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20 Reasons Why Lyme Disease Is Undiagnosed

Miguel Perez-Lizano, June 2010

Note to Reader;

This paper was written to outline some of the problems associated with the diagnosis of Lyme disease. It turned out much longer than expected. The paper has been broken up into brief sections. A two page summary is available.

Nevertheless, Steere's paper has had an oppressive effect on the diagnosis of Lyme disease which, in turn, has caused much harm to Lyme disease victims and is, at least, partially responsible for destroying countless lives and causing unnecessary deaths.

Steere continues to propagate misleading and inaccurate information claiming that Lyme disease tests are accurate. Scientific studies have proven his views to be wrong.

<http://online.wsj.com/article/SB10001424052970204044204574356592054801208.html>

Below are some of the reasons Lyme disease is, in reality, vastly underdiagnosed.

Extremely poor "screening" test

No standard presentation of Lyme disease

Highly restrictive CDC surveillance criteria

Misleading implications of low "reported" cases

Lack of reliable tick and tick borne disease studies

The Infectious Diseases Society of America (IDSA)

The Centers for Disease Control

Potential expense to HMO's and insurers

Medical conformance enforcement and licensure threats

The media's role in promoting public and medical ignorance

Pharmaceutical windfalls

The research racket

Test and vaccine patents

Medical testing laboratories
Potential impact on disease charities
Potential impact on specialty diseases doctors
Potential impact on disability payments
Potential impact on tourism and real estate prices
Potential employer liabilities
Biowarfare aspects

A summary follows:

Extremely poor “screening” test;

Doctors who are not knowledgeable about Lyme disease follow the Lyme disease guidelines issued by the Infectious Diseases Society of America (IDSA). The guidelines promote the use of the ELISA test as a first-step screening test and claim the test is highly accurate. This is to be followed by Western Blot tests only if the ELISA is positive. In fact, a study by Johns Hopkins released in 2005 showed that this approach only picks up 25% of proven Lyme cases. (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1248466/>)

The Johns Hopkins tests were done at specialty laboratories. Serologic tests performed at mass volume laboratories used by HMO's will likely result in even lower sensitivity. Also, most tests are designed around East Coast strains. Tests for West Coast strains and strains in other areas are even less likely to be positive using standard serologic testing.

Many, many peer-reviewed studies have shown the very poor results to be expected from the Lyme disease ELISA tests. Yet Steere and the IDSA continue to mislead insisting it is extremely accurate.

<http://canlyme.com/labtests.html>

<http://lyme.kaiserpapers.org/nytimesart.html>

The Centers for Disease Control (CDC) modified their serologic criteria to accommodate financial interests in the failed Lyme vaccine making the test even less reliable and even more likely to underdiagnose. <http://jcm.asm.org/cgi/reprint/34/6/1353.pdf?ck=nck> (“...the exclusion of the 31-kDa and 34-kDa protein bands from the diagnostic criteria may result in the underdiagnosis of Lyme disease by those who would rely too heavily on serological confirmation.”) The 31-kDa and 34-kDa are highly specific to Lyme disease.

Another source of diagnostic confusion is that the myth that the “Lyme Rash” (erythema migrans) has a distinctive “bull’s-eye” shape and occurs in a very high percentage of those infected, in the order of 90%. The truth is that the Lyme rash can have a variety of presentations and occurs in fewer than 50% of those infected. Some believe the classic “bull’s-eye” only occurs in 10% of those infected.

<http://canlyme.com/lyme-basics/symptoms/>

The unsatisfactory state of Lyme disease testing prompted a U.S Senate directive in Public Law 107-116 signed in 2002.

Selected excerpts... “The Committee recognizes that the current state of laboratory testing for Lyme disease is very poor. The situation has led many people to be misdiagnosed and delayed proper treatment.” “The Committee is distressed in hearing of the widespread misuse

of the current Lyme disease surveillance case definition. While the CDC does state that 'this surveillance case definition was developed for national reporting of Lyme disease: it is NOT appropriate for clinical diagnosis,' the definition is reportedly misused as a standard of care for healthcare reimbursement, product (test) development, medical licensing hearings, and other legal cases. The CDC is encouraged to aggressively pursue and correct the misuse of this definition."

<http://lyme.kaiserpapers.org/presbush.html>

For an excellent presentation on Lyme disease testing (and treatment) see;

http://www.ilads.org/lyme_disease/media/pdf/Ray_Stricker_Presentation.pdf

No standard presentation of Lyme disease

Lyme disease can have a variety of presentations that can confuse doctors. The result is that Lyme disease is commonly misdiagnosed as fibromyalgia, MS, Parkinson's, chronic fatigue syndrome, Lou Gehrig's, arthritis, cardiac problems, Alzheimer's, ADD, and other conditions. When doctors are baffled, they may diagnose Lyme disease complaints as a psychiatric disorder and place the blame for their incompetence on the patient.

Highly restrictive CDC surveillance criteria;

Since Lyme disease can have multiple presentations, the CDC designed the two-tier serologic testing procedure described above. The purpose was to make the criteria so stringent that only those with "certain" Lyme disease would be counted. Very few with proven Lyme disease, perhaps in the order of 10%, can meet these criteria.

Doctors with little or no knowledge of Lyme disease mistake the surveillance criteria to mean diagnostic criteria. These figures are then used to issue statistics on "reported" cases. The focus for the CDC definition is on arthritic rather than the more serious neurologic and cardiac manifestations. For reasons listed below, many doctors do not report Lyme disease diagnoses even for cases meeting strict surveillance criteria.

Laboratories are required to report test results as "positive" or "negative" depending on whether or not they meet the CDC surveillance criteria. Uninformed doctors incorrectly interpret this to mean the patient has Lyme disease or does not have Lyme disease.

Misleading implications of low "reported" cases;

Regional doctors who are not well informed interpret reported Lyme cases as being indicative of the prevalence of Lyme disease in their region. The very low number of reported cases in most regions misleads doctors into believing that Lyme disease is rare or nonexistent in their area. As a result, Lyme disease is not even considered as a possible diagnosis and the patient is either diagnosed with another condition or is abandoned.

Compounding this problem is the disclaimer by some state health agencies that the infection may have been acquired elsewhere. As a result, regional doctors are even less likely to consider Lyme as a diagnosis in a given area. Most people do not notice the tick and do not get a rash making it virtually impossible to know where one was infected.

Washington State disclaimer; <http://www.doh.wa.gov/notify/guidelines/pdf/lyme.pdf>

Stored at: <http://lyme.kaiserpapers.org/pdfs/lyme.pdf>

“DOH (Department of Health) has received 7 to 18 reports of Lyme disease per year in recent years. Almost all Washington cases are the result of tick exposure out of state. Endemic Lyme disease is not common.” Proof for this disclaimer is lacking.

In the case of Washington State, for example, the Lyme disease information provided by the DOH is obsolete and incorrect. Doctors who heed this information are unlikely to diagnose Lyme disease. Most state health agencies are misinformed about Lyme disease.

Medical professionals and health agencies are largely unaware that the CDC has stated actual Lyme disease cases can be as high as 12 times reported cases. This observation may apply to areas where Lyme disease is endemic and recognized. In areas where Lyme disease is endemic but unrecognized, the reported figures and multiplier are meaningless.

Lack of reliable tick and tick borne disease studies;

Reliable tick distribution and tick disease studies are sorely lacking outside of well recognized endemic areas such as the Northeast, the Midwest, and California. For the most part, such studies are either nonexistent, decades old, or poorly executed in parts of the country where Lyme disease is not acknowledged to be endemic.

Future studies should be designed to accommodate strain variations from region to region to achieve accurate results. New strains continue to be found.

(<http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=19846628&retmode=ref&cmd=prlinks>)

Such studies are critical in determining the risk of Lyme disease and other tick borne infections in a given area and would conclusively prove the existence of Lyme disease, which has now been reported in every state. It would also provide valuable information for doctors in order to give appropriate consideration for a diagnosis of Lyme disease.

Tick densities and infection rates can vary greatly within a short distance. Absence of infection in Ixodes ticks should not be taken to mean there is no Lyme disease in an area. However, positive findings are proof of infection in a given area. The presence of Ixodes ticks in a given area is the best indicator of the risk of contracting Lyme disease and eliminates the risk of poorly executed studies for tick infection rates.

The Infectious Diseases Society of America (IDSA);

The IDSA is the entity most responsible for creating the current unhealthy medical environment associated with Lyme disease.

The IDSA Lyme disease guidelines, the subject of an antitrust investigation by the Connecticut Attorney General

(<http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284>), have been an overwhelming detriment to the proper diagnosis (and treatment) of Lyme disease.

(<http://www.journals.uchicago.edu/doi/abs/10.1086/508667>)

The authors were found to have gross conflicts of interest which were not disclosed. These

included financial interests in test kits and vaccines, ownership interests in private companies that are present or future beneficiaries of Lyme disease products and services, income from HMO's and insurers, ties to companies that benefit from the guidelines, including pharmaceutical companies and laboratories, and patent interests in the Lyme organisms themselves. Their unfounded and unscientific claim that chronic Lyme disease does not exist is a windfall for HMO's and insurers to justify refusal to pay for appropriate, and possibly expensive, long-term treatment. Symptomatic treatment of Lyme disease is a gold mine for pharmaceutical companies who create and sell drugs to mask and alleviate the symptoms.

The authors are given undeserved credibility because of the institutions that employ them, presumably for their ability to generate NIH research grants through what appears to be a rigged process. These institutions include Yale, Harvard, New York Medical College, New York University, Johns Hopkins, University of Connecticut, and others.

Trivialization of Lyme disease, with certain authors claiming it is "hard to catch and easy to cure" has detracted from the seriousness of this disease and the attention it deserves. Unwitting physicians who accept this do not realize that Lyme disease is serious, can be life threatening, and may be incurable, particularly if not diagnosed at an early stage.

Although the IDSA Lyme disease guideline authors claim that their study is based on "science," the fact is that over 50% of their references were simply their own previous opinions. The selective "independent" references provided were supportive of their views. Over 95% of available Lyme disease articles and studies in the National Libraries of Medicine were ignored. Under the guise of labeling Lyme disease a medical "controversy," a stance which has been disproven with numerous scientific studies, the IDSA continues to propagate their views to a gullible public and medical profession.

Endorsement of these guidelines by the CDC has provided undeserved clout. Some of the authors were previously CDC employees and appear to have a significant influence on the CDC. In addition, CDC employees have their own conflicts of interest relating to Lyme disease. The IDSA Lyme disease guidelines also encourage the use of the CDC serodiagnostic surveillance criteria as diagnostic criteria. As previously noted, very few with proven Lyme disease can meet the CDC surveillance criteria for Lyme disease.

The CDC's Paul Mead is on the "faculty" to teach an IDSA Lyme disease course alongside some of the IDSA Lyme guideline authors investigated by the Connecticut Attorney General. <http://lymecourse.idsociety.org/> So it appears the CDC is clearly aligned with the biased and corrupted IDSA guidelines.

This is incomprehensible.

Many believe the IDSA may well be concerned about the great harm the Lyme guidelines have caused and its liability aspects. The numerous lawsuits and medical complaints filed against the Lyme disease guideline authors have not been disclosed.

Even the Lyme guidelines review forced by the Connecticut Attorney General appears to be ongoing evidence of IDSA corruption. The outcome was simply a "rubber stamp" of the flawed guidelines and the review procedure itself appears to have violated the terms of the settlement.

<http://lyme.kaiserpapers.org/pdfs/IDSA-Lyme-Disease-Final-Report.pdf>

The Centers for Disease Control

The entity most responsible for allowing this unfortunate state of affairs in Lyme disease to happen and continue is the CDC.

For many decades, the CDC has been viewed as a reliable source of health information. Some medical professionals in different specialties are starting to realize this reputation may no longer be warranted. The media is just starting to grasp this.

<http://articles.mercola.com/sites/articles/archive/2009/11/24/Superstar-CBS-Reporter-Blows-the-Lid-Off-the-Swine-Flu-Media-Hype-and-Hysteria.aspx> The CDC now appears to be in the vaccine business and creating imaginary pandemics.

<http://articles.mercola.com/sites/articles/archive/2009/10/24/CBS-Reveals-that-Swine-Flu-Cases-Seriously-Overestimated.aspx>

Certain CDC employees have patent interests in Lyme disease testing and vaccines.

The conflicts of interest made possible by the Bayh-Dole Act, enabling patent interests by government employees, and the revolving door between the CDC and pharmaceutical companies has compromised the CDC's previously deserved fine reputation. The latest example is the hiring of former CDC director, Dr. Julie Gerberding, by Merck.

<http://www.reuters.com/article/2009/12/21/us-merck-gerberding-idUSTRE5BK2K520091221>

The virtual control of the press and the dissemination of CDC information by mass media is the main reason why the CDC/IDSA misinformation on Lyme disease is so widely accepted and believed.

The CDC is clearly allied with IDSA and Lyme disease information apparently controlled by IDSA. As previously mentioned, Paul Mead, a medical epidemiologist with the CDC, is on the faculty of IDSA to teach an online course about Lyme disease;

<http://www.cdc.gov/lyme/>

The CDC endorses only the IDSA Lyme guidelines on its web page;

http://www.cdc.gov/ncidod/dvbid/Lyme/ld_human_disease_treatment.htm

The CDC has adopted a very limited, biased, and misleading definition of Lyme disease;
http://www.cdc.gov/ncphi/diss/nndss/casedef/lyme_disease_2008.htm

For example, the statement that the erythema migrans occurs in 60% - 80% of patients is not true. To cite another example, cardiovascular symptoms are limited to atrioventricular conduction defects. The more serious "palpitations, bradycardia, bundle branch block, or myocarditis alone are not criteria for cardiovascular involvement" according to the CDC. Potentially life threatening tachycardias are not even mentioned. In fact, the CDC states that Lyme disease is not fatal. This is false.

The CDC makes no obvious effort to correct the understated reported cases information to insure they are not misinterpreted as being the true number of Lyme disease cases;

http://www.cdc.gov/ncidod/dvbid/Lyme/ld_statistics.htm

The CDC's web page no longer has much useful content. Previous web pages by the CDC

used to have useful content but are now very difficult to access, even on archival web sites;
<http://www.cdc.gov/ncidod/dvbid/Lyme/>

Not a single patient friendly resource is listed on the CDC site;

http://www.cdc.gov/ncidod/dvbid/Lyme/ld_resources.htm

The information provided is deeply flawed and most originates from the same sources that authored the IDSA Lyme disease guidelines. For example;

http://www.mass.gov/Eeohhs2/docs/dph/cdc/lyme/tickborne_diseases_physician_manual.pdf

Stored at: http://lyme.kaiserpapers.org/pdfs/tickborne_diseases_physician_manual.pdf

The CDC promotes two-tier testing for diagnosis and claims the ELISA is highly accurate which has been disproved in medical studies.

http://www.cdc.gov/ncidod/dvbid/lyme/ld_humandisease_diagnosis.htm

The fact that the CDC and an employee hold a patent interest in ELISA is not disclosed;

<http://www.lymediseaseassociation.org/images/pdf/ConflictReport.pdf> (Page 119)

The CDC attempted to eliminate Lyme disease guidelines that differed with IDSA

(i.e. The International Lyme and Associated Diseases Society <http://www.ilads.org/>)

<http://www.cdc.gov/maso/FACM/pdfs/BSCNCID/20050512%20BSCNCID%20Minutes.pdf>

See:

<http://lyme.kaiserpapers.org/pdfs/NCID-CDC-May-2005-meeting-synopsis.pdf>

“Dr. Stamm (President of IDSA at the time) commented that rogue guidelines are legitimizing long-term treatment for chronic Lyme disease; as long as these guidelines can be accessed, this type of treatment can be legitimized.” This meeting was the genesis of the 2006 IDSA Lyme disease guidelines.

Potential expense to HMO's and insurers;

Early or acute Lyme disease can normally be cured with a relatively short treatment using inexpensive antibiotics. However, the protocols in the IDSA Lyme disease guidelines virtually insure that the disease will not be caught at an early stage. This is due to inherent delays with testing and diagnostic procedures and the poor accuracy of the IDSA/CDC recommended ELISA screening test.

Late-stage Lyme disease cases can be expensive to diagnose and can be difficult or impossible to cure requiring long-term and potentially expensive treatment. Accurate testing for Lyme disease and coinfections at specialty laboratories can be costly. Very few physicians have the knowledge and skill to diagnose complex cases of Lyme disease.

It is well known that the number of Lyme disease cases far exceeds the number of AIDS cases. HMO's and insurers lost significant amounts of money on AIDS patients and do not want to re-experience this many fold with Lyme disease cases. An excellent analysis of the true numbers of Lyme disease cases can be found at;

<http://underourskin.com/blog/?p=337>

Several strategies have been developed to avoid this potential expense problem for HMO's and health insurers. One is to enforce the use of the IDSA Lyme guidelines to limit diagnosis

and treatment. For example, IDSA falsely claims there is no such thing as “chronic Lyme disease” that may require extended treatment. A second strategy is to deny that Lyme disease is a problem in certain market areas so a Lyme disease diagnosis will not be considered. Other strategies are also used. Kaiser Permanente has been known to ship blood samples for Lyme disease across the country with two or more weeks transpiring between blood draw and analysis. Even IDSA has condemned this practice because of the risk of sample degradation which virtually insures a negative result.

It is noteworthy that the CDC deleted a previous reference stating that out of 117 Kaiser Permanente blood samples from a Lyme endemic area of California, only one was positive. <http://www.harp.org/eng/kaiserslymesummary.htm> Kaiser Permanente, incidentally, has used Steere’s laboratory for Lyme disease testing.

The flip side of this is that Lyme cases misdiagnosed as MS, ALS, or Parkinson’s or other conditions can be very expensive to treat. So it is difficult to justify the logic of HMO’s and insurers. One rationale might be that some of these diseases are fatal within a certain timeframe so costs can be identified and end upon death of the patient.

Medical conformance enforcement and licensure threats;

“Not long ago, most doctors ordered tests, prescribed drugs, admitted patients to hospitals or referred them to specialists, and performed procedures based on their own experience and professional judgment. No longer. Now doctors who want to be on the “approved” list must agree to practice medicine based on a health plan’s guidelines. For most doctors, the guidelines mean fewer tests, fewer referrals, and fewer hospital admissions.”
<http://www.econlib.org/library/Enc/HealthInsurance.html>

Many of the IDSA Lyme guideline authors and their associates have testified against physicians who treat outside of IDSA guidelines.

Doctors who diagnose Lyme disease frequently and who do not conform to the IDSA guidelines have been reported to medical boards by HMO’s and insurers. The first instance of medical board harassment because of Lyme disease occurred in 1993. This case was reported by Kaiser Permanente NW in Oregon.
<http://www2.lymenet.org/domino/nl.nsf/b18db4ad8571a779852565e3007d9d16/996155967e71fb8f852565e30012f1c0?OpenDocument>

Since then, there have been more than 40 cases of harassment of legitimate Lyme disease clinicians by medical boards. Some states have adopted legislation to protect physicians who diagnose Lyme disease and who do not conform to the short-term treatment protocols dictated by IDSA. Mentioned before was one exceptional instance of IDSA Lyme guideline enforcement that took place at a closed meeting between the NCID/CDC and the President of IDSA at the time, Walter Stamm.

<http://www.cdc.gov/maso/FACM/pdfs/BSCNCID/20050512%20BSCNCID%20Minutes.pdf>
<http://lyme.kaiserpapers.org/pdfs/ncid-cdc-bsc-minutes.pdf>

A concerted effort to eliminate competing Lyme disease guidelines was discussed.

The threat of medical board investigation has greatly limited the number of doctors willing to diagnose and treat Lyme disease

The media's role in promoting public and medical ignorance;

The mainstream media have been instrumental in promoting the IDSA Lyme disease guidelines. Reporters associated with large media sites parrot the IDSA guidelines and do no research. Part of this is due to the influence and now undeserved credibility of the CDC and their support of the IDSA Lyme disease guidelines. The IDSA/CDC/NIH are experienced and well structured to promote their medical opinions in the medical and public press. Another factor involved in spreading misinformation about Lyme disease may be the influence of HMO's, health insurers, and possibly pharmaceutical companies since they are significant contributors to the advertising income of major media outlets.

The number of articles in major media newspapers is extremely low compared to other diseases that have a much lower prevalence than Lyme disease. A Google news archives search showed 36,400 citations for "Lyme disease" since 1980. In comparison, a search for "Parkinson's disease" (since 1950) resulted in 92,200 citations, "West Nile virus" (since 1999) returned 97,000 citations, "AIDS virus" (since 1983) had 337,000 results, and "H1N1" (since 2008) showed 565,000 results. The peak number of Lyme disease articles occurred in 1987 and has been declining since. The disease, on the other hand, has been steadily increasing.

The alternative guidelines issued by the International Lyme and Associated Diseases Society (ILADS), which are written for the benefit of patients' health, are rarely mentioned in the mainstream media.

Pharmaceutical windfalls;

The market for symptomatic treatment of Lyme disease through pharmaceuticals is undoubtedly immense. The pharmaceutical market for arthritis alone generated \$15.9 billion in revenues in 2008. http://www.wikinvest.com/wiki/Arthritis_Drug_Market

Worldwide sales of Parkinson's disease therapies will increase modestly from \$2.5 billion in 2008 to \$2.8 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

<http://www.bio-medicine.org/medicine-news-1/Growth-in-the-Parkinsons-Disease-Drug-Market--Fueled-by-the-Launch-of-Several-New-Therapies--Will-be-Offset-by-Generic-Erosion-of-Key-Agents-48287-1/>

According to PharmaLive, pharmaceutical industry experts expect the fibromyalgia drug market to quadruple to \$2 billion by 2016. Leonard Sigal, a rheumatologist and contributor to the IDSA Lyme guidelines, is heavily involved with promoting fibromyalgia as an alternative diagnosis. Sigal, a former academician, now works for a pharmaceutical company. He has also testified in legal cases, on behalf of insurers, against Lyme disease doctors and victims. <http://underourskin.com/blog/?p=137>

The denial of chronic Lyme disease by IDSA is an important factor in pharmaceutical marketing. According to the IDSA Lyme guideline authors, regardless of how long one has

had the infection, how entrenched it is in immune protected sites, or how disabling it is, a short course of antibiotics will eradicate the disease from the body. This has never been proven. Numerous scientific studies have shown IDSA's claims to be false. Irregardless, according to IDSA, after a few weeks of antibiotic treatment a person is "cured" of Lyme disease. Then, suddenly, ongoing symptoms are due to some other unidentified problem which can be managed with ongoing drug treatment. IDSA Lyme guideline authors have known financial ties with pharmaceutical companies, making perfect financial sense for this false claim of cure.

It is only the undeserved clout of the CDC and IDSA and the gullibility of the media that give this incredible information any credibility.

The widespread misperception that Lyme disease is relatively rare may be an additional possible reason why more research on new antibiotics or a cure is not performed by drug companies who are attracted by expensive drugs and large markets.

The research racket;

Allocations of Lyme disease research grants by the National Institutes of Health (NIH) appear to be clearly biased. Many of these were awarded by the former Lyme disease program manager, Phillip Baker, who is now heading the American Lyme Disease Foundation (ALDF), an IDSA ally. The Lyme disease guideline authors and their cohorts received an exorbitant share of available grants. For example, from 1976 to 2008, the aforementioned Allen Steere received 71 grants from the NIH. Of these, 33 were titled "Lyme Arthritis; A New Epidemic Disease." It appears that Steere has yet to enlighten the world with the fruits of his research efforts for this particular study.

Many of these studies were designed around arriving at a predetermined outcome. One example is a study by Mark Klempner, one of the IDSA Lyme guideline authors, to "prove" that long-term antibiotic treatment is not effective, "Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease" published in 2001. There is some question whether or not this study was, in fact, designed to fail. Treatment doses, choice of antibiotics, and duration of treatment have been criticized as being inadequate. Selection of patients in the study was also biased.

This study has been discredited, most recently in the IDSA Lyme guideline review forced by the Connecticut

Attorney General. The statistical manipulations used in the Klempner study were exposed during these

review hearings. Yet it continues to be a mainstay of IDSA treatment guidelines.

(<http://www.idsociety.org/Content.aspx?id=150260>)

Perhaps the most damning comment regarding Lyme disease research by these favored few is by Willy Burgdorfer for whom the Lyme bacterium was named. He recently stated, "Money goes to people who have, for the past 30 years, produced the same thing—nothing."

<http://underourskin.com/blog/?p=191>

Trivialization of Lyme disease and the denial of chronic Lyme disease by IDSA also contribute to the lack of meaningful research in Lyme disease.

Funding for Lyme disease research, concentrated in the hands of a few, is dwarfed by funding for other diseases with no known cause such as fibromyalgia, MS, and Parkinson's that can be a misdiagnosis of Lyme disease and also a source of profit for drug companies through symptomatic treatment. Researchers in these other conditions with no known cause do not want their cash flows threatened.

Test and vaccine patents;

As of yearend 2009, there were 2126 US patents using the search term "Lyme + disease" issued since 1976. For purposes of comparison, using similar search terms there were 82 patents for Multiple Sclerosis, 328 patents for Parkinson's disease, 862 patents for Alzheimer's disease, and 1292 patents for fibromyalgia. Considering that the IDSA authors, some of which have patent interests, state that Lyme disease is "hard to catch and easy to cure," a number of people seem to believe it has enormous profit potential.

The lack of significant scientific progress in Lyme disease and the dismissal of scientific evidence that does not support IDSA's views may be partially as a result of the protection of financial interests in these patents.

Apart from the patent conflicts of the IDSA Lyme guideline authors, the most disturbing aspect of this are the patents held by the CDC. Barbara Johnson, a microbiologist with the CDC, has a patent interest in the ELISA test recommended by IDSA and the CDC. Dr. Johnson is also listed as an advisor for the IDSA Lyme disease guidelines. The CDC also has Lyme disease vaccine patents.

Some informed observers believe that the scientific fraud associated with Lyme disease is mainly due to vaccine interests. One example of this is the elimination by the CDC of bands 31-kDa and 34-kDa, both specific to Lyme disease, in the serodiagnostic criteria formulated by the CDC. As previously mentioned, this has been a contributing factor to the underdiagnosis of Lyme disease. The elimination of these two bands is a direct result of the failed Lymerix vaccine which used outer surface protein A (band 31 kDa).

Lyme vaccine patents have been summarized in the following document;
<http://www.lymediseaseassociation.org/images/pdf/ConflictReport.pdf>

Medical testing laboratories;

Medical testing laboratories are beneficiaries of Lyme disease directly and indirectly.

Directly, medical testing laboratories benefit from the large numbers of Lyme disease tests (and coinfections) ordered in the US and abroad. In the US, Lyme tests are ordered mostly in known endemic areas. The number of tests for Lyme disease and other tick borne infections will undoubtedly increase as the spreading geographic distribution is recognized.

Precise figures for the size of the Lyme test market are difficult to obtain and those that are available vary greatly. In a 1999 NIH grant, Brook Biotechnologies, a manufacturer of Lyme tests, stated that in the US there are more than 5 million Lyme Elisa tests and 500,000 Lyme

Western Blot tests performed each year. (NIH Grant 2R44AI038724-02 from National Institute Of Allergy And Infectious Diseases IRG: ZRG5) Including foreign testing, the figures would about double.

Assuming the number of tests ordered has increased in line with CDC reported cases (about 65% since 1999), this would bring the 2008 figures to over 8 million for ELISA tests and over 800,000 for Western Blot tests. Again, inclusion of foreign tests would double these figures. Figures for specialized Lyme and coinfection tests are not included.

Using \$70 as the price for an ELISA and \$200 for Western Blots, this would put the size of the US market at approximately \$600 million for the ELISA and \$150 million for the Western Blot, or a total of \$750 million. The worldwide figure for Lyme testing approaches or exceeds \$1.5 billion for the ELISA and Western Blot tests alone.

The two-tier requirement dictated by the IDSA/CDC is a major factor in the volume of ELISA tests ordered. As mentioned previously, the CDC's Barbara Johnson has a patent interest in the ELISA. IDSA Lyme guideline authors and/or their associates have financial interests in tests and in medical laboratories. An example would be Raymond Dattwyler, an author of the 2000 and 2006 IDSA Lyme guidelines, having a financial stake in Brook Biotechnologies mentioned above. The technology is now under license to Baxter Diagnostics. <http://www.biotech.sunysb.edu/industDev/comp-dev.html> Dr. Dattwyler is/was also said to be an advisor to the CDC and the FDA.

Indirectly, "no Lyme" is a financial bonanza for test laboratories. Typically, a multitude of tests are ordered to try to find the cause of the diverse symptoms experienced by Lyme disease patients. Market figures are difficult to determine but the amount most certainly dwarfs Lyme disease testing and is most certainly in the multibillions of dollars per year.

The current unreliable and inaccurate tests for Lyme disease not only lead to underdiagnosis but also lead to repeat testing and testing for other conditions if Lyme is ruled out by tests. Medical testing laboratories would prefer that the current state of affairs in Lyme disease continues for their immense financial benefit.

Potential impact on disease charities;

There are many charities built around diseases that may in fact be misdiagnosed Lyme disease or caused by Lyme disease. This is a multimillion dollar business and to name a few examples, includes The National Fibromyalgia Association, The National Multiple Sclerosis Society, The Parkinson's Disease Foundation, and The ALS Association. For example, The National MS Society tax statement filed with the IRS shows over \$109 million in 2008 income. Foreign MS Societies are not included. The ALS Association shows over \$50 million in revenues for 2008. The Arthritis Foundation states revenues of \$133 million in 2007. In 2001, Allen Steere, one of the IDSA Lyme guideline authors, was honored as a "Research Hero" by the Arthritis Foundation.

While the MS Society has suggested screening for Lyme disease, the unreliable ELISA test is used and probably not consistently done. As far as is known, none of the other disease charities suggest any screening for Lyme disease.

If Lyme disease was found to be the causative factor of a significant portion of these conditions, charitable funding for these organizations would suffer a significant drop.

Potential impact on specialty diseases doctors;

Similar to disease charities, specialists who treat patients diagnosed with diseases that can be misdiagnosed Lyme disease also have monetary turf to protect. There would be a significant drop in their patient base if their patients were found to have Lyme disease instead of diseases with no known cause which Lyme disease can mimic. So this is another group that may not want to see many Lyme disease accurately diagnosed.

Potential impact on disability payments;

Currently, it seems to be an exception for a person to get disability benefits with a diagnosis of Lyme disease. People who tend to be successful in applying for disability benefits do so with proof of inability to work.

Trivialization of Lyme disease by IDSA and the CDC discourage doctors from offering opinions that would support a diagnosis of inability to work. Doctors who evaluate cases for the Social Security Administration are uninformed about Lyme disease and likely use the IDSA guidelines as their source of information. The serious and disabling consequences of Lyme disease are ignored.

Proper recognition of the disabling consequences of Lyme disease would undoubtedly add to disability payments by the government and employers.

Potential impact on tourism and real estate prices;

It does not appear that real estate prices in areas where Lyme disease is known to be endemic have been significantly affected by this knowledge. Even in the epicenters of Connecticut and New York, real estate prices have been more recently impacted by macroeconomic factors, not Lyme disease.

Similarly, the potential impact of Lyme disease on tourism is difficult to assess. But it could provide an explanation of why states that are not clearly recognized as endemic areas minimize or refute the threat of Lyme disease in their state.

Some other observations are provided below;

<http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=PureSearch&db=pubmed&term=1771965%5BUID%5D>

“Lyme disease, the multisystem illness caused by the tick-borne spirochete, *Borrelia burgdorferi*, has emerged as a threat to public health worldwide. It is a particularly vexing problem in the United States where it is growing in range and intensity. In fact, in some hyperendemic regions of New York and New England, Lyme disease is now such a threat that it interferes with all sorts of outdoor activities, and has even led to depreciation of real estate values.” (1991)

<http://www2.lymenet.org/852565e200065c16/b641e6ff46917218525670a0009bcc1/2c0feff30e7d8cfb852565e20009c50a?OpenDocument>

“Acknowledgment of Lyme disease in a geographic region, and particularly that it may be an incurable infection, has painful economic consequences to affected regions: tourism adversely affected, home values may decline, local government may suffer a serious economic burden due to the high cost of treatment for employees covered under self-insured Workers' Compensation plans.” (1993)

Potential impact on employer liabilities;

Employers, particularly those who hire workers for outdoor work in areas known to be endemic for Lyme disease, may be exposed to potential liability. Possibly the best known case of employer liability for Lyme disease is summarized below;

<http://www.leagle.com/unsecure/page.htm?shortname=inneco20091117274>

“The district court also found, as a matter of law, that Deviney's injuries were not reasonably foreseeable. “The essential element of reasonable foreseeability in FELA actions requires proof of actual or constructive notice to the employer of the defective condition that caused the injury.” *Grano v. Long Island R. Co.*, 818 F. Supp. 613, 618 (S.D.N.Y. 1993). In *Grano*, employees of a railroad who contracted Lyme disease while working on signal equipment brought FELA claims. The court found the railroad was aware that there were tick problems and that ticks, known carriers of Lyme disease, were found in areas where workers would be. The railroad sprayed, but the spraying was mainly to kill poison ivy and no particular attention was given to ticks. There was no testimony from any of the plaintiffs that they were bitten by ticks. The court also noted that although Lyme disease was discussed as a problem, no comprehensive program was developed to protect employees working in tick-infested areas. The court held that the railroad knew or should have known of the tick infestations and of the risk of infection by ticks which transmit Lyme disease. The court then held that it was foreseeable that the employees would be bitten by ticks and thereafter infected with Lyme disease.”

More recently there was a case involving a store manager who filed a lawsuit claiming that she could not perform basic job functions due to Lyme disease.

<http://www.leagle.com/unsecure/page.htm?shortname=infdco20100201816>

Clearly, employers are another group who do not want to see Lyme disease recognized for the serious and disabling infection it can be.

Biowarfare aspects;

Some knowledgeable observers have suggested that biowarfare considerations are an important factor to explain the currently poor state of affairs in Lyme disease.

Jerry Leonard, a Lyme disease victim and advocate, has produced a documented investigative report on Lyme disease and biowarfare aspects titled *Lyme Disease and Biowarfare: A Summary of the Connections*

<http://xa.yimg.com/kq/groups/4321767/1008047940/name/jerryleonard999.htm>

There is no doubt that Lyme disease is being investigated in government bioterror laboratories;

[http://www.ctlymedisease.org/pdf/Sen.%20John%20Cornyn%20opens%20UTSA%20\\$10.6%20million%20science%20lab.pdf](http://www.ctlymedisease.org/pdf/Sen.%20John%20Cornyn%20opens%20UTSA%20$10.6%20million%20science%20lab.pdf)

There is a very high degree of suspicion that Lyme disease was being investigated at Plum Island Animal Disease Center and that an outbreak initiated the spread of modern day Lyme borreliosis, or Lyme disease, in nearby Old Lyme, Connecticut.

http://books.google.com/books?id=aLyWOYcC3zAC&dq=plum+island+lyme&printsec=frontcover&source=in&hl=en&ei=jO39S-jFlpeSMoD70c8N&sa=X&oi=book_result&ct=result&resnum=12&ved=0CFoQ6AEwCw#v=onepage&q=plum%20island%20lyme&f=false

At least two Lyme experts, Alan Barbour and Mark Klempner (an IDSA Lyme guideline author) have been placed in charged of BSL-4 laboratories, the highest level of bioterror laboratory security. This also supports the suspicion of Lyme disease as a bioweapon.

Some have suggested the interest in Lyme disease as a biowarfare weapon stems from its stealth characteristics (the ability to mimic many other conditions), to go undetected because of the poor diagnostic tests available, and the ability to be genetically modified. In addition, a naturally occurring tick that most people don't feel or notice may be viewed as an excellent method of delivery. Lyme disease also affects animals.

While not necessarily causing immediate death, the disease can debilitate a population and cause significant resources to be allocated to addressing this, placing a strain on a nation. It also seems that the Lyme bacterium can be altered with infections that would cause fatalities, if desired.

Incapacitating agents have been recognized as a legitimate tool in biowarfare arsenals.

<http://lymesentinel.blogspot.com/search/label/Politics%20of%20Disease>

Bioterror considerations may also help to make sense out of the nonsense of low research funding levels for Lyme disease, the allocation of these research dollars to an unproductive select few, why there are still no timely and accurate tests for Lyme disease, the apparent lack of an effort to find a cure, and its inherent underdiagnosis.

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