme reported for surveillance purposes, and recommends its use for clinical diagnosis also. Some doctors wonder why bother with ELISA when Western blot is so much more sensitive and specific.

The **Western blot** detects the immune system's reaction to specific Bb antigens. The test report looks like a bar code on a grocery item. Some of the proteins are unique to Bb, and if you have those antigens, there is

nothing else it could be besides Lyme. If the lab reports reactive bands (as IGeneX and BBI do), rather than a simple "positive" or "negative," your doctor can determine whether you have any Bb-specific bands. Even if you do not have the number required by the CDC to report your case, you might still have Lyme.

Direct Tests

The direct tests are ostensibly the "gold standard" and there are several direct tests for Lyme. The specimen to be tested may be a biopsy of skin from a suspected Lyme rash, tissue or fluid from an inflamed joint, or spinal fluid in the case of neurologic disease (neuroborreliosis).

The **polymerase chain reaction (PCR)** gained fame in the OJ Simpson trial. It is extremely sensitive, being able to detect as few as one or two Bb in a specimen. It is also highly specific, since it targets unique features of the organism's DNA. The downside is that PCR will be negative if no organisms are in the specimen. If this happens, it is important to remember that absence of proof is not proof of absence.

IGeneX reports the highest recovery rate on EDTA whole blood, cerebrospinal fluid, and joint fluid. Their new multiplex PCR is even more sensitive and can be performed on all types of samples: EDTA whole blood, serum, cerebrospinal fluid, synovial

fluid, urine, breast milk, tissue biopsy, and ticks.

Bb is a slow-growing organism and **culture** is considered expensive and low yield. Culture at present is only done in a research setting. A new test focusing on cyst forms, a dormant stage of Bb, can reportedly culture Bb from blood, but the test is still very controversial and is not available commercially. Labs trying to confirm the test hope to publish their results this summer.

Antigen capture is another direct test. Antigens are proteins displayed on the surface of germs and are unique to each organism, like a fingerprint. Laboratories have designed a test to target specific Bb antigens. They can then determine whether Bb is present in a specimen. The Lyme Urine Antigen Test (LUAT) is a proprietary test done only at IGeneX. Many Lyme-knowledgeable doctors are using LUAT to confirm their diagnosis, since the indirect tests may miss cases.

If your diagnosis is in question, you may have to try more than one test, to find what works for you. Don't give up too soon because the answer may be just around the corner. Keep informed by using the Internet – there are a discussion group at sci.med.diseases.lyme, and several websites devoted to Lyme disease (www.lymenet.org is a good place to start).

The Top 10 Signs you've joined a cheap HMO

10. Annual breast exam conducted at Hooters.
9. Directions to your doctor's office include "Take a left when you enter the trailer park."
8. Tongue depressors taste faintly of Fudgesicle.
7. Only proctologist in the plan is "Gus" from Roto-Rooter.
6. Only item listed under Preventive Care feature of coverage is "an apple a day."
5. Your primary care physician is wearing the pants you gave to Goodwill last month.
4. "Patient responsible for 200% of out-of-network charges" is not a typo.
3. The only expense covered 100% is embalming.
2. With your last HMO, your Viagra pills didn't come in different colors with little Ms on them.
1. You ask for Viagra. You get a popsicle stick and duct tape.

From the Internet, source unknown

Patient Stories

NIH Study participant sees MS reversed by antibiotics

by Ann Richmond

All of my childhood summers and most of the vacations in adult life have been spent in the great outdoors. In my younger years I spent ten summers on Nantucket Island, one summer on Block Island, one summer in Nova Scotia and three summers in Jackson Hole Wyoming. My mother, being the avid biologist and believer in fresh air for health young bodies would send us out to discover the gifts of the land, paying heed to mosquitos, wasps and snakes. Ticks would be removed with tweezers with no thought of disease besides Rocky Mountain Spotted Fever. Each fall, my family would spend our weekends on the Jersey shore, surf casting for bluefish and striped bass. When “we kids” were not fishing we were playing in the dunes. These trips as a youngster took place during the 1960s and 1970s. As an adult I vacationed in the wilderness with camping trips and fishing expeditions along the eastern US border. My health as a child was good except for sinus problems that seemed to clear up when I became a young adult. The sinus problems would return with a vengeance in my late 20s.

Prior to a fishing trip in August of 1995, I had been on antibiotics off and on for the last year or two with terrible sinus problems and flu like symptoms. Additionally, I had pain in my muscles that did not coincide with any physical strain. I would see doctors for these complaints, never connecting any of these symptoms. At this time in my life I had a promising career at the Chubb Group of Insurance Companies as an Underwriting Analyst, your basic project manager. I was on the fast

track and the world was my oyster. On the fishing trip in August, 1995, in Vermont I was bitten by a variety of bugs including spiders, black fly, deer fly, mosquitos, and who knows what else. Within a few days I had to go to the emergency room in a local hospital because I could not move my neck, my lymph glands were swollen and I felt exhausted. The doctor prescribed 10 days of oral antibiotics and sent me on my way. And so it began...

After I returned home my sinuses became severely infected. I went to the doctor for antibiotics constantly. Every time I went off the oral antibiotics the sinus infection would return with one or two more additional symptoms until I knew there was something else very, very wrong. I saw an ENT who thought sinus surgery would help. So I did it. I felt great for about 4 weeks after the surgery, and then I had a rapid decline in my condition. I went back to the ENT and he suggested a neurologist.

Meanwhile my job was beginning to suffer. I could not remember things, dates, meetings, phone calls. I had difficulty speaking, stuttering and forgetting words. I was getting confused in meetings when more than one person spoke. I had to lay my head on my desk at 11am every day because I could no longer support my neck because of the pain. The headaches were blinding. The dizziness was uncontrollable.

Stress and depression?

In April of 1996 I was off to the first neurologist. He told me that I was under stress and could be depressed. I insisted on an MRI of

my brain. He hesitated and then agreed. Much to his surprise brain lesions were evident on the MRI results. He then told me that it could be a myriad of diseases such as MS and Lupus. I asked about Lyme disease and he said that my blood work was negative. In my ignorance of the early years I accepted his answer, but found a new neurologist and a new primary care doctor.

In May I was off to the new and improved neurologist. He ordered another brain MRI and performed a spinal tap. Now I had enhancing brain lesions and my spinal fluid showed 3 oligoclonal bands, an elevated white blood cell (WBC) count of 14 and a high normal protein level. The neurologist was now leaning towards MS and sent me to one of the best neurologists in the country for a second opinion. The second opinion consisted of a possible MS diagnosis and a suggestion for a second spinal tap. This doctor was concerned about the elevated WBC count, and so was I.

The second LP [*lumbar puncture* = *spinal tap*] was performed and the WBC count was now up to 25. I had asked the neurologist about a Lyme test with the spinal fluid on both LPS. The first LP he did not draw enough fluid and the second LP there was contamination so a Lyme test on my spinal fluid was never performed.

OK diagnosis time...

The new and improved neurologist said I had MS. I said, “What about the WBC count, isn’t that a sign of infection?” Maybe, he said, and that was it. I got a prescription for Avonex, an MS drug, and given instructions on how to give myself weekly inter muscular injections. I had asked this doctor, “Why do I feel better when on antibiotics?” He said, “It’s a coincidence.”

I went home and felt sorry for myself. I was on the verge of losing my job, my self respect, my ability to walk, think, speak clearly. It was not getting any better with the Avonex. I now walked with a cane and slept at

least 12 hours a day. The company I worked for was more than understanding. They allowed me to work two days from home and three days in the office. Most of my peers in the office were supportive, along with management. I was truly blessed in that sense.

I pulled myself up by my bootstraps and began doing research in into MS and anything else my symptoms resembled. My primary care doctor supported my research, but was in agreement with the neurologist. I figured if I had MS I had to find a cure within 6 months because I had too much to do. OK, it was a little ambitious. So the search began...

I went to the library, got on the Internet, learned how to read my lab reports and used my skills as an analyst. My conclusion was that I had an infection, didn't know what, but that is what it was. I read a posting by a woman in Ohio who had the same symptoms, brain lesions etc. She had Lyme disease. I wrote her an email. She put me in touch with a woman in New Jersey, my home state, who could help. This wonderful woman, I will call her Martha B., saved my life. Martha put me in touch with Dr. Liegner, in Armonk NY.

Finally, a Lyme specialist

I had my first appointment with Dr. Liegner in late August of 1997. After spending 2 1/2 hours with Dr. Liegner I had hope. He listened to me, took all lab reports and MRI's to do his analysis. Dr. Liegner also drew blood to send to various highly regarded laboratories. He did not diagnosis me within those 2 1/2 hours. We had to wait for the blood work and his opinion after reviewing my records. Well, my lab work from Stony Brook can back with a positive Lyme test which met all CDC requirements for a positive test. I took these results to my primary doctor who reran the blood work at Stony Brook. Once again, it was positive.

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Upon my second visit Dr. Liegner diagnosed me with Lyme disease with chronic meningoencephalitis and suggested that I see Dr. Coyle, a well regarded MS specialist at Stony Brook, for a second opinion. He also suggested that I apply for entry into the National Institutes of Health (NIH) Collaborative Study of Chronic Neuroborreliosis. I made an appointment with Dr. Coyle and filled in my application for the NIH study. Dr. Coyle's conclusion about my case was, "My best bet would be that this is a person in whom Lyme exposure brought out an occult MS but I cannot absolutely rule out a late Lyme encephalomyelitis and clearly she does warrant antibiotic treatment." Additionally, Dr. Coyle thought I would be an excellent candidate for the NIH Study.

I am accepted into NIH study

With the blessings of Dr. Liegner and Dr. Coyle, two positive Lyme tests from Stony Brook and some additional pleading from my primary, I was finally accepted into the study. I removed myself for the MS drug Avonex, and went to the NIH. Finally, after two years of searching I thought it was finally over. A diagnosis, entrance into a prestigious study and antibiotics. I was on the road to recovery. My six week plan was down the tubes, but now I could get on with my life.

The nature of my participation under the Chronic Lyme disease Study at the NIH is to characterize the natural history of the disease. The NIH tested me with lumbar punctures, MRIs, blood work, hearing and vision tests. Although the Lyme blood tests performed at the NIH and the New England Medical Center were negative by CDC standards, specific bands present in Lyme did appear on my tests. Also my WBC count in my spinal fluid remained at a high of 25.

Once the evaluation was completed at the NIH, my primary, in concert with Dr. Liegner, placed me on IV Penicillin for three months.

During the time on the IV antibiotics the insurance company that I had at the time, Cigna, twice threatened to pull me off of treatment, as I had the textbook amount given of 30 days. With much pleading from my primary, and the promise that I would have a spinal tap at the six and twelfth week the insurance company allowed me to stay on IV.

The first spinal tap at the six week mark showed a decline in my WBC count from 25 to 5, which was the first time in two years at a high normal. I remained on the IV for another six weeks. The next WBC count at the end of treatment was now down to 1. I was then placed on oral antibiotics as maintenance throughout the next year. I returned to the NIH for periodic check-ups. Slowly, but surely my WBC count began to increase again, however, I had no new brain lesions.

To the present...

Within a year after the end my IV penicillin treatment, my WBC count was at 30 and I had a new brain lesion. At this point I would not accept no for an answer with IV treatment. The oral antibiotics may have slowed the progression of the disease but had not stopped it. I was placed on IV Primaxen, one gram every 8 hours. As I write this story I have two more weeks of IV treatment to go. Within the first six weeks of this treatment my WBC count was down from 30 to 7. Also, my active brain lesion is gone. The NIH offers no explanation for its disappearance. It could have gone away by itself or the antibiotics could have helped. My answer is, "I am not the only one in the study where an active enhancing lesion has disappeared with IV antibiotic treatment. Secondly, why didn't any of my other lesions go away by themselves? The scar tissue remains."

My opinion of the NIH study

There is no other study in this country where such a wide variety of tests are performed on chronic Lyme patients. However, I am tired of the

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NIH standing on the sidelines watching some of the patients decline due to their inability to get ample IV antibiotic treatment. Proving persistent infection should be the NIH priority, not disproving its existence. Additionally, why do I have to beg treatment from an insurance company when I have been seen by some of the best doctors in the world who agree that I respond to IV antibiotic treatment?

The chief investigator of the study is Dr. Adriana Marques. I have great faith in her ability to make scientifically based conclusions as a scientist, physician and caring human being. However, I do fear that the NIH may be forced to listen to those who do not have the patients' best interests in mind.

Being a guinea pig

I do not know what the future holds for my health. After this latest round of IV antibiotics I have chosen to stop taking all antibiotics to see if and when the infection will rear its ugly head. I will be evaluated at the NIH every six weeks with spinal taps and MRIs. I do hope that the infection is entirely eradicated from my body. But my experience suggests that it will just be a matter of time before the WBC count in my spinal fluid starts to head up again and a new brain lesion appears. If I do not go off the antibiotics, how will I prove that persistent infection exists? If I don't, who will? I have great faith in my doctors now. They will watch me carefully as we try this new experiment. Hopefully we will all learn something and maybe make it easier for the next patient down the road to finally get the treatment they deserve.

My greatest fear is that the doctors who treat the disease will no longer be able to, with the witch hunt that is now happening within the medical community, where licenses are removed for treating a patient with a chronic illness, where treatment protocols for a neurological disorder are created and dictated by a

rheumatologist.

With the treatment I have had, I have improved both physically and mentally. I no longer walk with a cane and I have improved strength in muscles. I know I need additional IV treatment and will receive it somewhere down the road. In conclusion, my personal life has been greatly affected by this disease. I am currently going through a divorce and

dealing with the loss of a career. I find that humor, the love of friends and family and a determination to fight for what you believe has given me the strength to go on with my life and create new dreams.

Ms. Richmond's physician, Dr. Liegner, was the recipient of the 1999 LDRC Distinguished Physician Award.

Diagnosis means relief may be coming to Oregon patient

by Rebecca Merritt

For the first time in a long time, Tom Norris is dreaming of playing a round of golf with his family—without a golf cart. The Bend [Oregon] man, who is dependent on a wheelchair, was recently diagnosed with Lyme disease after nine years of being told he had multiple sclerosis. Gerald Simons, a physician assistant for Dr. Joseph Burrascano's office in New York, said Norris has chronic Lyme, in addition to a co-infection called Ehrlichiosis—similar to Rocky Mountain Fever—and a virus that may have been triggered by Lyme disease. The New York clinic is prescribing treatment for Norris.

"It's probably been in his system for many years," Simons said. "It's exciting that we're able to pinpoint these things."

Most people wouldn't be excited to hear they have Lyme disease, which has numerous symptoms, including joint pain, heart palpitations and facial paralysis and can lead to crippling arthritis if left untreated. The disease is an infection caused by a bacteria called *Borrelia burgdorferi* and is transmitted by deer ticks. But for Norris, this diagnosis was a long time coming. This means he can take antibiotics that may improve his condition. Simons said there is no clear re-

search to say how much he will improve, but "We've seen people have some pretty incredible results."

When Norris was told he had MS, which is an inflammatory disease of the central nervous system, there was not much hope for treatment. Now there is the possibility that his body may recover. And, he hopes, maybe he can walk someday.

"It's a big relief," said Norris, at work at his desk at Pearson Mortgage Services. "It's like coming out of the desert into this big pool of water. There is hope."

Under the guidance of the New York clinic and Dr. Ron Rosen in Bend, Norris is beginning to take oral antibiotics. After about a month of oral medication, he could begin taking the drugs intravenously, depending on how his body responds to the oral medication. He also is visiting a physical therapist to help his recovery.

Norris's case, which was featured in *The Bulletin* in September, is one worth following. On a local level, Norris is a well-known figure in the community. A lifelong resident of Bend who married his high school girlfriend, he can always be spotted at Mountain View High School sporting events cheering on his two

children. The baseball community rallied behind him and raised money to send him to the specialist.

On a larger level, his case calls attention to a surprisingly emotional and political debate about Lyme disease. The medical community is divided about how to diagnose and treat Lyme, according to Rita Stanley, director of the Northwest Lyme Disease Support Network in Portland, who operates a resource center at Good Samaritan Hospital. One faction claims Lyme disease is overdiagnosed and overtreated, while another insists that the disease is underdiagnosed and undertreated. Some doctors claim it would be easy to confuse MS with Lyme disease, while others argue that an MS diagnosis is not taken lightly and it is rare to mix the two. Norris, whose brother also was diagnosed with MS, has found himself in the middle of a highly controversial issue. The situation is so intense that some people claim there is a perceived witch hunt for doctors who challenge the traditional methods of treating Lyme Disease, Stanley said. "He's flying in the face of convention here," Stanley said.

The 41-year-old man recalls being bit by a tick during an outing near Bend nine years ago, and he believes his symptoms better match the description of Lyme than MS. But he said he had a hard time finding someone who would believe him about the possibility of Lyme. He said doctors told him he was in denial about his MS diagnosis. Lyme disease is rare here. In fact, no cases of the disease were reported to the Deschutes County Health Department last year. The ticks that carry the disease are known to survive better in warmer, more humid climates. A recent study showed that virtually none of the ticks here carry Lyme. The disease is more common on the East Coast. In Oregon, it's more likely to be found in the valley or at the coast.

But Norris, who has researched

the disease on the Internet and at the library, was determined enough to visit the specialist in New York. An initial urine test showed high levels of Lyme, but many members of the medical community doubt the reliability of that test, according to a spokesman at the American Lyme Disease Foundation. To be sure, the New York clinic ordered a series of tests, including several blood tests, a spinal tap and SPECT scan to help make the diagnosis. Simons said the clinic wanted to look at the possibility of a number of diseases.

"You can't have a narrow focus and look just for Lyme," Simons said. "He really got the run over."

Norris had not undergone a spinal test when he was diagnosed with MS. He said doctors recommended it but at that point he was upset and didn't want to go through with it unless he could get tested for Lyme, too. Simons said the spinal tap indicated the presence of Lyme disease. In addition, the SPECT scan, which is a nuclear brain scan, showed a high presence of the disease. The report from the radiologist said it looked like what he sees with Lyme patients, Simons said. The test also showed the presence of Ehrlichiosis, the disease similar to Rocky Mountain Fever that may have been transmitted from the same tick that gave him Lyme. However, a blood test came out negative for the disease and another blood test was equivocal.

When diagnosing Lyme, Simons said it's important that physicians pay close attention to symptoms and patient history because the tests available are not completely accurate and it's possible to have false negatives or false positives. They see all the signs and symptoms with Norris, he said.

But this is another area of disagreement. Dr. Michael Caldwell, health commissioner for Dutchess County, New York, who sees many Lyme patients, said earlier that it's rare to have false negatives but it's

common to have false positives. Simons said he is pleased with the Center for Disease Control's decision recommendation about diagnosing Lyme, telling doctors to look at the patient's history and symptoms before taking into account the blood tests. He believes this is a positive step forward in treating the disease. "You need to listen to the patients and hear them out," Simons said.

Although Norris has the diagnosis he was hoping for, things aren't going to be easy. He expects to feel worse before he gets better and the improvements will be gradual. "It's a long road ahead," he said. Stanley, who counsels many Lyme Disease patients and has suffered from the disease for six years, said Norris faces many challenges, both political and physical. On the political side, Stanley said many people will continue to doubt whether Norris has Lyme. Also, it is tough for some patients to receive the medication for as long as they need it.

"As he goes through treatment, a lot of people will just say, 'You have MS. Give it up,'" she said. There's also the challenge of getting insurance companies to cover the treatment, Stanley said. Norris said he is in discussions with his insurance company to see if it will cover the treatment. He expects his medical bills to run between \$30,000 and \$60,000. Also, Stanley said the treatment will be frustrating for him because it may be a while before he sees significant improvement. For most patients, there is a reaction to the antibiotics that can cause patients to feel worse for a while. But Norris said he's determined to follow through with this. He'll do whatever it takes. "It feels good to at least know there's some hope," he said. "If I have to, I'll go to Mexico and get my treatment."

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Patient Support

Helpful sources of medical information for laypeople

by Anthony Peranio

In response to several questions raised by users of the Internet newsgroup sci.med.diseases.lyme, here is a selected list of medical references that I, a 12-year sufferer of Lyme Disease (LD), have found affordable and useful. It is meant for use by laypersons and does not include overly technical material. Note that the material does not just apply narrowly to Lyme disease, but is intended to cover information from a wide spectrum of medical science which is often sorely required by LD sufferers.

The references

1) The Merck Manual of Diagnosis and Therapy, 17th Edition, 1999, cost: about \$35, also available online at www.merck.com. Although this has been written with the medical practitioner in mind, don't be intimidated. Using some of the other references given below, you should be able to 'translate' the medical jargon to concepts we simple mortals understand. If you don't buy any other book this year, buy the 17th ed., 1999, Merck Manual. It is a MUST! In our family we have used this manual since its 9th Edition in 1956.

Do NOT confuse this volume with Merck's Manual of Medical Information - a kind of 'Medicine for Dummies' book, with its 1st Merck edition, 1997. The information on LD in this second Merck 'Manual' is 5 or more years old; already too outdated for us to use and rely upon. Besides, it doesn't get into the nitty-gritty details of what is accepted by the medical community and what still needs more research to establish adequate LD treatment.

Tracing Lyme Disease over the

years, we find that in the 15th ed. of 1987 emphasis was almost entirely upon the 'arthritic' symptoms, and prescribed short courses of antibiotics. But, it was acknowledged that "...optimal treatment for later neurological problems is not yet clear." Five years after this, 1992, 16th ed., we find many more serious symptoms of LD written up, and that some of the antibiotic regimens are being prescribed "for at least 21 days." The later generation antibiotics are included along with the 'classic' mainstays, and, simple aspirin is prescribed for pain relief. (For chronic sufferers of LD knee arthritis, they speak of surgery!)

Merck owns up to the chronic and persistent nature of LD, reporting "...late findings [several symptoms] occurring years after onset." The recommended Merck, 1999 edition, covers 4 pages on Lyme Disease (Lyme Borreliosis). The major symptoms are now categorized and expanded, there is considerable material about testing, differential diagnosis, and treatment. They even add a paragraph that qualifies Vaccines; "In adult populations examined so far, they (the vaccines) APPEAR to be effective." (Emphasis added.)

In this latest Merck section on LD three aspects are of particular interest to LD sufferers: (a) The Lyme bull's eye is noted as the "hallmark and best clinical indicator and develops in about 75% of patients." (b) Symptoms can occur in days, weeks, months, and even years after being bitten; and continue, and may not be amenable to treatment. (c) In a Table on p. 1192 is a Table of Recommendations (qualified as

guidelines) for antibiotic treatment.

Finally, it is acknowledged that: "There are no controlled trials of therapy longer than 4 weeks for any manifestation of Lyme disease."

It appears to me that using the material in this Merck article (plus the recommendations in the Table) a medical practitioner should logically be able to extend indefinitely almost any antibiotic protocol decided upon. However, since research results are lacking, long, extended treatment with antibiotics may yet prove to be harmful.

2) The Signet, MOSBY Medical Encyclopedia, rev. ed. 1996, is a must at about \$9.

3) Nursing 2000 Drug Handbook, Springhouse Corp. Cost \$35. (MOSBY also publishes a similar book) Excellent for COMPLETE details on new drugs, applications, administration, and adverse reactions with nursing considerations.

4) Helpful will be an illustrated Anatomy book for laypersons that you can understand. Several choices exist, browse through them. Each may cost about \$40 or so.

5) "Mosby's Medical, Nursing, & Allied Health DICTIONARY." 5th ed. 1998. Costs about \$50. A well-recommended, illustrated, giant (easy-to-read) volume.

6) James A. Duke, Ph.D., THE GREEN PHARMACY, 1997, costs under \$8. This is a GEM of a book I just discovered. It is a MUST for everyone, especially those interested in herbal treatments. I've learned to make wonderful teas, drinks, and foods. The herbs may not cure Lyme, but they sure make life more livable.

The author, and I believe his wife, have Lyme disease, and Dr. Duke devotes a section to herbs to supplement treatment of LD. He concentrates on herbs and spices that can be purchased inexpensively at any supermarket or health food store.

The above 6 items are a start. For general information and background,

history, economics, culture of medicine and diseases see the latest COLUMBIA ENCYCLOPEDIA (5th ed., 1985) This costs about \$60 and in my opinion is well worth it since everyone in the family will benefit by its presence and use. (You need a stand for this volume, or a dedicated table.)

Also, the Encarta Encyclopedia (Microsoft on 2 CD's) is great for computer users with late model machines (after 1998) having plenty of RAM and storage on hard disk. It's amazing what medical and other associated information you can get out of this digital encyclopedia. It is also great for any youngsters going to school and college and old-timers writing their memoirs. Cost about \$30, less with mail-in rebate.

If you're reluctant or skeptical about ordering these things via

Internet, any bookstore will gladly order. Although a 'child of the computer age' I've given up ordering anything by computer for the duration! A few bad experiences, plus somehow, I like the idea of thumbing through the books, BEFORE I buy them. I do pay by cash, personal check, or credit card. I still prefer the old idea of looking into the face of another human at the time I purchase anything.

The above references and occasional deeper ones, plus the interesting communication in our newsgroup have kept me from going bonkers during prolonged LD suffering and flares! Have fun!

Anthony Peranio, a Lyme disease patient, lives in the mountains of North Carolina. He may be reached by email at anaton@earthlink.net.

copies of the Reportable Events Table.

The VAERS report form has been designed to facilitate and standardize the process of reporting adverse events following vaccination to VAERS. The report form consists of a single sheet, pre-addressed, postage-paid form for entering pertinent information, including a narrative description of the adverse event. Directions for completing the form are on the back of the form and should be followed carefully. Consumers are encouraged to obtain the assistance of their health care provider in completing the form. For a sample copy of the VAERS report form, see the last page of the 1997 Physician's Desk Reference (PDR) or page 28 of the 1997 Red Book (Report of the Committee on Infectious Diseases of the American Academy of Pediatrics, 24th Edition).

For people who are online, a copy of the VAERS form in PDF format may be downloaded from the VAERS website. Photocopies of the PDR form may also be used.

Reporting by Health Professionals

Additional information about the Reportable Events Table (RET) and the Vaccine Injury Table (VIT) can be obtained from the National Vaccine Injury Compensation Program (NVICP).

In addition to the adverse events covered by the Reportable Events Table, the Vaccine Adverse Event Reporting System (VAERS) accepts all reports of suspected adverse events, in all age groups, after the administration of any U.S. licensed vaccine. Reports which involve a serious event, which involve a positive rechallenge, or which involve reactions not included in the product labeling are of particular interest in identifying events with impact on the public health.

Information in this article was taken from the VAERS website at vaers@cber.fda.gov.

Consumers should use the Vaccine Adverse Event Reporting System (VAERS)

The Center for Biologics Evaluation and Research of the Federal Drug Administration is interested in any adverse reaction consumers experience after receiving a vaccine. This applies to the newly approved LYMERix vaccine for Lyme disease. It is important for people who have experienced adverse reactions to vaccines to take advantage of this reporting system so that statistics on vaccine safety can be compiled at the federal level.

The Vaccine Adverse Event Reporting System (VAERS) accepts reports from the public of any unusual event which occurred after a vaccination was given. In order to collect all information that may be of value, there is no restriction on the time lapse between the vaccination and the start of the event, or between the event and the time the report is made.

"Our main concern is identifying events which affect you and your family," says the VAERS website.

There is a toll-free VAERS information line 1-800-822-7967 to obtain copies of VAERS forms or to receive assistance from a VAERS staff member in filling out the VAERS form. Other services include general information on VAERS, information about vaccines from a health care professional and mailed

Lyme Humor

Doctor: You have MS.

Patient: If I have MS, why do I feel better when I am on antibiotics?

Doctor: It's a coincidence.

Patient: Isn't 10 years a little long for a coincidence?

Thanks to A. Richmond

Flagyl may be effective against cell-wall deficient form of spirochete

by James D. Hajicek

Some patients have begun to take Flagyl for Lyme disease because of recent research suggesting that it may kill the cyst form of the Bb spirochete.

Many spirochete experts believe that the Bb spirochetes can exist in two forms: “serpents” and “cysts”. The “serpents” – or classic form – have the long, thin, corkscrew shape which is usually associated with spirochetes, and they can move around. The cysts are much smaller; they may be round or comma-shaped; and they appear to be inert. The two forms are said to change back and forth, from one form into the other.

Some scientists also think that the spirochete can double and quadruple inside of the cyst, forming what are called “granules”. Each granule then grows and develops into the classic helical form.

People are commonly calling this second form of spirochete a “cyst,” which is easy to say and to write, but has the disadvantage of being a word which is already overused in medicine with other meanings. Some people use the words “granules,” “gemmae,” and “cysts” interchangeably. More scientifically accurate expressions are “spheroplast,” or “L-form” after the Lister Institute in London where they were first studied.

In the simplest version of this theory, the cyst does not reproduce, but the spirochete granules inside of the cyst can divide. Microbiologist Lida Mattman, author of the book *Stealth Bacteria*, has slides which suggest that classic spirochetes were forming inside a large spheroplastic form. However, research has suggested that the cysts can reproduce on their own, growing and dividing

while remaining entirely in the cyst form. If this were true, the cyst form would be a variant form of spirochete, resembling the mycoplasma bacteria. The mycoplasmas are cell-wall deficient bacteria, usually considered to be intermediate in complexity between the regular bacteria and the viruses.

In any case, according to the theory, the cyst form is produced when the spirochete is confronted with a hostile environment. This hostile environment might be antibodies produced by the host immune system to the outer-surface proteins, or it might be the presence of antibiotics. The classic form then changes into a cyst as an emergency survival measure, because the cysts are then relatively safe from attack by the antibodies or by the antibiotic.

It has been suggested that the existence of the spirochete cysts in the human body is the reason for the lack of effectiveness in treating Lyme disease with antibiotics. The hypothesis is that the antibiotics normally kill only the classic form, or perhaps causes them to change into cysts. Antibiotics must invade the bacteria’s protein metabolism to kill. A dormant cyst with no active ribosome protein synthesis would be unaffected by antibiotics. Then when the antibiotic is no longer being taken by the patient, the cysts change back to the classic form. They continue to multiply, and the patient has a relapse.

The cyst form of spirochete has been reported in medical papers since at least 1911, when researchers described relapsing fever borrelia. The existence of such forms should not be a surprise, since it is well-known that other bacteria adopt other

forms in order to survive adverse conditions, particularly cell-wall-inhibiting antimicrobial agents.

Not every medical expert agrees with this spirochete theory, and some entirely deny the existence of the cyst form. One reason for such a view may be that the spirochete that causes syphilis, *Treponema pallidum*, has also been claimed by some researchers to have a cyst form. If this is true, it would seem likely that syphilis is not so completely cured with penicillin as is commonly claimed by the medical authorities. It would indeed be an embarrassing development for them if they had to admit this.

What is Flagyl?

“Flagyl” is a trade name for the generic drug “metronidazole”. Metronidazole is relatively inexpensive, and is frequently used in underdeveloped countries due to its low cost. It is effective against most anaerobic bacteria and also against some of the protozoa.

The reason for the recent patient interest in metronidazole in the treatment of Lyme disease is that this antibiotic is effective in laboratory tests against the cyst form of the Bb spirochete. Other antibiotics have virtually no effect on the cysts, and killing the cysts as well as the classic form is presumed to be an essential part of achieving a cure for Bb infection. Metronidazole is less effective against the classic form, and it may be necessary to combine metronidazole with another antibiotic in order to kill both forms of the spirochete. However, if a patient has an adequate immune response against the classic form, using only metronidazole to kill the cysts might be sufficient. All of this is still experimental.

The name “Flagyl” is apparently derived from the word “flagella”. Flagella are the small whiplike projections which are used by spirochetes, protozoa, and other motile microbes to propel themselves. However, possession of flagella does not appear to be the feature essential

in making the microbes vulnerable to metronidazole. Rather, the place of attack seems to be in the anaerobic metabolism of the susceptible microbes.

Metronidazole also penetrates the tissues well. As a rule of thumb, a large complex molecule has a more difficult time in passing through various membranes in the body, such as the blood-brain-barrier. Since the problem with getting enough antibiotic into secluded portions of the body is critical for a cure, it is interesting to note that metronidazole seems to have the lowest molecular weight of any of the antibiotics. Penicillin is used in a variety of different forms, which vary from 356 to over 900 in molecular weight. Tetracycline is 444. Doxycycline is 462. In comparison, metronidazole is a simple molecule with a molecular weight of only 171.

The trade name "Flagyl" is owned by the Searle company. Metronidazole which is sold under this name is significantly more expensive than the generic brands. However, Flagyl is a coated tablet, and some patients have had less problem with an unpleasant metallic taste when taking Flagyl than with the generic, uncoated brands.

A Searle company web page for Flagyl is <http://www.searlehealthnet.com/pi/flagyl.html>. Here you will find 10 or 11 pages of information about Flagyl, its usage and its side effects. For example, there is a warning about this drug having been shown to be carcinogenic in mice and rats at a very high dosage. The relative safety and effectiveness of this antibiotic will have to be evaluated by the physician who prescribes it. It should be noted that other antibiotics also have various warnings about their use.

When alcohol is taken together with Flagyl, there are some horrible side effects. Some patients have reported that they have had no trouble using a mouthwash which

contains alcohol, but others cannot tolerate even this much alcohol while taking Flagyl.

Antibiotics may help rheumatoid arthritis

Rheumatologists are divided among themselves as to merit of using antibiotics for rheumatoid arthritis. The more conservative group believes only in using anti-inflammatory drugs like steroids to reduce inflammation. The more progressive group believes that arthritis has an infectious cause, and that antibiotics can be effective in treating this disorder.

The main problem with claiming that the Bb spirochete is the cause of the usual kind of rheumatic arthritis, is that the arthritis patients do not seem to test positive any more frequently to Bb than the normal population does. Another problem is that if Lyme disease were the cause, one would expect a strong geographical association with the incidence of arthritis. Frankly, in most cases it is easier to put the blame on some still unknown microbe, than it is attribute this disease to the Bb spirochete.

In general, the physicians who prescribe antibiotics for arthritis do not claim to know the nature of the microbe which causes the disease they are treating. However it appears that most of the rheumatology people who use antibiotics believe that they are treating mycoplasma infections. If they give any consideration to Lyme disease or to spirochetes as a possible cause, they do not seem to admit it.

However, it is possible that another spirochete species is involved, of which there are many. For example, over 20 different species of *Treponema* have been identified in different people with gum disease. In fact, spirochetes are said to be common in the mouth and other places in the body. In the mouth they hide in the pockets around the teeth, out of the air and out of the blood. They can be a cofactor in the more serious type of gingivitis, formerly

called trench mouth, the kind that causes people to lose their teeth. Other species of bacteria also play a role.

The point here is that given the scarcity of knowledge about proper treatment for Lyme disease, clues should be taken from whatever source possible. Since antibiotics have been used for many years by some physicians in treating arthritis, what has been learned here may also be of benefit for the Lyme disease patient.

Role of mycoplasmas

Mycoplasmas are simple organisms which cannot survive on their own without a host cell to provide many of the necessary metabolic substances. They are small compared to a human cell, and many of these can be attached to a single human cell. They can even live inside of the human cells, hiding from both the physicians and from the immune system.

Mycoplasma infections are well-known. For example, the *Mycoplasma pneumoniae* organism is recognized as the cause of "walking pneumonia".

It has long been believed that mycoplasmas can cause arthritis in animals. The first strains of mycoplasma were found in animals with arthritis over 100 years ago. For this reason it is reasonable to suppose that human arthritis also has a mycoplasma cause. This is not a new theory, as mycoplasmas were first found in the diseased tissue of a rheumatoid patient in 1939.

In light of these facts, those rheumatologists who refuse to even try antibiotics of some kind for the various rheumatic diseases seem to be really stodgy.

Information about mycoplasmas can be found many places on the Internet. The following sites especially discuss the possible connection with arthritis:

- <http://arthritis.tqn.com/health/arthritis/library/weekly/aa072998.htm>

– Antibiotic Treatment for Rheumatoid Arthritis

• <http://www.hitter.net/users/hwcmri/mycol.htm> – The Mycoplasma Cause of Arthritis

• <http://www.hitter.net/users/hwcmri/patients.htm> – The Facts: What Patients Should Know!

The Arthritis Trust

Here are some excerpts from another source. “The Arthritis Trust” is an association of physicians who believe in using antibiotics to treat rheumatic diseases.

If you start at the following Internet page, you will be asked to register with your name and address. This will give you access to the entire site.

<http://telalink.net/~taf>

The Arthritis Trust aka The Rheumatoid Disease Foundation

The following consists of some extracts from two of the associated pages. The first of these is especially interesting because it implies that metronidazole is used routinely by physicians to treat arthritis. It is listed NUMBER ONE. This does not seem to be a new procedure. Doxycycline is not even on the list.

<http://www.telalink.net/~taf/7-ways.htm> – The Rheumatoid Disease Foundation

Ways to Ease Arthritis Pain

In the United States, the most frequently used first-trial oral medicine (tablet or capsule), for Rheumatoid Disease (RD) is Metronidazole. It is listed in the Physician’s Desk Reference as being FDA approved for marketing and human use. It is easily available by prescription and is relatively well known. Its use has resulted in a large number of remissions/cures. It is taken with allopurinol or furazolidone during the first week to ten days, respectively.

Metronidazole is used intravenously frequently for bacterial infections, especially when the patient has been hospitalized. But

there is no evidence that metronidazole when used intravenously has any effect on halting RD, but it has been reported to temporarily knock out inflammation that shows itself as swelling and heat.

The following page claims that rheumatoid arthritis can be cured. It takes about 36 pages of printer paper to print the entire Internet page.

<http://www.telalink.net/~taf/rdtreatm.htm>

Arthritis’ Primary Treatment Protocol

The recommended protocol is metronidazole, and they claim an “improvement” rate of over 80%, and support their claims in part with studies which were published 12 years previous. This article is copyright in 1988 and in 1996, so I cannot accurately place that date, but it seems that Flagyl has been used for arthritis for a long time. One interesting aspect of their protocol is the pulsing which they recommend. For example, they suggest a pattern of 2 days on antibiotics, and then 5 days off.

There is much supplemental information and recommendations here about the use of Flagyl, so this information should also be useful for people taking it for Lyme disease. Some of this information is technical. These people recommend against taking steroids while using their treatment protocol. They also discuss the Herxheimer reaction which is said to occur with their protocol, and which can be quite severe.

Personal story is inconclusive on benefits of Flagyl

I myself have not taken Flagyl, and I am not personally recommending it. So far I have not read very much on the Lyme newsgroup from people who claim to have been cured with Flagyl. On the other hand, I have read too much about “Herxes from Hell.”

Here is some feedback from one person who has been taking Flagyl

for Lyme disease, which I am including with the permission of the author.

This person had been disabled for ten years by exhaustion, daily sleep attacks, severe muscle pain, chronic headaches, and confusion. There had been a diagnosis of Chronic Fatigue Syndrome, but then Lyme tests were taken which produced a positive ELISA and an equivocal Western Blot. This ultimately led to a decision to try the Flagyl.

It was found that the Herxheimer reactions were severe, even horrible. The information in the above internet site of “The Arthritis Trust” was described as follows:

“ ... a website that had an exact, blow-by-blow description of what I am going through on Flagyl. It was just amazing to read this doctor’s description of Jarisch-Herxheimers he’s seen after giving Flagyl for arthritis to many people. Everything he talked about has happened to me, and until I read this, I was actually thinking there was something wrong because I’m so up and down.

“ ... He said temporary memory loss is common, I sure hope he’s right that it’s temporary ...

“ ... Also experience burning pains in tissue that has never been painful before, and other strange things that I couldn’t believe he wrote about. ...”

Later:

“ I am still taking Flagyl, 4Xs daily, for a total of 1000mg. daily. Every six hours. It’s a hassle, ...

“This is also a small dose, I know, but it did make me seriously sick for the first month, so I figured it must be effective enough. ...

“Anyway, the Flagyl has made me feel quite a bit better in certain respects, though I’m not symptom-free, and it is still a very up and down thing. ...”

Later:

“ ... Due to Flagyl, I believe, I am greatly improved ...

“... I am not absolutely symptom-free, ...

“I discontinued Flagyl after 3 1/2 months, because I decided I was having symptoms of possible liver trouble (nausea, fatigue, liver tenderness,). ...

“... I will give my liver at least one month to rest; it already is no longer tender, I've been off Flagyl for about a week. ...”

Three weeks later:

“I went back on it because I started feeling even worse when I was off it.

“Flagyl basically got me back to a semblance of a life. This information might help to encourage someone to tough out the Flagyl treatment, it isn't very pleasant.”

Later:

“I am now taking 1500 mg ... I now wish I hadn't quit, and also wish I had taken 1500 from the beginning, since the 1500 doesn't seem any harder to tolerate.”

Most recently:

“The problem is that certain things are definitely better, but with this chronic infection, I know that I have extreme fluctuations constantly, in almost every symptom.

“... Brain fog and dizziness/ vertigo are much less disabling than they were before Flagyl. ... When I am taking Flagyl, my gastrointestinal problems are basically gone.”

All of this may sound better than was intended, because in summary no solid claim could be made that the Flagyl was reason for the improvement.

After an entire year since starting this antibiotic, it is impossible to determine whether or not any of the improvement is due to the treatment, or due to a spontaneous recovery. Moreover, a complete cure has not been yet achieved.

James Hajicek may be reached online at <hajicek@execpc.com>.

Online shopping can help Lyme Disease Resource Center

by Carolyn Cramoy

As you all know, the goals of Lyme disease advocacy and education, and fund-raising for Lyme disease research are always on my mind. I have found a way to help further these goals which I think may be of interest to you. I have signed up for iGive.com and have designated the Lyme Disease Resource Center as my designated charity. Take a look by using the link below and think about joining me. We will whip this disease together.

I'm supporting Lyme Disease Resource Center just by shopping online for brand-name merchandise from over 100 well-known merchants. And I'm getting free gift certificates and more by being an iGive member.

How it works

1. Become a Member (it's FREE, private and easy)
2. Choose a Cause (see below)
3. Shop (we'll leave that up to you, but iGive is giving \$10 to Lyme Disease Resource Center when you do)
4. Raise money every day (up to 15% of each purchase)
5. Get Involved with their Six Degrees of Donation (just like me)

Shop for just about anything. Books, CDs, computers, flowers, clothing, groceries, software, office supplies, electronics, toys, gifts, posters, you name it. Up to 15% of each purchase goes to a worthy cause. Your donation may also be tax-deductible.

They have great merchants

And just in case you're thinking, "Oh yeah, who wants to buy something from Never-heard-of-it.com," here are just a few of their merchants: CdNow, Reel.com, J.Crew,

Sharper Image, Whole Foods, Beyond.com, American Greetings, PlanetRx, Dell Computers.

\$10 for your cause—the \$800,000 challenge

If you make your first purchase at the iGive Mall within 45 days of joining, iGive will donate an extra \$10.00 to Lyme Disease Resource Center or another worthy cause of your choice. Be sure to read complete details at the site once you join.

Join now!

If you use this clever link below (ugly as it may be), you can register with Lyme Disease Resource Center already selected as the cause you will support. At any time, you can select another cause from a list of over 5,400 or list YOUR OWN favorite.

<http://www.iGive.com/html/ssi.cfm?cid=8504&mid=113934>

More incentive

- GIFT BASKET from their merchants worth hundreds of dollars in discounts and offers
- EXCELLENT PRICES and exclusive member offers from our merchants
- VIRTUAL KARMA from supporting a cause that's personally meaningful
- SHOPPER'S BONUS for clicking around the site
- SIX DEGREES OF DONATION helps your cause even more when you tell your friends

I hope to see you soon!

P.S. iGive.com would like you to know that all the causes at iGive have been listed by members for their own and others benefit. They don't endorse the cause, and the cause doesn't endorse them. But I DO! So, c'mon, click on that link above.

Review

“Ira Maurer — The Lyme Disease Lawyer — on Legal Issues of Lyme Disease”

From Dolly Curtis Presents. Released 1999; 60 minutes duration, \$35 plus shipping; 15% Discount for Lyme Disease Support Group Leaders.

by Lee Lull

To watch this Dolly Curtis video of “Ira Maurer, Lyme Lawyer” is to become acquainted with Ira himself. A very warm and personable Ira reveals how he inadvertently, and reluctantly, first became involved with litigation for railroad workers who had contracted Lyme, and then how both he and members of his family, including his dog, came to know Lyme on a more personal level. He explains how he became “the Lyme Lawyer,” with two-thirds of his practice consisting of Lyme-related issues.

Although Ira does go into some detail concerning ERISA, perhaps the most important aspect of this easy-to-watch video is that it highlights the major problems facing Lyme patients and their doctors. It’s a wakeup call to those of us who have not yet been touched by insurance company denials and who still have doctors able and willing to continue treatment as long as we need it. It’s frightening to hear of an insurance company terminating a doctor’s participation when that doctor has close to 1000 families afflicted with Lyme disease depending upon him. And positively Orwellian to hear of doctors who have had their practices restricted or are constantly investigated and harassed because they’re willing to treat Lyme patients.

Ira suggests two things that need doing: More doctors must be educated about the diagnosis and treatment of Lyme Disease (overcoming the conservative forces), and insurance companies must be induced to provide coverage beyond some arbitrary point that has no clinical relevance.

Ira feels the only way this will happen is to hit them hard where it hurts. This means litigation for a DRAMATIC punitive damage award.

One is left with the feeling that what we need are a few more Ira Maurers to help us win the battle of Lyme.

This video and other Dolly Curtis interviews can be obtained by contacting:

Dolly Curtis Interviews, 35 Flat Rock Rd, Easton, CT 06612-1703
Tel/Fax 203-372-4511, on the Internet at www.dollycurtisinterviews.com.

Lyme pins raise awareness and benefit research

Lime green – or is it Lyme green? Ribbon pins (made of metal) are available for a \$5.00 donation which will be given to the Evans Medical Foundation – Lyme Unit in Boston, Massachusetts. Send payment with your name and address to: Jessica Craven, 6 Takoma Circle, North Reading, MA 01864.



Actual size, 1 inch

Free email service offers advice on disability issues

DISINISSIONS is an email distribution list designed to exchange information and advice about the process of applying for, appealing, and renewing disability insurance from private long-term disability insurers and the U.S. Social Security Administration. People can sign up on the DISINISSIONS website and discussions will automatically be emailed to their home computers.

Because the authors of the DISINISSIONS website have the disease CFIDS/M.E. (chronic fatigue syndrome, chronic fatigue and immune dysfunction syndrome, or Myalgic Encephalomyelitis), the website tends to emphasize information of help to people with those and similar disorders. In addition to CFIDS/M.E., the site can be of particular help to those who suffer from Fibromyalgia, Multiple Sclerosis,

Lupus, and other neuro-immunological disorders. It provides helpful information to people with Lyme disease as well.

The page currently focuses on the United States legal and welfare systems.

All of these illnesses can impact severely the cognitive abilities of the person affected. The complexity, red tape, and endless forms required of the disability insurance system (both public and private) places a special burden on those who are so disabled by these diseases that they can no longer work their way through the maze alone. Subscribing to DISINISSIONS can help.

For more information about the free Online DISINISSIONS listserv go to the URL <http://www.cfids-me.org/disinissues/list.html>.

Concerns newly approved Lyme vaccine can cause arthritis

by Ridgely Ochs

Lyme disease vaccinations led to 298 reports of adverse reactions last year, the first year the vaccine was on the market, according to reports to the Food and Drug Administration obtained by *Newsday* under the Freedom of Information Act. Of those, about 10 percent reported symptoms of chronic arthritis, which some doctors and scientists fear could be a potential side effect of the vaccine. The theoretical possibility of the vaccine's prompting such an autoimmune response, in which the body attacks its own tissue, was known to the scientists, drug makers and the FDA before the vaccine was approved, although it is not included in the warning label.

"I'm stunned. Looking at these data, I'm highly concerned by the number of the reactions and the severity of the reactions," said Karen Vanderhoof-Forschner, chairwoman of the board of directors of the nonprofit Lyme Disease Foundation in Hartford. Vanderhoof-Forschner testified in May, 1998, before the FDA advisory panel urging the vaccine's approval by the FDA. "This is a voluntary reporting system, so this is probably the tip of the iceberg. How is the public supposed to evaluate this data?"

Most of the other events reported—a very small number of the 600,000 people who took the vaccine in its first year—appear to be allergic reactions, some quite severe, or failures of the vaccine to work. About one-third of the patients who had a reaction ended up in the emergency room.

Both the FDA and SmithKline Beecham Pharmaceuticals of Philadelphia, maker of the vaccine marketed as LYMERix, say that the reports of adverse events don't raise any red flags.

An FDA spokeswoman, Lenore Gelb said the reports are not proof the adverse events were caused by the vaccine. "If we do have concerns, we make an effort to change the labeling to reflect that ... There is no effort to change the label," she said. She declined to comment further.

Dennis Parenti, group director of adult vaccines for SmithKline Beecham, said 600,000 people got the vaccine in 1999, after it was approved in December, 1998; 20,000 more had participated in trials testing it, and there is no evidence of an increase in arthritis because of it.

"We've sliced it and diced it and every way looked at it and repeated some tests, and we and the FDA found there was no association," Parenti said.

But several lawsuits, including a class action suit in Pennsylvania, have been filed against SmithKline Beecham alleging the vaccine can cause arthritis in some people. The suit charges that the drug-maker failed to warn doctors and the public that LYMERix exposes people of a certain genetic type—20 to 30 percent of the population—"to the risk of a chronic, degenerative and incurable autoimmune disease which is much greater than the risk posed to these individuals by an ordinary Lyme-carrier tick bite."

The suit wants the company to relabel its vaccine, warn the public and tell doctors to screen for those who might be susceptible to a reaction. And it wants the drug manufacturer to create a trust fund to pay for blood tests for those who already have had the vaccine to see if they are at risk.

"There is a lot of smoke here, and underneath we believe there is a fire. This is a chance for SmithKline

Beecham to do the right thing and do it early on their liability," said Albert Brooks of Sheller, Ludwig & Bader of Philadelphia, which filed the suit.

A New Jersey minister, Zelma Johnson, is also in the process of filing a lawsuit against the drug company alleging that the vaccine caused her arthritis.

Ira Maurer, a White Plains lawyer representing Johnson as well as three others who were in the clinical trials for the vaccine, said, "You go under the assumption that side effects will be the typical aches and pains, but when you look at these reports [of adverse events], many are far more serious."

All drugs have potential side effects that may not show up until used in a large population. What is unusual about this vaccine is that the chief researcher, the drug company, the FDA advisory panel that recommended its approval and the FDA knew beforehand there was the theoretical possibility this one could lead to arthritis.

The question, some say, is whether the risks of the vaccine's side effects outweigh the potential benefits.

"I wouldn't take the vaccine," said Ronald Schell, a Lyme disease researcher from the University of Wisconsin. "I recognize that's a prejudice based on my animal research." He recently published a study that found hamsters injected with the vaccine were more likely to get arthritis.

"I want people to be aware; they should know of the potential [to cause arthritis]. Right now, there's a lack of choice," said Dr. Charlene DiMarco, an emerging-diseases specialist in Egg Harbor, N.J., who has served as a consultant in the class action suit. DiMarco believes people who carry a gene that may predispose them to an autoimmune response should be warned before getting the vaccine.

The vaccine works by stimulating

the immune system to produce antibodies to a protein found on the outer surface of the bacterium *B. burgdorferi*, which causes Lyme disease.

But the lead researcher for the SmithKline vaccine, Dr. Allen Steere of New England Medical Center in Boston, knew—and indeed published the fact six months before the vaccine was approved—that a part of that outer-surface protein, called OspA, has the potential of inducing a “cross-reaction” with a human protein (hLFA-1) in about 20-30 percent of the population (those people who have the HLA-DR4 gene). Cross-reacting means that in these people, the body’s immune system could attack the human protein, thinking it was part of an invading bacterium. Some experts think it is this part of the bacterium that induces so-called Lyme arthritis, which resembles rheumatoid arthritis.

Steere’s study, published in the journal *Science* in July, 1998, was a test tube study, not proof it could occur in humans. But it has added fuel to concern about the possibility.

In it, three groups of four to seven hamsters each were given different doses of a Lyme vaccine suspended in aluminum hydroxide. The vaccine was not LYMERix but was very similar to it. Seven others were injected with a commercially available canine version of the vaccine. A group of nonvaccinated hamsters and a group injected with just aluminum hydroxide were comparison groups.

All were then infected with the Lyme bacteria.

All the vaccinated hamsters developed “severe destructive Lyme arthritis;” in some groups 100 percent of the vaccinated hamsters were afflicted. By comparison, none of the unvaccinated hamsters developed higher than normal levels of arthritis typical of hamsters with Lyme disease.

The study, published last month in the journal *Infection and Immunity*,

has caused a stir among Lyme experts. In fact, Schell initially refused to discuss the article, saying it was “too political.” But he and his colleagues state unequivocally in the study:

“Recently the Food and Drug Administration approved the use of OspA for vaccination of humans despite indirect evidence and concerns that OspA is associated with arthritis. In this study, we present direct evidence that vaccination ... can induce severe destructive

The vaccine maker denies the evidence, but lawyers think where there's smoke, there's fire.

arthritis in hamsters after challenge with the Lyme borreliosis spirochete.” Schell says his study does not prove the vaccine can induce arthritis in people, but “it raises the flag, and I am concerned.”

While Schell was reluctant to discuss his findings, others were quick to assail them. Dr. Neal Halsey, director of Johns Hopkins University’s Institute of Vaccine Safety, questioned the study’s relevance, saying that hamsters are prone to develop arthritis and that the vaccine used was not LYMERix.

Schell countered that hamsters are not particularly prone to arthritis. “There’s no evidence of that in the literature,” he said. And he said he avoided using LYMERix in the study “for political reasons.” His own formulation was different by “one amino acid.”

But Halsey and others said that animal studies are not as significant as the results of clinical trials in humans. Halsey was head of the data monitoring and safety board for the SmithKline vaccine trials.

In that trial of 10,936 people begun in 1995, most side effects were minor, and only about 1 percent of those vaccinated and 1 percent of those in the placebo group developed arthritis, Halsey said. A trial of 10,305 of a similar vaccine made by Pasteur Merieux Connaught of Swiftwater, Pa.—never brought for FDA approval—showed similar results.

“No way would I have gone on to the pediatric studies if I had seen anything in the study to show there were worries,” he said.

Members of the FDA’s advisory panel also said the data they saw showed no pattern of serious side effects in the clinical trial vaccine.

“The advisory panel was aware of the theoretical risk of this vaccine causing autoimmunity. A careful evaluation of study patients did not reveal any problems, but the panel recommended the vaccine be monitored post-approval to see if anything occurred as greater numbers were vaccinated,” said panel member Raymond Dattwyler, director of the Lyme disease research center at the State University of New York at Stony Brook.

“Regarding cross-reactivity, we were all very aware, and we looked at it very carefully,” said Kathryn Edwards, a vaccinologist at Vanderbilt University in Nashville and a panel member. “I think we take the very best data we can; we think about it very seriously ... No one has a crystal ball.”

Dr. Leonard Sigal, chief investigator for the Connaught vaccine trial, said there were no untoward side effects in his study. “Cross-reactivity wasn’t seen in the Connaught trial under very controlled conditions.”

But there were signs that some participants felt they were having bad reactions.

Before the vaccine was approved, at least four lawsuits were filed by people who had participated in the vaccine trials — highly unusual since

participants sign informed consents. Three were filed against Connaught; the other was filed against SmithKline. In two of the Connaught suits and the SmithKline case, the participants said they had had debilitating arthritic-like problems. One case was settled for an undisclosed amount, another dropped and two are pending, said Maurer, the lawyer in those suits.

And others who have experience with the vaccine since its approval are sure it has done them more harm than good, regardless of the clinical studies.

An East Northport woman who did not want to be identified decided to have her son, 16, get the vaccine after the repeated urging of his doctor. He had been diagnosed with Lyme disease in January, 1998. Now she thinks it has made his knee swell, sidelining the promising track star at a time when colleges are looking to offer athletic scholarships.

“Had I known then what I know now, I never would have let him have it,” the mother said.

Reprinted by permission from the March 9, 2000 Newsday. Newsday website is at www.newsday.com.

Illinois Attorney General sues clinic and medical lab

Gensys Medical Facility and Laboratory of Aurora, Illinois, popular with some Lyme disease doctors and patients for testing services, has been sued by Illinois Attorney General Ryan. In November, Ryan charged Life Care Systems, L.L.C., GenSys, Inc. (Life Care's associated lab), Stephen Wechter and John Peterson with violating the Illinois Consumer Fraud and Deceptive Business Practices Act. He accused them of making gross misrepresentations and promising to cure consumers suffering from devastating diseases such as multiple sclerosis, lupus, amyotrophic lateral sclerosis (Lou Gehrig's Disease), as well as Lyme disease.

“We are alleging that these defendants preyed on vulnerable consumers,” Ryan said in a PRNewswire report, “selling them false hope of a cure and cheating them out of thousands of dollars for ineffective and sometimes dangerous treatment.”

The suit alleges that Wechter and Peterson told patients that they could cure or improve their conditions within six months to two years. In addition, the defendants claimed to have cured 50 percent to 75 percent of their patients. Seven patients filed affidavits with Ryan's office detailing gross misrepresentations made by defendants and hundreds of dollars spent on blood tests, antibiotics, and other treatments.

In August, the U.S. Department of Health and Human Services suspended the defendants' lab from operation. Life Care Systems remained open and the defendants are appealing the shutdown of the lab.

Vaccine lawsuit from page 1

disease to become active.

According to a report in the February issue of the journal *Infection and Immunity* (2000;68:658-663), hamsters inoculated with OspA (outer surface protein A), a protein found in the Lyme disease vaccine, develop severe destructive arthritis if they are later exposed to the organism that causes Lyme disease. The researchers say their findings provide “direct evidence that OspA can induce arthritis” and insist that the vaccine must be modified to eliminate potential side effects. New England Medical Center rheumatologist and Lyme expert Allen Steere, MD, who was part of the vaccine research team, has previously admitted his concerns about inoculating people with OspA.

Sheller, Ludwig & Badey attorney Albert Brooks said that the lawsuit is unusual in that it was instigated by a group of New Jersey doctors upset by what they considered unethical promotional practices by SKB. The blatant scare tactics and lack of mention of possible risks in the vigorous SKB ad campaign encouraged the public to demand the vaccine from their doctors, they claim.

The allegation that SKB knew beforehand of possible complications in people with the HLA factor, but did not inform doctors, is serious.

The lawsuit will concentrate on public health issues rather than claims for injuries, although the firm is also accepting claims from individuals which will be prosecuted separately. The class action, if successful, will require SmithKline Beecham to inform doctors of the importance of testing patients for the HLA factor, as well as to screen for asymptomatic and early Lyme disease. It will require SKB to monitor people for side effects from the vaccine and to reimburse people who thought they were receiving long-term protection by having the vaccine. The vaccine is probably only effective for a short time, and periodic boosters will likely be necessary to maintain antibody levels high enough to provide protection.

The law firm is also encouraging people who experience problems to file adverse event reports with the FDA.

Sheller, Ludwig & Badey is receiving calls at the rate of 2-3 a day from individuals who report “very serious” side effects to the vaccine. People who have suffered disabling symptoms after receiving the vaccine, including those who were part of the original clinical trials, should call toll-free 1-800-883-2299. The law firm's website at <http://www.sheller.com> contains a copy of the legal complaint filed against SmithKline Beecham.

Action Alert

Lobbyist asks for patient input in campaign to defend Lyme specialists

by **Monica Miller**

This letter from FAIM lobbyist Monica Miller was sent to people who have been participating in the campaign to help Lyme specialists fight charges of overdiagnosis and overtreatment.

Dear supporters of patients' rights:

So many letters have been received in Albany that one senator reports a stack over a foot high. In addition, many meetings have been held at the capitol and in various district offices. I wish to consolidate the feedback we have received to date. I need your help.

If you have received a letter back from a lawmaker could you please fax it to me at 518-758-7967, or snail mail to: FAIM, PO Box 410 Kinderhook, NY attn: Monica Miller

If you have received any email reply, please forward that to me at Monica@Healtlobby.com.

If you have met with a New York lawmaker, please inform me of who and when (that should include autumn visits) and the gist of their reaction.

Lastly, *if you have permission*, please advise me of the physicians in your states (outside New York) who have been investigated or charged for improper care of tickborne illness. Please include approximate time period.

All 14 of my meetings have been positive, at least as far as showing sensitivity and concern for the issue, except for one. So far, the legislative leadership is taking cautious yet progressive steps in our defense. They are asking a lot of good questions of us (and of the Office of Professional Medical Conduct (OPMC), as they should. We are

compiling the documents and data that answer them.

Our organizational meetings (LymePAC/FAIM) are happening regularly —over two a month. Our progress is considerable, yet we are only at the beginning of this. At the end of February I will assess the feedback to this email and report to you all further.

Check the FAIM website for updates: www.faim.org/lymefight.htm.

Patients are urged to write to lawmakers

by **Cheryl Orłowski and Ellen Lubarsky**

Many of you have asked for an update on what you could be doing to help the efforts here in New York regarding the investigations of physicians treating Lyme disease. Below you will find the up-to-date suggestions. These requests are for everyone, no matter where you live. Thank you for your efforts thus far. We must keep the pressure on so that the OPMC changes its procedures. This will ultimately help not only today's Lyme patients, but future Lyme patients and sufferers of other illnesses as well. Those patients could be yourself or people in your family. Thank you again for your continued interest and effort.

Continued on next page

Foundation protects freedom of choice in healthcare

The Foundation for the Advancement of Innovative Medicine (FAIM) has been instrumental in lobbying Congress on behalf of Lyme disease specialists who are being investigated and disciplined by state medical boards. Lyme patients are being encouraged to join FAIM to support this effort.

Since 1986, FAIM has been at work protecting freedom of choice in healthcare. One highlight of their

work was the successful passage of the Alternative Medical Practice Act, which gives physicians wider options to use non-conventional treatments. FAIM provides research and consulting service to state health freedom campaigns in 18 states. FAIM follows closely the changes in health legislation across the country, advising practitioners and consumers of the possible effects and facilitating challenges to changing and existing legislation.

Members receive **Innovation**, a quarterly newsletter, and are informed about lectures given by participating FAIM practitioners. For information, write to FAIM, 485 Kinderkamack Rd, 2nd floor, Oradell, NJ 07649, or call 201-634-3246, email faim@fcc.net.

Support our LLMDs
Support the
lobbying effort by
joining FAIM today!

History

In December, Dr. Ansel Marks, Executive Secretary of the Office of Professional Medical conduct, in response to the investigations of Lyme treating physicians, wrote that 2-3 weeks of antibiotics is adequate to cure Lyme. This letter makes it clear that the OPMC considers the prescribing of more than 2-3 weeks of antibiotics to be medical misconduct. They are investigating AND CHARGING doctors who violate this extremely biased and unscientific standard of care. Their methods, which allow an investigation based on unsubstantiated complaints and force doctors into an investigation without knowing the charges against them, are inherently unfair. They can view patient records without the consent of the patient. Charges unrelated to the original complaint can be added at any time during the investigation. The result of these actions is that doctors are forced to limit their care out of fear of being investigated. Thus the Department of Health, in the body of the OPMC, is limiting the treatment of Lyme patients to 2-3 weeks.

Letters to legislators

Below is a list of legislators to be writing to. Some have just been added to the list, some were on previous lists. Even if you have written to some of them already, which I know most of you have, it is time to write again and follow-up. Don't worry if you can't remember what you wrote in the first letter, or even if you wrote. Dr. Joseph Burrascano, one Lyme treating physician who has helped thousands of patients and is currently being charged, has asked that we now focus on the way the OPMC operates. He writes:

“Currently, when they receive a complaint, that allows them access to MD's (and YOUR) charts. Then, they are free to go after the doctor for anything they find- even if it has nothing to do with the original charge, which is always kept secret.

This is one example of the lack of due process inherent in the OPMC system. Why are physicians in New York exempt from their constitutional rights? What I am suggesting we all do is to write again to the Governor and senators and assemblymen in New York to have them change this immediately. What is most pressing right now is to restrict the scope of OPMC investigation and penalties to only the original allegation, and not have free reign to be able to trump up new charges whenever they want to attack an individual physician.”

What is most important from the

“Thank you everyone for your work so far. Please keep it up, we are only in the beginning stages and need to make it clear we are not going away.”

*LYME-PAC member
Cheryl Orlowski*

grass roots is to bring passion to the issues. It is your letters that WILL overcome the resistance of lawmakers. Your letters are extremely important. If you can, get your friends and family to write as well.

Your letters should include any or all of the following: 1. Your story; 2. Your objection to the investigation procedure (discussed above); 3. Your objection to the DOH limiting treatment to 2-3 weeks; 4. Your struggles with insurance companies over treatment coverage; 5. The details of having one doctor dismiss a diagnosis or treatment followed by positive lab confirmation with another doctor.

If your letter includes #3 and/or #4, (insurance issues and/or diagnosis/treatment denial by a physician) please send a copy of your letter to FAIM (Foundation for the Advancement of Innovative Medicine) at the following address:

FAIM PO Box 410 Kinderhook, NY attn: Monica Miller FAX: 518.758.7967 or email Monica@healthlobby.com

You can also write to other senators and assemblymen throughout the state, whomever you choose. Write to your own representatives, either in New York or out of state. New York lawmakers are found online at: <http://www.assembly.state.ny.us/> <http://www.senate.state.ny.us/>.

Those out of state: <http://www.ncsl.org/public/sitesleg.htm>

You may also call the League of Women Voters: (202) 429-1965 National (518) 465-4162 in NY or check the front of your local phone book

Letters to Editors

“Letters to the editor are impossible to overuse. We clip them and circulate them through the office like gossip sheets of what's going on. The press represents an overall buzz in the community.” -Congressional Aide

We must create that buzz!

Please continue to write letters to the editors of various newspapers and magazines. Some addresses are found below. Your letter may get published, but regardless it will put the pressure on for the paper to do a full story. Your letters should be unique for each paper. Only Dr. Burrascano--no other doctors-- has given permission for his name to go to the press.

You can also distribute the Press Release below (on page 29).

Meetings with Legislators

We still need people to be meeting with their legislators. I have

made several requests for people in New York (especially Nassau, but anywhere in the state is good) to contact me about this, and no one has. The numbers of LYME-PAC are small, and we need much more help. Please, if you live in New York State, email me about meeting with your assemblyperson or senator. If you do not, you can still arrange to meet with your representatives to discuss the Lyme issues and tell your story. After meeting with your local reps, you can keep them informed of new developments or the stories of other people.

One more request

Those who received reply letters from senators and assemblymen, please send copies to Monica at: Monica@healthlobby.com or at the above address for FAIM.

Addresses of Legislators

Lobbyist Monica Miller writes, "Please write original letters. Tell your story and why this matters to you. Your personal words are valued more than a hundred form letters. Snail mail is preferred but use email if you must. At this time, please focus on the following lawmakers:

Hon. Vincent L. Leibell
New York Senate
802LOB
Albany NY 12247
LEIBELL@SENATE.STATE.NY.US

Hon. Stephen M. Saland
New York Senate
946LOB
Albany NY 12247
SALAND@SENATE.STATE.NY.US

Hon. Nicholas A. Spano
New York Senate
509LOB
Albany NY 12247
SPANO@SENATE.STATE.NY.US

Hon. Thomas P. Morahan
New York Senate
808LOB
Albany NY 12247
MORAHAN@SENATE.STATE.NY.US

Hon. William J. Larkin, Jr.
New York Senate

Number 28

915LOB
Albany NY 12247
LARKIN@SENATE.STATE.NY.US

Hon. Michael A.L. Balboni
New York Senate
Room 803LOB
Albany NY 12247
BALBONI@SENATE.STATE.NY.US

Hon. Joel Miller D.D.S.
New York Assembly
Room 531LOB
Albany NY 12248
MILLERJ@ASSEMBLY.STATE.NY.US

Hon. Kemp Hannon, Chairman
Senate Health Committee
Room 609LOB
Albany NY 12247
HANNON@SENATE.STATE.NY.US

Hon. Richard Gottfried, Chairman
Assembly Health Committee
Room 822LOB
Albany NY 12248
GOTTFRR@ASSEMBLY.STATE.NY.US

Hon. Sam Colman
New York Assembly
Room 939LOB
Albany NY 12248
COLMANS@ASSEMBLY.STATE.NY.US

Addresses of New York media

These addresses are just some suggestions. Please write to other

papers as well.

Editor, The New York Times, 229 West 43rd St New York, NY 10036

Editor, New York Newsday, 235 Pinelawn Road Melville, NY 11747-4250

Editor, New York Daily News, 450 West 33rd Street New York, NY 10001

Editor, The New York Post, 1211 Avenue of the Americas, New York, NY 10036

The Village Voice, 36 Cooper Square, New York, NY 10003 Att: Ron Plotkin

You might also like to write to New York Magazine in response to their recent article on Lyme disease.

Editor, New York Magazine 444 Madison Avenue New York, NY 10022-6999
NYLetters@primediamags.com

Updates found online

<http://www.faim.org/lymefight.htm>

<http://www.aerovision.net/~cheryl/activism.html>

The authors may be contacted by email: <cheryl@cougar.aerovision.com> and <ellenlu@webtv.net>

LYME-PAC requests public hearings

NEW YORK, Feb. 21 /PRNewswire/ — LYME-PAC (Lyme Political Action Coalition), a coalition of 12 regional Lyme patient advocacy groups in New York State, is requesting public hearings regarding the Department of Health's decision to take sides in a heated scientific and medical controversy concerning the appropriate standard for diagnosis and treatment of Lyme and other tick-borne diseases.

In a letter dated December 21, 1999, Dr. Ansel Marks of the New York State Department of Health (NYS DOH), stated that, "Rarely if ever

have the published guidelines indicated that anything more than two to three weeks of antibiotics are required to cure Lyme disease." The experience of thousands of patients, together with extensive articles in peer-reviewed medical literature, refutes this assertion.

There is no scientific proof that 3 weeks of antibiotics will eradicate the Lyme bacteria in most patients.

Extensive articles in peer-reviewed medical journals establish that the testing for Lyme disease is unreliable and that the bacteria is

often not destroyed by this 2 to 3-week treatment protocol.

Physicians who do not adhere to this arbitrarily dictated standard of 2 to 3 weeks of antibiotic treatment are being targeted by the DOH for licensure revocation hearings. LYME-PAC believes that the DOH is violating its role as an honest arbiter and protector of medical conduct.

“The DOH is taking sides in a scientific dispute, before all the science is in, at the cost of New Yorkers’ lives and well-being. It’s inexcusable,” says Monica Miller, a spokesperson for the Foundation for the Advancement of Innovative Medicine.

LYME-PAC calls for public hearings into the conduct of the DOH in order to preserve the ability of New York State’s physicians to practice clinical medicine in accordance with their experience, best judgment and the complete body of scientific evidence available. Physicians must be allowed to tailor treatment on a case-by-case basis. Lyme disease is a multi-systemic disease. Therefore, it is absurd to treat all people with different clinical symptoms the same way. The “one size fits all” approach is inherently incorrect in the practical application of medical science, and it is specifically failing to effectively address the real life medical tragedy in a large number of Lyme disease patients.

Antiseptic products may be contaminated

On March 10 the Food and Drug Administration announced that Clinipad Corp. of Rocky Hill, Conn., is voluntarily recalling antiseptic sterile skin preparations because of a potential for bacterial contamination.

The reason for the recall is that the company has confirmed bacterial contamination in some lots of its sterile products, including one lot with *Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia* (recalled in December 1999), and therefore cannot assure the sterility of products labeled and sold as sterile. These organisms can cause skin, wound, or other infections that may be serious or life-threatening in some cases.

The nationwide recall of the Clinipad sterile-products line includes Povidone Iodine, Tincture of Iodine, Benzoin Tincture, Acetone Alcohol and Alcohol Antiseptic Products, as well as Sterile Cliniguard Protective Dressing Labeled as “sterile,” manufactured since Jan. 1, 1997.

The products (swabsticks, prep pads, towelettes, ointments and pouches, as well as protective dressings) are distributed under the names: Cliniswab, Clinipad, Clinidine, Cliniguard, EZ Prep, Cooper Instru-

ment Corp., Moore Medical Corp., and Rauscher. They are sold separately or packaged in various institutional kits and are widely distributed to blood banks, hospitals, clinics, and retail pharmacies and are used to control and prevent infection.

Although there have been no known instances of blood contamination traced to the recalled products, clinicians should remain alert to this possibility.

All lots of the sterile products line involved in the recall have a lot number beginning with 7, 8, 9, or 0, and are labeled as “sterile” on the unit of use packaging, or “sterile unless opened or damaged.” The lot numbers are also found on the shipping carton or its label.

Health professionals and consumers who have the product with the involved lot numbers should destroy the product. Health professionals and consumers who have these products can obtain more information about the recall from FDA’s MedWatch Website at www.fda.gov/medwatch/. Also, consumers with questions may contact the Clinipad Corporation at 860-571-0100.

Lyme patient Brian Carroll of Ansonia, Connecticut had half of a box of “sterile” alcohol wipes left over from his last round of IV, so he called Clinipad.

“Their Customer Service agent said that I shouldn’t be ‘majorly’ concerned over having used this product,” Carroll said. “I understand how recalls work and most likely these are okay but the company has to recall all of them to be sure. It is disconcerting nonetheless.

“I asked if they have a replacement policy since they didn’t offer. She said she would fax a form that I will have to fill out and once received, they will send another box free.”

Evidence sought for conflict of interest on state boards

State Boards exist to protect patients from harm. The threat of professional reprimand or loss of license has a powerful effect upon a physician’s manner of practicing medicine. The question exists whether the actions of these licensing boards are ever improperly influenced by the insurance/managed care industry or any other special interest groups.

Does anyone who has worked within these systems have objective proof that improper influence occurs or has occurred? Would you be willing to be interviewed on network television regarding this issue? If so, please reply to Robert Bransfield, MD, 25 Highway 35, Red Bank, NJ 07701, tel. 732-741-3263.

Lyme Bill stalled - public pressure needed to get it moving through committee

from page 1

million over 5 years to fight Lyme disease on several fronts. Research at the NIH, the CDC, the Dept of Defense and the Dept of Agriculture will be dramatically expanded. Patients can play a crucial role by educating their legislators and encouraging them to support the bill.

Bill will fund research and education

Rep. Smith explained that the Dept. of Defense (DOD) performed \$1.5 million in research on Lyme last year to protect soldier and military dependents who live or train on bases with a high risk, which includes every base in New Jersey. The DOD is developing new methods of tick control where targeted use of pesticides is combined with aggressive tick habitat management techniques. The Lyme Disease Initiative would extend this program for 5 years.

In addition, \$7.5 million (\$1.5 million/year) is earmarked for the Dept. of Agriculture to enhance its exploration of innovative techniques to reduce and manage tick populations with minimal pesticide exposure to humans. The same amount would be set aside for the Dept. of the Interior's efforts to improve public awareness and understanding of the risks of Lyme disease on federally owned lands.

In addition to new funding, the bill establishes very ambitious public policy goals for federal agencies including: a 33% reduction in Lyme disease within 5 years of enactment in the 10 highest and most endemic states; better coordination between the scattered Lyme disease programs within the federal government; additional research into other related tick-borne illnesses to address the problem of coinfection; and the

creation of a Lyme Disease Task Force to present the public with an opportunity to hold our public health officials accountable as they accomplish these tasks.

Public pressure needed

As of March 31, only 32 congresspeople have signed on. Only 5 senators have joined Sen. Santorum in sponsoring the Senate version. NJLDA president Pat Smith urges people to contact their legislators and get them to sign on as cosponsors. The volume of business transacted in Washington makes it easy for one bill to become stalled in committee and never reach the floor for a vote.

"We need to reach 100 Congresspersons to get the bill moving out of the House committee

and several more Senators to move the Senate version," Smith said. "Have all your friends and relatives call or write, too."

Regular mail is preferred to email, and phone calls are taken seriously at Capitol offices. Addresses and phone numbers of legislators may be found in local phone directories, libraries, and online at www.senate.gov and www.house.gov. The bill may be viewed by entering the identifying number (HR-2790 for the House bill, S-1905 for the Senate version) in the appropriate box.

In an Oct. 22 statement to NJLDA, Rep. Smith wrote that "according to some estimates, Lyme disease costs our nation \$1-\$2 billion in medical costs annually. The number of new confirmed cases of Lyme disease (according to the Centers for Disease Control and Prevention) was nearly 16,000 last year, an increase of 24.5 percent from the previous year, and that is only the tip of the iceberg!"

The Lyme Disease Initiative 1999 is a chance to turn those figures around.

Activist mom of Lyme-disabled child supports Lyme Bill

This is the text of a speech given at a March 13 press conference with Congressman Joseph Pitts and Senator Rick Santorum in West Chester, Pennsylvania.

by **Mary Halinski**

I would like to personally thank Sen. Santorum and Congressman Pitts for their support of this very important legislation, the Lyme Disease Initiative of 1999.

My name is Mary Halinski and I am the PA Chapter Director of the Lyme Disease Association of NJ. My son was diagnosed with Lyme disease about 2 years ago. Because he was not diagnosed until years after he contracted the disease, the disease had invaded his nervous system,

eyes, joints, skin, muscles and heart. This, of course, had devastating consequences. The disease left him unable to read or write, and he could barely walk.

As if it was not hard enough to handle an illness that presents so many debilitating effects, we also found out how many steep obstacles there would be to climb beyond just the physical manifestations. Difficulties in finding physicians that were knowledgeable about this disease,

inaccurate testing, poor treatment protocols, insurance company issues, and an educational system unequipped to handle this disease, all mounted serious problems against the backdrop of a serious illness.

That is why this legislation is so important to me and I know it is important to all of you here today. This legislation will provide 125 million dollars over 5 years to fight this disease from all sides. Research at the NIH, the CDC, the Dept of Defense and the Dept of Agriculture is dramatically expanded. We need to attack this disease on all fronts, as all of us gathered here today, have certainly been attacked on many fronts by this disease.

Accurate, reliable testing is a most critical issue in the fight against Lyme disease. With the current testing, ELISA and Western Blot antibodies tests, many people with the borrelia infection test negative, or are told to

ignore positive tests as they are not accurate. This allows time for the illness to tighten its grip, robbing us of the precious time needed for early treatment. Couple this with CDC surveillance criteria that is not representative of the vast number of Lyme disease cases, and is often misused as clinical criteria, and the diagnosis of Lyme disease becomes exceedingly difficult and often arrives too late. This bill provides the vital research required to make testing more accurate and by doing so, facilitating the diagnosis of the disease.

We also need to attack Lyme disease at its source, through reduction of the tick population. This legislation funds research into natural, nonpesticidal, and more effective means of reducing the tick populations. Importantly, the bill calls for a one-third reduction of Lyme disease incidence over five years in

the ten most endemic states, including Pennsylvania. We must eliminate this disease, instead of seeing it spread unchecked to thousands more.

The bill also provides for increased awareness, testing, surveillance, diagnosis, treatment and effective strategies to prevent and control tick-borne illnesses other than Lyme disease. These include ehrlichiosis, babesiosis, rickettsial diseases, tick-borne encephalitis and various viral diseases to name a few.

Knowledge is a powerful weapon, and this legislation funds education about this poorly understood illness. Much of the medical community is grossly ignorant of the proper way to diagnose and treat Lyme, and must be educated to stop Lyme in its tracks. Public awareness is crucial to prevention and early detection.

This legislation is an auspicious beginning in the fight against Lyme disease. It lays the groundwork for a more positive future for Lyme disease patients, and brings us closer to conquering this disease. I am proud to have been a part of this process, and once again our special thanks to Sen. Santorum and Congressman Pitts for their support of Lyme disease patients everywhere.

Use the sample letter below to write your own letter, including personal details if you wish. But remember, keep it brief! If writing to your Representative, refer to HR-2790; if to your Senator, refer to S-1905.

Sample letter:

Dear Representative/Senator_____:

Even by CDC reckoning Lyme disease is seriously underreported, and [YOUR STATE NAME] is no exception. Many doctors do not recognize Lyme disease, and even those who do, do not always report it.

New Jersey Congressman Chris Smith is looking for cosponsors for HR 2790, [Pennsylvania Senator Rick Santorum is looking for cosponsors of S-1905], the Lyme Disease Initiative. The Bill contains a package of desperately needed reforms, combined with additional resources totaling \$125 million over five years, to help combat this emerging public health threat. The goals of the Bill in priority order are as follows:

- A detection test that will accurately indicate who has Lyme, who does not, and who is cured
- Improved surveillance and reporting system
- Lyme disease prevention and development of indicators in the ten highest endemic states
- Prevention of tick-borne diseases other than Lyme
- Improved public and physician education

Please join Congressman Smith and Senator Santorum in their effort to improve what has become a desperate situation for many Lyme disease patients and their families.

Cosponsor HR 2790 [S-1905], a bill that has been endorsed by Lyme patient advocacy groups all over the country.

Special offer of free Lyme Times

If you would like a copy of the Lyme Times #27 with the picture of the protest at NIH on the front, to include with your letter to your representative or senator, send your name and address on a mailing label and \$.99 in stamps to Lyme Times Editor, PO Box 1423, Ukiah CA 95482. The Lyme Times will be sent to you first class mail in a large manila envelope. You can then readdress it and enclose your own cover letter. If our legislators start receiving many Lyme Times, we may make an impression.

Offer good while supplies last.

International professional Lyme group has first general meeting

by **Teresa MacKnight, DO**

The first general meeting of ILADS – the International Lyme and Associated Diseases Society – on April 29th in central Pennsylvania will feature a workshop on the legal concerns of caring for Lyme patients. The meeting will be held in conjunction with a Lyme disease public education seminar.

ILADS is a society for healthcare professionals whose development has been welcomed during the last year by patients, providers, and support groups from coast to coast, as they have realized that the doctors are in need of their own support group.

ILADS' purpose is to protect the rights of doctors to care for Lyme patients and to protect the rights Lyme patients to receive quality medical care. One of the primary goals is to develop position statements and practice parameters related to Lyme and associated diseases. The priorities of ILADS are:

1. The education of providers on how to protect themselves medicolegally in caring for Lyme patients. Michael Shoppman, a New Jersey lawyer whose firm has represented many Lyme specialists, understands that there are things doctors need to know with regard to documenting properly the care of Lyme patients. This information needs to be widely disseminated to doctors.

2. The opening of the general membership of ILADS, and from this body to elect to the administration, those doctors with energy and leadership qualities.

3. The organization of state level ILADS groups for the purpose of providing local support, and to educate and mentor newcomers.

4. The maintenance and utilization of the websites' public areas and the healthcare provider's "private entry" areas for the sharing of questions, cases studies, bad outcomes, initiating practice-based research, and

networking responses to media and legal challenges at the state, national, and international level.

All people working on ILADS do so as volunteers. Interested healthcare professionals are invited to visit the ILADS website at www.ilads.org where a membership form may be filled out, or to write ILADS at PO Box 367, Andover, Maine 04216, or Phone/Fax 207-392-1373, or Email ilads@megalink.net.

ILADS Mission Statement

The mission of the International Lyme and Associated Diseases Society (ILADS) is to create an interdisciplinary forum for health science professionals where they can communicate their collective wealth of knowledge, as accumulated from their many years of experience, in the management of Lyme and associated diseases. As an effective advocate for physicians engaged in the treatment of Lyme and associated diseases and by seeking cost-effective, state-of-the-art therapies, ILADS will achieve the ultimate goal of providing successful treatment regimens for patients suffering from Lyme and associated diseases, and thereby establish new standards of excellence in medical care.

Letters needed for doctor defense

Letters from patients in support of Dr. Bernard Raxlen of Hamden, Conn. are needed immediately. Raxlen is being investigated by the Connecticut Dept. of Health.

Patients should mention whether they were misdiagnosed or not diagnosed prior to being diagnosed and treated for Lyme by Dr Raxlen. They should also mention if they had difficulties in obtaining health insurance coverage for their Lyme treatment.

Letters should be addressed to Attorney Elliott B. Pollack, Pullman & Comley, LLC, 90 State House Square, Hartford, CT 06103. Email: EBP@Pullcom.com Fax#: 860-424-4370

According to Kathleen Dickson of the Southeastern Connecticut Lyme Support Group, Attorney General

Blumenthal would be interested in knowing whether doctors who adhere to the ideology that Lyme is overdiagnosed are also being investigated for physician negligence.

Dickson said she has reported two such doctors to Kathleen Boulware, RN (tel. 860-509-7552) who is in charge of Conn. Medical Quality Assurance, but has heard nothing.

"It would be within the Attorney General's realm of duties to look into the possibility that there is a difference in the extent to which these people are being investigated as compared to Dr. Raxlen," she stated.

She says if other patients have reported negligence they need to come forward and give a status report. If there is a bias, the Attorney General needs to know.

Regional News

Southeast appears to have a unique type of Lyme disease

The Southeast appears to have its own version of the tick-borne ailment Lyme disease that is not detectable by most standard tests, according to Georgia researchers.

Extensive laboratory testing of 23 adults with the characteristic bull's eye rash showed that 70 percent were not infected with the spirochete known to cause Lyme disease, according to the study published in the November issue of Archives of Dermatology.

Thirty percent of patients did test positive for the spirochete, but on closer analysis, even in those patients, the spirochete—called *Borrelia burgdorferi*—had a different protein composition than that causing Lyme disease in New England and the Midwest, said Dr. Michael Felz, family medicine physician at the Medical College of Georgia and principal investigator on the study.

“There is some kind of tick-transmitted illness here that acts like Lyme disease but only fits the laboratory pattern 30 percent of the time, at least when you apply a test that was designed for New England and the Midwest where Lyme disease is more common,” Dr. Felz said. “In other words, we may need a whole new testing system for this illness in the Southeast.”

MCG collaborated with Georgia Southern University in Statesboro and the Centers for Disease Control and Prevention in Fort Collins, Colo., on the CDC-funded study.

The three-year study included Georgians and South Carolinians who lived within 200 miles of Augusta and came to the MCG Family Practice Center to see Dr. Felz after developing enlarging red rashes, 2 to 8 inches in diameter. Approximately 90 percent

were certain they had been bitten by a tick.

Before each patient began the standard therapy of a three-week oral regimen of the antibiotic doxycycline hyclate, photographs, biopsies and blood samples were taken for a complete series of tests. Tests included the sophisticated polymerase chain reaction assay for spirochete DNA in biopsy samples; the PCR was positive in five of 23 cases.

“These data say yes, there is some Lyme disease here that meets the criteria of current national lab testing standards. Yet the majority of cases—seven out of 10—are something different,” Dr. Felz said. “The tick species transmitting this illness seems to be different and may be transmitting an organism that is very different.

“Lyme disease in the southeastern United States seems to be due to genetically variant strains of the spirochete *Borrelia burgdorferi*,” Dr. Felz said. “These strains probably

have a different DNA backbone and cause different clinical symptoms and signs than is the case in other parts of the country.”

Dr. Felz, who has studied ticks and the diseases they carry for nine years, says this study is the “most scientifically rigorous analysis” of Lyme disease ever in the southeastern United States.

Researchers found no evidence that the disease progressed to the second stage in any of the study patients, leading them to believe that the Lyme disease organism in the Southeast may be a less virulent strain and/or more responsive to antibiotic therapy.

Dr. Felz's collaborators at MCG on the study include Dr. Francis W. Chandler Jr., director of Immunopathology and Histopathology Laboratories, and Dr. Daniel W. Rahn, rheumatologist and Lyme disease expert who is vice dean for clinical affairs in the School of Medicine. Other collaborators include Dr. James H. Oliver Jr., Institute of Arthropodology and Parasitology at Georgia Southern University, and Dr. Martin E. Schriefer, CDC in Fort Collins.

Contact: Toni Baker
tbaker@mail.mcg.edu 706-721-4421
Medical College of Georgia

Ohio support group launches new website

The Greater Cleveland Lyme Disease Support Group (GCLDSG) has launched a new website at <http://www.freeyellow.com/members8/gcldsdg>. The site includes excerpts from their newsletter, “Best of the BULL’S-EYE—1999,” as well as information about GCLDSG projects and meetings.

Founded in 1990, the GCLDSG, is a 501 (c) (3) non profit organization serving as a source of information and interaction for Lyme disease

patients, families, the general public and the medical community. They offer monthly meetings, telephone contact with fellow Lyme disease patients, a newsletter, information and education projects. There is no membership fee or charge for the meetings or materials.

GCLDSG meets on the third Sunday of every month from 3-5pm in the DeWitt Conference Rm - D 18697 at SouthWest General Health Center, Bagley Road, Middleburg Hts., Ohio.

University of Alabama hosts lecture by Steere

by Julianne Collins

Dr. Allen Steere gave a lecture on Lyme disease at the University of Alabama at Birmingham on January 26, 2000. The lecture was sponsored by the Rheumatology department and was open to the public. A hundred people were estimated to be in attendance, with physicians making up the majority of the audience.

Seven Lyme disease patients and family members from the Lyme Disease Support Group of Alabama attended this lecture. We wore green names tags stating who we were, where we were from, and how long we had Lyme disease to add a more human face to the lecture. The organizers of the lecture also let us give out brochures containing general information about Lyme disease in Alabama.

We were aware of the controversy surrounding Dr. Steere, and had all been affected by misdiagnosis or undertreatment of Lyme disease. However, we decided not to protest because of two reasons, the first being that no one would understand why we were protesting, and the second was that we wanted to hear what he had to say, since many other groups around the country haven't been able to.

Dr. Steere opened the lecture with some misleading graphics that made it seem like Lyme disease only occurs in the Northeast. He downplayed the risk in the South, and commented that the Lyme disease here was more treatable than the strain in the Northeast (which caused some amusement among the patients). However, he did mention that some patients, especially those who have late-stage Lyme, may be harder to treat. One important thing is that he went over the symptoms of Lyme and other tick borne diseases, so possibly

“Dr. Steere stressed that a doctor should not wait for the test results, but should treat immediately, as it is better to treat Lyme disease while it is in its early stages.”

the doctors in the audience will consider them the next time they see a patient with those symptoms.

They clearly ignored the patients at the question and answer period, but I finally stood up for a while and they allowed me to ask the final question.

I asked, “According to the CDC

Help needed on Tissue Bank Project

Lyme patients are dying, but are they dying of Lyme? Their death certificates often list other diseases. There is a need for more research, and to support it, a tissue bank to store specimens from Lyme patients, both alive and dead. An ideal site would be a facility that is also actively conducting tissue-based research and not only a storage facility. Specimens would be made available for research projects on Lyme disease. Collection protocols would be designed to make it simpler for the next of kin.

If you are interested and could help with this project, financially or otherwise, please contact the Lyme Times editor.

and FDA, surveillance criteria should not be used for a clinical diagnosis. Here in Alabama, we have had people with tick bites, bull's-eye rashes, and symptoms, who could not get treatment unless they met CDC criteria. Dr. Steere, would you treat a patient if they presented to you with these symptoms?”

He answered “Yes, I would treat anyone who I felt had Lyme disease.” He also stressed that a doctor should not wait for the test results, but should treat immediately, as it is better to treat Lyme disease while it is in its early stages. This is not the only question I wanted to ask, but it was the most useful to future Lyme patients here given the many doctors in the audience.

After the lecture, another patient and I went down and actually got to briefly talk to Dr. Steere. We told him that we both had Lyme disease and had had a lot of trouble getting diagnosed here. We thanked him for coming and raising awareness (Trust me, in Alabama we still have doctors who don't know what it is or even that it is here and many were present!). The other patient asked him what he thought about the controversy and conflicting research on treatment length. Steere responded that he didn't believe that there was any research (except on the Internet) supporting long term antibiotic treatment.

Even though we didn't necessarily agree with what Dr. Steere had to say, his visit was a decent start to raise awareness about Lyme disease in Alabama. We need to get doctors testing and treating patients for it first, and then we will work on informing them about problems with the tests, length of treatment, and coinfections.

Ms. Collins is a member of the Lyme Disease Support Group of Alabama. She has developed a website at <http://julianneSC.tripod.com/lyme.html> and may be contacted by email at julianne@uab.edu.

Infected ticks found in Southern California parks

After years of making light of patient claims that they had contracted Lyme disease in the Los Angeles area, health officials are finally warning hikers at Will Rogers State Historic Park to be wary of ticks this spring, because a pool of 10 male *Ixodes pacificus* collected on Jan 5 along the park's Betty Rogers Trail tested positive for the bacterium that causes Lyme disease.

A total of 274 ticks were collected, and divided into groups of 10. One of those groups tested positive for the Lyme disease bacteria, said Robert Saviskas of the Los Angeles County West Vector Control District.

Another batch of ticks collected at Charmlee Park in Malibu recently showed a range of four to possibly as high as 42% testing positive, according to the Los Angeles County West Vector Control District. Of 120 ticks pooled (10 per group), 5 of 12 groups were reactive on an IFA test.

According to a story in the March 29 Los Angeles Times, ticks that carry the disease were first discovered locally in Malibu State Park in 1999, and researchers say the infected creatures now appear to occupy a 22-mile stretch of the Santa Monica Mountains, from Malibu to the Palisades. Saviskas said it isn't clear whether infected ticks are spreading or whether they had always existed in these areas but are only recently being discovered because of increased testing.

This year's findings show an increase from last year, when the county found almost 2% of ticks collected in the Santa Monica Mountains tested positive for Lyme disease.

Mark Miller, director of Communicable Disease Control of Placer County Health Department, stated that the adult tick infectivity rate statewide has historically been about

1 to 2%, and may be on the rise. However the infection rate of the tiny nymphal ticks, suspected of being the source of most human cases of Lyme disease, is known to be several times higher in areas inhabited by lizards. The low state figures lead to underrecognition and underdiagnosis of Lyme disease.

Annie Konklin, a Beverly Hills resident, saw seventy physicians before she was diagnosed. "The unacknowledged suffering is the worst thing I've suffered," said

Konklin. "People would say get your act together."

Barbara Barsocchini, a Malibu resident who caught Lyme in her backyard, was also misdiagnosed for months by local doctors. She joined the board of directors of the Lyme Disease Resource Center and started trying to educate people. Largely because of her efforts, health department researchers started investigating LA parks, leading to the new discoveries which vindicated patients' claims.

People with questions may contact the Los Angeles County Acute Communicable Disease unit at (213)240-7941.

California residents "Make a Difference"

Santa Cruz resident and Lyme patient Sarah Weiss is proud of herself.

"Not only are TICK WARNING signs going up at State Parks around here because of my efforts," she wrote, "but I have just gotten off the phone with the Environmental Health officer of SC County and he is going to do a News Release to the local press about the dangers of Lyme disease in SC County."

Weiss hopes the pediatrician who refused to treat her daughter's tick bite and told her there was "no Lyme disease in Santa Cruz" reads it. The 3-year old child came down with the disease and is being treated by a different doctor.

Malibu resident and LDRC Board Member Barb Barsocchini received a 1999 Citizen of the Year Dolphin Award for her educational and support work in her community. Given annually to outstanding citizens, the Dolphin Awards are awarded by The Malibu Times.

An article in the Feb. 3 Malibu Times said: As late as 1998, doctors maintained that Lyme disease did not

exist anywhere in Los Angeles County. Barsocchini knew better, having suffered for years with debilitating symptoms misdiagnosed as everything from arthritis to chronic

Support Groups in California

The **Santa Cruz** Support Group meets at the Aptos Library Group Room. For information email Sarah Weiss AramSarah@cs.com or call her at 831-662-3628.

The Mid-Peninsula Lyme Disease Support Group meets at the El Camino Hospital, 2500 Grant Road, **Mountain View**, on the second Tuesday of alternate months from 6:00pm to 8:00pm in Room D. For information email tom7s@aol.com or call the hospital.

The **Marin** County support group is run by Lee Lull. Email her for information at leema@earthlink.net or call 415-927-9553.

Mike wants to set up a **southern California** network including San Diego, Los Angeles, Orange, Ventura, San Bernadino, and Riverside Counties, possibly kicking it off with a family picnic in July at Mile Square Park in Fountain Valley. If you are interested email Mike at mike7701@my-deja.com.

fatigue syndrome. When she finally received the correct treatment, she made it her personal mission to educate other Malibu residents to the threat of the tick-borne disease and to get the attention of state and county health officials. It was a struggle.

Barsocchini has devoted the last five years of her life to helping those who have suffered from the long-term effects of the disease to get effective treatment and to inform people how to protect themselves.

She also organized a meeting of Lyme patients and their friends at the Holiday Inn, in Ventura, California, on

January 19 to coincide with the Gordon Research Conference on the Biology of the Spirochetes, where Dr. Allen Steere was scheduled to speak.

In Marin County, Larry Gambol, 45, is suing Novato Community Hospital, alleging that doctors there were negligent for failing to diagnose him with Lyme disease, leading to complications that cost him his strength and his job. The lawsuit says that doctors failed to make the diagnosis even though they saw his tick bite with a rash and Gambol and his wife, an RN, suggested that he might have Lyme.

the Lyme disease spirochete.⁷

California's climate ranges from desert to temperate rain forest. Ticks are active year-round except in extremely dry areas. High risk outdoor occupations common in the state include agriculture, ranching, and forestry. Outdoor recreation is also enjoyed by many Californians. Both work and play put many people at increased risk for Lyme disease.

In the late 1980s, a Ukiah (Mendocino County) physician undertook an informal survey of health care providers in the northern counties to determine whether Lyme disease was being recognized and reported. His data, which suggested that many cases were being diagnosed but few reported, led CDOHS to initiate an active surveillance program whose results are noted below.

Over 1400 cases of Lyme disease meeting the CDC case surveillance definition have been reported from California since the early 1980s. With a population of almost 32 million, this works out to an incidence of 0.4 per 100,000 population (Note: Compare Connecticut at 94.8, New York at 29.2 in 1996.).⁸ We present epidemiologic data from three studies to compare with official incidence figures.

Methodology:

We selected three studies for comparison. The first was an active surveillance program conducted in four northern coastal counties by C. Ley and colleagues at University of California School of Public Health and CDOHS. The second was UC Berkeley entomologist Robert Lane et al.'s one year prospective study of risk factors for Lyme disease in a small rural community in Mendocino County. A second Mendocino County study examined the incidence of erythema migrans in a rural community. We compared these data with CDOHS and CDC figures.

Results:

The CDOHS active surveillance study of four northern counties

Risk of Lyme Disease in California

by Phyllis Mervine

This paper was presented as a poster at the VIII International Conference on Lyme Borreliosis in Munich in June, 1999.

According to hundreds of calls received yearly by the Lyme Disease Resource Center, a national educational nonprofit group located in northern California, many sick people cannot find a physician who will consider a diagnosis of Lyme disease, in spite of tick bites and symptoms compatible with the diagnosis. Many Californian physicians believe that Lyme disease is rare or is an East Coast disease. Some refuse to test people for Lyme disease or to diagnose it, with the consequence that some bona fide cases progress to severe chronic disease states. People who eventually are diagnosed find that their chronic fatigue, their multiple sclerosis-like disease or other symptoms improve with antibiotic treatment. Physicians say that they do not report cases because the forms are too time-consuming or complicated, or they fear harassment or investigations by health department officials or state medical boards as has happened in other states.^{1,2,3,4}

California residents are at risk for

Lyme disease. Studies conducted by the California Department of Health Services (CDOHS) have demonstrated the existence of the vector tick, *Ixodes pacificus*, in all but two of California's 58 counties. Infected ticks have been found in 34. Adult ticks have relatively low infection rate (usually 1-2%, as high as 5%), but the nymphal tick infection rate is significantly higher, up to 14% in some areas.⁵ Nymphal ticks are implicated in most human cases of Lyme disease.

Unique enzootic cycles have been identified. Western fence lizards (*Sceloporus occidentalis*) and Columbian Black-tailed deer (*Odocoileus hemionus columbianus*) are major hosts of *I. pacificus*. Antibodies to *Borrelia burgdorferi* (Bb) have been detected in 12 species of wildlife in California. Species exhibiting the highest seropositivity rates include brush rabbits and black-tailed jackrabbits (=100% and =90% respectively).⁶ Dusky-footed woodrats (*Neotoma fuscipes*) and California kangaroo rats (*Dipodomys californicus*) serve as reservoirs of

concluded that Lyme disease was both underdiagnosed and underreported and subsequently the low 14.2/100,000 incidence figure in Humboldt County was revised upward to 65.7/100,000 [Note: more than double the New York incidence].⁹

In 1988-9 researchers conducted an epidemiologic study of a small rural community in Mendocino County. They determined that the rate of seropositivity for Bb among study participants was between 20-24%. Residents completed a questionnaire about outdoor activities and of 83 participants were examined by a physician, 31 (37%) had definite or probable Lyme disease. The researchers concluded that the cumulative frequency of serologic infection with Bb in the resident population was probably higher than 24 percent. The annual incidence was 1.7%, "comparable to or higher than the cumulative frequencies/incidences from the Northeast."¹⁰ [Note: 1.7% translates into an incidence of 1700/100,000, but the sample size was very small and cannot be considered representative of the state as a whole.] This unusually high incidence is explained by the high infection rate of nymphal ticks, averaging 12.7% (range 4-41%).¹¹

Clinical symptoms experienced by Lyme disease patients in the community include (but are not limited to) pancarditis, arrhythmia, absent reflexes, arthritis, ankylosing spondylitis, juvenile rheumatoid arthritis, chronic bad back, "tennis" elbow, carpal tunnel syndrome, paralysis of the vocal cords, Bell's palsy, Parkinson's-like syndrome, excessive hair loss, night sweats, depression, and psychosis.

In a nearby valley, 76 cases of Lyme disease were diagnosed during the same time period. Of these, 31 had pathognomonic erythema migrans rashes.¹² With the valley population of about 1,500, the incidence works out to 2.0%. The patient data are consistent with Clover and Lane's finding that 13.6% of the nymphs

from one site in this valley are infected with Bb.¹³

Discussion and Conclusions:

These three northern California studies show a high incidence of Lyme disease. There are many other similar communities where Lyme disease is not being diagnosed and reported. A similar study in Sonoma County did not find a high incidence of Lyme disease, but did find a high risk of two other tick-borne diseases,¹⁴ suggesting that the study group was being bitten by ticks. Also, the researchers in that study employed the controversial two-tier testing method for Lyme disease which is accused of being insensitive. Reports of infected ticks have just been confirmed in southern counties, although the CDOHS is downplaying their significance for fear of "causing hysteria." In conclusion, the true incidence of Lyme disease in northern California is several orders of magnitude greater than the official state estimate.

These research findings of high incidence in certain population groups in the state are not well known. Health care professionals who are aware only of the state figures think Lyme disease is rare and are reluctant to diagnose it, even in hyperendemic areas. Of cases that are diagnosed, a large percentage is not reported. Passive surveillance is not working. And as is true in other states, cases accepted for inclusion in official incidence reports represent only a fraction of the total cases reported.

According to CDOHS figures, four sparsely populated northern counties (Mendocino, Humboldt, Lake, and Sonoma) are responsible for most of the reported cases of Lyme disease in the state. If the cases reported in 1991-1995 from these counties are considered in relation to the population of the county alone, the incidence ranges from 9.8 to 74.3/100,000.¹⁵ Averaging with zero incidence from many other counties, however, brings the state figure down

to a low 0.5 for this timespan.

The popular but erroneous perception of the whole state of California as a low risk environment for acquisition of Lyme disease has significant public health consequences. Failure to diagnose combined with failure to report leads to low incidence rates. It leads to widespread denial of Lyme disease by physicians, leaving undiagnosed and untreated patients to progress to a late stage of the disease with severe disability and suffering.

More education and further research on the West Coast are urgently needed to combat the significant morbidity associated with undiagnosed and untreated Lyme disease and other tick-borne diseases and to encourage physicians to diagnose and report it.

References:

- 1 the Lyme Times, "Missouri Lyme disease controversy still simmers." 3.2:1ff, 1992.
- 2 the Lyme Times, "Federal study raises questions about treatments." 10:1ff, 1993.
- 3 the Lyme Times, "Investigations create tension for Lyme doctors." 13:1ff, 1994.
- 4 the Lyme Times, "Judge vindicates Lyme disease doc." 14:1ff, 1996.
- 5 Clover JR, Lane RS. Evidence implicating nymphal *Ixodes pacificus* (Acari: Ixodidae) in the Epidemiology of Lyme Disease in California. *Am J Trop Med Hyg.* 53(3):237-240, 1995
- 6 Lane RS. Epizootology of Lyme Borreliosis in the Western US. *Proc 14th Vertebr Pest Conf*, Davis & Marsh, Eds. UC Davis, 1990.
- 7 Lane RS, Brown RN. Wood Rats and Kangaroo Rats: Potential Reservoirs of the Lyme Disease Spirochete in California. *J Med Entomol* 28(3):299-302 (1991).
- 8 Centers for Disease Control and Prevention. *Lyme Disease Surveillance Summary*; 8;1 (1997).
- 9 Ley C, Davila I, Mayer N, Murray RA, Rutherford GW, Reingold AL. Lyme Disease in Northwestern Coastal California. *Western J Med.* 160:534-539. 1994.
- 10 Lane RS, Mannweiler SA, Stubbs HA, Lenette ET, Madigan JE, Lavoie PE, 1992. Risk factors for Lyme disease in a

small rural community in northern California. *Am J Epidemiol* 136:1358-1368.

11 Talleklint-Eisen L, Lane RS. Variation in the Density of Questing *Ixodes pacificus* (Acari: Ixodidae) Nymphs Infected with *Borrelia burgdorferi* at Different Spatial Scales in California. *J Parasitol*, 85(7), 1999. Data being prepared for publication; see poster on Tuesday.

12 Katzel J, Ritter R. Erythema migrans. *Abstr V Int Congr Lyme Borr*, 1992

13 Clover JR, Lane RS. Evidence

implicating nymphal *Ixodes pacificus* (Acari: Ixodidae) in the Epidemiology of Lyme Disease in California. *Am J Trop Med Hyg.* 53(3):237-240, 1995.

14 Fritz CL, Kjemtrup AM, Conrad PA, Flores GR, Campbell GL, Schriefer ME, Gallo D, Vugia DJ. Seroepidemiology of Emerging Tickborne Infectious Diseases in a Northern California Community. *J Inf Dis* 175:1432-9, 1997.

15 Murray RA. Lyme Disease in California, 1991-1995; Average Annual Incidence by County. CDOHS, unpublished.

Wilton Task Force has been a key driver in efforts to combat Lyme. Lyme disease is a priority health issue for him.

Dr. Brian Fallon, who will be coordinating the various research projects funded by the benefit, also thanked the Task Force. David Canary, the Emmy award winning star of *All My Children*, also spoke. He is concerned that his own children may have Lyme. He mentioned that the Wilton Task Force has worked hard to educate the community and increase safety on school grounds and public fields. He is proud that Wilton is a leader in the fight against this widespread problem.

Cathy Morrissey, President of the Task Force, spoke movingly about the motivation behind the efforts of the Task Force and the controversies surrounding Lyme disease [*see below*].

“There are several communities in Connecticut following our lead and I believe we will see significant money raised in the next 2 years,” said Morrissey. “This was a very good response to a first time project. The Wilton Task Force is continuing its educational and research efforts with events planned throughout the next year. We are planning another large fund-raiser, and welcome new volunteers.”

Ms. Kosakow is the secretary of the Wilton Task Force.

Wilton (Conn.) Task Force raises big bucks for research

by Yvonne Kosakow

“Dance the Lyme Away” was the first fund-raiser in the State of Connecticut to raise funds for Lyme Disease research and education. It was held March 23 at the Rolling Hills Country Club in Wilton and 307 seats were sold. The event raised in excess of \$160,000 which will be used to support scientists collaborating with Dr. Brian Fallon of Columbia University, who recently received a \$4.7 million dollar NIH grant to study persistent Lyme encephalopathy. Under Fallon’s direction, researchers will begin to do important work in immunology, microbiology, and epidemiology. (*see story p. 43*)

When Fallon spoke at the fund-raiser he told the attendees that pilot studies are what led to his large grant. The pilot studies were made possible by a grant from the New Jersey Lyme Disease Association.

In honor of St. Patrick, the event had an Irish flavor. Music was provided by the Sean Fleming Band, and the audience very much enjoyed a performance by the children’s dance troop, The Emerald Dancers, who were expert step dancers. Silent and live auctions were held. Well over one hundred items were auctioned, including sports memorabilia and

tickets, an oriental carpet, works of art, vacation homes, even dinner prepared by the opera star Anna Moffo in her NYC penthouse. The live and silent auctions raised nearly \$60,000, including \$1,100 for cookies baked by the children.

Connecticut Attorney General Richard Blumenthal, who conducted insurance hearings on Lyme Disease last year, made a surprise appearance to thank the attendees for supporting “one of the most important public health causes in the nation today.” He said that the Task Force’s benefactors were literally saving lives, not just physically but emotionally and spiritually. He said that he was proud and grateful to be supporting the work of the Wilton Task Force.

Congressman James Maloney, who cosponsored the much-needed Lyme Disease Initiative of 1999 (still pending in Congress, see article on page 1), also spoke. He praised the work of the Task Force and said that the attendees’ participation will resonate throughout Connecticut, the Northeast and Congress itself. He noted that Lyme disease is seriously underreported and costs the country billions of dollars. But, he said, the real cost is personal. He said the

Speech given at Wilton event

by Cathy Morrissey

There is no denying the pain and suffering of those afflicted with Lyme disease. Because members of the Wilton Task Force and their families have experienced its devastating effects firsthand, we are dedicated to preventing and curing the disease in others especially children who are at

particular risk.

There is a public perception that we live in a time of great medical advances. That is basically true. But in the case of tick borne illnesses we are just beginning to understand their potentially serious effects, especially in the brain. But much of what is in print about Lyme disease is very simplistic, outdated and controversial.

Because there are so few scientific facts available to the public and the medical community, LD has become an illness that is perfectly positioned to engender controversy. Who has it? Who doesn't? How do is it treated? How do is cure defined? What do ongoing symptoms mean? These questions cause frustration for patients and doctors.

I suspect each of you knows someone with Lyme disease who seek answers to these questions . They turn to their physicians—some of whom may be brilliant or compassionate—but just don't have the answers. Patients often endure a maddening range of diagnoses and suggested treatments. One can find medical experts to support any one of the diverse range of opinions about what constitutes LD and how it should be treated.

Some doctors recognize a difficult diagnostic and treatment dilemma. They do as much as they can to help their patients. But if they stand up to the real challenge of diagnosing clinically and do what they believe is in the best interest of their patient, they risk losing their licenses.

Doctors are under tremendous pressure not to treat or to treat cheaply. Many more physicians shy away from treating ongoing or complex cases. Others discount them entirely. You can find experts to support opinions to deny medical coverage.

Unfortunately there are institutions in a position to help who chose instead to downplay the reality of the illness because of financial or political interests. This only reinforces the lack

of knowledge and understanding of the disease.

How can we find the truth if we adhere to the strictures of simple principles for a disease that has clearly become more complex? How does science progress? How is any cure discovered?

The Wilton Task Force believes that open discussion and unbiased scientific research are what is needed to find answers. We began our fundraising effort for this particular event only two months ago. The fact that we were able to accomplish so much in so little time is nothing sort of miraculous. But the reality of tonight's success is due to the response of people with an urgent need for research. They have been waiting for this opportunity for a long time. We have been overwhelmed by the outpouring of support from all across the country.

Wilton is hard hit by Lyme disease. Wilton values quality of life and cherishes its children. We are honored by the community's positive response and that our first selectman, Paul Hannah is here. Connecticut reports the highest incidence of Lyme disease. We are delighted to have the support of our State Attorney General Richard Blumenthal and are happy to

see advocates here from other communities in the state: The Greenwich LD Task Force, Weston, New Canaan, Darien, Norwalk and Newtown.

The demand for research comes from all across the country. I welcome our guests from Texas, especially our friends from Senator Harris's office, who are here to learn how they can help patients in their state.

We are so grateful to Congressman Jim Maloney for his presence here tonight and his continued commitment and support at the federal level.

The foundation for our work was laid by many people who came before us and continue to work for a better understanding of Lyme disease. Barbara Goldklang, President of the LD Coalition of NY/CT has been a particular inspiration to me, especially in understanding scientific and research issues.

Tonight, hundreds of scientists and physicians from around the world will gather for the LDF's 13th annual international medical conference in Hartford. We are enormously grateful for their extraordinary commitment to seek answers through science."

Minnesota doctors turn away Lyme patients

by Lynn Olivier

It is not that we are afraid of giving names, it is that we no longer have any names to give here in Minnesota. Every referral has met with a refusal in the last year.

Board members of the Lyme Disease Coalition of Minnesota (LDCM) were polled to see if any of them knew any doctor who was seeing late Lyme disease patients. Their answer was, "No." There is no infectious disease, rheumatologist or

other specialist who will see Lyme disease patients in Minnesota.

This is because of the impending hearings in New York State, the lawsuits filed against Michigan doctors, and the fact that Mike Osterholm, former MN State Epidemiologist, through his start-up company ICAN has been examining the records of patients being treated long term with antibiotics for Lyme disease. Osterholm is being hired by the

HMOs and insurance companies to cut costs by forcing doctors to stop treating Lyme disease patients or face sanctions. LDCM is getting reports of deaths of patients who are unable to get treatment for late stage or chronic Lyme disease here in Minnesota and across the county. It is unknown how many undiagnosed patients are dying of complications.

The LDCM therefore passed a resolution that is in line with other states' Lyme disease support and education groups that it would no longer send people on expensive, time consuming and at the moment almost futile attempts to try to find a doctor to treat them, even if they have gotten a positive Lyme test. They are asking people to educate themselves, and they will send information. They recommend that people work with their regular physician, or an associate of their physician.

E-copies of the monthly LDCM newsletter "Tick Talk" may be

ordered by emailing lymenet_mn@yahoo.com. For mailed copies we ask \$5 donation for postage and copies.

Lynn Olivier is president of the Lyme Disease Coalition of Minnesota and editor of "Tick Talk." She lives in St. Paul, Minnesota.

The Lyme Disease Network North Metro support group meets at the First Lutheran Church, 1550 40th Ave. NE. Columbia Heights, MN 55421.
 For further information please call Nancy at 612-612-521-9917 or Lynn at 651-644-3756 (after noon).
 Email: lyndy@crosswinds.net Fax: 651-644-7239
 The Lyme Disease Coalition MN newsletter TICK TALK [Internet Edition], containing information about Lyme disease in Minnesota may be obtained by emailing [<lymenet_mn@yahoo.com>](mailto:lymenet_mn@yahoo.com)

Patients sought for investigation

The Massachusetts Lyme Disease Coalition is seeking patients with Lyme disease who were misdiagnosed or denied treatment for Lyme disease by Dr. Allen Steere or other physicians at the New England Medical Center, or whose bloodwork was sent to the NEMC laboratory. The Coalition is also looking for patients who have been misdiagnosed or refused treatment because of the influence of Dr. Steere on other physicians or diagnostic centers.

A Coalition spokesman said that several patients have already come forward with complaints that Steere failed to diagnose them and/or treat them adequately, and that consequently they developed late stage chronic Lyme disease.

The Coalition claims that many other complaints are in the files at the Medical Board of Registration, and have never been acted on. Because Steere's guidelines for diagnosis and treatment are widely accepted as the standard of care by the medical community, more complaints are needed to trigger a full investigation, according to a Coalition spokesman.

In his paper *Overdiagnosis of Lyme Disease* (JAMA 1993;269:1812-16), Steere found that most patients who were referred to him for confirmation of Lyme disease diagnosis, did not have Lyme disease according to his standards.

For more information contact the Massachusetts Lyme Disease Coalition, P.O. Box 1916, Mashpee, MA 02649, phone 508-563-7033.

Patients can make a difference by contacting their legislators and telling their Lyme story.

Illinois legislature asks Health Dept. to study Lyme

By Candy Sandford

Senator Kathleen Parker introduced a bill into the Illinois Senate in February 2000 which should offer a greatly broadened recognition of the status of Lyme Disease in Illinois. The synopsis of Senate Bill 1510, as introduced, reads:

"Amends the Department of Health Powers and Duties Law of the Civil Administrative Code of Illinois. Requires the Department to conduct a study regarding the prevalence, identification, and evaluation and treatment of Lyme Disease. Sets forth the matters to be studied. Requires the Department to issue a report to the Governor and the General Assembly by January 1, 2002."

The information to be gathered through this new law will go beyond

the guidelines of the CDC on the definition and treatment of Lyme Disease. It should have far-reaching impact on recognition of Lyme in Illinois.

S.B. 1510 was passed rapidly through the Illinois Senate and received an almost unanimous vote from the full Senate. It was passed in the House of Representatives on March 29.

Patients should contact the bill's legislative sponsors, Senator Parker and Rep. McKeon, to make sure the funding gets put into place as it goes to Gov. Ryan's desk for signing

Ms. Sandford lives in Lake Zurich, Illinois.

Conference Report

Antibiotic treatment of rheumatic diseases

by Raphael B. Stricker, M.D.

A report from The Road Back Foundation Meeting, Los Angeles, March 2000.

So those weird symptoms that you've been having in the months since that tickbite have finally been diagnosed as Lyme disease, and your doctor has recommended antibiotic treatment for three months. But you are worried. Is it safe to take antibiotics for that long?

How about 35 years?

Carol Lange was diagnosed with rheumatoid arthritis at age 16. She was told by her doctor that she would eventually be crippled for life. After 10 years of progressive joint pains and swelling that failed to respond to standard antiinflammatory drugs, she met Dr. Thomas McPherson Brown, who started her on antibiotic therapy for her rheumatoid arthritis. She has taken various antibiotics for the past 35 years on a continuous basis. Today at age 61 her X-rays show minimal evidence of joint disease, she is active and relatively pain-free, and (perhaps most telling) she has outlived two of her doctors, including Dr. Brown.

Carol's odyssey was described at a recent Los Angeles symposium of the Road Back Foundation, an organization dedicated to Dr. Brown's principles of treating rheumatoid arthritis, scleroderma and other rheumatic diseases with antibiotics. The view that antibiotics are helpful in these "noninfectious" diseases is based on the idea that atypical infectious agents similar to spirochetes are responsible for the devastating complications of rheumatic diseases. Treating these infectious agents with antibiotics over long periods of time can arrest

the disease process in a manner similar to treating Lyme disease with antibiotic therapy.

Dr. Brown's theory was considered pure heresy by the medical establishment when it was first proposed over 50 years ago. But the discovery of Lyme disease as an infectious cause of arthritis lent credibility to the heretical concept, and the recent discoveries of other infectious causes of "noninfectious" illnesses such as peptic ulcer disease, diabetes and coronary artery disease have further validated Dr. Brown's theory. Of course the medical establishment is still skeptical, but tetracycline is now an approved treatment for rheumatoid arthritis in the United States.

In turn, Lyme disease patients and their doctors have much to learn from Dr. Brown's theories. The approach to treatment of rheumatic disease with antibiotics involves both intravenous and oral medications given on a pulse basis varying from once a week for the intravenous drugs to three times a week for the oral medications. This type of intermittent antibiotic treatment would be considered inappropriate for acute bacterial infections. But for a chronic low-grade infectious process causing rheumatic symptoms (and similar to Lyme disease), Dr. Brown argued that long-term pulse antibiotic therapy made perfect sense.

The speakers at the Road Back symposium included Dr. Emil Wirostko, an ophthalmologist from Columbia Presbyterian Medical Center in New York City; Dr. John Sinnott, a general practitioner from

Iowa and a former student of Dr. Brown; Dr. Robert Franco, a rheumatologist from Riverside, CA; Dr. Aristo Vojdani, an immunologist in charge of Immunosciences Laboratory in Beverly Hills; and Dr. David Brownstein, a holistic health practitioner from Michigan. Also on the program was Pat Ganger, who described the successful use of antibiotics to treat her scleroderma - for a mere 12 years.

Dr. Wirostko pointed to electron microscopic findings of infectious particles in the joints and tissues of rheumatoid arthritis patients. Since these infectious agents have been impossible to culture, their existence remains controversial. Dr. Vojdani reviewed his work on the molecular diagnosis of mycoplasma and related organisms in rheumatic diseases. He noted that the molecular technique known as PCR (polymerase chain reaction) is extremely sensitive and shows evidence of infection in about half of the rheumatic disease patients tested. Dr. Sinnott described his clinical experience in treating rheumatic diseases with antibiotics. Many of his patients have had clinical courses similar to those of Carol Lange and Pat Ganger. Dr. Franco gave an excellent review of rheumatic diseases and the effects of antibiotic treatment. He pointed out that many antibiotics have both antimicrobial and antiinflammatory properties, and he outlined the rationale for pulse therapy in various rheumatic diseases. Dr. Brownstein stressed the importance of hormonal and nutritional supplements in his treatment approach, referring to his book entitled "The Miracle of Natural Hormones" (Medical Alternatives Press, \$14.95).

Participants in the Los Angeles symposium came from as far away as Canada and Australia. The Australian contingent was particularly vocal in its support of pulse antibiotic therapy for diseases ranging from rheumatoid arthritis to fibromyalgia and chronic fatigue syndrome. Drs. John Whiting

and Kerrie Davis related their experiences with these disease states and stressed the nutritional aspects of successful treatment. Other participants included Dr. Pieter DeWet, a holistic practitioner from Texas who combines antibiotic and nutritional therapies in treating his rheumatic disease patients, and Dr. Alan Cantwell, who is well known for proposing that infectious agents play a significant role in cancer. Dr. Harvey Heinrichs, a plastic surgeon from Newport Beach, gave an intriguing talk on breast implants and rheumatic diseases based on his wife's experience and treatment.

What about the potential dangers of chronic antibiotic therapy? After all, resistant infections are a concern. Carol Lange says that she has learned how to increase or decrease her dose of antibiotics depending on her symptoms. She hardly ever gets a respiratory infection despite living in the snowbelt of New Jersey, and she has never had a resistant infection in 35 years. Pat Ganger echoes this experience after 12 years of pulse antibiotic therapy. Dr. Franco points

out that patients with acne may take tetracyclines for years on end, and patients with rheumatic heart valve disease may need penicillin prophylaxis for an entire lifetime. And for many years, pulse antibiotic therapy has been the standard of care for patients with AIDS.

Despite the fact that many antibiotics are inexpensive, readily available and safe, only a few controlled clinical trials of antibiotic therapy for rheumatic diseases have been performed. As patients with chronic Lyme disease know all too well, the medical establishment has much to learn about treating chronic rheumatic diseases. The teachings of Dr. Brown and the information generated by the Road Back Foundation should help to bridge the gap between medical knowledge and patient care in the new millennium.

Raphael Stricker, M.D. practices medicine at Union Square Medical Associates, 450 Sutter Street, Suite 1504 San Francisco, CA 94108 (415) 399-1035

dedicated to her service with Honeywell where she worked for 34 years. She was a member of the National Association Property Management, National Contractors Management Association; past Chair of the United Way; active with the Junior Achievement, City of Angels, and Community Relations Council which included the Christmas Adopt a Family, Food Share, school supplies for needy children, and Chair person for the Christmas Card Recycling project. (*From the St Paul Pioneer Planet Saturday March 4, 2000.*)

Kathy Cavert passed away Tuesday, February 8, 2000 in Independence, Missouri. She had been suffering from late Lyme disease for many years. Sunday night she entered the hospital emergency room fighting severe pain. On Monday, February 7, her condition declined and she became delirious. She was placed on a ventilator and then slipped into unconsciousness. She died at 6:50 in the morning with her fiance, John Haynes, at her side. She was 52 years old.

Cavert was the founder of the Midwest Lyme Disease Association and publisher of LymeAide, a publication devoted to helping victims of Lyme disease. In spite of her own substantial physical problems, Kathy worked tirelessly, helping thousands of victims with Lyme disease over the course of many years. She received countless calls from people needing help and she was always there for them answering their questions and mailing them information. Every caller received information from deep inside her heart. She cared deeply about helping people and wanted to further the understanding of the seriousness of Lyme disease.

The Lyme disease community mourns the premature death of these women and offers sincere sympathy to their families and friends.

Thanks to John Lushenko for his contribution to this report.

In Memoriam

Chantal Semans, of Big Bear, California, died on January 11, 2000 from complications of Lyme disease. She was in her early fifties.

Her friend Barbara Barsocchini of Malibu wrote: "Chantal Semans was a fighter. She saved the tick which infected her; transported the tick down the mountain to the local vector control agency in Southern California to have it tested. The tick was identified as an *Ixodes pacificus*.

As ill as Chantal was, she brought Lyme disease to the attention of her rural community, including the medical establishment."

Her brother wrote: "Lyme disease ravaged her body and she wound up paying the ultimate price. She was airlifted from Big Bear to Loma Linda

Hospital because she was having difficulty breathing. They put her on a special trach ventilator and into a drug-induced coma. They believe she had a stroke, paralyzing her arms and legs. For over a month, you could not tell if she understood what anyone was saying or if she recognized them. She was in isolation because she had a fatal blood disease that was antibiotic resistant."

Gayla Diane Keyes, age 52, of Mounds View, Minnesota went up to our Lord on February 25, 2000, after a long struggle with Lyme disease and lupus. Gayla was an associate member of the Sunrise United Methodist Church and a member of her home church, Henry (South Dakota) United Methodist Church. Gayla was very

Research

NIH gets record \$17.9 billion for biomedical research

by Linda Finn

The fiscal year 2000 budget recently passed by Congress gives the National Institutes of Health a total of \$17.9 billion, another record increase in funding. This is part of a series of increases intended to double the budget by 2004. NIH is the largest biomedical research organization in the world.

The biggest piece of this budget pie—\$3.3 billion—goes to the National Cancer Institute, with the National Heart, Lung, and Blood Institute in second place, at \$2 billion. Fourteen other institutes and a number of centers share the remaining funds. The National Institute of Allergy and Infectious Diseases received \$1.8 billion; more than half is earmarked for AIDS, but every institute got some AIDS funding also. \$19.6 million has been allocated for Lyme disease. No breakdown was available on the Lyme program. It is assumed that funding for the continuation of two chronic Lyme studies is provided, along with program administration and research grants. Research on a cure was not funded, it goes without saying.

Two major backers of the big NIH budget were Representatives John Porter (Illinois) and David Obey (Wisconsin). It should be noted that Obey is from a state with many Lyme disease cases. (Does he know this?) Porter is retiring at the end of this term.

Director Harold Varmus, though pleased with the budget increases being won by NIH, left his post at the end of 1999 to take up a new job as head of the Sloan Kettering Cancer Center in New York City. Varmus' 1989 Nobel Prize was for cancer research. According to a report in

Science magazine, his salary will go from \$150,000 to nearly a million dollars as a result of the job change.

Nonconformity marked his tenure at NIH. A series of controversial ideas were proposed, among them a new on-line archive of scientific research papers, intended to shorten the time it takes to get research findings made public. A two-tier system was suggested, with the second tier to be

“Research on a cure was not funded, it goes without saying.”

less peer-reviewed than in traditional print journals. Most of these journals, fearing a drop in subscriptions and loss of control, opposed the idea. A revised version of the concept begins this year, as “PubMed Central.”

The NIH under his leadership has been resisting Freedom of Information access to data produced with federal funding, for the reason that researchers' ability to benefit from commercial applications will be compromised, and therefore researchers will be less willing to work on NIH grants. Since grants are crucial to most research, however, there may not be many abstainers, even with conditions they do not like. NIH also has suggested that they, not Congress, are in the best position to determine how research funding should be spent. For the most part, Congress defers to NIH priorities.

Varmus' successor

Until a successor is named, Deputy Director Ruth Kirschstein will occupy the top job in an acting capacity. Some sources have predicted difficulty filling the job now on a permanent basis because of the coming change in administration. However, three names from inside NIH have been suggested as possible candidates: National Cancer Institute Director Richard Klausner, National Institute of Mental Health Steve Hyman, and National Institute of Allergy and Infectious Diseases Director Anthony Fauci. Fauci was involved in the AIDS wars of the 1980s; his handling of that program led to the formation of the ACT UP campaign to combat the AIDS epidemic and included major protest events and marches.

Not enough public involvement

In 1998 the National Academy of Science's Institute of Medicine prepared a report requested by physician/senator Bill Frist (Tennessee) and Dan Coats (Indiana). It recommended more public participation in the NIH decision-making process. It described NIH interaction with the public as weak, compared with its relationship to researchers. Since then, in response, a Council of Public Representatives was established, with 20 members selected from around the U.S., many in high ranking medical jobs.

NIH has also set up a new Office of Public Liaison with a liaison officer in each institute. NIH suggests that these measures will significantly expand “its efforts to solicit public comment on NIH research goals and related activities to help ensure that our programs meet the need of patients and other health consumers.”

Surely this is an arena in which Lyme sufferers should become more active; of particular interest is the selection of researchers to receive grants and the nature of the research to be accomplished.

Ms. Finn may be contacted by email at overman74@hotmail.com.

NIH awards \$4.7 million for chronic neuroLyme study

As part of the grant proposal he made to NIH, Dr. Fallon used findings from a brain imaging project made possible by a grant from NJLDA.

The National Institute of Neurological Disorders and Stroke branch of the NIH has awarded Dr. Brian Fallon, a Columbia University psychiatrist, \$4.7 million to study chronic neurologic Lyme disease. Fallon is looking for patients with persistent cognitive problems who have already received at least 8 weeks of IV antibiotic therapy and who are Western Blot IgG or PCR positive. Patients must also have a well-documented history of Lyme disease by CDC criteria at some time in the past. Patients will be screened and those qualifying will be extensively tested before being randomized to a double-blind, placebo-controlled treatment program. The researchers will have to confirm the current PCR and Western Blot positive results with a central research lab and determine the amount of cognitive impairment at entry. Patients will receive 3 types of PET imaging at baseline; one looking at glucose metabolism, one looking at vascular flow at rest, and one looking at vascular flow after a CO₂ challenge. They will also receive five types of MRI sequences, and more neuropsychological tests. The brain imaging will be conducted by one of the most advanced brain imaging teams in the country using the PET and MRI brain imaging facilities at the Columbia Presbyterian Medical Center.

Two in three patients will receive 10 weeks of intravenous ceftriaxone; the remaining 1/3 will receive placebo. After the IV treatment (which occurs at home) the patients must agree to stay off other antibiotics for another 14 weeks. At the end of 12 and 24 weeks from baseline, the patients are given the same set of PET and MRI and neuropsych tests. The week 12 tests will look for response. The week

24 tests will look to see if the response improves over time, stays the same, or worsens.

“We will be looking to see whether brain imaging changes correlate with cognitive changes, as well as trying to identify markers at baseline that might be associated with response,” explained Fallon. “The study should be able to tease out brain problems due to vascular disease from brain problems due to metabolic disease. Lyme disease might be causing both or either in any one patient.”

This study will be a definitive test of the efficacy of a repeated course of IV antibiotic therapy for patients who have previously had at least 8 weeks of IV.

Incentives for patients to participate

First, all patients will get treated with IV ceftriaxone free of charge at some point. One group (2/3 of the patients) will get 10 weeks right away, the other group (1/3 of the patients) will get offered 6 weeks of free ceftriaxone after the 24 weeks. Although patients may think this sounds unfair, Fallon explained that since it is not yet known whether 10 weeks is really superior to 6 weeks of treatment, doing it this way will provide some information on whether 6 weeks is as good or less good or the same as treatment with 10 weeks followed by 14 weeks off. The 6 week group will be invited to come back after 24 weeks to get retested.

All patients will get a report at the

end of the 24 weeks summarizing the results of the sophisticated MRI, PET, and cognitive test results. This cognitive report will provide a breakdown of the different cognitive domains of the brain and show how the patient did over the 24 week period on each domain (e.g., attention, memory, verbal fluency). The brain imaging report will reveal whether the patient had a normal enhancement of flow after the CO₂ challenge — the “hypercapnic” challenge test can detect the presence of vascular disease — and whether that deficit (if present) improved over the 24 weeks or not.

“Patients will be getting brain imaging that is not done elsewhere,” said Fallon. “Although they can get PETs elsewhere, the hypercapnic challenge is only done for research studies.”

Fallon expressed a hope that patients will want to participate just because they are interested in promoting good scientific research of chronic Lyme disease. He suspects NIH will be reluctant to ever again risk funding a major chronic Lyme disease study if this study is not able to attract enough patients.

The entry criteria represent a very high bar for most Lyme patients to jump over, however Fallon stressed the importance of making sure that everyone would agree that patients who enter the study have Lyme disease.

“We are not saying that other patients don’t have Lyme disease,”

To be eligible for the study, patients must:

- Be between the ages of 18 and 60.
- Have a well-documented history of Lyme disease with a currently positive result on one of the two tests used in confirming a diagnosis of the disease.
- Reside in New Jersey, New York, or Connecticut.
- Experience ongoing problems with their memory and other cognitive problems.
- Have undergone at least four months of antibiotic treatment.
- Have no allergies to ceftriaxone, which is marketed under the brand name Rocephin.

he said. "Rather, we're saying that we have to do a study that even the most skeptical critic could be comfortable with. Given the enormous expense of the procedures (PET and treatment) and of the highly technical data analysis, we have to."

Rita Stanley, patient advocate and educator in Portland, Oregon, feels the study deserves patient support.

"This is a well devised study and it goes well-beyond the typical placebo controlled study in that it does offer the patients treatment after they have received placebo," she said. "How many studies do that? Dr.

Fallon is using a considerable amount of the money allotted to him to give those patients in the placebo group treatment," she continued. "If the 6 weeks is beneficial, that is a good start (at no cost to the patient) that can be continued."

To make a phone appointment to discuss this Lyme research study, please call 212-543-5367 between 9-5pm EST or leave a message at other times at 212-543-6510 to speak with a member of the Lyme Disease Research Program Staff. The study website will be at www.columbia-lyme.org.

disease patients, presumably by greatly enhancing the elimination of endotoxin(s) released by *Borrelia* spirochete lysis and/or antibiotic treatment. The intensification reaction may result from different gene activation by mobilized toxin(s) which induces release of cytokines, including tumor necrosis factor alpha, but can be countered or blocked by the PPAR gamma agonist activity of pioglitazone.

Studies are underway and it is hoped that 2000 patients will be enrolled in the study using CSM in the antibioticly treated patients with monitoring by visual contrast sensitivity testing. A third study will deal with prevention or reduction of severity of the intensification (Herxheimer) reaction by treating with pioglitazone double-blinded, placebo-controlled trial.

Laser doppler studies are also being researched. As part of the study, when taking the pioglitazone or placebo patients must have random, finger stick blood sugar tests done on a regular basis. The patient must agree to fax VCS scores at regular intervals if not accessing the website www.chronicNeurotoxin.com

The costs to the patient are the expense of CSM (approximately \$3.00 per day), whatever physician fees by the attending physician, and whatever expenses involved in sending the data. Extensive support will be offered at no charge to the patient and caring physician while in the clinical trials. An individual report will be sent to the patient and the attending physician at the conclusion of the trial. A final summary and final report, with the results of the trial, will be sent to the patient.

With the CSM treatment, the cholestyramine binds toxins in the intestine and which are then removed in the bowel. The Laser doppler test shows the microvascular (capillary) hypoperfusion changes in the retina and optic nerve head that VCS represents. The test will show distinctive differences in capillary

New study tries cholesterol-lowering drug to bind toxins in neuroborreliosis

by Steve Nostrum, R.N.

Ritchie Shoemaker, M.D. was a guest on the "Lyme *Borrelia* Outreach Foundation TV Series, April 26th, 2000. Shoemaker is a medical doctor and holds a B.S. in Molecular Microbiology. He is an author, writer, ecologist, and naturalist. He has written the world's first article on the diagnosis and treatment of Chronic Pfiesteria Human Illness Syndrome, and his book entitled **Pfiesteria** discusses this and the toxin involved. He has been published in the *Lancet*, about learning and neurocognitive problems. He is a graduate of Duke University and resides in Pocomoke City, Maryland.

Shoemaker's book is a story of media, politics, economics, medicine, and a remarkable scientific discovery.

Abstract of Shoemaker article

Chronic neurotoxic symptoms refractory to antibiotics in 51 patients following a tick bite were treated with cholestyramine (CSM) according to protocol previously used successfully in patients with Estuary Associated Syndrome. Prior to treatment, the chronic Lyme disease patients, 27

with and 24 without a positive Lyme diagnostic test, had a statistically significant deficit in visual contrast sensitivity (VCS), greatest at 6 cycles per degrees of visual arc, relative to 23 control patients. After CSM treatment, all patients had abatement of their clinical syndrome.

A symptom intensification reaction, similar to "but more intense" than typical Herxheimer reactions, experienced previously during antibiotic therapy, occurred early in CSM therapy, especially in patients ill longer than three years. The intensification reaction was reduced with pioglitazone therapy or prevented by pretreatment with pioglitazone, a known peroxisome proliferator-activated receptor (PPAR) gamma agonist. No relapse of symptoms was observed in patients followed as long as eleven months.

These results suggest that VCS measurement is a useful tool for assisting in the diagnosis of chronic Lyme disease, and that CSM treatment restores VCS and provides symptomatic relief in chronic Lyme

flow produced variously by obstruction, spasm or margination of white blood cells (TNF effects).

A Lyme patient currently undergoing antibiotic treatment was also a guest on the show and the VCS test was performed. The patient agreed to be treated with CSM and will return on another show in approximately two months so as to measure how and if the treatment with CSM assisted her.

Cholestyramine is an FDA-approved medication used to reduce, lower cholesterol in patients with high cholesterol levels. It binds bile salts, cholesterol, and biological toxins in the small intestine. Because it binds toxins tightly, they cannot be

reabsorbed, and are harmlessly excreted in the stool, thus curing the chronic toxin-mediated illness.

This therapy is NOT a cure for Lyme borreliosis. It does not kill spirochetes.

If you have questions regarding this article, contact me and I will answer to the best of my ability. The show was one hour in duration, and not everything can be covered in this space. Those interested may contact me directly.

Steve Nostrum may be reached at Lyme Borrelia Outreach, PO Box 496, Mattituck, NY 11952, tel. 516-298-9606, email Borrelias@aol.com

Participants sought for new treatment study

by Donna Herrell

Ritchie Shoemaker, MD, of Maryland, has completed a preliminary study of the use of cholestyramine (Questran) a benign powder used to lower cholesterol on 100 patients with long-term, antibiotic-treated Lyme disease. Based on the dramatic positive results of the study, Dr. Shoemaker is ready to submit his work to a major journal for publication. He will also be ready to perform an FDA-IND (more rigorously monitored by FDA than an independent research study) study shortly.

Dr. Shoemaker believes that neurotoxins play a major role in the symptoms of, if not the cause of symptoms of, chronic Lyme patients, and he has been able to successfully utilize cholestyramine to bind and remove the toxins from the body. He became involved with this treatment when he discovered the cause and treatment of Pfiesteria, a dinoflagellate disease which also involves neurotoxins, that was killing fish along the east coast.

Attending physician approval is necessary to participate in the study, an informed consent must be signed, and certain criteria must be met. If you are interested in receiving the informed consent packet, write (no faxes) to Dr. Shoemaker, 1604 Market Street, PO Box 25, Pokomke City, MD 21851. You must include a self-addressed PREPAID PRIORITY MAIL ENVELOPE.

From Invisible Threads - www.lymedisease.about.com/library/blinthreads.htm

Information sought on legal actions associated with Lyme

by Robert Bransfield, M.D.

There are a significant number of legal actions associated with Lyme disease. I am conducting a survey of lawsuits and other legal actions associated with Lyme disease and other tick borne diseases. I recognize some are individual suits, while others are class action suits. I'll be organizing the information based upon the type of suit, which may be categorized, but not limited to the following areas: 1) Insurance company denial of coverage for Lyme disease treatment. 2) Disability determination (including liability issues if the tick borne disease was acquired in the workplace). 3) Malpractice suits related to direct care &/or insurance company consultant opinion. 4) Requests for special education from school districts. 5) Domestic violence. 6) Violence, aggression or other illegal behavior resulting in criminal or civil actions. 7) State board issues. 8) Auto, train or plane accidents or other liability issues associated with impairments associated with tick borne diseases. 9) Product liability cases. 10) Munchausen by proxy

allegations. 11) Research related issues. 12) Lyme disease patients accused of driving under the influence. 13) Patent issues. 14) Other issues not listed.

Please respond with a single, concise page stating the nature of the case, date entered, case number, jurisdiction, plaintiff(s), defendant(s), experts, a brief summary of the case, current status or outcome of the case, date resolved, consent to publish and distribute this information, email, address, phone number and fax. Send to Robert Bransfield, MD, 225 Highway 35, Red Bank, NJ 07701, tel. 732-741-3263.

The Journal of Spirochetal and Tickborne Diseases (JSTD) is now listed on the Internet on Medscape. All back issues are also going online. All words in all articles can be searched by the Medscape search engine. The URL is <http://id.medscape.com/SLACK/JSTD/public/JSTD.journal.html>.

Abstracts

Borrelia burgdorferi detected by culture and PCR in clinical relapse of disseminated Lyme borreliosis

AUTHORS: Oksi J, Marjamaki M, Nikoskelainen J, Viljanen MK
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 REFERENCE: Ann Med 1999 Jun;31(3):225-32

ABSTRACT: A total of 165 patients with disseminated Lyme borreliosis (diagnosed in 1990-94, all seropositive except one culture-positive patient) were followed after antibiotic treatment, and 32 of them were regarded as having a clinically defined treatment failure. Of the 165 patients, 136 were tested by polymerase chain reaction (PCR) during the follow-up. PCR was positive from the plasma of 14 patients 0-30 months after discontinuation of the treatment, and 12 of these patients had a clinical relapse. In addition, *Borrelia burgdorferi* was cultured from the blood of three patients during the follow-up. All three patients belonged to the group with relapse, and two of them were also PCR positive. This report focuses on the 13 patients with clinical relapse and culture or PCR positivity. Eight of the patients had culture or PCR-proven initial diagnosis, the diagnosis of the remaining five patients was based on positive serology only. All 13 patients were primarily treated for more than 3 months with intravenous and/or oral antibiotics (11 of them received intravenous ceftriaxone, nine for 2 weeks, one for 3 weeks and one for 7 weeks, followed by oral antibiotics). The treatment caused only temporary relief in the symptoms of the patients. All but one of them had negative PCR results immediately after the first treatment. The patients were retreated usually with intravenous ceftriaxone for 4-6 weeks. None of them was PCR positive after the retreatment. The response to retreatment was considered good in nine patients. We

conclude that the treatment of Lyme borreliosis with appropriate antibiot-

ics for even more than 3 months may not always eradicate the spirochete. By using PCR, it is possible to avoid unnecessary retreatment of patients with 'post-Lyme syndrome' and those with 'serological scars' remaining detectable for months or years after infection.

An in vitro study of the susceptibility of mobile and cystic forms of Borrelia burgdorferi to metronidazole

AUTHORS: Brorson O and Brorson SH. REFERENCE: APMIS [Acta Pathologica, Microbiologica et Immunologica Scandinavica] June 1999, 107(6):566-576.

ABSTRACT: The aim of this study was to examine the susceptibility of mobile and cystic forms of *Borrelia burgdorferi* to metronidazole. Because *B. burgdorferi* is a microaerobic bacterium like *Helicobacter pylori*, metronidazole (MZ) [Flagyl, for example] was chosen in the susceptibility test. For both microaerobic and aerobic incubation, the normal mobile spirochetes were resistant to this antibiotic with an MBC [minimal bactericidal concentration] ≥ 512 microg/ml. Conversion of mobile spirochetes to cystic forms was not observed when they were incubated with MZ. When they were incubated under microaerobic conditions, the biologically active cystic forms had an MBC ≥ 4 microg/ml, but the MBC was ≥ 32 microg/ml with aerobic incubation at 37 degrees C. Staining with acridine orange, dark field microscopy and transmission electron microscopy revealed that the contents of the cysts were degraded when the concentration of MZ was \geq MBC. Some cysts were also ruptured. When incubated with a sufficient concentration of MZ, core structures did not develop inside the cysts, and acridine orange revealed less RNA in the cysts. Our observations may help efforts to treat resistant infections caused by *B. burgdorferi* with a combination of

MZ and other antibiotics in order to eradicate both cystic and mobile forms of *B. burgdorferi*.

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Calendar

LDRC West Coast Lyme Disease Conference

Saturday, November 11, '00
time to be announced
California Pacific Medical Center Auditorium
San Francisco, California

New York Psychiatric Institute researcher Brian Fallon, MD, will be the keynote speaker on neuropsychiatric Lyme disease. Fallon has just been awarded \$4.7 million by the NIH to study chronic Lyme disease (*see article on page 43*).

The conference will also focus on Lyme disease and other tick-borne diseases in the western United States. Topics to be covered include the ecology of Lyme disease, testing for Lyme and other TBDs. New entomologic findings on ticks in California will be presented. A public forum is being planned.

For more information email info@lymedisease.org or phone 707-468-8460.

Patients who want their doctors to receive an announcement for this meeting should send us his/her name and address.

LDANJ offers grants for cure

The Lyme Disease Association of New Jersey, Inc. (LDANJ) has funds available to those conducting research that could potentially lead to a cure for chronic Lyme disease. Fall 2000 Grants will be awarded in varying amounts up to \$25,000. Grant application deadline is June 30, 2000. Applications can be found online at the LymeNet (<http://www.lymenet.org>) or LDA-NJ (<http://ldanj.tripod.com/about.html>) websites, or call LDANJ president Pat Smith at 732-938-4834 for more information.

Grass Valley Lyme Disease Seminar

Tuesday, October 24, 2000
5:00 pm to 9:00 pm
Sierra Nevada Memorial Hospital
Grass Valley, California

This 4-hour seminar for medical professionals will feature the following speakers and topics:

Mark Miller, P.H.M. Director of Communicable Disease Control – Placer County Lyme Disease in the Sierra Nevada Foothills

Lucia T. Hui, M.S. Senior Public Health Biologist, State of California Department of Health Services, Vector-Borne Disease Section – Ecology of the Lyme Disease Spirochete

Raphael Stricker, M.D. Union Square Medical Associates Hematology/Internal Medicine – Diagnosis & Treatment

Nick S. Harris, Ph.D. President/CEO, IgeneX, Inc. Diplomate, American Board of Medical Laboratory Immunology – Role of a Diagnostic Laboratory in the Diagnosis of Lyme Disease

Richard Tilton, Ph.D. Senior Vice President, BBI Laboratories Past Editor in Chief, Journal of Clinical Microbiology Editor in Chief, Journal of Spirochetal and Tick Borne Diseases – Coinfection with Tick-borne Microbial Agents

Maryllynn Barkley, M.D., Ph.D. Associate Professor of Physiology Section of Neurobiology, Physiology and Behavior University of California, Davis – Understanding Endocrine-Immune System Interaction during Bacterial Infection in Women: The Lyme Borreliosis Model

An informal seminar for patients is being planned for earlier in the afternoon.

Patients damaged by Lyme vaccine sought for class action lawsuit

The Philadelphia lawfirm Sheller, Ludwig & Badey is conducting a class action lawsuit against SmithKline Beecham, manufacturer of LymeRix, the Lyme disease vaccine. They are seeking people who have suffered disabling symptoms after receiving the vaccine, including those who were part of the original clinical trials. People interested in participating should call Sheller's toll-free number 1-800-883-2299. The lawfirm's website at <http://www.sheller.com> contains a copy of the legal complaint filed against SmithKline Beecham.

See story on page 1.

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