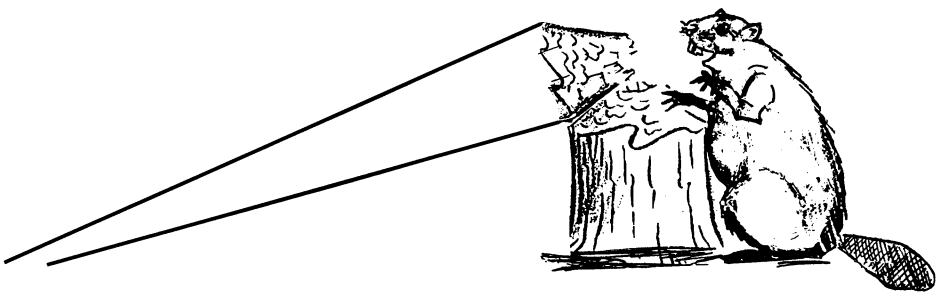
Oh, Canada:

The "Politicks" of Lyme Disease
PART TWO

A Brief to The Minister of Health
and to the Attorney General for Canada

Paul Haefling, M.A., LL.B

"Lyme Awareness Month,"
May 2010



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The views and opinions expressed are those of the author and may or may not be shared by others.

Nothing in this document should be read or taken as medical advice.

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SECTION ONE: EXECUTIVE SUMMARY. "Oh Canada," Part Two: "Politicks" and Lyme disease conflicts and controversy

This Brief is a sequel to "Oh, Canada" (part one), an earlier brief (published in May of 2009: "Lyme Disease Awareness Month"), which urged the responsible ministers at the Department of Justice and Health Canada and its sub-agencies to take steps to address the emergence of Lyme disease in Canada. Nothing of any real importance or significance has been undertaken to address this emerging threat to public health. This document, "Oh, Canada," Part Two, is a more candid and detailed sequel to "Oh, Canada," Part One. Its aim is to show in some detail "what is wrong" and how Lyme disease politics (or "Politicks") has hindered any effective response to the rapid emergence and spread of Lyme disease in Canada.

Canada's Lyme disease treatment guideline: "The Laboratory diagnosis of Lyme borreliosis: Guidelines from the Canadian Public Health Laboratory Network," was written in 2006 and published in 2007.[1] Its authorship is attributed to the Canadian Public Health Laboratory Network ("CPHLN"). The individual authors are not named. Therefore, their affiliations, credentials and expertise are not known. The Canadian guideline is flawed and unreliable, in part because it is based on other flawed and unreliable diagnostic and treatment Lyme disease guidelines and recommendations published in the United States through the Centers for Disease Control ("CDC") and the Infectious Diseases Society of America ("IDSA"). The latter organization includes Canadians among its members. One object in this Brief is to call attention to some egregious examples of the flawed and unreliable information found in those guidelines. Historically, there has been little accountability, or transparency and oversight of published Lyme disease guidelines, until recently that is.

In the U.S., the Lyme disease guidelines, as well as some research results published and relied upon by CDC and the IDSA concerning the nature and spread of Lyme disease, have evoked recent public criticism and brought about significant controversy. In 2008-2009, the IDSA's Lyme disease guidelines came under close scrutiny. That included some serious challenges to the credibility of the IDSA's guidelines and about the merit of some of the research underlying its (2006) Lyme disease guidelines.[2] Unfortunately for Canadians, the CPHLN guideline closely follows the U.S. guidelines. Consequently, most of the charges, criticisms and reproaches aimed at the CDC / IDSA approach and position on Lyme disease can and do also apply to the CPHLN (Canadian) guideline.

One of many problems is the evidence of inherent biases in the U.S. and Canadian guidelines. Such biases are evident in rather obvious attempts to downgrade, limit,

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[1] Can J Infect Dis Med Microbiol. 2007 March; 18(2)

[2] http:www.guideline.gov/summary/summary.aspx?ss=15&doc_id=9537&nbr=5085.

oversimplify and plainly to minimize the complex character and nature of Lyme disease, which is and remains a mysterious disease with a huge knowledge gap still to be filled. Uncertainty continues even today about the pathogenesis of Lyme disease, as well as in debates about best practices for diagnosing and treating Lyme disease. It is sometimes referred to as "the Great Imitator" since, in some patients, chronic Lyme disease can mimic other serious diseases and show parallel and similar symptoms.

It is now known that the Lyme disease bacterium, *Borrelia burgdorferi,* can assume different forms. Its complex and diverse protein manifestations are so little studied or understood as to beg the question: How does the bacteria's morphology change? It is believed that the *Borrelia burgdorferi (Bb)* bacterium has a capacity to evade treatment and escape a host's immune response, allowing it "to hide" or "escape" known testing and treatment modes. That is a broad description of the complex nature of the *Borrelia burgdorferi* bacterium responsible for the disease now commonly spoken of as Lyme disease.

While more is being learned about *Borrelia burgdorferi* and Lyme disease, evidence of inherent bias in the CPHLN guideline and the CDC / IDSA published guidelines also arises from the fact that the guidelines often omit (that is, they simply ignore or overlook) historical and other factual matters, including alternative, objective medical research evidence now available about the nature of Lyme disease, its symptoms, diagnosis and treatment. But, the truth of the matter is that even today no one can offer full and definitive guideline information based on complete, incontrovertible, and evidence-based medical science that is accurate, reliable and unequivocal. Part of the reason may well be that Lyme disease differs in manifesting symptoms and can have varying impacts upon individual patients.

It is likely many Canadians have Lyme disease but have not been diagnosed. Canadians are denied adequate and appropriate public health services in respect of diagnosing and treating Lyme disease because health professionals have placed reliance on the flawed CPHLN guideline. Another problem is not knowing how prevalent Lyme disease is because there is no formalized, nation-wide access to that information. Canada has had no structure for gathering such statistical data. As a result, no one really knows for sure or can answer accurately how widespread is Lyme disease in Canada.

Many of the problems we have in Canada are the result of limited and sometimes poor quality medical literature about Lyme disease, including reports on Lyme disease research. In Canada, there is a lack of access by physicians to appropriate practice information pertaining to diagnosing and treating Lyme disease. The result is, in following and applying the CPHLN guideline, one can foresee a risk of harm to the health of Canadians both from what the guideline says and what it omits.

SECTION TWO: "Quality Analysis" and Lyme disease literature and research

The IDSA's Lyme disease guidelines controversy just referred to reveals a much deeper problem relating to the overall quality of many other guidelines and recommendations that organization has published in many fields of practice, not just in relation to Lyme disease. Such guidelines, in various fields, are aimed at and intended to be relied upon by physicians and allied health professionals.

We Canadians can learn and benefit from a recent published study here in Canada having to do with quality of medical literature. The study findings are as important as the academic-sounding title suggests: "A systematic evaluation of the quality of meta-analyses in the critical care literature".[3] That study offers comprehensive and thorough insights into the world of "meta-analyses" in general, and, specifically, in relation to "critical care" medical practice. "Meta-analyses" is a term often used to describe high-level information summaries from published medical research. The study's authors screened 139 reports of meta-analyses pertaining to the area of critical care practice, for example, and concluded that "the overall quality of meta-analyses was . . . poor". They rated the information studied with a mean overall OQAQ ["Overview Quality Assessment Questionnaire"] score of 3.3 Any score below "4" was "a poor score". The authors found that 69% of 139 reports studied scored below 4. Their analysis means that high-level, summary practice information available to medical professionals involved in critical care practice was, in more than two-thirds of the studied literature, "flawed" and deficient and, hence, of doubtful reliability.

The findings and conclusions from that study (as will be seen) are closely linked to conclusions reached in other recent reports on overall quality of various published IDSA guidelines. The Canadian "critical care" study's "Discussion" section concludes with this cautionary message about the studied meta-analyses: "The result of this study raises questions about the quality of those reports" and "whether they can be recommended without qualification as the best evidence to guide clinical practice at the present time".

To be more precise, the article was aimed at assessing "quality of meta-analyses in critical care literature." "Critical care" articles selected for that review were related to Intensive Care Unit ("ICU") practice topics. As the structure for their research, the writers relied upon two neutral and objective instruments for the quality measurement analyses. One is entitled the Overview Quality Assessment Questionnaire ("OQAQ"), and the second is a "statement" entitled, Quality of Reporting of Meta-analyses ("QUORUM"). The earlier (1991) questionnaire, OQAQ, is footnoted and described by the authors as being "the only validated instrument available to grade the quality of reports of review articles". The later

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[3] Delaney, A., S.M. Bagshaw, A. Ferland, B. Wlanns, K.B. Laupland and C.J. Doig: *Critical Care* 2005, 9: R575-R582, available online at http://www//ccforumicom/contents/9/5/R575

QUORUM statement was first published in *Lancet* 1999, 354; 1896-1900. The most striking conclusions in the Canadian study about meta-analyses and the identity of areas in need of improvement in the critical care literature had to do with "comprehensiveness of searches," the "avoidance of bias" in the selection of studies, and, finally (but most importantly), an "assessment of the validity of all the included studies". The authors of the critical care study also reported having encountered similar problems and results from their examination of other studies of meta-analyses in published "overview" literature in certain other important, major fields of practice: emergency medicine, general surgery, and anaesthesia, where the same or similar kinds of problems were found.

The Canadian researchers also found that, in instances where reports of meta-analyses did follow and apply the tenets of the QUORUM statement, there was a measurable improvement in quality of those reports. The Canadian study authors also footnoted an improvement in the quality of reports on randomized clinical trials ("RCT"s) subsequent to publication of another quality-control instrument called the Consolidated Standards of Reporting Trials ("CONSORT") statement: published in *JAMA* 2001, 285; 1992-1995. Significantly, however, the authors also reported that there were differences (discordances) in quality between actual reports from the RCTs and the meta-analyses summarizing reports of RCTs.

The Canadian study's authors came to the following two deeply worrying conclusions in their overall quality analyses:

> Physicians wishing to use the results of these studies to guide their clinical practice would need to employ strategies other than browsing critical care journals in order to access all the relevant reports. The overall quality of the reports is low, and the majority of reports of meta-analyses are not of a methodological quality whereby the results of the study could be reliably used to guide clinical practice.

While the preceding research relates to "critical care" and several other named fields of medical practice literature, the conclusions reached have more general significance for other areas of medicine and practice.

In this case, the "guidelines" literature on Lyme disease is implicated. The evidence is clear that the (2006) IDSA Lyme disease guidelines, as well as the CPHLN guideline (2007), are replete with content showing the most obvious forms of intellectual bias: such as ignoring alternative research and studies, while at the same time basing their guidelines and recommendations on sometimes flawed and unreliable medical research studies.

One historical component of the Lyme disease debates and an illustration of the contested research adopted by the IDSA's adherents can be found in a 1993 published

study entitled "The Overdiagnosis of Lyme disease".[4] In the report outline and analyses of clinical data, reference was made to the "diagnosis, serological test results and treatment results of patients" (a grouping of 788 patients was selected from a university hospital and studied over a 4 ½ year period) who were "thought by the referring physician or the patient to have a diagnosis of Lyme disease". That study found 180 patients (23%) with active Lyme disease and 156 (20%) who had "previous Lyme disease and another current illness, most commonly chronic fatigue syndrome or fibromyalgia; and in 49 patients, these symptoms began soon after objective manifestations of Lyme disease". But, the remaining 452 patients (57%), the study found, "did not have Lyme disease". But, it was said, "the majority of these patients . . . had chronic fatigue syndrome or fibromyalgia" while others "usually had rheumatic or neurological diseases". (Those are, of course, all symptoms that may be manifested in Lyme disease patients. Hence, the need is for differential diagnosing.) Among the patients categorized as not having Lyme disease, the study went on to report that 45% had been diagnosed "incorrectly" as positive for Lyme disease by other laboratories. That study also reported that 409 patients had previous (prior to referral) antibiotic treatments, and, of those, the study suggests, 322 were "misdiagnosed". The conclusion then was that any lack of response by patients to, and any failure of, antibiotic therapy was simply a result of misdiagnosis.

A rebuttal study was published in May of 1993,[5] in which the authors suggested that the 1993 *JAMA* study had "multiple serious flaws". The rebuttal study also raised a concern that the JAMA study's publication could "lead to ill-advised complacency about Lyme disease" and could "compromise patients' access to treatment at all stages of the disease". The rebuttal study also questioned the "overdiagnosis" study's structure, analyses and conclusions.

Both sides in the historical Lyme disease debate acknowledge that the diagnosis of Lyme disease is a clinical one. But, mainly because of deficient testing systems, as well as withholding information and the spread of misinformation or partial information, there are likely many persons in Canada with a *Bb* infection who are undiagnosed and, unsuspectingly, have Lyme disease symptoms. That is to say, many will have the disease, a *Borrelia burgdorferi* infection, but have never been so diagnosed. Some persons may have sought attention but, based on the use of current guidelines, were left undiagnosed or mis-diagnosed. Why are more effective forms of testing not available for use in Canada? In the U.S., the CDC now recognizes and allows reporting of "suspected" Lyme disease cases.

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[4] Steere AC, "The Overdiagnosis of Lyme disease," (1993).

[5] LymeNet Newsletter. May 1993 – Response to 'The Overdiagnosis of Lyme Disease'.

In the "Lyme debates," it is important always to recall that the CDC has recognized that under-reporting of Lyme disease occurs regularly and that the numbers of persons suffering with this debilitating and sometimes deadly disease may actually be ten-fold higher than the numbers of cases that do get reported. Here in Canada, the expected negative outcomes for patients have also been compounded by a deficient testing system, the lack of availability and access to important and useful Lyme disease information, the lack of appropriate physician training about Lyme disease, and last, but certainly not least, the CPHLN's "minimizing" guideline and the weak and tentative response (to date) by the Public Health Agency of Canada ("PHAC") in regard to alerting Canadians to the emergence and rapid expansion of vector-borne Lyme disease. All of those problems could together add up as causative factors that have led to the present untenable and unacceptable situation in Canada. The result potentially leaves many Canadians at great risk from this invidious and, as yet, little understood, complex disease.

Through the CPHLN's Lyme disease guideline's misleading, naive, and simplistic approach of downplaying the spread and prevalence of Lyme disease in Canada, it is entirely likely that same guideline has resulted in the same level of under-reporting of Lyme disease cases here as the CDC recognizes as happening in the U.S.A. From where we are now, it is highly likely that Canada will be playing "catch up" for years, unless appointed and elected government officials use their access to the levers of power to move Canada forward through responses aimed at dealing effectively and much more quickly with the emergence of Lyme disease.

How did we reach this stage? What should be done? There are solid "Canadian" reasons to justify a decision to abandon and discard the CPHLN Lyme disease guideline. The CPHLN guideline, as will be seen, lacks merit and is inadequate (leaving aside the fact that it was based on the IDSA's model, which should no longer be regarded as being comprehensive, objective or based on sound clinical or scientific evidence). The CPHLN guideline, both when it was written and now, was and is still far "behind times" in relation to a growing knowledge base built upon quality research and investigation into Lyme disease already planned or underway in other countries such as in the the U.S.A., Europe and Asia, where similar or related species of bacteria create havoc in the lives of patients and their families.

The study on "quality of meta-analyses" information in "critical care literature" paints a troubling picture of the quality and reliability of information available to critical care ("ICU") practitioners, and the same appears for other practice areas. The critical care "meta-analyses" literature studied was described as including "any study that statistically integrated results of a number of primary trials, randomized clinical trials or observational studies". The study's authors carefully and closely evaluated the underlying quality of that literature and, in scoring the results, noted the approach and methodologies used in the

literature under review in order to assess quality and reliability of the conclusions. Their analyses of what are the flaws point to what most often is missing in published Lyme disease literature. The CPHLN guideline, for example, omits specific notes and references to support its listings of Lyme disease diagnostic and treatment "recommendations".

The "quality" study's authors relied on the formalized OQAQ questionnaire (note 8, Table 5) to support their findings and conclusions about the quality of the "overview" literature. The CPHLN Canadian Lyme disease guideline could never stand up to similar scrutiny. For instance, the OQAQ questionnaire referenced in the quality study on "meta-analyses" aims at assessing and determining how practice information ranked based on these criteria:

- avoidance of bias in study conclusions;
- performance of thorough searches; and
- combining study results appropriately.

The CPHLN guideline, as will be seen, comes nowhere close to satisfying those criteria.

In the U.S.A., recently, two reports were introduced at the IDSA's annual meeting in which the study authors reached the same sorts of conclusions in connection with the IDSA's numerous and varied medical guidelines. How can physicians and health-care professionals in any field of medical practice undertake to fulfill their professional duties lacking the availability of reliable and trustworthy diagnostic and treating information? The Canadian "meta-analyses" study authors had concluded, and, given that the specialist literature they studied was found to be deeply flawed, they also warned:

> Physicians should critically evaluate [such] studies prior to considering applying the results of [the] studies in their clinical practice.

Surely policy makers, researchers and officials from all levels and agencies within the orbit of Health Canada, including the Public Health Agency of Canada, are and have been aware of the "meta-analyses" problem. Are they able and willing to act, to accept responsibility and to take effective action to address and resolve the publication "quality" issues? How did the Canadian Lyme disease guideline get launched, seemingly without any qualitative analysis or any vetting of the information contained in it?

In "Oh, Canada" Part one (May, 2009), the writer urged Health Canada to go forward and lead in the creation of a national information clearinghouse for Lyme disease. But, we know now that much more than that is needed, as the quality analyses indicate. Canadians need to know that structures exist and will be used to analyze and vet the quality of published medical information available to physicians and other medical professionals. The importance of developing, enhancing and using such tools for validation, particularly in relation to the Lyme disease literature, undoubtedly would have helped to counter and

balance what the IDSA publishes in its (2006) guidelines, which is adopted and followed in the CPHLN guideline. All too often, their research is little better than opinion-based information. But such information is followed and used as if it were comprised entirely of evidence-based research of a high quality, that is, able to be counted on as being peer reviewed, respectable, objectively factual and reliable information. That simply has not been the case. The CPHLN Lyme disease guideline pretends to be based on reliable research, but it relies on the CDC / IDSA approach that has been challenged. Why is such biased, one-sided, unreliable, incomplete and inaccurate information being published, sometimes posing as authoritative, evidence-based research and offered as medical practice advice by our own public health agencies? The CPHLN Lyme disease guideline exercise has sowed seeds of doubt and caused confusion where there should be none. That also seems to describe the nature of the Lyme disease conflicts and the debate occurring in the U.S.A.

A November 2009, issue of *Medscape News* reports that, at the annual meeting of the Infectious Diseases Society of America (the "IDSA") held on October 31 and November 1, 2009, two reports were delivered and published having to do with the quality of numerous medical guidelines published by that organization. The conclusion reached in one report was that the bulk of the IDSA's published medical treatment guidelines (in that study some 68 guidelines dealing with 50+ different topics) are based on "expert opinion," "nonrandomized trials" and "case studies".[6] When interviewed for *Medscape Medical News,* one of the study authors cautioned that physicians who consider using the IDSA's guidelines or recommendations in a practice setting should carefully examine the strength of the evidence on which those are based. That report warned that "when clinicians are using the guidelines, they should not assume that they are all based on well designed studies". The remark was also made that "clinicians should remain cautious when using current guidelines as the sole source for guiding patient care".

The second report came from another independent study of 44 sets of guidelines (from among 65 IDSA guidelines published between 1994 and 2009) in total comprising 420 IDSA recommendations. As with the first study, the latter concluded that a mere 15% of the studied guidelines had what is described as level 1 supporting evidence. That means, as the report stated: "Only about 15% of the [IDSA's] guidelines are supported by randomized, controlled trials ("RCTs"), considered the highest level of evidence" (also referred to as "Level I" evidence). The converse of that statement is more shocking in that these studies provide evidence that 85% of all IDSA guidelines recommendations are based on low-level, unreliable information. Indeed, one finding was that 40-50% of the aggregated total numbers of treatment "recommendations" in the IDSA's various medical

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[6] http://www.medscape.com/viewarticle/71234/: "Infectious Disease Treatment Guidelines Weakened By Paucity of Scientific Evidence".

guidelines are solely "based on expert opinion" and are "not supported by properly controlled trials". Can medical practitioners trust in or rely on such information?

One IDSA spokesperson, when interviewed for *Medscape Medical News,* is quoted as having said:

> One always has to be concerned when we don't have randomized, controlled trials that provide evidence-based medicine to write guidelines. Without a shadow of a doubt, the best evidence comes from controlled clinical trials that are adequately powered with a sample size to answer the targeted question.

Even if there were not enough patients recruited to conduct complete and adequate trials, the IDSA position apparently was that "expert opinion" or "small uncontrolled studies" could be sufficient support for guidelines and treatment recommendations. The IDSA spokesperson also commented in the interview that that organization intends to continue working collaboratively on developing medical guidelines with the European Congress of Clinical Microbiology. It was said as well that the IDSA "will also work with Canadian colleagues" towards achieving care that is "standardized around the world".

But, for Canadians who are skeptical about the IDSA's approach concerning Lyme disease, it is questionable whether, among those who raise objections to the effectiveness to date of our country's response to the emergence of Lyme disease, any of those would be interested in pursuing that offer of collaboration.

Reputable critics have in the past pointed out flaws and challenged the CDC / IDSA Lyme disease diagnostic and treatment guidelines. Such criticisms are relevant in the Canadian context because (as noted) the CPHLN Lyme disease guideline closely follows the IDSA's guidelines. The two reports just cited, coupled with other criticisms of the IDSA's approach to Lyme disease diagnosis and treatment, indicate that the IDSA's hegemony and its once lauded and respected status in the field of medical guidelines publishing are likely to begin to wane.

The IDSA's current (2006) Lyme disease guidelines was made subject to review and scrutiny, and that likely would have led to a comprehensive revision, as a result of a compulsory review process the IDSA was required to undertake through a settlement agreement reached following an anti-trust investigation into IDSA practices through the office of the Attorney General for the State of Connecticut in 2008. By way of summary, the Attorney General's investigation determined in 2008 that the (2006) IDSA Lyme disease guidelines came about through a process that had deliberately excluded participation by other interested and knowledgeable persons with divergent views, expertise and opinions about diagnosing and treating Lyme disease. The IDSA, in other words, had excluded alternative evidence and research about Lyme disease in its deliberations. In "legal speak,"

such conduct would be said to have created "an apprehension of bias" in the development of the IDSA's (2006) Lyme disease guidelines. In layman's terms the IDSA position is "one sided".

As a result of a settlement in 2008, the IDSA was required to undertake a review process that led to a (partly public) hearing, which was held on July 30, 2009, in Washington, D.C.[7] Many substantive complaints were brought to the IDSA at the review hearing, and many presentations by researchers and critics at the meeting disclosed numerous flaws and shortcomings in the IDSA's (2006) Lyme disease guidelines.

As but one example, a statistical analysis (soon to be published) of some research underlying the IDSA guidelines was delivered at the review-panel hearing,[8] which called into question what for many adherents is at the heart of the IDSA position on Lyme disease. The IDSA's adherents repeatedly express doubt that "persistent" or "late-stage" or "chronic" Lyme disease exists and also about the need for and the efficacy of offering patients continuing or long-term antibiotic treatment for persistent or late stage ("chronic") Lyme disease. The related slide presentation from the analytic study (n. 4, at p.22) and accompanying text (n. 4, at p. 9) led to a (politely worded) conclusion that the IDSA's guidelines "need to be changed". The reason given was that, whereas the IDSA's adherents maintain that antibiotic treatment for chronic ("persistent" or "late-stage") Lyme disease may not be warranted (Klempner *et al.* 2001),[9] in reaching that conclusion, say the critics, the IDSA failed to consider other relevant evidence and alternate possible scenarios. Also, in the (2006) guidelines, the IDSA cited and relied upon two studies they asserted had been based on "E-1 evidence".

But, it was argued and clearly demonstrated at the July 30, 2009, review panel hearing (Appendix "B"), that the two IDSA studies relied upon were measurably "underpowered," "incomplete" and "inconclusive". That analysis and statistical presentation at the IDSA review panel hearings aligns with the conclusions reached in the two studies presented in the Fall of 2009 at the IDSA's annual general meeting. Those, too, concluded that the quality of evidence for the guidelines and recommendations published through the IDSA is poor and, hence, as the studies suggest, those guidelines are to be seen as unreliable.

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[7] http://lymewebcast.idsociety.org

[8] DeLong, A., "Challenge to IDSA Recommendations for Late Neurologic Lyme Disease Treatment and Post Lyme Syndrome: A Statistical Review of NIH-Funded Treatment Studies," Presentation Text and power-point display.

[9] Klempner MS, Hu LT, Evans J, *et al.* "Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease". *New England Journal of Medicine.* July 12, 2001, 345(2): 85-92.

In the July, 2009, review hearing the panel was shown contradictory evidence (n. 4), two alternative, preliminary studies (Krupp, 2003; Fallon, 2008),[10] which, in each instance, had obtained results demonstrating that patients had improved and gained benefit from continued, long-term antibiotic treatment for chronic Lyme disease. Ultimately, as the statistical presentation at the review panel hearing concluded, there is no real scientific or medical basis for the IDSA's position and its treatment recommendation against long-term antibiotic use because, as that critique succinctly concluded, "E-1 evidence against re-treatment does not exist".

Well before the IDSA's (2006) guidelines were published, the International Lyme and Associated Diseases Society ("ILADS") had also published a rebuttal "Position Paper" entitled, "Evaluation of Antibiotic Treatment in patients with Persistent Symptoms of Lyme Disease,"[11] which was also a critique of the studies undertaken by Klempner *et al.* [note 9, *supra*] questioning the use of antibiotic treatment for Lyme disease beyond 28-30-days. The authors of the "ILADS Position Paper" at the time foresaw the following situation as one likely to result from the IDSA position against using long-term antibiotic treatment:

> Based on its many errors, much of the article by Klempner *et al.* is, in our opinion, scientifically invalid and risks harming patients if it is accepted uncritically by physicians who may not have the time or the expertise to analyze the work. Indeed, a majority of medical practitioners may, after reading this paper, inappropriately withhold treatment from patients with persistent Lyme disease. This would be especially troubling since other peer reviewed medical research demonstrates that extended treatment with months of the correct choice of antibiotic therapies can be remarkably beneficial for patients with late-stage Lyme disease. Certainly long-term antibiotic treatment is medically accepted and approved for other chronic infectious diseases such as tuberculosis. . . .

But, in spite of that critique (or, perhaps, choosing to ignore it), the IDSA's (2006) published Lyme disease guidelines assert:

> There is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful

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[10] Fallon BA, Keilp JG, Corbera, KM *et al.* "A randomized, placebo-controlled trial of repeated IV Antibiotic therapy for Lyme encephalopathy". *Neurology,* March 25, 2008; 70(13): 992-1003;

Krupp LB, Hyman, LG, Grimson R, *et al.* "Study and treatment of post Lyme disease: a randomized double masked clinical trial". *Neurology,* June 24, 2003; 60(12): 1923-1930.

[11] http://www.ILADS.org/about_ILADS/position_papers2.html.

> and is not recommended for patients with chronic (≥ 6 months) subjective symptoms after recommended treatment regimens for Lyme disease.

That example is clear evidence that the IDSA chose to ignore existing alternative research and other information that contradicts its position. But, the IDSA position is, as the critics have argued, based on little or no evidence. The IDSA position is also biased and misleading through ignoring or withholding the rebuttal or contradictory evidence and information from physicians and other practitioners. The information that has been withheld would obviously allow for better diagnostic and clinical treatment options for patients.

How is it that the IDSA and CPHLN guidelines also manage to hold onto and apply other weak concepts like the requirement referred to as a "pretest probability" from exposure to an area endemic for Lyme disease infected ticks as a diagnosing criterion? Is it not the case that their approach serves only to limit and restrict diagnosing and treatment for Lyme disease? Is there no recognition that the lives and well-being of patients can be put at risk if any mistakes are made in the guidelines, and that, when strictly applied, those guidelines can lead to the denial of timely treatment? Short of a legal inquiry and investigation, answers to questions like that can only be guessed at or simply left open to speculation.

Some patients may well have been initially overlooked, left undiagnosed or untreated, or, perhaps, been told they had a psychiatric condition, not a bacterial infection. The evidence uncovered in the Connecticut Attorney-General's anti-trust investigation about IDSA members' conflicts of interest, the publication of guidelines without considering alternative research and the adoption of practice recommendations from low-level, unreliable research undoubtedly will negatively affect many individual patients and households. But, if that has been the case in the U.S.A., the same situation applies for Canada. That is especially the case for Lyme disease patients now suffering with late-stage, persistent, or chronic Lyme disease. It is being said by those who adopt the IDSA and CPHLN position that such persons have what they call "post-Lyme syndrome". But, that, it seems, is presently "a disease without a pathology".

SECTION THREE: Critique of CPHLN and IDSA Lyme Disease guidelines

Here in Canada, the truth is that countless patients with Lyme disease have received little or no support and there are likely many others who live with continuing clinical signs and symptoms of undiagnosed chronic Lyme disease. That situation in Canada most likely results from refractory or untreated chronic Lyme disease that is only chronic because of a mis-diagnosis or "missed diagnoses". But, it can never be forgotten that the guidelines debacle also interferes with and has brought about untold harm and detriment to fundamental doctor-patient relationships.

The physician community in Canada all too often hears and heeds only the messages of "Lyme deniers" (those who adhere to the IDSA's position on chronic Lyme disease and assiduously follow current Lyme disease guidelines). For example, doctors unfortunately hear and accept the guideline message that there is no such thing as chronic Lyme disease infection and that, beyond a maximum 28-30-day course of antibiotics, long-term antibiotic treatment for Lyme disease is not appropriate. Physicians also hear and believe that Lyme disease infection is uncommon or can only come from a small number of tick endemic areas. The Lyme deniers' messages continually usurp and intrude upon the clinical area and interfere in the sorts of conversations that should take place between an informed doctor and an enquiring patient. The problem is that doctors are convinced, through the guidelines approach, that those IDSA / CPHLN recommendations are to be strictly followed and applied. Not even common sense is allowed to intervene. Only the dictates of the inaccurate and incomplete guidelines are today given credence by public health agencies. Yet, some IDSA adherents are now willing to concede that some form of chronic, long-term illness or disease process ("diseases of unknown origin") is and has been occurring (but their preference still is to label that as the unproven illness called "post-Lyme syndrome").

That shift in consciousness does little to advance the public's health, however, since it still leaves unrecognized and unassisted countless patients who are ill and are not receiving needed, appropriate, active treatment. The IDSA and CPHLN positions are completely at odds with the growing body of clinical and laboratory evidence that continuing or longer-term antibiotic treatment can halt or alter progression of a *Bb* infection even in the more serious cases of chronic Lyme disease. Those guidelines have not yet publicly acknowledged that new diagnostic and treatment research results, including genomic studies, along with more and better research and more appropriate and more generous research funding, are likely to bring about better outcomes for Lyme disease sufferers. But, the situation we face in Canada goes far beyond those few examples of neglect and ineptitude.

The CPHLN guideline document has a list of "recommendations" relating to

diagnosing Lyme disease. The document lists a series of 11 specific "comments" aimed, presumably, at physicians and other health-care providers for purposes of diagnosing and treating Lyme disease. Those listed "recommendations" should also be described as normative practice directives since that is how they are being perceived and interpreted and applied by the medical community. But, those CPHLN guideline recommendations are recited without supporting references or footnote links to indicate the source for or any evidence relied upon as supporting each of the recommendations. The guidelines insist, for example, that serologic testing could follow after a diagnosis is made that would indicate "symptoms and signs" or "objective findings" of Lyme disease. If one were able to go that far in diagnosing Lyme disease clinically, why do we bother with serologic testing? But, the CPHLN guideline fails to identify in any meaningful way what it is that physicians are supposed to be looking for as symptoms and signs of Lyme disease.

The recommendations also warn about inaccurate serologic testing, but the guideline document on that point is unclear, unhelpful and equivocal. Many of the recommendations are confusing or contradictory. Others seem to follow a form of circular analysis. One example showing a lack of clarity is the following:

> 3. Patients with symptoms and signs suggestive of early disseminated or late Lyme disease should be tested for antibodies to *B. burgdorferi*.

That is a recommendation in favour of doing a serological test for potential chronic Lyme disease. Recent Lyme disease research suggests that serologic testing for an infection through measuring for an immune response may not always be effective or allow for observable results immediately or even long after a tick bite. Again, in order to decide a patient's eligibility for serologic testing, there is no information about what are the specific "symptoms and signs" considered to be "suggestive" for a case of "early disseminated" or "late Lyme disease". What symptoms might distinguish "early disseminated" from "late" Lyme disease? Either term can be taken to mean the patient has a chronic infection or may mean that a patient could manifest "whole body" symptoms.

The guideline's authors later recommend:

> 7. Patients without objective findings suggestive of *B. burgdorferi* infection should not be screened for *B. burgdorferi* antibodies.

How would a clinician know how to distinguish "objective" from "subjective" findings or symptoms of Lyme disease? What are the specific presenting signs or symptoms (clinical descriptions) that will satisfy recommendations 3. and 7? Are there cutoff points to help a clinician to differentiate and distinguish between those two sets of patient diagnostic recommendations?

The Canadian guideline also asserts that "screening" or serological testing should always be done (in accordance with the IDSA's position) through a two-step procedure (ELISA testing, followed by a Western blot test, but only if the first test result was returned "positive"). Yet another contradiction follows in the same series of recommendations:

> 7(c). (1) Patients should be made aware that antibody testing is subject to false-positive results, and that a positive test in the absence of objective findings and credible exposure histories usually represent[s] *(sic.)* false positive results."

The authors also say, in 7(a), that patients need a "credible epidemiological link to infected ticks" as support for a diagnosis, as well as "objective findings of infection". But, aside from having the patient capture the tick which has bitten him or her or showing a Lyme disease rash (sometimes seen but not always), there are no descriptions in the recommendations to indicate what actual evidence and other presentations or findings are to be considered definitive or clinically significant. The guideline asserts that serological antibody testing can give "false-positive results". But, its authors also assert that, even with a "positive" test result, in the absence of "credible exposure histories," that "positive" result should instead be looked upon as a "false positive" test result.

If a patient has no recall or history of a tick bite and no "credible exposure" and the serology is positive do they really mean to say that the first-level serologic analysis and testing is to be chalked up as being faulty? That would then mean recognizing that serologic testing is sometimes, or often, fruitless and ineffectual. The CPHLN guideline authors assert several times (as do the CDC and IDSA guidelines) that initial, or first step, ELISA testing is a credible test. The CPHLN authors insist in 7(b) that bypassing two-step testing "is strongly discouraged". Why, then, if an ELISA test is to be considered accurate or credible, is a Western blot test needed? Is the latter merely a follow-up test to corroborate or ascertain the accuracy of an ELISA test? Why is any serologic testing considered to be necessary as evidence to support a physician's "clinical diagnosis" of Lyme disease? If, as the U.S. CDC position has it, a physician's diagnosis of Lyme disease should be a clinical one, why then is the decision or determination not one to be left entirely to a fully informed, trained and educated "Lyme literate" clinician?

As if to add depth to all of the apparent confusion, in a previous commentary, the CPHLN guideline acknowledges that ELISA testing is likely to be flawed:

> Used alone, EIA [ELISA] tests presently in use lack the specificity necessary to base a diagnosis of Lyme disease on an unconfirmed result.

What constitutes a "confirmed" ELISA test (is it the follow-up Western blot test?), or, conversely, what is an "unconfirmed result"? If an ELISA is used as a stand-alone ("gate keeper") test, but it is lacking necessary specificity without a further test as confirmation, why bother using it? Why should the ELISA test not be "scrapped" in favour of a single, more specific and more sensitive form of Western blot testing? Why does the CPHLN guideline tend to downgrade other diagnostic tools, like PCR (Polymerase Chain Reaction) testing? Is it not the case that, because it is a direct test, PCR testing may be accurate and sometimes useful?

If one were to read the CPHLN guideline, followed by a reading and comparison with alternative Lyme disease diagnostic and treating guidelines, such as are available from the International Lyme and Associated Diseases Society (ILADS), it is instantly apparent that the latter guideline offers a true clinical diagnostic and treatment approach with information that is detailed and precise and has a focus on achieving a patient-centred differential diagnosis.[12] Why are Canadian physicians not being told about and encouraged to consider using the ILADS clinical guideline as an alternative to the CPHLN guideline for diagnosing and treating Lyme disease? Why are Canadians being misled in matters relating to diagnosing Lyme disease and why are physicians being denied access to the full panoply of Lyme disease information?

Many patients with Lyme disease have no recollection of a tick bite. They may not live in or have visited any known "tick endemic" areas. Yet, the CPHLN guideline asserts that such an exposure history from a possible contact with an infected tick in an endemic area is a major clinical criterion for diagnosing Lyme disease. However, there are no geographic boundaries for infected ticks. The notion that ticks (most apparently introduced by migratory birds) are present only in a few endemic areas is one that lacks common sense and logic. It is more likely the case that infected ticks are spread annually by migratory birds to both "endemic" (known) and new areas. It is believed also that some mosquitos may be carrying the *Borellia burgdorferi* bacteria. No one has yet "flagged" every wooded area or even begun to look into every potential habitat area to and from which birds migrate. Why does the CPHLN guideline (based upon the IDSA position) adamantly insist that an "exposure history" of a possible tick bite in a Lyme endemic area is a major or even a necessary criterion for a clinical diagnosis?

That position alone, coupled with the CPHLN guideline authors' acknowledgement that an initial ELISA test should always be used, results in creating a true logical quagmire because a patient in fact could be infected in a "new," previously non-endemic area, and, then, according to the IDSA position and the CPHLN guideline, that person would not

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[12] http://www.ilads.org/files/ILADS_Guidelines.pdf.

qualify on a clinical examination for ELISA testing because they lack the required exposure history. Even if they had such an exposure history and did get tested, the ELISA result may well be a "false negative" one, and, again, such patient with a *Bb* infection would be left untreated.

The ELISA is being used as a first-stage screening mechanism, but, both critics of the IDSA's testing approach, as well as Canadians knowledgeable about Lyme disease politics, have repeatedly complained that the ELISA test returns too many "false negative" findings. There is also the complaint that an ELISA is not specific enough to be used. Yet another complaint is that the ELISA is not sensitive since it often misses many infected patients who then would not, under the current testing protocol, receive a subsequent Western blot test. If persons are being missed who have a *B. burgdorferi* infection, but do not appear as "positive" on an ELISA, they could remain untreated and, ultimately, end up in the state described as "late-stage" or chronic Lyme disease. The continuing and most convincing proof of the inaccuracy and inadequacy of the two-step testing approach comes from the fact that many Canadians have tested positive through Lyme disease testing outside of our country after having first obtained a false negative ELISA test result in Canada.

The CDC / IDSA's current two-stage testing protocol and the exposure criterion is often linked to the phrase: "pretest probability," as a basis for the position that a patient suspected of having or showing signs of Lyme disease needs evidence of a previous exposure from a tick-endemic area in order to reach a conclusive clinical diagnosis. But, do the guidelines always require evidence of a patient's having been bitten (such as the E-M rash or even bringing in an attached tick), or is it enough for a patient merely to have visited or lived in an endemic area? The problem, as we now know for sure, is simply that some persons with Lyme disease do not satisfy those criteria.

Those "probability" concepts were further asserted and refined in a "Strategies" study published in 1998:

> In our analysis, the pretest probability of Lyme disease before testing or treatment was the annual incidence of new infection within a given area.[13]

In the CPHLN guideline, the concept of "pretest probability" is reduced to a lesser standard the authors call a "pretest *likelihood* of disease" (apparently realizing that a true probability analysis is elusive). However, the CPHLN guideline continually asserts that the diagnosing physician must look for a "credible exposure history".

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[13] Ann Intern Med 1998; 128: 37-48. "Test Treatment Strategies for Patients Suspected of Having Lyme Disease: A Cost-Effective Analysis".

Among the authors of the "Strategies" or "cost-benefit" article are some Canadians; others are from U.S. hospitals, universities and the Centers for Disease Control and the U.S. National Center for Infectious diseases. So, it is apparent, at least in that paper, that U.S. and Canadian guidelines are being closely linked in and through shared sets of ideologies.

The concept of a "pretest probability" of having contracted Lyme disease from living in or having visited a Lyme endemic area and then linking that notion to an "annual incidence of new infection within a given area" is problematic, however. The necessary inferences are that there are known, constant and identifiable geographic Lyme endemic areas and that one is able to determine the rates or incidence of infection in those areas. That is, they suggest there is a datum whose parts are quantifiable, known and measurable. But, such assertions are based on shaky assumptions and are likely to be mistaken and inaccurate. For example, infected ticks are not always likely to be so cooperative in choosing a known habitat. In order to find the probable Lyme disease incidence, one must find the degree or rate of infectivity among the tick populations or the prevalence of infected ticks within those populations. In order to sustain the propositions of the IDSA adherents, one would need to be able to measure the rate of infectivity, quantify the number of ticks and, then, by some other sort of calculus or estimate determine numbers carrying the actual *Borrelia burgdorferi* bacteria, and take into account as well the size of the human population and the proportion likely to come into contact with an infected tick, all of which would be needed to calculate and conclude for an area under consideration what the "probability" is of becoming infected with *Borrelia burgdorferi* bacteria.

Even if the "incidence of new infection" for an area is thought of only as being the statistical measure of new cases of diagnosed Lyme disease in humans, that, too, is unlikely ever to prove useful as a baseline because (as the CDC recognizes) there are many (potentially "ten fold" more) cases going unreported or being misdiagnosed. For example, if the total recognized number of diagnosed and reported Lyme disease cases in the U.S.A. were 200,000, then the CDC estimate for likely and potential Lyme disease cases, including what are undiagnosed cases, would rise to two million U.S. citizens infected with *Bb.* But, without determining an infectivity ratio for ticks, the IDSA-type analysis may never apply because the fact is that some ticks that bite or feed on a human or animal host are not infected at all. It is also quite possible, even probable, that strong winds can alter bird migration flyways so that any of the known geographic locations for infected ticks ("endemic areas") are likely to change seasonally and from year to year. All the IDSA / CPHLN position can ever really add up to is that there is a greater probability, meaning likelihood, of receiving a bite and an infection from exposure to infected ticks in

a known endemic area. That is not a global or all-inclusive analysis. It does not mean that infected ticks in other areas will not infect an adventitious human or animal host.

The point simply is that the IDSA's "clinical" requirement (a history showing an exposure to a tick infected area), which is also carried forward to the CPHLN Lyme disease guideline, is really not always helpful and ought not to be considered the most significant or necessary determinant to be used in all cases as a diagnostic criterion or even as an assumption that can be supported by what those writers say is based on "probability" analysis. (That may explain why the CPHLN guideline downgrades its diagnostic criterion to a "likelihood of infection".) Obviously, for clinical purposes, a tick bite from exposure to infected ticks in a known endemic area is one potential clinical consideration and warrants attention, but it should not get rated as *the* determinative diagnostic requirement. To suggest otherwise is misleading.

The IDSA / CPHLN "exposure" criterion should not be looked upon as a definitive basis for a clinical decision to rule in or rule out Lyme disease or even as a basis to allow or deny testing and treatment particularly when many Lyme disease patients have no recollection of ever having had a tick bite or of having visited a known endemic area. If the IDSA and CPHLN notion of tick endemic areas as a major diagnostic criterion ever had merit, that paradigm has probably now shifted and, with the spread of tick populations, is unlikely in everyday medical practice to be used other than simply as one potential diagnostic consideration.

Just as the CPHLN guideline and the IDSA's overall general approach aim at minimizing and limiting recognition of the incidence and prevalence of Lyme disease, so, too, the chosen guidelines and recommendations on diagnostic criteria aim at a similar result. That is, the aim is to downplay the actual geographic spread of Lyme disease. That outcome is a result of what in reality are "practice policies," but are being labelled as "guidelines," which really aim at controlling, directing and influencing each country's agenda and approach to Lyme disease. The sad fact is that the extant "guidelines" of the IDSA and CPHLN now in use may well account for the physician community's often hapless and low-key clinical diagnostic and treating efforts up to this point in addressing Lyme disease.

SECTION FOUR: Links and the "Missing Links"

Some argue, in opposition to the rigid IDSA / CPHLN guidelines approach, that the preferred path in all cases of suspected Lyme disease is to apply a differential clinical diagnostic approach because that simply is more comprehensive and more appropriate to the case when one considers the complex nature of Lyme disease, the morphology of this bacterium and its differential impact on individuals who become infected. There can be no "one-size-fits-all" diagnostic or treatment approach for Lyme disease that will work always and in every case. The key to treatment success is obtaining an early diagnosis, and that means accuracy and availability of information about Lyme disease must be assured. That is so because it is now known that individual patients can and do manifest differing levels of immune response to the *Bb* bacteria and, also, may show differing and sometimes unusual combinations of symptoms of infection. It is also extremely doubtful whether any approved serologic assay in use today will be able to identify or catch all of the known tick species, since different strains are still being discovered, some with unique and local protein manifestations. Are we in Canada ever likely to get around to altering present test limitations by introducing more sophisticated testing in time, say, to catch the emergence one day of our own *"Canadensis" (Bb sensu lato)* bacterial strain? We literally need to look carefully into our own backyards since there is now evidence, and a growing recognition, that infected ticks can be found almost anywhere in Canada, in any small urban woodlot where migratory birds inhabit or visit.

The CPHLN guideline also misses the mark because of all that it leaves out. For example, the CPHLN guideline fails to note or recognize that coinfections often occur with a *(Bb)* Lyme disease infection. Such coinfections may be caused by infection from other bacteria or viruses, which may be cross-reactive and can also, if left untreated, be deadly or seriously threatening to patient health. Such situations complicate the diagnosis and treatment of Lyme disease since it is unclear how effective current serological testing in Canada is in being able to detect a secondary bacterial or viral infection (co-morbidity). In fact, Canadian critics say, it too often fails to detect Lyme disease infection. The IDSA guideline recognizes co-morbidity, but does not clearly communicate what impact that may have for testing and diagnosing purposes. The "monocular" (one-sided) viewpoint of the CPHLN guideline is obviously incomplete and inadequate for the task that was undertaken. Indeed, it is questionable whether the CPHLN guideline shows anywhere the levels of care, diligence and skill that are needed and required to serve the purposes for which a medical diagnostic and treatment guideline is to be used.

One other questionable notion the "Strategies" ("cost-containment") paper considered was the linking of a "treatment costs" analysis and having that as part of a

published guideline for the diagnosis and treatment of Lyme disease. That study's choice of treatment options, for example, included the concepts of "treat" or "not treat" / "test" or "not test" for Lyme disease and those concepts were then linked to a "cost-benefit" or cost-analysis approach presumably (as with other precepts) aimed at "containment" or curtailing testing and treatment costs for Lyme disease. Using U.S. Public Health Service criteria, the Strategies paper illustrated the computed "net cost" for various diagnostic and treatment approaches linked to the concepts of "treating / not treating" and "testing / not testing" for different possible manifestations of Lyme disease. In the model analysis, a "no testing - no treatment" option, for example, was "recommended" within the study for "a patient with a low probability of disease" (including someone having "only myalgic symptoms"). But, for patients seen as having an "intermediate probability of disease," including a patient with late-stage Lyme disease symptoms (such as recurrent arthritis symptoms or other sequlae), the full-blown, two-step testing approach was considered appropriate and was recommended.

That study also suggested (without listing any detailed criteria) that a physician's personal estimation about the "probability" of a Lyme disease infection could determine which would be the appropriate testing choice and treatment decision. That study also suggested the physician's decision in that regard would be one based on the guideline's "cost-effectiveness ratios" for differing "probability of disease" cases and varying presentations of symptoms.

Such a costing approach might excite interest or seem relevant to people living in the U.S.A. with its mixture of approaches and its mixed "private" and public healthcare system ("private-pay," insured, sponsored, or "user-pay" arrangements). However, such an analysis has no real significance, that is, no clear meaning or relevance, in relation to Canadians who participate in our system of public health care.

Most Canadians assume, rightly or wrongly, that, if they become ill, our health care system can be relied upon to help them. The *Canada Health Act* created, and is intended to be operated, as a system of public, not-for-profit health care that will cover the costs of needed diagnostic and treatment services that are provided through physicians or hospitals. Under the *Canada Health Act,* federal funding and our national health care policy initiatives are put in place so that our provinces and territories are encouraged to offer health care services that are typically referenced as "physician" and "hospital" services that Canadian patients may require. In Canada, then, the only relevance of a cost-analysis approach to Lyme disease diagnosis and treatment might have to do with adjunct or specialized services that could have added or "incremental" costs attached. Such costs are, in any event, unlikely to be incurred anytime soon in Canada in the case of Lyme disease patients because the present monopoly guideline approach already serves (even if we do not know

how effectively) to control and curtail the numbers who manage to get access to appropriate diagnosing and treatment services pertaining to Lyme disease.

The suspicion many Lyme disease patients and their families share is the belief that our present system and approach based on guidelines effectively creates a vehicle for limiting access to health care by withholding testing and treatment information. Thus, there is a belief that, by design, there are no adequate diagnostic and treatment services available for hundreds of persons who may have become infected but are not being diagnosed with *Borrelia burgdorferi,* including some with coinfections. In short, while it is unfortunate, the "guidelines" approach is being seen as a system that serves to block and to limit access to effective Lyme disease diagnosing and treatment. Yet, we know that any such measures and approaches would unquestionably violate and seriously offend the concept of health care "accessibility" as a key principle in the *Canada Health Act.*

In regard to our health-care expenditures, many Canadians would be surprised to find out that, in 2006, total spending was $151.3 billion. For "hospital" services that year, total spending was $43.0 billion and for "physician" services, $20.0 billion.[14] Those particular program spending areas, hospital and physician services, are the twin pillars of our public health care system and are also the principal fiscal "drivers" relating to the federal-provincial cost-sharing arrangements for our public health care system under the *Canada Health Act.*

In recent months, Canadians have been told (with the same message being repeated often) that we soon may no longer be able to afford our public health care system and that changes are needed. In the near future, federal-provincial cost-sharing (fiscal) arrangements for health care spending are to be re-negotiated. But, Canadians should be cautious and wary of claims made that public health spending for hospital and physician services needs to be curtailed. Indeed, we may not be spending enough in those two key areas through not funding adequate research on Lyme disease, as but one example of the growing need for new spending for chronic illness preparedness because of our "aging population".

Another revelation in the Canadian Institute for Health Information's 2006 expenditure report is that spending for "drugs" as a component of total health care expenditures for that year amounted to $25.3 billion, which is higher than the total spent that year for physician services. Indeed, the CIHI report notes that "since 1997, pharmaceuticals have consumed the second-largest share of health dollars". That report also included an estimated 2008 amount of spending for pharmaceuticals, observing that such spending would grow to $29.8 billion. Aside from our spending for hospital and

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[14] "Did You Know?" 16 Jul 2009, www.cihi.ca>CIHI. Analytic Reports, Canadian Institute for Health Information: Research and Reports. Alt: http://www.cihi.ca/cihiweb/dispPage.jsp?cw_page=didyk_profile_e .

physician services, if one were to combine all of the "other" reported health care spending the total amount of that "other" spending for 2006 was $88.3 billion, which is more than half the entire amount of health spending for that year and is two to four times what was spent on hospital and physician services, respectively.

Assuming the CIHI information is correct, those data make the point that almost 60 percent (58.4%) of our health dollars went to pay for programs "other" than hospital and physician services. Thus, if cost-containment measures are needed, it should be obvious that reductions in those "other" spending categories need to be considered first as prime areas to cut. Was any of that "other" spending for 2006 directed into needed programs (research, healthcare, diagnostics and treatment) linked to the emerging threat from the spread of Lyme disease in Canada? The most likely answer is: little or none. The guideline approach to diagnosing and treating Lyme disease in Canada creates barriers and limits where none should exist. Is it acceptable that we need to face Lyme disease as a serious emergent public health issue, but what we are seeing is inadequate and insufficient public spending and very limited oversight? Why should Canadians not feel uneasy when hearing that health services may not be affordable or cannot be funded? How should we feel when we see, for example, that Lyme disease, an emergent public health threat in Canada, has no single spending line in our national accounts?

The guidelines process at issue here is a federal responsibility undertaken by the Public Health Agency of Canada (PHAC). What did it achieve? Anyone's thought or hope of seeing specialized services for Lyme disease patients or the availability of adequate diagnostic services and accurate treatment information for physicians has not been borne out as a product of the guideline process. Instead, any real progress in dealing with the emergence of Lyme disease in Canada has effectively been attenuated or is being stifled through the CPHLN guideline's control and censorship of information, as well as many other limitations in the CPHLN Lyme disease guideline already mentioned. Those who defend the CPHLN guideline may say the guideline process had no such aim, or that controlling and limiting Lyme disease information was an unintended result. But, the fact is that adherence to the CPHLN guideline approach and its recommendations inevitably leads to denial of access to diagnostic and treatment services for Lyme disease patients. The statutory (*Canada Health Act*) principle of "accessibility" is effectively being violated whenever a false negative test result occurs under the two-tier testing system, or when physicians and the public are told, for example, that Lyme disease is rare in Canada, as the CPHLN guideline suggests. No one knows what is the true scope of Lyme disease infection in Canada. The situation in Canada facing many Lyme disease patients undermines the very purpose and intention of our health care program, under the *Canada Health Act,* as Parliament created it. That situation is repugnant and offensive generally, and most

Canadians would readily agree that the result of such neglect runs entirely counter to the principles, objectives and intent of the *Canada Health Act.*

Do responsible officials at the Department of Justice, Health Canada, or the Public Health Agency (PHAC) acknowledge or recognize that, in the Lyme disease case, the failed CPHLN guideline process has led to censoring and controlling health care access (through, on the one hand, omitting information or limiting and withholding some Lyme disease information) and, as well, on the other hand, by limiting or removing access to other known, trustworthy and reliable (clinical) practice systems and other Lyme disease diagnosing, testing and treatment options? It seems unlikely. Yet, one must ask: Why did PHAC authorize and permit publication of the inaccurate and incomplete CPHLN Lyme disease guideline? In "Oh, Canada" (part one, May, 2009), this writer quoted and made reference to the following statements of policy and principle that are clear and unequivocal as to the intentions, policy objectives and program purposes outlined in the *Canada Health Act:*

> – that Canadians can achieve further improvement in their well-being through combining individual lifestyles that emphasize fitness, prevention of disease and health promotion with collective action against the social, environmental and occupational causes of disease, and that they desire a system of health services that will promote physical and mental health and protection against disease;
>
> – that future improvements in health will require the cooperative partnership of governments, health professionals, voluntary organizations and individual Canadians;
>
> – that continued *access to quality health care without financial or other barriers will be critical to maintaining and improving the health and well-being of Canadians.* . . . [Emphasis added.]

Any reasonable person can read and understand the meaning of those statements and would accept and recognize that any wrong act or omission by any groups or individuals, whose duty it is to uphold those statutory principles, would interfere with and thwart those principles. What is referred to as a legal "duty of care" potentially arises whenever someone undertakes to perform an action. The Lyme disease guideline publication debacle warrants a formal investigation. In fact, given the levels of inertia and inattention to the emergence of Lyme disease in Canada by the responsible ministries and public health agencies, that approach may ultimately be the only effective recourse open to offer some reassurance to Canadians that the need for effective action is finally being recognized.

We as Canadians should continue to expect that policies and programs undertaken through our public health care system will follow Parliament's carefully chosen, consensual

national standards that recognize and foster accessibility and the availability of needed quality health care programs. Canadians will also expect elected and appointed representatives to continue to allow public funding for all recognized and needed patient health care programs and services, throughout Canada, and in each province and territory. Canadians with Lyme disease, too, expect and need and deserve no lesser levels of services than are offered to other Canadians with any other serious and debilitating illness or disease.

SECTION FIVE: "At the crossroads," where present, past and future meet

It is worthwhile to trace the situation we face regarding the emergence of Lyme disease by looking at recent past history in order to understand and decide to where we can and should turn next.

The CDC / IDSA two-stage testing protocol adhered to in the CPHLN guideline has historical roots in an earlier study[15] involving a sample group of patients who had some of the identifiable and known physical symptoms of *Borrelia burgdorferi* infection, such as a "Lyme rash," or E-M, sometimes appearing as a "bullseye" rash, and including also persons who had Lyme arthritis symptoms. That study, too, was aimed at suggesting Lyme disease was being overdiagnosed. It, too, tried to cast doubt on the existence of chronic or persistent Lyme disease. In order to follow the circuitous path of that research, it should be noted, the studied patient group had included 17 individuals who had received previous antibiotic treatment for Lyme disease. (That, apparently, can have a potential impact on subsequent serologic testing.) That study, too, was challenged as having too narrow and too restricted a patient cohort, and, also, because it was difficult to repeat or replicate.[16] The other notable criticism of that historical study was that it had neglected to include patients with more complex and serious late-stage neurological symptoms ("neuroborreliosis") or other chronic or "late" Lyme disease symptoms and sequellae.[17] Those were all conclusions reached by the IDSA's critics, most of whom are persons with ties to the International Lyme and Associated Diseases Society (ILADS), an organization that publishes its own clinical guidelines for diagnosing and treating Lyme disease.[18] That organization as well undertakes education and research, training and accreditation for physicians and allied health professionals whose fields of practice would include diagnosing and treating Lyme disease patients.

One of the leading IDSA researchers who participated in the 1993 study on Western blot testing (*supra*, footnote 15) later delivered a prepared statement on Lyme disease at a hearing held in 1995 before the U.S. Senate Human Resources Committee. In the Senate Committee address, the observation was made that "no serologic test distinguishes

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[15] Dressler F., J.A. Whalen, B.N. Reinhardt, and A.C. Steere. 1993. "Western blotting in the serodiagnosis of Lyme disease". *Journal of Infectious Diseases* 167: 392-400.

[16] http://www.lymediseaseassociation.org: "politics"; "Conflicts of Interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines". See especially text and footnote 21.

[17] http://www.ilads.org/position.htm.

[18] http://www.guideline.gov/summary: "Evidence-based guidelines for the management of Lyme disease.

between active and past infection". In other words, serologic testing was limited because a patient with symptoms and a diagnosis of acute Lyme disease infection might be a patient with refractory Lyme disease, one who continued to manifest symptoms, or one who could have experienced a relapse even after some initial treatment. The speaker then made the observation that "some patients continue to have symptoms after treatment" and "that the Lyme disease spirochete may sometimes persist in the nervous system for many years".[19] Those remarks appear to recognize chronic or late Lyme disease neuroborreliosis. Such statements also contradict the logic of the "overdiagnosis" position and the earlier, commonly held IDSA position that "late" stage, or persistent, or "chronic" Lyme disease does not exist.

Another omission in the IDSA's research and testing approach is that rarely or never is notice given that the *Borellia burgdorferi (Bb)* bacteria can change form, which means it may be difficult to treat. The Lyme disease bacterium shows genetic variations and different expressions of protein. Research on the Lyme bacterium has found an unusual array of lipoproteins suggesting *Bb* is able to alter its protein structures and shift its genetic expression and presentation. This bacterium's genetic properties, as other recent research suggests, may allow it to react to and evade a host immune response. It may even escape the effects of antibiotic therapies by altering its protein and "hiding" in an altered (cystic) form in areas of the body with limited blood circulation, such as in synovial fluid (large joints). *Bb* can shed its outer surface protein and assume a cystic state. It then is more difficult to detect and treat with antibiotics.

The *Borrelia burgdorferi* bacteria's morphogenic capabilities could account for how it is that some chronic Lyme disease patients can, when tested, appear to be seronegative when, in fact, they have a *Bb* infection. The bacterium has likely not disappeared at all but may be sequestered in the body in an altered form. It is now being recognized as well that individual patients can have varied, differing immune responses to the bacteria's presence. Many notions espoused as part of the IDSA and CPHLN approaches to Lyme disease have simply not kept pace with modern research.

In any consideration of diagnostic and treatment guidelines, we expect and assume that such guidelines will be complete and thorough, that their reliability will be assured, that the quality of the information has been assessed and validated, *and,* above all, that their ultimate use by physicians in medical practice has been safeguarded and assured. However, we know from the "quality of meta-analyses" study and from the two reports presented at the IDSA's annual meeting, as well as from critics of the IDSA's position on

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[19] As cited in "Conflicts of Interest," at footnote 66: Steere, Allen C., 1995. Prepared statement before the Senate Committee on Labor and Human Resources Lyme Disease: An Emerging Infection that Threatens the Nation's Health, Wednesday, October 18, 1995. File 660, U.S. Federal News Service.

Lyme disease, that the (2006) Lyme disease guidelines, and other guidelines across the entire spectrum of IDSA medical guidelines, have fared poorly on any of the qualitative measures. Surely, those guidelines must now be treated with caution and suspicion.

Published critiques suggest, too, that the IDSA Lyme disease guidelines are now recognized as being one sided, incomplete and unreliable. How, then, could the CPHLN, after having adopted in substance the major tenets of the CDC / IDSA Lyme disease diagnostic and treatment guidelines, try to hold out its Lyme disease guideline as one that can be safely used in Canada, or trusted or even regarded as being accurate and complete? Canadians should be cautious and skeptical about giving any weight to the CPHLN guideline for all of the reasons identified earlier. But, suspicions arise because the CPHLN guideline was hastily published in 2007, after the Public Health Agency of Canada (PHAC) had convened a multi-party meeting, to which participants with varied Lyme disease interests and backgrounds were invited, for the purpose of addressing issues arising from the emergence of Lyme disease in Canada. As PHAC reported, "The intent of the meeting was to begin a process to review and update . . . guidelines from the 1991 consensus conference on Lyme disease".[20] But, as the Executive summary of the March, 2006, Lyme disease consensus meeting acknowledges, "Consensus was not reached on a number of issues or statements related to the clinical and laboratory diagnosis of Lyme disease . . .".[21] If that is so, how did the CPHLN guideline get published? Since, in Canada, there was no consensus outcome from the 2006 Lyme disease meeting, how can one explain and what can possibly lend legitimacy or allow some kind of status to the CPHLN guideline? It is not a "Laboratory" guideline in any sense, as its title would suggest, because the recommendations it contains are plainly addressed to physicians and intended for clinical diagnostic purposes.

That meeting originally appeared to be the start of a collaborative process to develop a Canadian Lyme disease guideline. Instead, the ineffectual and inept CPHLN Lyme disease guideline was published unilaterally. Committees were to have been set up to carry on with the collaborative effort, but that work never got off the ground. We Canadians are now left to "pick up the pieces," move on, and get past the CPHLN Lyme disease guideline fiasco.

How did we get to this point? By whom was publication of the CPHLN guideline officially reviewed and authorized? Was the guideline ever vetted for quality-analysis purposes? How did the guideline process end up being usurped by a little-known, quite possibly self-appointed, group, the Canadian Public Health Laboratory Network (CPHLN)?

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[20] http://www.phac-aspc.gc.ca/id-mi/lyme032006-eng.php.

[21] *Ibid.*

Was it the intention, in that exercise, to take control of the Lyme disease agenda, to monopolize Canada's Lyme disease information network and to supplant the collaborative guideline process? Canadians who suffer from Lyme disease have a right to challenge the situation, ask such questions and to hold accountable those who produced and published the failed Lyme disease guideline if only because it is biased and one sided and replete with inaccuracies. But, it should also be subject to challenge because the CPHLN guideline is missing important Lyme disease information and, thus, is seriously lacking balance and completeness. The CPHLN guideline and its recommendations offer a series of confusing, tenuous, unsupported and unreliable treatment recommendations grounded in and based on the challenged IDSA guidelines. For all of the foregoing reasons, the CPHLN guideline should be looked upon as being irreparably flawed.

What personal or professional ties link the CPHLN guideline authors and members of the IDSA? Why did the CPHLN guideline authors choose to be anonymous? Were their academic and professional credentials appropriate and adequate for the task they chose to undertake? How can we ever know the answers to such questions since the authors chose anonymity? Was that a result of temerity, an inability to face their critics and be seen face to face as part of a "Lyme disease debate" in Canada?

One can learn from the CPHLN website that that organization identifies itself as an "Expert Group" affiliated to the "Pan Canadian Public Health Network (PHN)". The Pan Canadian Health Network comprises more than 100 appointed individuals, some of whom are public servants, while others come from the private sector. PHN itself is an umbrella organization whose members and participants are linked to the statutory body we know as the Public Health Agency of Canada ("PHAC") whose head is one of the co-chairs, along with a co-chair representing public health agencies in each of Canada's provinces and territories. One of the listed tasks those PHN "expert groups" purport to undertake is *preparation of medical guidelines.*

Canadians recognize that public health dollars spent on indirect activity or for secondary purposes mean that fewer dollars then will be available for direct health care expenditures which would include services delivered by hospitals and physicians for the purposes of diagnosing and treating patients. The costs of a bureaucratic structure like the PHN as a subsidiary of PHAC are likely to be significant. If primary health care expenditures and fiscal transfers are linked principally to the delivery of hospital and physician services under the *Canada Health Act,* any third parties can be looked at as "hangers on" whose role in the public health care system needs to be examined cautiously and carefully measured and scrutinized in every instance when health care dollars are being allocated.

But, the PHN may fulfill an important role in linking some interprovincial and federal

public health undertakings. The recent (June 2009) Final Report of Canada's Senate Subcommittee on Population Health, entitled "A Healthy, Productive Canada: A Determinant of Health Approach," recognized that support should be given to the creation under PHAC of "a policy and knowledge node" to address issues of "population health and health disparities" through integration of measures "horizontally (at the federal level) and vertically (through intergovernmental collaboration)," which means, presumably, linking programs and policies among our provinces, territories and federal public health agencies.

Such activity will involve creating necessary data reporting and collection systems. Even more significantly, that report called for revisiting what is known as the statement on "Health Goals for Canada agreed upon in 2005," in and among which were listed various "public health goals," such as "addressing the gaps," "focussing on vulnerable populations," and aiming to "ensure that public health education, information and programs are accessible to all Canadians and that public health goals are inclusive of all Canadians". One of that report's "overarching goals" for improving public health care in Canada includes "reducing systemic inequalities" in health. It is beyond question that, except for the CPHLN's ineffectual guideline, Lyme disease patients have been systemically neglected and overlooked in regard to health care access when compared to other Canadians who suffer with a serious disease or illness. The "Executive Summary" for the 2005 "Health Care Renewal in Canada" study put forward the view that "access" is an obviously important objective and then went on to say that "health care renewal efforts are not forcefully addressing the increasing evidence that our more deep-rooted problem is quality of care".

One other notable set of directives in that study came from the suggestions that health care renewal should be "sustained," "coordinated" and "accountable". One of the most significant proposed areas of endeavour for improving population health, which the report identified, is Canada's "high burden of chronic diseases". That led to these proposals, which are said to require the following kinds of actions:

> **Chronic diseases**
> - Invest in programs to prevent chronic diseases, ensuring that strategies are integrated with the work of primary health care teams;
> - Modernize the management of chronic diseases by ensuring that health care teams have access to information tools to help them manage patients with complex disease in the safest, most effective and most appropriate way possible.

How can such measures even begin when we do not yet have in place a system to recognize and identify and then appropriately treat those patients, as we see in the case of chronic Lyme disease? Such policy statements ought to be seen and accepted as our "national health guidelines" intended to direct and govern Canada's public health officials

and agencies in the work they are required to do in implementing policies and programs. Those policies recognize the need to address and seek the elimination of Canada-wide threats to public health. The principles the report enunciates are meant to be acted upon and given paramountcy in our public health care spending and in undertaking all other activities and efforts for improving our system of public health care. Yet, surely, in Canada we now are past the *bon mot* phase of policy making and can begin to act on the espoused directions and principles that should be able to advance our nation's public health enterprize.

Canadians who are aware of and concerned about Lyme disease demand and want action from all levels of government to address all of the public health implications arising from the emergence of Lyme disease. Those suffering with Lyme disease can no longer accept, nor can Canadians permit or allow, the levels of inertia that we have seen to date in response to the emergence of Lyme disease in Canada by our public health agencies.

In the face of that outline of the public health care system's objectives for Canada, how can anyone defend or justify retaining the CPHLN Lyme disease guideline? Despite all the purposed, published statements that inform us about expertise and talent within our public health organizations, why are we given a document like the CPHLN Lyme disease guideline that is so patently flawed and unhelpful? Why are there so many remaining issues having to do with addressing and managing the emergence of Lyme disease in Canada that are still today unresolved?

Canadians will remember our federal and provincial public health bodies taking responsibility to manage and oversee the 2009-2010 "H1N1 flu pan- - -ic" in Canada. Few can forget seeing full-page newspaper ads and TV bites featuring the Director of PHAC offering warnings about an imminent flu pandemic and advising that everyone should get vaccinated; that enough vaccines were being bought to innoculate every Canadian who wished to be vaccinated. How many billions of dollars were spent from the summer of 2009 and through the winter of 2010 to manage the expected H1N1 flu pandemic? Was there misinformation that guided Canada's response or an over-reaction in that situation by public health officials? How was such a costly mistake made, leading some Canadians to doubt and seriously question our present public health system, its knowledge base and our country's planning and preparedness efforts? Surely, some of the money spent for unused influenza vaccines could, for example, have been better allocated and directed to spending for Lyme disease research.

Too many Lyme disease sufferers are ill and too weak to fight their governments as well as the disease. Most are dismayed and disheartened by the "do little" or do-nothing stance adopted by our public health agencies in the face of the spread of Lyme disease and the fruitless "hide and seek" Lyme disease policy debates we are having in Canada. Canadians have witnessed too little benefit or progress to date for patients who have Lyme

disease and all because of too little and too few serious efforts from our public health establishment to recognize and address the emerging threat of Lyme disease.

The CPHLN Lyme disease guideline was unattributed as to authorship. Why was there no transparency? Who are the authors? What academic, medical or professional credentials do they hold? Obviously (as pointed out earlier in "Oh, Canada") viewed from the health and safety perspective for Canadians, the CPHLN guideline authors are unlikely to be clinicians or treating physicians. The latter group is bound by ethical standards and have a practice concern for patients. Someone needs to give an accounting, to explain to Canadians with Lyme disease, for whom an early diagnosis was missed or their symptoms ignored and discounted because of the CPHLN guideline, why that situation ever occurred.

One serious and challenging commentary about the IDSA's politicized position and approach to Lyme disease comes from a letter sent by Pat Smith, President of the U.S. national Lyme Disease Association in April of 2008, which was addressed to all members of the United States Senate. That letter made reference to the launching of the State of Connecticut's Attorney General's investigation into the (2006) IDSA Lyme disease guidelines and that organization's members because of their commercial affiliations. The letter also noted that the IDSA had opposed the (then) new Federal Lyme Disease Treatment and Research legislation[22] that had been introduced in the previous Congress. The strongly worded letter criticized that organization's Lyme disease guidelines position in these words:

> While the IDSA emphasizes its dedication to helping prevent Lyme disease, IDSA-authored guidelines prevent the sickest patients with the disease from receiving diagnosis and treatment. With minimal clinical experience in chronic Lyme and only "highly selective" science to back its positions, IDSA has taken upon itself to dictate policies that have been extremely detrimental to patients and those charged with providing quality health care across the country.
>
> . . . .
>
> After years of IDSA domination of Lyme disease research, diagnosis and treatment, there is still no test that can conclusively confirm or deny the presence of Lyme infection and other tick-borne diseases. Hundreds of thousands of people may be misdiagnosed or diagnosed late and improperly treated. IDSA's required tests use antiquated technology, repeatedly shown in prestigious peer review, to allow negative results when patients really have Lyme disease. Additionally, some of the guidelines' committee members have commercial interests in the tests they mandate in the guidelines.

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[22] The 2008 legislation has been re-introduced and is now before Congress: U.S. House Bill HR1179/U.S. Senate Bill S 1352: *Lyme and Tick-Borne Diseases Prevention, Education, and Research Act of 2009.*

Those comments illustrate the deep divide in the U.S.A. over the IDSA's position and approach to Lyme disease. The letter also points to the magnitude of issues and problems the IDSA's guidelines have caused. The U.S. Congress may vote soon on the proposed legislation to cover Lyme disease education, treatment and research, since the Lyme Bill has again been introduced in the Senate and the House of Representatives in 2009.

The most notable evidence of deficiency in the two-tier Lyme disease testing system (setting aside all of the problems with the inaccurate ELISA test) is that there apparently is incomplete reporting through the second-level Western blot testing now in use in the U.S. and Canada. What is "missing" is reporting of results on certain specific Western blot test bands. The missing bands are considered as species-specific "markers" for Lyme disease. It has long been known that certain Western blot test bands, when showing a positive immune response, can be viewed as "species specific" bands that serve as "markers" to indicate the presence of an active Lyme disease bacterial infection. It is astonishing, then, that our CPHLN guideline makes the following statements concerning reporting Western blot test results:

> 4. Western blot tests should be interpreted using criteria set forth by the CDC Working Group.
>
> a. Western blot tests that fail to meet all of the criteria set out by the CDC Working Group should be reported as negative; testing may be repeated when it is appropriate to do so.
>
> b. The specific banding patterns seen on Western blots should not be reported.

That means, on the one hand, that any Western blot test undertaken through the Canadian laboratory testing system strictly follows the U.S. CDC / IDSA testing approach. That, in turn, means that the Canadian Western blot test omits reference to or reporting on certain species-specific Western blot bands. That, as well, means that some persons may actually have Lyme disease but have not been found or reported as a true positive on a Western blot test in Canada because there is no reporting of results on the species-specific, or "marker," test bands.

The CPHLN guideline makes reference to weak ELISA testing but still insists on the two-stage testing approach. But, even with a positive ELISA test result, patients may still have difficulty obtaining an accurate or conclusive Western blot test. The CDC's protocol for Western blot test reporting requires positive results appearing on multiple bands. But, other available, alternative Western blot tests will show a true positive result on two or three of the species-specific bands. Why, then, does one of the CPHLN Canadian guideline recommendations state:

4. B. The specific banding patterns seen on Western blot tests should not be reported.

Does that mean, following and applying the CPHLN guideline, Canadian testing laboratories have a green light to disregard and to hide from physicians and patients the fact that they are not reporting on the species-specific bands? Is it not a matter of common knowledge among persons in public and private life who are moderately literate about Lyme disease that reporting Western blot test results on the known species-specific bands can show a characteristic antibody response to the bacteria's outer surface proteins (such as "Osp A"). Such testing, accordingly, is more likely to yield more accurate results from a Western blot test.

It has been known from at least the early 1990s that greater "specificity" (meaning the ability to find and include those who have the disease, and to exclude those who do not) can be achieved with Western blot testing when the species-specific test bands are being included and reported (shown in the table below). In the table, "Group A" lists the "highly specific" bands. When those particular bands show an immune response, the reported test result can indicate the presence of the tick-borne disease, *Borrelia burgdorferi,* and an active Lyme disease infection. A "highly specific" band showing positive as an immune response to one or more of the *Borrelia burgdorferi* bacteria's proteins is considered to be accurate and significant and, thus, can be taken as a "marker" for Lyme disease. (Positivity is shown and measured as a numeric molecular weight: "kDA" = "kilodaltons".):[23]

• IgG Western Blot	Bands
Group A (Highly Specific):	23-25, 31, 34, 39 and 83-93kDA
Group B (Tick-borne Disease Specific):	18, 41 and 58kDA
Group C (non-Specific):	28, 30, 45 and 66kDA.
• IgM Western Blot	Bands
Group A (Highly Specific):	23-25, 31, 34, 39 and 83-93kDA
Group B (Tick-borne Disease Specific):	41kDA.

[23] Shah, J.S. Lyme Disease: Overview and Laboratory Testing (slide presentation) publisher: IgeneX.

The species-specific Western blot testing results are normally reported by a laboratory in California, IgeneX.

Many Canadians with Lyme disease have tested positive for Lyme disease upon being tested in that laboratory after having previously tested negative on an ELISA test in Canada. That helps to explain why many Canadians who first tested as "negative" for Lyme disease infection in Canada and later, when tested through the U.S. laboratory, are found to be positive. If such a reliable test result is "positive," then, of course, appropriate treatment can begin.

But, then, as it turns out, the problem for many Canadians is to find a doctor who is not intimidated by the fact that their governing professional bodies, the physician colleges, recognize only the CPHLN guideline which, in turn, includes only results based on the CDC / IDSA testing protocol. That system, as we know, omits or ignores reporting test results for the species-specific test bands. So, doctors are left in the untenable situation where they are either unaware of or are being deterred from paying heed to alternative serologic testing that is likely to be more accurate than our current system allows.

When our provincial governing bodies, the physician colleges, choose to undertake practice investigations and appear unwilling to allow physicians in Canada to use international information and standards or to recognize out-of-country test results, the colleges, too, become part of the systemic Lyme disease denials and omissions. They participate in and are then implicated in Canada's flawed and faulty Lyme disease guideline approach and the too-often inaccurate testing system. Not only that, but, when the flawed CPHLN guideline approach is given credence and accepted by the colleges, physicians can be intimidated and are wary about diagnosing and treating Lyme disease based on a clinical diagnosis alone. Yet, the U.S. CDC acknowledges a clinical diagnostic approach is appropriate for diagnosing Lyme disease. Obviously, that situation results in detriment for patients. Patients are also compromised and prejudiced when colleges choose to investigate, and, in some cases, have undertaken prosecutions or placed restrictions on the practice activities of some knowledgeable physicians in Canada (referred to by patients as "LLMDs"-"Lyme-literate doctors") who use international standards to treat Lyme disease. In the U.S.A., certain states now accord special legal ("save harmless") protection for doctors who follow accepted practice and properly treat Lyme disease, in contrast to what the situation is here in Canada.

The CPHLN guideline document goes so far as to name (and, thus, it clearly promotes) a particular U.S. serologic test for Lyme disease called the "Mar Dx Western blot" that is made available in Canada from a private corporation named "Mar blot, Mar Dx Diagnostics Inc., U.S.A.". That organization apparently is a competitor of the California lab (IgeneX). Each uses differing testing approaches. A respected Ontario public health official (obviously an adherent and proponent of the IDSA's Lyme disease testing protocol) when

interviewed recently on CBC Toronto morning radio was heard to assert[24] that the Canadian Lyme disease testing protocol applies and follows a more rigorous or a higher standard than some foreign labs. It was also suggested that the latter do not follow proper test practices. If that were so, why does the Canadian Western blot testing omit reporting on the IgG/IgM highly species-specific test bands referred to above? Why should Canadians not have open (that is, across-the-board) and full access to all available testing and test facilities so that physicians here may choose and so that patients, with the help of their doctor, eventually will be able to learn about and judge the efficacy of various tests? It is largely because of the CPHLN guideline's status accorded by PHAC, and from its being mandated for exclusive use, that so many diagnosing and testing problems have arisen in Canada.

During the 1990s, at a time when some planned (later unsuccessful) vaccine trials took place, the known species-specific Western blot test bands were put to use in the vaccine trials. In particular, those vaccine trials relied on obtaining an immune response on the species-specific bands (at 31-34kDA) which is a response to the Lyme bacterium's most recognizable protein, Osp "A" (Outer Surface Protein "A"). During and after the vaccine trials, however, the species-specific Western blot test bands that readily identify Lyme disease were removed from consideration and, ever since, have remained sequestered.[25] Obviously, Lyme disease patients were not served. In a situation as curious as that, the approach of an investigator, journalist or lawyer would be to first say, "Follow the money," and then ask, "Who benefits; who gets paid?" Added to that, almost contemporaneously, the two-tiered system of testing was put in place. Why, to this day, should the known species-specific Western blot test bands not be used and reported in Canada to bring about more certainty and greater accuracy in our Western blot testing? Surely, patients can benefit from reversing and changing the present system since persons with symptoms, or suspected of having Lyme disease, then would no longer have to travel out of country to be tested and treated earlier and likely successfully.

It appears that the process of two-step testing, concurrent with the withdrawal of several species-specific Western blot testing bands for the *Borrelia burgdorferi* protein (Osp "A"), came about formally as an outcome of a U.S. public health policy meeting, called the Second National Conference on Lyme Disease Testing, held in 1994 in Dearborn, Michigan. At the meeting were various national (NIH), state, and territorial organizations representing and including, for instance, the CDC and the U.S. Food and Drug

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[24] Heard said on CBC radio "Metro Morning," January 12, 2010, in comments made to the morning show radio host Andy Barry (now retired).

[25] http://www.lymedisease.org : go to "Conflicts" (website reference) footnotes. Also referenced in "Oh, Canada" Part One.

Administration ("FDA"), as well as the organizations (then) known as the Council of State and Territorial Epidemiologists and the National Committee for clinical Laboratory Standards. It was claimed at the time that the meeting was held and intended as a forum for creating and introducing "standards" to be used "for surveillance of Lyme disease," as opposed to developing "clinical standards" for diagnosing and treating human Lyme disease. But, as we now know, the standards adopted became an earlier (1996) set of guidelines and went on to be accepted as mandatory and prescriptive for clinical diagnostic and treatment purposes.

In Canada, what was purportedly published as a "surveillance" policy paper became the CPHLN guideline for Lyme disease diagnosing and treatment which, unfortunately (we can say), the provincial colleges recognize and accept, as does the Public Health Agency of Canada (PHAC). The CPHLN guideline is currently Canada's official Lyme disease clinical diagnostic and treatment guideline. Thus, its flawed and questionable recommendations (already referred to) now are being applied as normative and mandatory directives that are intended to be followed and applied by Canadian physicians in diagnosing and treating Lyme disease. Given what we know about the quality of the CPHLN guideline and its antecedents, that situation is preposterous. That set of circumstances holds potential risk to the health of Canadians.

The introduction of new Western blot testing criteria and the system of two-tier serologic testing for Lyme disease, which came into being following the 1994 Dearborn, Michigan, Conference, was poorly received at the time. One contemporary study and analysis reported the following test results (see box).[26] Comparing the prior, more open-ended Western blot system of serologic Lyme disease testing for a previously diagnosed pediatric patient group, the study authors noted the following results obtained for that same group, after re-calculating, using the Dearborn meeting ("NIH") criteria.

Sixty Six Children with Bull's Eye Rash Tested by Both Criteria

Old Western Blot Criteria:	100% positive	False positives on controls: 0%
New NIH criteria:	31% positive	False positives on controls: 0%

That comparison demonstrates clearly the potential for negative outcomes resulting from

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[26] http://www.centuryinter.net/tjs11/bug/blot1.htm. "Western Blot and False Negatives in Children: 1995 Rheumatology Symposia Abstract #1254: Dr. Paul Fawcett *et. al.* (From Abstract listed in "ELISA and Western Blot: Lies that can kill you?")

the historic change in Western blot testing in the 1990s, which then led to the current system. It shows (in contrast to the previous, more open and inclusive forms of Western blot testing, in which all of the children with a Lyme rash were seen and considered as positive for Lyme disease) that, under the new system, more than two thirds of the group (69 per cent) or 46 children with confirmed Lyme disease would have been excluded and never diagnosed and treated for Lyme disease.

Is it conceivable that the CPHLN guideline, based on its challenged antecedent guidelines, could have failed to take into account or to give thought or consideration to any of the potential impacts and legal issues that the document's publication and its contents might create? Was there ever any recognition that the CPHLN's adoption of the Mar Dx Diagnostics testing system as the exclusive test format for use in Canada potentially opens the door and could invite challenges by other testing agencies under the NAFTA (North American Free Trade Agreement) rules? The "monopoly" CPHLN guideline approach effectively constrains other prospective testing agencies from supplying services. They are then effectively excluded from doing business in Canada.

How can one not question also whether other "competition" or "combines" issues arise, since one of the guideline's objectives and outcomes has been to assert exclusivity and control over the field of practice information and knowledge about Lyme disease in Canada? The CPHLN Lyme disease guideline adopts a monopoly approach that omits recognition of alternative information and has little or no reference to other valid alternative diagnostic and treatment resources. That factual situation could potentially be viewed as an "abuse of dominance" scenario, which is sufficient to raise eyebrows and evoke concern under Canada's *Competition Act.* The flaws that have been noted in connection with the CPHLN guideline can also raise questions about potential tort liability when Lyme disease patients and their families are being left behind or placed in harm's way and physicians are misled as to the accuracy, credibility and completeness of that guideline. As a consequence of using the CPHLN guideline, we are seeing in Canada many instances of "missed" diagnosis or misdiagnoses of Lyme disease that, if left alone, ultimately can lead to more difficult to treat, late-stage or chronic Lyme disease. In that event, public health care will become more costly and a patient's illness more difficult to treat. All of the foregoing was and is foreseeable as a component of risk.

Many now know that the CDC / IDSA approach to serologic testing is outdated. It has been seriously challenged on many fronts. Better testing for Lyme disease can be used. There was a suggestion by a CDC spokesperson at the July, 2009, IDSA review panel hearings that a C6 peptide test may give more accurate results than current testing allows. Other new research, such as an assay for assessing "T cell proliferation," could someday be a significant tool for patients with Lyme disease as a means to track responses to treatment. Even if the CPHLN guideline and the recommendations supporting two-tiered

testing were created without giving thought to any potential legal implications, such an excuse, although likely, still leaves the problem that more harm than good will have been done. But, can there be any doubt that consequential harm has resulted from the botched CPHLN guideline exercise?

Three more years in the lives of patients have been lost where earlier diagnosing and treatment services would have allowed some control over a Lyme disease infection. The same three "lost years" has resulted in a further loss of opportunity to advance the cause of Lyme disease research leading to potential progress in understanding the bacteria's variable morphology and how differences among patients' immune responses can affect the tasks of diagnosing and treating Lyme disease. It takes only one session of watching family video records to see first-hand evidence of the deep hardships created for families in Lyme disease cases, particularly where a child has been infected and may be observed having to endure the crippling and debilitating effects of a Lyme disease infection, while also creating a delay or halt in school progress. Besides just wasting time and allowing the Lyme disease "naysayers" a voice through the CPHLN guideline, little else of a positive and constructive nature has been accomplished or undertaken by our public health agencies in Canada in that time period. There is, in fact, nothing to point to that is purposeful in regard to policy and program development or action-oriented in regard to implementing planning for an adequate and appropriate response in Canada to the emergence of Lyme disease.

One presenter at the July 30, 2009, IDSA review panel hearing in Washington, D.C., was Dr. Lorraine Johnson, JD, MBA, a lawyer who holds the position of Chief Executive Officer of the California Lyme Disease Association ("CALDA") and who is also a member of the ILADs Board of Directors. In a slide presentation at the hearing, Dr. Johnson delivered, in note form, the following summary on behalf of CALDA.[27] That summary reported the results of a survey conducted by that organization in 2009 involving more than 3,000 Lyme disease patients from the State of California:

Results of CALDA 2009 Survey

- 73% diagnosis delay > 1 year;
- 90% difficult to find a physician to treat, and 53% travelled out of state for diagnosis or treatment;
- 41% can't afford to purchase the medications they need;

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[27] See: www.lymedisease.org; www.lymepolicywonk.org.

- *58% remained ill after treatment under IDSA protocols, and > 60% of these improved with additional courses of antibiotics;*
  [Emphasis added.]

- 88% had to cut down on normal activities such as work or school and 50% were not able to go to work or school.

That is a mirror representation of our Canadian society's "local" diagnostic and treatment failures and issues.

That summary reflects the same kinds of personal and domestic consequences many Canadian Lyme disease patients have had to face. The only difference is that, here in Canada, our system of public health care exists. It is supposed to be accessible to help such patients. Our system of health care was created and intended to offer appropriate and effective medical services for Canadians, such as diagnostic and treatment services, and to actually provide such supports to patients who need and expect to receive those services. But, in the case of Lyme disease, most patients, if they get any support, are too often not being provided adequate or enough help in a timely manner except, in very many cases, through self-help or joining a Lyme patient group. They find in their home communities that effective, needed medical and physician services are often not available or not able to be provided to them because, all too often, our physicians know very little about Lyme disease.

The *Canada Health Act* specifically acknowledges and is founded on the notion that our public health care system is designed and intended to ensure that patients receive and are entitled to have available necessary medical services either in a hospital setting or through a treating physician as and when they need those services. Why do Health Canada and PHAC not own up to that responsibility and undertake effective measures to ensure that needed health care services, as well as accurate and complete information about Lyme disease, are and can be made available and will be distributed in Canada to assist physicians and their patients?

At the Washington, D.C. review panel hearing, Dr. Johnson concluded the CALDA presentation with a call to abandon and change the monopoly CDC / IDSA Lyme disease recommendations and guidelines so as to recognize the need for differential diagnoses and treatment approaches; to allow for flexibility and clinical judgment in the treatment of Lyme disease; and to allow for treatment options to patients through the use of better, more comprehensive information that would more accurately reflect the current state of the science in this area. The U.S. guidelines' checkered history serves to underscore the fundamentally flawed nature of the CPHLN guideline simply because it is based on the U.S. guidelines. Recognition of the many apparent failings in our approach to Lyme disease and

of the need for change here in Canada has never been more urgent. When can Canadians expect to see a wiser approach and more effective and responsive actions taken here by our public health bodies?

As the examples cited earlier show, many of the various guidelines meta-analyses are based on flawed research studies, including the referenced studies that underlie the IDSA's (2006) Lyme disease guidelines. The IDSA's guidelines have been repeatedly challenged and openly questioned by critics. The CPHLN guideline has the same foundational problems as the parent (IDSA) guidelines. The IDSA's reputation likely suffered as a result of its actions uncovered through the Connecticut Attorney General's anti-trust investigation of the activities of IDSA members. That investigation was, in part, prompted by the fact that the IDSA's (2006) guidelines' development procedure had deliberately excluded divergent views and alternative medical research and scientific evidence from consideration in that process.

Yet, here in Canada, we have exactly that same situation. The Public Health Agency of Canada (PHAC), or CPHLN or other allied agencies, chose to ignore the advice and interests of Canadian and international Lyme disease scientists and others by allowing CPHLN to publish a biased guideline with a highly questionable history and pedigree. In so doing, PHAC or its agent, the CPHLN, systematically and unilaterally shut down and excluded from participation in the once-anticipated Lyme disease guideline process any input or representation from organizations like the Canadian Lyme Disease Foundation, the Lyme Disease Association of Ontario, and other groups, including physician associations and patient organizations, all of whom share concerns about the emergence of Lyme disease in Canada.

It is time to change all of that and restore the balance needed by abandoning the CPHLN guideline. It is time for re-thinking the entire approach that Canada has so far taken. We can re-start the process by which Canada may begin to address seriously the issue of the emergence of Lyme disease in order to serve Canadians with a much-needed and better set of reliable and trustworthy diagnostic and treatment approaches.

One additional example to illustrate the problem of "politicization of Lyme disease" in areas of policy and practice management in the U.S.A. arrived early in 2010 as a headline in various Lyme disease newsletters.

One would hardly expect - - after the IDSA was investigated, then confronted with the possibility of an anti-trust suit and then allowed to settle the issues voluntarily through the July, 2009, guideline review panel hearings - - that anything else would "go wrong". But, it did. The Settlement Agreement ("SA") between the State of Connecticut and the Infectious Diseases Society of America (IDSA), referenced earlier, required the latter organization to create a review panel to hold public hearings as part of a review of the IDSA's (2006) Lyme disease diagnosing and treatment guidelines. After that, the approach

and intention in the SA was that each individual Lyme disease guideline or recommendation would be considered and reviewed separately by the review panel. A decision would then be made, and voted on, to decide if each guideline or recommendation is or is not "medically / scientifically justified" in the light of the evidence received and submissions made during the review panel hearings. Voting by the review panel would then take place on each individual guideline recommendation. A questioned or contested recommendation among the (2006) guidelines would require a "super majority" (75%) vote from the panel to allow it to continue to stand. Following that, another super-majority vote would be taken to decide whether the 2006 guidelines as a whole required: (1) no changes, (2) partial revision, or (3) a complete revision.

As it turned out, the agree-to approach apparently was not followed and applied by the review panel. Additional facts came to light following an oversight review of the SA voting process by the State of Connecticut's Attorney General's Office. It appears that, rather than allowing the process just described to unfold and to allow for a review of individual guidelines, the IDSA-appointed review panel instead proceeded to adopt its own voting procedure. The result was, as the Attorney General's office found, that the review panel failed to conduct the initial round of voting to determine whether in each individual case the science was sufficient to support a particular guideline recommendation. Instead, it seems, the review panel's chosen voting process attempted to combine steps in the two-stage voting procedure and, thus, to substitute its own voting procedure. In the end, the effect would have been, as critics reported, to change the super-majority voting requirement to favour a "no-change" position. The IDSA's critics have also said that, if this had not been discovered, the review panel would have corrupted the review process.[28] The Connecticut Attorney General's *pro tem* letter (dated February 1, 2010) outlined the results of the most recent investigation and the conclusions of that office regarding the IDSA's attempt to thwart the (2008-2009) guidelines review process. The IDSA was urged to re-do the two-step voting on the guidelines' recommendations and to comply fully with the Settlement Agreement.

Since that time, a "no change" vote was taken. As a result, it now appears that the IDSA's (2006) Lyme disease guideline remains intact and unamended, but not unquestioned.

Our most urgent need is for a fully open and transparent approach and for adopting a system aimed at publishing better, more accurate and complete information about Lyme disease in Canada. That should be given priority because of the failed CPHLN guideline and the lack of quality in the official guideline information currently available. But, the same

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[28] California Lyme Disease Association. See: http://www.lymedisease.org/news/lymepolicywonk/336.html, and www.lymepolicywonk.org.

requirements apply and are made necessary because the Lyme bacterial disease is only now beginning to be seen and recognized as a complex, multi-system disease with various and diverse manifestations among individual patients. The narrow and restrictive approach the IDSA and CPHLN guidelines have consistently taken in regard to diagnosing, testing and treating Lyme disease is singularly unhelpful for patients and physicians because so much new and additional information is omitted and because much included information is often inaccurate, incomplete or misleading, to the obvious detriment of both physicians and patients.

The most helpful kinds of information needed for physicians would, for example, be in the form of a full clinical compendium cataloguing all of the known and confirmed symptoms, covering the full range of possible symptoms and manifestations of *Borrelia burgdorferi* infection. Such an information source should also include reference to all of the other, potentially cross-reactive, bacterial or viral infections that apparently can and do often co-exist in Lyme disease patients as a major complicating feature for diagnosis and treatment. A Lyme disease compendium could also include summary references to all of the known, reliable clinical practice and treatment guidelines available worldwide.

But, all such information will need to be screened and vetted through systematic quality analysis procedures underwritten and accepted by carefully selected, independent Canadian academic-professional-medical review and research bodies. Such a compendium will need structures for continuous updating with each piece of new and better clinical information that evolves in order to assist physicians in arriving at a proper differential diagnosis.

As we proceed with DNA research and move towards unlocking the bacteria's genomic structure, the diagnostic approach for Lyme disease must include a recognition that not all patients have a similar immune response or show "typical" or any "common" Lyme disease patterns and symptoms. A principal objective must also be to provide better tools and better access to reliable information to permit clinicians to fulfill their duty to patients. Yet another goal is to re-establish and restore a "patient centred" practice viewpoint. But, another important objective must also be to re-establish the role of physicians as front-line advocates for their patients in the health care system.

It may also be necessary to adopt a policy approach that recognizes high-level, meta-analyses, such as "guideline" information, in a more appropriate context as being little more than tools or points of reference to assist clinical practitioners in choosing needed measures and appropriate levels of patient care. How is it that, in Canada, the CPHLN, a rather small number of laboratory and infectious diseases "experts" or professionals, ever gained so much influence as to permit them to act unilaterally in developing Canada's monopoly diagnostic and treatment guidelines in the first place?

In the case of Lyme disease, many different areas of practice and the combined wisdom available from a wide variety of medical specialties will be better able to offer relevant information and bring to bear other useful clinical and practice insights to assist with the diagnosing and treating of the many complex symptoms and manifestations of Lyme disease. The governing colleges, now bent upon disciplining and reviewing physicians, many of whom are in family practice, should realize that it is time to "back off". They should begin to reconsider their position and start to recognize and accept, for example, that U.S.- or European-trained "specialist" doctors, many of whom are presently certified or qualified internationally to treat Lyme disease, and now operate and manage a Lyme disease clinical practice on the basis of recognized U.S. and E-U clinical diagnostic and treatment standards, should, instead of being hounded and disciplined, be openly and enthusiastically encouraged to continue to practice on that basis.

The physician colleges, that is the governing bodies, should, instead of investigating or prosecuting, recruit those relatively small in number Lyme literate doctors ("LLMDs") as front-line clinicians or as physician practice mentors and allow them to assist in sorting through, disseminating and evaluating what Lyme disease clinical practice information ought to be published. Medical-professional organizations, as well as our public health authorities, at a minimum, should start to recognize and acknowledge that there are divergent viewpoints regarding the diagnosing and treating of Lyme disease. We know that physicians who encounter Lyme patients in daily practice need every available, validated tool to assist them in managing and treating patients with this dreaded disease.

The recent spate of news stories about the IDSA's political actions likely does little or nothing to enhance or rehabilitate that organization's reputation in the public health sector or in the medical community. The Connecticut Attorney General's initial (2007-2008) investigation of the IDSA's practices uncovered the fact that the IDSA's guidelines process had excluded any reference to other valid clinical information and research about Lyme disease. The initial investigation leading to the SA (Settlement Agreement) was intended to see that the IDSA's corrupted guidelines would be re-done, in a manner that would recognize and include consideration of all relevant Lyme disease information and research. Canada should now adopt and follow that approach. But, in view of recent experience in the United States, Canada must now "go it alone" in the policy arena. Our public health sector heads should authorize the commitment and undertaking to create and develop Canada's own Lyme disease approach and position that will better serve patients and the physician community. In so doing, public health officials, too, must act in a creditworthy and transparent manner, and must be held accountable. To whatever degree may be necessary, our public health agencies need to be directed to act, if necessary by ministerial or parliamentary fiat, and must be compelled to hold true to the fundamental objectives and principles of the *Canada Health Act* and other related statutes.

SECTION SIX: Back to the Future

What should Canadians do about the CPHLN guideline?

It should be ordered withdrawn and then be scrapped.

Also, because so many serious mistakes have been made, it is clear that remedial steps are needed. Canadians need an explanation so that mistakes of the past will not be repeated. We also need an accounting and reckoning for the more-than-three years' delay by public health agencies in handling and managing effectively the emergence of Lyme disease in Canada. We also need to have new and better information about Lyme disease available and published as soon as possible.

What can Canadians expect from Health Canada and the Department of Justice? Will there be an acceptable and credible response and explanation from PHAC or the Canadian Public Health Laboratory Network (CPHLN) that explains satisfactorily how and why the deeply flawed CPHLN Lyme disease guideline came to be published? A major step would be for our public health agencies to assume responsibility, then to declare and admit openly that the CPHLN guideline was and is seriously flawed and ought not to be followed any longer as a clinical diagnostic and treatment tool. Finally, we need a commitment from Health Canada to undertake a new and different approach.

How well might Health Canada respond if a physician were to choose and decide, for the sake of properly treating a patient who clinically or potentially has or is suspected of having Lyme disease, to order a confirmatory diagnostic (serologic) test based upon the following specific orders directed to our national or provincial laboratories: (1) no ELISA test; (2) IgeneX-type Western blot (IgG / IgM) testing for bands 23-25, 31, 34, 39, and 83-93kDA; and then (3) return full and complete copies of actual test results directly to the requesting physician(s) in electronic or paper format? That approach to testing may or could disclose the presence of an acute or chronic Lyme disease infection, in a suspected case, in contrast to what little help would be likely to come from our current testing system. Such an approach would, in a single stroke, recognize the existence of better alternatives to current testing and, undoubtedly, would enhance and improve the accuracy and effectiveness of Western blot testing in Canada.

But, without action at the federal, provincial and territorial levels, doctors may continue to be reluctant to treat Lyme disease patients openly because they fear reprisals. The colleges now follow the practice of looking over the doctor's shoulder whenever they treat chronic Lyme disease patients, using intravenous, long-term antibiotics, as an example. As a symbolic first step, Canada will need to be seen to scrap the CPHLN guideline. The CPHLN should be allowed only a nominal role in any future steps to develop a Canadian Lyme disease guideline if that is contemplated.

It is also important to recognize that a revived and strengthened patient-centred

approach to Lyme disease diagnosing and treatment is needed. That step, too, requires a major policy intervention to restore and recognize the role of physicians as the party holding primary responsibility in advocating for and delivering patient care. If action and progress going forward were to need a "legal" push, the issuing of "Parliamentary orders," or departmental, or ministerial orders under the joint auspices of the Minister of Health and the Attorney General would surely speed progress. The path to be taken is to implement reforms and to undertake a new approach for addressing Lyme disease in Canada as quickly as possible so as to correct and overcome the mistakes of the past. A new, more transparent approach is needed to ensure that all needed steps and arrangements for consulting between and among federal, provincial and territorial Health departments, ministers and staffs are going to be undertaken. Perhaps the needed oversight and scrutiny to ensure public accountability can take place through bodies like the Pan Canadian Health Network (PHN) which, presumably, already has a structure in place that will allow for accountability to Parliament and the provincial and territorial legislatures. Any such organizational structures must have in-built accountability and transparency.

New measures and structures for vetting and validating medical information handling, too, are obviously necessary. That is now unquestionably necessary and urgent in the case of Lyme disease because patients, physicians, the colleges, as well as our federal and provincial health ministries, have to this point operated with highly suspect information, much of it having little real merit in clinical practice. The CPHLN guideline offers only incomplete, inaccurate, misleading and unreliable information relating to treating and diagnosing Lyme disease. For instance, the lack of any reference in that guideline to co-morbity and the omission of any information about the *Borrelia burgdorferi's* complex morphology should not simply be overlooked. We need to disseminate accurate and detailed biologic and genomic information to physicians. That is part of the knowledge and information gap that needs to be overcome.

Much broader and more open consultation is also needed between governments and the public, along with structural changes. We know that Lyme disease, if it is discovered early, may be readily treated. If not, an infected patient can be left undiagnosed and untreated, simply because accurate information about the disease is not being widely disseminated. But, Lyme disease can also advance rapidly to a degenerative and chronic state. It then becomes more debilitating or deadly as well as more costly to treat, and it then will continue to wreak havoc in the lives of those who become infected and their families. Thus, there is a growing urgency for publishing and disseminating accurate and appropriate practice information if only to diminish the growing risk to the public's health as a result of the knowledge and information gap.

But, there will be no real progress achieved unless and until the accuracy and quality of meta-analyses and other commonplace information about Lyme disease (as with other

areas of medical practice) can be assured. That will benefit physicians and their patients.

Such key steps for progress within the most important areas of Lyme disease treatment and diagnosis only begin with the step of eliminating and scrapping the CPHLN guideline. That must be coupled with a warning to provincial health authorities and practitioners that the current CPHLN guideline is inaccurate and incomplete, and, if followed, potentially puts at risk the health and safety of Canadians. The *status quo ante* (that is, the information quality issue relating to practice guidance described in this Brief) shows clearly that content in meta-analyses and in medical literature generally is all-too often unreliable and inadequate. Much valuable and reliable information about Lyme disease was hidden or was simply ignored or was left unacknowledged.

Some of the physician colleges could be at the bright line where actions against physicians treating Lyme disease may border on being an abuse. The legislation granting self-regulating authority may need review. If the provincial physician governing colleges balk at reconsidering their approaches to physicians who treat Lyme disease, federal-provincial collaboration may be necessary to reform current medical-practice surveillance routines through new oversight policies. If necessary, changes may be needed in governance legislation. The objective will be to ensure that physicians treating Lyme disease patients are going to be accorded the kinds of protections that are being or have been introduced and even legislated in some U.S. states. At this writing, legislatures in states like Massachusetts, Minnesota and Virginia were contemplating new legislation. New York State has a new policy guideline. Other states, including California, Connecticut and Rhode Island have enacted state legislation to give protection from prosecution by review bodies for doctors who treat chronic Lyme disease patients in accordance with known best practices, including the use of long-term antibiotic therapy.

There can be no acceptable or defensible reasons why we in Canada have been stuck in what has been truly a race to the bottom, leaving our country far behind some other countries in regard to pursuing better understandings and research into Lyme disease. We have been too slow in accepting the need for, and in undertaking, measures to address the emergence of Lyme disease as a major threat to the health of Canadians.

But, despite our failings, in Canada we are able to point to a few noteworthy accomplishments. In addition to the reported Canadian research study on the “quality” of “meta-analyses” in the “critical care” literature, there have been several important recent research studies on Lyme disease that have been undertaken in Canada. One is an interesting and highly readable Master’s thesis entitled *Knowledge and Perception of Lyme*

Disease in Manitoba: Implications for Risk Assessment (to be published),[29] in which there is, *inter alia,* a wide-ranging discussion about spatial distribution of Lyme disease (epidemiology) in that province, as well as a detailed discussion of the pathology of Lyme disease (symptoms), in particular, its "mimicry" of many other known serious diseases. But, the most interesting and revealing part of the study lies in its purpose and "thesis" (objective) which was to explore knowledge levels and risk perceptions of Lyme disease among several groups or populations and to show the public health policy implications arising from the study.[30] Two rather startling findings and conclusions in that study are the following:

> Little understanding of the complexity of the pathogen or the variety of genospecies is evident from discussions with . . . policy makers and . . . clinicians . . . and the related complications to diagnosis and treatment.

. . . .

> Important epidemiological information that is critical for policy makers and clinicians is not being relayed effectively or in a timely fashion from the scientific community.

Those are obviously real and serious shortcomings that demand attention in Canada.

Yet, more often than not, Lyme disease research in Canada is being undertaken on "a shoestring basis," often with little backing or financial support from our public health agencies or other governmental research funding sources. Why, when the emergence of Lyme disease can be seen as a major public health issue, is there no specific line budget item within the public health spending area that can be pointed at to identify amounts available for funding Lyme disease research? Other recent research identifies new areas of understanding about Lyme disease and even points towards measures that can be pursued to confront this debilitating and deadly disease.

The first article referenced below,[31] is an important report and analysis of new and promising areas of genomic (DNA) research on the Lyme disease bacterium. That research shows to the world that Canada can and is able to undertake a significant role in genomic

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[29] Crang, Kathleen. Thesis submitted to the Faculty of Graduate Studies of the University of Manitoba in partial fulfilment of the requirements of the degree of Master of Environment (2009), Department of Environment and Geography, University of Manitoba, Winnipeg.

[30] *Ibid.,* p.199.

[31] A.R. Dresser, P.-O. Hardy, G. Chaconas, Plos Pathog 5(12) (2009)."Investigation of the Genes Involved in Antigenic Switching at the *vlsE* Locus in *Borrelia burgdorferi:* An Essential Role for the RuvAB Branch Migrase."

studies aimed at investigating and, perhaps, ultimately, unlocking the complex gene-switching capability manifested in the *Borrelia burgdorferi* bacterium. By continuing and widening such research, it is conceivable that the study authors and others may one day soon find ways to control or even halt the growing spread of Lyme disease by interfering with the *Borrelia burgdorferi* bacteria's DNA and genetic properties.

The second noted report[32] provides detailed analytical and descriptive information about Lyme borreliosis and the *Borrelia burgdorferi* bacterium. That article, too, is of major significance because the authors link up-to-date knowledge and information about *Bb* heterogeneity and the complex microbial aspects of Lyme disease with current vector information and research derived from the field of entomology. As one instance, the authors recite the following (at p.524):

> Unexpectedly large genetic diversity has . . . been found within *B. burgdorferi* s.s. For example, nine distinct clonal lineages were found at one field site in the northeastern USA (Bunikis *et al.* 2004). Differences in fitness between two of these genotypes, one isolated from blood and the other from skin, were studied in mice by Hanincová *et al.* (2008). The blood isolate retained its infectivity to xenodiagnostic ticks, whereas the skin isolate did not, suggesting partial diversification into more specialized subtypes in North America. *Additional research in North America and Europe has shown further diversity in B. burgdorferi s.s.; at least 12 distinct sequence types defined by DNA sequence differences in outer-surface protein C (Osp C) co-exist in the northeastern USA and at least 17 Osp C types are found across the USA and Europe* (Qiu *et al.* 2008). [Emphasis added.]

That study contains current information and analyses of vector issues that need to be addressed in order to confront the widening threat posed by the emergence and spread of Lyme disease into many parts of Canada. Another significant earlier study[33] reported on evidence showing persistence of the *Borrelia burgdorferi* bacterium and the potential link between Lyme neuroborreliosis and Alzheimer's disease. As it turns out, most of the authors of those studies are members of the Board of Directors, as well as members of the Research Advisory Panel, of the Canadian Lyme Disease Foundation. That organization appears to be poised and intending to advance and undertake important and much-needed Lyme disease research.

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[32] For example, see: Can. Entomol. 141:521-549 (2009), F.A.H. Sperling and J.L.H. Sperling, Lyme borreliosis in Canada: biological diversity and diagnostic complexity from an entomological perspective.

[33] Referenced in "Oh, Canada," Part One: Judith Miklossy *et al.* "*Borrelia burgdorferi* persists in the brain in chronic Lyme neuroborreliosis and may be associated with Alzheimer disease": Journal of Alzheimer Disease 6 (2004); 639-649.

Other significant, recent reports from Canadian researchers warrant attention.[34]/[35] The significance of those studies is that there is greater heterogeneity in *Bb* than was previously thought in Ontario. The existence of different strains of *B. burgdorferi* found in Canada means that such genetic diversity could significantly alter clinical manifestations of Lyme disease and force changes to be made in our ability to assess serologic test responses. Ultimately, we will need to usher in new points of reference and better, more sophisticated techniques for vector analyses and consequently also new points of reference for serologic testing and detection. The rather simplistic CPHLN / IDSA "one-size-fits-all" approach to diagnosing (testing) and treatment for Lyme disease should no longer be considered adequate or realistic. Evidence of a wider dispersal of infected ticks contradicts the CPHLN guideline's notion that the risk from Lyme disease infection occurs in only a few isolated, "endemic" locations in Canada. There is also evidence that "new" and "local" genotypes for *Bb* exist in Canada that have not yet been recognized and are not likely being accommodated within any current Canadian testing protocols. Those types of study findings in Canada are reinforced in another international study, just released (published May 14, 2010),[36] wherein the authors found in both North America and Europe multiple Lyme *Borrelia* genotypes in *Ixodes* ticks, which, as those authors suggest, "increases the probability that a person will be infected with more than one genotype". This study, too, suggests that those findings will have "potential clinical consequences".

The CPHLN and IDSA guidelines proponents can argue or suggest that these important new research results could not have been contemplated or accommodated in their antecedent Lyme disease guidelines. However, the fact is that, more than a decade earlier, another published research study[37] had already reported and called attention to the issue of genetic diversity of *Borrelia burgdorferi.* As the study's title indicates, it was addressed to the "taxonomic, epidemiological, and clinical implications" of finding different *Borrelia burgdorferi* strains in both Europe and North America, including the complexities for diagnosing and testing and treating "diverse" and "local" forms of Lyme disease

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[34] J. D. Scott and L.A. Durden. North American Bird Bander. Jul-Sept. 2009. "First Isolation of Lyme Disease Spirochete, *Borrelia burgdorferi* from Ticks Collected from Songbirds in Ontario, Canada".

[35] John D. Scott, *et al.* Journal of Vector Ecology, June 2010: "Detection of Lyme disease Spirochete, *Borrelia burgdorferi* sensu lato, including three novel genotypes in ticks (Acari: Ixodidae) collected from songbirds (Passeriformes) across Canada."

[36] Chris D. Crowder, *et al.* See: http://www.plosone.org/article/info%3Adoi%2F10.137/%2Fjournal...

[37] Wang G, *et al.* clinical Microbiology Reviews, October 1999, Vol.12, No.4, p.p.633-653. "Molecular typing of Borrelia burgdorferi sensu lato: taxonomic, epidemiological, and clinical implications." See: http://cmc.asm.org

infection. That study is another example of research evidence and information overlooked (or ignored) in the extant CPHLN and IDSA Lyme disease guidelines.

The studies just referenced illustrate clearly that, rather than restricting Lyme disease research to a few subjects that intrigue only infectious diseases professionals, by undertaking more comprehensive interdisciplinary and multi-disciplinary studies we can and will achieve much better understandings than hitherto about the complexities of Lyme disease. In order to bring forward in a full and comprehensive way the multitude of policy, research and social issues that are presently seen only as challenges, it is also necessary for Canada to undertake to invest significant levels of financial support for Lyme disease research. That is absolutely necessary, not tomorrow, but right now.

It is imperative for us as Canadians living in this vast country to address issues that cross many fields left open for investigation and avenues of research that still remain for us to tackle in order to confront the emerging, widening threat from the spread of Lyme disease throughout many different parts of Canada. An emphasis on dedicated Lyme disease research will allow Canadians to see and recognize that steps are being taken to address and manage this debilitating and sometimes deadly disease, all of which can not but help to bring more success than we as Canadians have witnessed or experienced to date. Also, for chronic Lyme disease patients, new research soon may yield results to help those who have only hoped for help up to this point. There can be no acceptable or reasonable excuses from our public health agencies for further delaying necessary action, including opening the federal purse to allow for significant new funding for more and better research into Lyme disease.

Will we ever see changes, given PHAC's and Health Canada's apparent inertia, which we can readily see from the recent past history in dealing with Lyme disease? The CPHLN's unhelpful Lyme disease diagnostic and treatment guideline, coupled with the inaccurate and inadequate two-tier Lyme disease testing protocol used in Canada, as well as many delays and the avoidance of responsibility by our public health agencies in addressing Lyme disease issues to this point, when taken together, have potentially left many hundreds (if not thousands) of Canadians suffering needlessly in the more advanced state of *Bb* infection, known as chronic or "late" Lyme disease. Who can tell those persons how and why our public health system failed them? How will those with chronic Lyme disease feel if our public health agencies continue with their languorous approach and do not respond in a more timely and effective way to begin to address the emergence of Lyme disease in Canada?

Does our public health care system need to be fixed? "Yes," since we have not yet even begun to plan or undertake appropriate preparedness measures for dealing with the rapid advance and emergence of Lyme disease in Canada.

We can fix what needs fixing. That undoubtedly requires rethinking many public

health priorities so as to address Lyme disease as a growing public health threat.

The Canadian past experience needs to be investigated as in the U.S. when the Office of the State Attorney General for Connecticut took action after the initial investigation showed the IDSA in the guidelines development process had excluded alternative research and other information and viewpoints about Lyme disease.

The situation we have here in Canada is an exact parallel to the U.S. situation. The CPHLN guideline process supplanted the collaborative process PHAC had originally started. CPHLN published a unilateral guideline and, in doing so, ignored alternative Lyme disease information and research.

How did the CPHLN guideline authors manage to usurp the process initiated in March of 2006 at a PHAC meeting intended to launch a consensus approach and a process of collaboration to address the emergence of Lyme disease? Who are the guideline authors? What professional accreditation do they have? What are their affiliations? Were they ever required to declare and identify any of their personal affiliations and interests? How did CPHLN obtain funding and permission to undertake publication of the guideline? What fiscal arrangement or funding mechanism produced and paid for the CPHLN guideline? Why was CPHLN permitted to publish the guideline (to the detriment of Canadians) without other points of view or perspectives on Lyme disease being considered? What, if any, part did officials at Health Canada and the Public Health Agency of Canada take in the process leading to publication of the (2007) CPHLN guideline? What, if any, role did the IDSA or its members have in the course of developing the Canadian guideline? Since the CPHLN is an affiliate of the Pan Canadian Health Network, what role did PHN have in publishing the guideline? Canadians are entitled to ask and to have public health officials provide answers to such questions.

The circumstance that most rankles Lyme disease patients and their families, and which is offensive to others affiliated to national and provincial Lyme disease support agencies, groups and individuals, is the apparent insouciance about the well-being of patients with Lyme disease that has been demonstrated throughout the CPHLN guideline process. In Canada, as we know, neglect of duty and acts or omissions that show carelessness, recklessness, or indifference as a state of mind, taken together, can be looked upon as culpable behaviours.[38]

Did any of the participants in the guideline process affiliated to our public health agencies at any time give consideration to the individual, social and legal implications of their actions? Such concerns are considerations that needed attention as part of any risk assessment and for Lyme disease preparedness in Canada. How could anyone not see

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[38] *Criminal Code* R.S.C. 1985, c. C-46, ss. 217, 217.1, 219: *R. v. Sharp* (1984), 12 C.C.C. (3d) 428.

that publication of the flawed CPHLN guideline potentially opened up all manner of issues as a result of the numerous inaccuracies and mistakes to be found in that document? The situation requires more than passing censure because it raises not only a variety of legal issues, but also other moral and ethical concerns. We need remedial action by Health Canada and the Department of Justice to resolve and action to mitigate and overcome any and all potential prejudice to any Canadians left at risk because of inadequacies in the CPHLN Lyme disease guideline.

But, any such response should not become an excuse to forestall action needed to address the many public health issues that require attention in regard to the emergence of Lyme disease going forward. Those entrusted with the responsibility to administer policy and programs linked to the *Canada Health Act* and related legislation must begin to act responsibly towards Canadians diagnosed with Lyme disease, as well as those who have the disease but have not been diagnosed or may yet contract Lyme disease, by better managing and facilitating patient access to needed services and programs and by properly assessing and openly publishing all available and reliable information about Lyme disease, including its nature and prevalence. It is a measure of the disgraceful state of affairs we now have that none of our provincial and national public health agencies can state with certainty or accurately what number of Canadians actually have and are living with a confirmed or suspected Lyme disease infection.

Our elected and appointed officials have been entrusted with responsibility to manage our public health care system and must now do so by introducing measures for diagnosing and treatment that are adequate and up to date for those Canadians who are victims of Lyme disease. We could, quickly and easily, reinstate the consultative Lyme disease information process started by PHAC in 2006 and renew earlier collaboration with, for example, the Canadian Lyme Disease Foundation, provincial and territorial patient organizations, and other interested medical and professional organizations concerned about the emergence of Lyme disease in Canada. The situation outlined here illustrates many, but certainly not all, of the problems we have from continuing and past neglect in the matter of addressing the emergence of Lyme disease in Canada.

To this day, there are public parks (provincial and federal) in Canada that have no conspicuously posted information about Lyme disease or instructions for dealing with a tick bite, such as how to remove an embedded tick. Canadians should be told that infected ticks are to be found at or near where they live and work and play, or even in their own back yards. We have vector analyses that were undertaken in Canada through publicly funded agencies, that have revealed “endemic” locations (so called) for Lyme ticks. But, we need simple follow-up measures like pamphleteering and placing signage in parks and any other suspected or known tick habitat areas to give instructions and to alert members of the public about how to recognize and avoid the risk from being bitten by a tick. There is a need

for published information to be made available in doctor's offices, hospital emergency rooms and elsewhere to give advice about what to do if bitten by a tick or what does one do upon acquiring symptoms (such as an "out of season flu") which may point to a suspected Lyme disease infection? When should anyone first visit a doctor? People could be told to try to locate and capture ticks to be sent for testing. How many Canadians will know that the smallest tick is smaller, or certainly no bigger than, the dot on the letter "i"?

As a counterpoint to the situation in Canada, here is what one E-U country, Germany, offered its citizens as a warning about the risk of contracting Lyme disease even in winter:

> Families who bring Christmas trees into their homes should watch out for ticks this holiday season because the tiny blood-sucking, disease-ridden creatures often survive winter temperatures. [*Bild:* December 21, 2009][39]

Surely, with the growing numbers of the "tiny, blood-sucking, disease-ridden creatures" we now host here in Canada that should compel similar warnings, as well as other useful kinds of action and more attention from Health Canada and the Public Health Agency of Canada in collaboration with provincial public health agencies. Those can undertake warning measures tomorrow, issue similar, timely alerts to Canadians and bring forward other needed steps to disseminate accurate information about potential risks from infected ticks and from the emergence of Lyme disease in our country. But, we Canadians surely deserve and are entitled to expect and demand much more than that from our public health institutions and governmental agencies.

The greatest and most serious challenge that we still have to face and address effectively as Canadians is, first, how to recognize, and, then, how best to diagnose and treat human Lyme disease infection appropriately. The CPHLN Lyme disease guideline, rooted in an unreliable U.S. guideline, is inadequate and potentially harmful as a medical tool. But, even today, there is no federally sponsored source of information and no coordinated approach to Lyme disease in Canada that we can point to as being capable of giving out trustworthy and useful and complete information about Lyme disease that is characterized by accuracy, clarity and transparency.

Many Lyme disease families who have corresponded with public health officials about Lyme disease, seeking help or information, are being heard to complain about receiving a written reply that amounts to nothing more than simplistic assertions about various governmental actions that are "to be" undertaken, often amounting to what today is called "spin". What we need instead is a "one stop" government-sponsored, public

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[39] Http://www.thelocal.de/society/20091222-24105html.

information source to which at one level physicians and at another level members of the public can turn for full and adequate (i.e. accurate, complete, and up-to-date) information about Lyme disease: prevention, risks, research, and symptomatologies, as well as diagnosis and treatment information that will be comprehensive and understandable at each appropriate readership level. But, we also know that such information must be closely monitored and carefully edited and vetted through a formal review system that will ensure that all such information will be kept up to date, is accurate, complete and unbiased.

The sad truth is that, for Lyme disease patients, feeling weak and helpless is almost a daily and universal symptom of the disease. They or their families may or may not see advantage in adopting a litigious approach to press for action from our public health agencies. It is questionable whether many Lyme disease patients or their families would have the strength or capability even to participate in the process for filing a *mandamus* application aimed at obtaining an order seeking to compel public health officials to act responsibly. On the other hand, there is growing public awareness and concern about Lyme disease. The spread of information and knowledge about Lyme disease can and does and will influence and affect public opinion. That may or likely soon will lead to appropriate actions when the necessary questions begin to be asked in a manner that can demand and ultimately compel answers.

Yet, if Health Canada and the Department of Justice should refuse to act, or show no willingness to accept responsibility, or continue to show reluctance to take action to implement appropriate and necessary measures, Canadians could then be left with no alternative but to press for answers and action through the mechanism of a Parliamentary Review Committee on “Lyme disease” or, alternatively, through the establishment of a Public Inquiry to address Lyme disease in Canada in order to determine what remedial actions are to be taken and what other steps will be necessary as part of the preferred and best approach for Canada in responding to the widening threat and spread of Lyme disease.

Afterword

“Lyme Awareness Month 2010"

Completed May 31, 2010, this Brief is dedicated to Lyme disease patients and their families who know too well the terrible consequences from the failure to diagnose and treat Lyme disease effectively and early. Many of them hope greater awareness and knowledge about Lyme disease will be spread into every region of Canada and that that will benefit all Canadians.



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