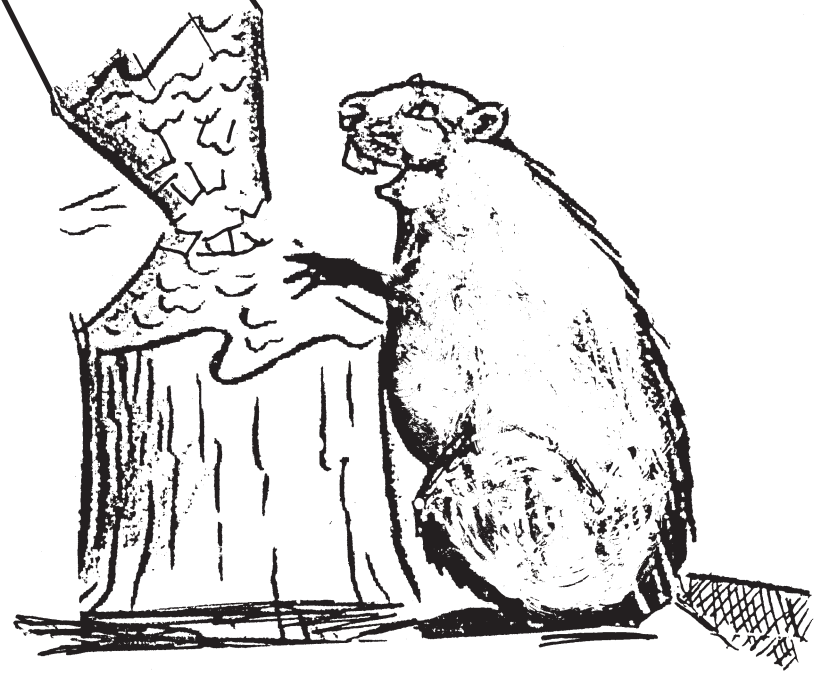


Oh, Canada:

The "Politicks" of Lyme Disease

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



Author: Paul Haefling, M.A., LL.B

"Lyme Disease Awareness Month,"
May 2009

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The comments and opinions expressed in this document are those of the author, and such views may not be shared by others. Nothing in this Brief is to be read or taken as medical advice. For that, please see and consult your family doctor.

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PART ONE

Chronic ("late stage") Lyme Disease in Canada:

"Conflicts" in Diagnosis, Treatment and Research

The Canadian protocols in the form of "guidelines" for diagnosing and treating Lyme disease, particularly late-stage or chronic Lyme disease, are woefully inadequate and incomplete, and need to be changed immediately to protect people diagnosed with Lyme disease. The official protocol document in Canada is entitled, "The Laboratory diagnosis of Lyme borreliosis: Guidelines from the Canadian Public Health Laboratory Network". It first appeared in December 2006 and was later printed and published in March-April 2007.[1] That document opens with these observations:

> Lyme borreliosis is uncommonly seen in Canada. Most cases have occurred in close proximity to small geographical areas where infected ticks have become established. Although few cases are seen, thousands of patients are tested yearly. Unless patients are carefully selected and an appropriately sensitive and specific testing algorithm is applied, large numbers of patients without Lyme borreliosis will be diagnosed. The Canadian Public Health Laboratory Network has developed the present guidelines to assist physicians in assessing patients for Lyme borreliosis, and to help guide the choice and interpretation of laboratory testing.

Right from the start, that document's aim is to tell doctors: Lyme disease is not widespread, and you should be skeptical when confronted by persons with complaints or symptoms that could indicate or suggest a Lyme bacterial infection. The *Guidelines* go on to describe a few areas in Canada that are considered to have established tick populations (those being considered as "endemic" areas because they are known habitats for the *Ixodes scapularis* tick carrying the Lyme bacterium, *Borrelia burgdorferi*). But, the authors of the *Guidelines* then go on to say:

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[1] Can J Infect Dis Med Microbiol Vol 18, No 2, March-April 2007.

> Although it is possible to be bitten by an infected tick anywhere in Canada, the chances of being bitten and subsequently infected are considered low in areas where populations are not established.[2]

Again, the message to doctors is to minimize the potential that they could encounter patients infected with the Lyme disease bacterium by asserting that Lyme disease is not widespread in Canada and that the chances of a patient being bitten are very limited. All that the authors seem to be saying is that, in some populous parts of Canada, the disease-carrying ticks are endemic, and, thus, there is a higher probability of being bitten and possibly becoming infected. In fact, research shows that persons can be infected almost anywhere because migratory birds disperse vector ticks from the U.S. and Central America across Canada, many of which are infected tick species carrying *Borrelia burgdorferi* bacteria, as well as other zoonotic pathogens that can result in coinfections for human hosts who may be bitten.[3] As early as 1991, researchers published the *Borrelia burgdorferi* infection rate for the Long Point area, which is another endemic area in Ontario along the north shore of Lake Erie,[4] but other federally funded studies dealing with established populations of *Ixodes scapularis* ticks (the known most commonly infected species) have not been published. One must ask: Why are infection rates for all other endemic tick areas not being published?

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[2] Endemic areas, so-called, for the ticks in Canada are described as being concentrated in British Columbia "on the lower mainland, on Vancouver Island and the Fraser Valley", and in "a small number of localities along the shore of Lake Erie and Lake Ontario," and "near Lunenburg and Bedford in Nova Scotia".

[3] See, for example, findings and references in: Morshed *et al.,* "Lyme Disease Spirochete, *Borrelia burgdorferi,* endemic at Epicenter in Rondeau Provincial Park, Ontario, *J. Med. Entomol.* 40 (I) 91-94, January 2003.

[4] Lindsay, L.R., *et al.,* "Apparent incompetence of *Dermacentor variabilis* (Acari: Ixodiae) and flea (Insecta: Siphonaptera) as vectors of *Borrelia burgdorferi* in an *Ixodes dammini* [=*I. sapularis*] endemic area of Ontario, Canada," J. Med. Entomol. 1991; 28: 750-753.

It is primarily through withholding or lack of information that the present state of knowledge about Lyme disease is so inadequate and incomplete. Most importantly, lack of knowledge about Lyme disease, and about chronic or persistent Lyme disease in particular has left hundreds of persons in Canada infected with *Borrelia burgdorferi* to suffer needlessly from a disease that is known to be treatable.

While conceding the reality that people have been and can be bitten and become infected anywhere in Canada, the emphasis in the Canadian *Guidelines* document still rests with the proposition that there is a greater probability or likelihood of being bitten and being infected in human populous areas that are endemic for vector ticks. Unfortunately, one consequence of that restricted viewpoint in the *Guidelines'* approach is that numbers of Lyme disease patients report having been told by a doctor that they could not have a Lyme disease infection if they are not living in or have not visited one of the endemic areas listed by the *Guidelines'* authors. The *Guidelines'* point of view about the limited prevalence of ticks and the underlying suggestion that the tick vector for Lyme disease in Canada has some kind of boundaries or geographic limits must, however, be viewed with skepticism when one considers that at least 13 different established populations of *I. Scapularis* have been identified in Canada.[5] The U.S. Centers for Disease Control (CDC) has, since 1997, been reporting recorded and recognized cases of Lyme disease as far north as the State of Alaska, which lies between the 55° and 70° (north) latitudes, the same latitudes shared by Canada's

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[5] See Ogden, N.H. *et al.*: "Role of Migratory Birds in Introduction and Range Expansion of *Ixodes scapularis* ticks and of *Borrelia burgdorferi* and *Anaplasma phagocytophilium* in Canada". Appl. Environ. Microbiol., Vol. 74, 2008.

northern territories. The CDC statistics refer to "Alaska Native" cases, and it is not clear how many of those are indigenous cases of individual infections, as opposed to infections acquired through travel.

When the Canadian *Guidelines* state that "Lyme borreliosis is uncommonly seen," or "few cases are seen" or refer to a "low pretest likelihood of Lyme disease," the authors are again suggesting that clinicians have reason to be skeptical about encountering Lyme disease, but such claims are misleading and must not be accepted unquestioningly by clinicians because real-life infectious and other geographic data belie those conclusions.[6] As a statistical matter, the U.S. Centers for Disease Control (CDC) recorded in 2007 and recently reported that there were more than 27,000 Lyme disease cases in the U.S. That organization also estimates that the number of probable occurrences of Lyme bacterial infections in the U.S.A. could be more than ten times the number of reported cases because of the belief that Lyme disease cases there are being missed, by being under-reported and sometimes misdiagnosed.[7] There is no reason to believe that the percentage probabilities or proportional case numbers differ greatly in Canada. As a result, while there were 62 Lyme disease cases reported for Ontario in 2007, the number of actual cases in all of Canada that are missed, through being under-reported or not diagnosed, and, thus, presently not counted, would probably number in many hundreds or into thousands. The municipal region adjacent to

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[6] A group of Lyme patients in Ontario who keep in touch via the internet had contact from a person living in or near the James Bay lowlands who had been recently diagnosed as being positive for Lyme disease.

[7] See: "Surveillance for Lyme Disease – United States, 1992-2006," in *Morbidity and Mortality Weekly Reports (MMWR),* October 3, 2008 / 57 (SS10); 1-9.

where the author lives, in 2008, had 10 reported and confirmed cases of Lyme disease.[8] Although the data on the number of Lyme disease cases across Canada is collected and required to be reported, federal public health officials have suggested that the available data can be acquired only through individual provinces and territories. Why is information not collected and available nationally? What is there to be kept secret when an issue of public health has arisen?

The Canadian *Guidelines* document also makes reference to distinctions to be made among stages of Lyme disease infections, such as early ("acute"), "disseminated" and finally "late" or "chronic" (although the last word appears once only) stages of Lyme disease. But the typologies and descriptions of symptoms is confusing (or "confused") because various common symptoms and patient complaints can arise at any stage of the disease. The *Guidelines'* distinctions thus are not likely to be immediately of benefit or help to physicians or patients because the latter apparently can and do often present without having any recollection of having been bitten by an infected tick or any sign of the classic symptom: most often described as "a rash". There are in the *Guidelines* some listed possible aggregated symptoms suggested for "late" Lyme disease but the authors do not extensively cover any other late symptoms, which is one of the most serious major flaws in the *Guidelines* and the subject of many complaints made by the Canadian Lyme Disease Foundation ("CanLyme"), an organization (among whose members are Lyme disease patients) which advocates for patients and disseminates information about the disease. There are other studies, too, that suggest low reliability

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[8] *Waterloo Region Record,* pg B2, Saturday, April 25, 2009, reported: "Last year, 10 Waterloo Region residents had confirmed cases of Lyme disease".

for the Canadian *Guidelines* document, especially concerning the lack of sensitivity. The *Guidelines* document refers (with little emphasis and almost in passing) to the necessity for a clinical assessment in diagnosing Lyme disease, but the *Guidelines* authors also insist adamantly on the use of a confirmatory two-stage serological testing procedure. There, the lack of sensitivity indeed is brought into question.

On February 10, 2009, the Canadian Lyme Disease Foundation ("CanLyme") announced that it had received a private donation of $500,000 from an Ontario family to go towards funding an independent research facility to investigate the prevalence and nature of Lyme disease infection in Canada. In a news release announcing that grant, CanLyme President, Mr. Jim Wilson, on behalf of the Foundation made these observations:

> "This family struggled within the Canadian health care system, as are thousands of Canadians, and were let down by poor testing and a false confidence within the medical community that Lyme disease is rare in Canada. The medical leadership in Canada, including the federal and provincial governments, are letting us down. Doctors and patients are not told of the serious limitations of the tests used - limitations acknowledged by the global science community."
>
> Lyme disease is a bacterial infection carried by ticks. Ticks are brought into Canada in the hundreds of millions each season on migratory birds and are spread randomly across Canada following migratory bird flyways. You do not need to live in or have visited a known endemic area to become infected as some government agencies and medical organizations suggest.
>
> Inadequate testing, inconsistent reporting criteria, limited surveillance and poor clinical diagnostic knowledge have resulted in less than 50 cases of Lyme disease being reported yearly in Canada. On the other hand, the United States reports over 25,000 cases of Lyme disease annually - mainly in states adjacent to the Canadian border. Due to under-reporting the U.S. Centers for Disease Control estimates that annual cases in the U.S. could actually be 200,000. The European Union confirms in excess of 85,000 cases annually.

> Lyme disease, the fastest growing infectious disease in the northern hemisphere, is known as the "Great Imitator." It is a multi-system, multi-organ infection and can cause numerous symptoms including extreme fatigue, arthritis, heart abnormalities, bowel and digestive problems, abnormal skin sensations, muscle weakness or jerking, eyesight or hearing abnormalities, cognitive and memory difficulties, dementia, and in some cases paralysis.
>
> Lyme disease is commonly misdiagnosed as rheumatoid arthritis, Multiple Sclerosis, Lupus, Parkinson's disease, irritable bowel, fibromyalgia, and chronic fatigue. CanLyme says research, including postmortem study, is required utilizing all of today's technology to determine how frequently these other diagnoses are in fact caused by Lyme disease. We know a percentage are in fact Lyme disease, what we don't know is what that percentage is.

The symptoms and conditions described in the CanLyme news release are typical of the experiences reported by many Lyme patients. As was mentioned, when they initially visit the doctor, many are told they could not have Lyme disease if they are not living in an endemic area. Those patients sometimes describe having a general feeling of malaise, lacking specificity, or they also describe experiencing "brain fog," as well as short-term memory loss, including difficulty in remembering and concentrating, as well as flu-like symptoms, dizziness or imbalance, blurred vision, aching or weak muscles and joints, stomach pains or intestinal discomfort, and, often, they say those symptoms occur together or in succession. Some of those are also the kinds of symptoms that are also looked upon clinically as presenting symptoms for chronic fatigue syndrome and fibromyalgia.

The Canadian Public Health Laboratory Network's *Guidelines* document omits such references and does not make any such connections or links for physicians to consider. The *Guidelines* document instead describes categories of symptoms of illness relating to "acute," "disseminated" and "late stage" Lyme disease depending on the

timing and severity of infection but such symptoms may occur at any point when a person is infected. In contrast to the research results accessible through the CanLyme organization, the *Guidelines* document suggests that "Lyme borreliosis is uncommonly seen in Canada" and only "in close proximity to small geographical areas where infected ticks have become established." It makes no reference to the possibility that Lyme disease could be missed or misdiagnosed clinically because of shared symptomologies. Instead, the *Guidelines'* authors suggest that "unless patients are carefully selected and an appropriately sensitive and specific testing algorithm is applied, large numbers of patients without Lyme borreliosis will be incorrectly diagnosed". They, therefore, ignore the U.S. CDC's position that Lyme disease must be clinically diagnosed, and, again, they adamantly insist that any Lyme disease diagnosis must be subject to a two-stage confirmatory serological test. The *Guidelines'* authors purport to offer guidance "to assist physicians in assessing patients for Lyme borreliosis, and to help guide the choice and interpretation of laboratory testing". But, as the CanLyme organization suggests, the Canadian experience using the *Guidelines* as a resource for diagnosing and treating Lyme disease patients, most notably those with chronic Lyme disease, has been ineffectual and unworthy.

In this Brief, for reasons that follow, the conclusion is reached that the Canadian *Guidelines* must be given a "failed" grade as an aid to diagnosing and treating for both physicians and patients alike. The failure to offer information that is clear and unequivocal or to give adequate and accurate advice to physicians can be seen from the fact that the *Guidelines* fail to note, for example, that co-morbidity can occur, meaning that some patients, who may never have manifested the classic or typical sign

of infection, described sometimes also as a "bull's eye rash," and later are diagnosed as positive for *Borrelia burgdorferi,* may also have other, serious co-infections. That is to say, they may test positive with some other secondary bacterial or viral infection[9]. Contrary to existing information and evidence available through CanLyme research links, the *Guidelines'* authors offer this assertion: "A patient with typical findings of multiple sclerosis [MS] or chronic fatigue syndrome [CFS] without objective findings is highly unlikely to have Lyme disease, and both the physician and patient should be dissuaded from serological testing". In fact, CanLyme research sources suggest that such presenting symptoms can give rise to the very situation in which a clinical diagnosis is necessary to determine if Lyme disease may be present, while serological testing could potentially be supportive or used as an adjunct to rule in or rule out the presence of Lyme disease bacteria.

It is also known that some Canadian patients, who originally tested negative, have later been diagnosed as having *Borrelia burgdorferi,* after further and more accurate (usually U.S.) testing was done that showed them to be positive for Lyme disease. At least one Ontario Lyme disease patient[10] is known to have tested "positive" in Canada a number of years ago, based on an initial (ELISA) laboratory test report issued by the Ontario Public Health Laboratory. That report asserted on the same page indicating a "positive" ELISA test: "no evidence of infection." As a result, with no recommended follow-up Western blot test, patient "H" began to receive treatment

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[9] See: "other Lyme-like illness" and "coinfections complicate the diagnosis and treatment of Lyme Disease": www.canlyme.com/coinf.html.

[10] Now known as patient "H" (with permission).

several years later and only after further, more accurate and effective (U.S.) testing. The one obvious conclusion is that Canadian testing is indeed flawed and inadequate. It is also a fact that the *Guidelines* document offers inaccurate and misleading information in suggesting that persons who present with MS or CFS symptoms, but may not be living in an endemic location, for example, are "unlikely to have Lyme disease" and do not need to be tested serologically. In point of fact, the *Guidelines'* advice and comment on that is exactly the opposite from advice contained in the new clinical definition and guidelines on chronic fatigue syndrome and fibromyalgia (CFS/FM), recently published. The latter guidelines suggest that clinicians who diagnose and treat such cases must first eliminate the possibility that a patient may have Lyme disease.[11] How can that ever be accomplished with any degree of accuracy if our laboratory testing regime in Canada so often generates unreliable results?

Test results from two-tiered serological testing often can be unreliable because *B. burgdorferi* spirochetes and cystic forms (a seemingly dormant form of the bacteria) often can be hidden in body tissues without a patient's showing human immune response from a serological test. The fact that patients can and do test positive, after having been more accurately tested and diagnosed (out-of-country), for late-stage or chronic Lyme disease is itself evidence that methods and procedures used for diagnosing and testing in Canada are inadequate, often wrong and, plainly, in many cases, simply wasteful and ineffectual. But, the real resulting harm is to patients. Such failings mean that patients who later have been found to be suffering from late-stage or

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[11] See references in Alison C. Bested *et al. Hope and Help for Chronic Fatigue Syndrome and Fibromyalgia,* 2d ed.(2008), Cumberland House, Nashville, TN, pp. 12-15.

chronic Lyme disease, could have been (but were not) successfully treated earlier. As a result, the inadequate testing regime in Canada likely has caused such persons to suffer longer, with deeper and much more complex and serious and difficult to treat symptoms of late-stage, chronic Lyme disease.

The Canadian *Guidelines* document, while purporting to offer assistance and help for physicians and patients, contains no mention of the fact that post-mortem studies of some patients who had dementia as a result of Alzheimer's disease were found to be positive in tests (post-mortem tissue studies) showing the presence of Lyme *borreliae*.[12] At least two of those studies had been completed and reported prior to publication of the Canadian Public Health Laboratory Network's *Guidelines* document on Lyme disease. That kind of omission (the silence of the *Guidelines* on the potential link between Alzheimer's disease and chronic Lyme neuroborreliosis) is damning evidence, to say the least. Such an omission prompts one to ask these questions: On what research and science were the Canadian *Guidelines* based? and How is it that such significant clinical research findings could have been ignored or overlooked? More recently, the Canadian Alzheimer's Society (January, 2009) issued a news release that referenced results of a preliminary study indicating that approximately 500,000 Canadians now are living with Alzheimer's or a related disease, but, even more astonishingly, that report noted that more than 71,000 of those persons are under age

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[12] See: 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; also see: Alan B. MacDonald, "Dementia caused by *Borrelia* infection of the central nervous system": Columbia University LDA National Scientific Meeting, October 20, 2006; and now see: MacDonald, A.B. "Alzheimer's neuroborreliosis with *trans*-synaptic spread of infection and neurofibrillary tangles derived from intraneuronal spirochetes": Medical Hypothesis, 2007, 68, 822-825.

65 and 50,000 of those, under age 60.[13] It does not require a great stretch of imagination to suggest that, statistically, some proportion of those patients may be suffering from symptoms that can be linked to late-stage, chronic Lyme disease, and that they may be in a febrile state only as a result of never having been properly treated, that is, diagnosed and tested, in Canada to rule in or rule out the presence of chronic Lyme neuroborreliosis. The *Guidelines'* failure to acknowledge Lyme disease and Alzheimer's links and the dismissive comments denying possible links between Lyme disease and other serious health conditions, such as chronic fatigue syndrome (CFS) and MS, for example, in the face of contrary evidence allows one to ask the question: What clinical and diagnostic experience or skills do the *Guidelines'* authors have?

The real problem in this situation lies with the inadequacies of present-day serological testing for chronic or persistent Lyme disease. The *Guidelines'* requirement for a two-stage testing approach (an initial ELISA test, but only if and when there is some "clinical" evidence such as a rash and with a possible time or location for tick exposure, to be followed by a Western blot test but only if the ELISA test shows positive) is apparently copied from an almost identical set of procedures established in the U.S. by the Infectious Diseases Society of America (IDSA) that had also been accepted and recognized as the official diagnostic standard used by the U.S. Centers for Disease Control (CDC). The Canadian *Guidelines'* "Recommendations" concerning the approach to testing show that, in both the U.S. and Canada, the same fallacies concerning diagnosing and treating of chronic Lyme disease are prevalent: in fact, both

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[13] *Rising Tide: The Impact of Dementia on Canadian Society:* www.alzheimer.ca.

appear to deny that chronic Lyme disease even exists. One group of researchers in the U.S. has gone so far as to suggest that patients who complain of or present with symptoms of "chronic" (also referred to as "late-stage" or "persistent") Lyme disease, after they had been treated for Lyme disease previously with antibiotics, are unlikely to continue to have any *Borrelia burgdorferi* infection. But, that group seems to ignore the fact that the Lyme bacteria can change form and hide its presence. Those researchers suggest, instead, that such patients may suffer from a psychiatric disorder or from what they call "post-Lyme syndrome," which is said to be an "autoimmune disorder". However, post-Lyme syndrome has never been defined. In other words, they seem to suggest that there is no such thing as "chronic" or "persistent" or "late-stage" Lyme disease after initial short-course antibiotic treatment, and that those who complain that they continue to have chronic Lyme disease and symptoms of Lyme disease instead have post-Lyme Syndrome (which, it seems, they see as some kind of an autogenous disease, or some other autoinfectious novel condition, in which the patient has somehow caused the Lyme disease symptoms to recrudesce, or by some means has reintroduced or replicated the symptoms, but not the Lyme bacterial disease, within themselves). To date, there appears to be no acceptable or credible research evidence to support such a bizarre and far-fetched hypothesis. But, there is laboratory and scientific evidence that chronic Lyme disease exists and that *Borrelia burgdorferi* bacteria cause that disease.

The Canadian *Guidelines* document, however, does acknowledge that there are deficiencies in the two-stage serological testing procedure, which is one of the recurring complaints made by organizations like the Canadian Lyme Disease Foundation

(CanLyme), as well as the International Lyme and Associated Diseases Society (ILADS).[14] The latter is a professional medical society whose members are physicians, researchers and other health care providers, all of whom work in the area of managing and treating Lyme disease. The latter organization also offers medical training and accreditation in the U.S.A., as well as diagnostic and treating guidelines information for physicians and researchers, which includes, for example, reference to possible polymicrobial infections that may be encountered in individuals with Lyme disease. The ILADS organization's guideline also recognizes and offers practice suggestions and treatment recommendations for "persistent" or "chronic" Lyme disease.

The most startling omission in the *Guidelines* (Canada) and in guidelines published in the U.S. by IDSA (the Infectious Diseases Society of America) is the silence about, and absence of any reference to, the use of an IgG or IgM Western blot test for a human immune response to "Osp A" (or "Osp B" or "Osp C") protein ("Osp" means "outer surface protein"). Apparently, it has been known since the 1990s that there are species-specific proteins of the Lyme bacterium and that the outer surface protein from the *Borrelia burgdorferi* spirochete form of the bacteria can, as testing on certain bands shows, yield a specific human antibody immune response, to the degree that the finding of that kind of human immune response in the presence of the bacterial protein can be considered as "a marker" (a confirmatory test) that indicates the presence of the Spirochaetales bacterial infection.[15] The reason for the omission (as it

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[14] http://www.canlyme.ca/ and http://www.ilads.org.

[15] Go to: http://www.lymediseaseassociation.org. Click: "politics":"Conflicts of Interest". See especially footnote references 21, 22, 23, 53, 54, 73 in *Conflicts of Interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines,* 2001: Lyme Disease Association Inc.

appears) is that the science and knowledge was somehow kept "hidden" from diagnostic consideration . . . while private bodies involved in two separate commercial projects were attempting to use the knowledge to aid in their development of a vaccine against Lyme disease.[16] That apparently failed because of resulting complications to some patients who received vaccinations and participated in testing. In March of 2002, a domestic vaccine was withdrawn in Canada.

Yet another recent chapter in the history of Lyme disease "conflicts" came to light in May of 2008 following an investigation by the Office of the Attorney General for the State of Connecticut, which found that a number of persons who had participated in developing the IDSA (Infectious Diseases Society of America) treating protocols for Lyme disease that are used in the U.S.A. also had connections with interested third parties through ties to the pharmaceutical and insurance industries there.[17] As a result (through a compulsory process), the IDSA has undertaken steps for reviewing and re-writing the U.S. Lyme disease diagnostic and treating protocols, which process is now under way in the U.S.A. and is to be overseen by a neutral referee. Canada, however, continues to hue to the old path in which our public health agencies hold a belief in and reliance upon the earlier impugned guidelines and practice standards that now are, presumably, disgraced in the U.S.A. In view of what transpired in the U.S.A., why is Canada still using a treating and diagnostic approach that was tainted by scandal?

One serious consequence resulting from adherence to the practice standards in

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[16] See footnote references 66, 67, 74 in *Conflicts of Interest in Lyme Disease, supra.*

[17] http://www.ct.gov/AG/cwp/view.asp: "Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guidelines, Install Independent Arbiter." (May 1, 2008).

the Canadian *Guidelines* document is that medical governing bodies responsible for practice oversight of doctors in at least two provinces[18] also continue to hold allegiance to the same sets of limited and questionable practice standards. The B.C. and Ontario colleges have investigated physician members who dared to treat chronic Lyme disease patients in accordance with ILADS practice standards or known best practices that have been used and adopted in the U.S.A. and some E-U countries. In Ontario, a number of patient files were seized in October of 2008 after investigators from the Ontario College made entry to a physician's office. One of the files take was the confidential file of patient "H". A number of patients were in the doctor's office at the time of the raid by the Ontario College, and, since then, many of those patients have banded together to form a support group, calling themselves the "Lyme Action Group".[19] They identify their purpose as being to raise funds to support a defence for the physician and also to lobby governments and spread information publicly about Lyme disease in Canada. One other result of that raid on the doctor's office is that the Ontario College of Physicians and Surgeons has had possession of patient "H's" file, including results of the initial Canadian ELISA test for Lyme disease: reported "positive," but with a comment of "no evidence of infection". Thus, the Ontario College now has before it clear evidence showing the kind of slipshod laboratory testing that can occur in Canada, as certainly was apparent in that case. All indicators now are pointing to the fact that public health and medical governing bodies in Canada have begun taking sides in what is obviously

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[18] The British Columbia College of Physicians and Surgeons and the College of Physicians and Surgeons of Ontario, in particular.

[19] Lymeactiongroup.blogspot.com

an area of professional disagreement ("conflict") over Lyme disease treatment and diagnostic approaches. But, in so doing, those public bodies may be creating risk and jeopardizing the health and well-being of patients living with chronic or late-stage Lyme disease, rather than (as the governing statutes require) assisting physicians in attempting to return those patients to a state of better health. Such actions by government bodies, including the publication of the inapt Canadian *Guidelines,* obviously have the effect of inhibiting and interfering with the ability of physicians and clinicians to undertake and fulfill their professional responsibilities to their Lyme disease patients. This situation is untenable and unacceptable. It is most emphatically not a situation where an exercise of statutory powers can or should be permitted to run wild, with no apparent accountability, and, ultimately, with detriment to patients.

Added to the finding that "undisclosed financial interests" warranted "a reassessment of IDSA guidelines," the report of the investigation completed in May of 2008 by the State of Connecticut Attorney General's Office also made the following additional findings:[20]

- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";

- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded.

In Canada, there have been repeated complaints through the Canadian Lyme Disease

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[20] See footnote 17, *supra.*

Foundation, as well as through the Ontario Lyme Disease Association of a similar nature, to the effect that dissenting voices and alternative research findings about Lyme disease are being stifled and ignored by public health officials. Such complaints followed from a conference held by the Public Health Agency of Canada (PHAC) in March of 2006 at which Canada's public health officials, laboratory personnel and a smaller number of "CanLyme" representatives attended, including experts from the U.S. brought in by the latter. Not surprisingly, while that meeting was intended initially to lead to agreement among those groups on a whole range of laboratory, clinical and surveillance guidelines pertaining to Lyme disease in Canada, no consensus emerged. Although a resolution was passed and an understanding reached that committees were to be struck to follow up and create a set of "made in Canada guidelines," nothing like that happened. Instead, what happened shortly after was that the Canadian *Guidelines* as they now exist were produced and published unilaterally by the Canadian Public Health Laboratory Network. Forgetting the cynicism that provoked, their action undermines the credibility of public health officials in the eyes of the wider community concerned about Lyme disease. That is, the *Guidelines* now used in Canada came to be published without any formal or direct input from CanLyme, which offers alternate views and which represents patients, researchers and medical practitioners and others whose interest is to work for the betterment of Canadians suffering with Lyme disease. That situation must now be corrected.

As an example of what went seriously wrong at that point, CanLyme had been pressing for recognition of chronic Lyme disease as an emergent serious public health problem, and Canlyme also urged abandoning the necessity for the initial (most often

inaccurate) ELISA screening test in favour of a more comprehensive and sensitive form of Western blot test (referenced earlier) to be used to measure human immune response to *Borrelia burgdorferi.* Such testing would require and mandate inclusion of the specific test bands used to detect a human immune response to Osp A and the other proteins specific to Lyme disease. CanLyme's President, Mr. Jim Wilson, continues to question why there has been so little research on Lyme disease when nearly one billion dollars has been paid by Canadians through taxes, money that has been used up and invested elsewhere, which was the amount paid out in 2005-2006 by our federal government through the Canadian Institutes of Health Research. In the absence of effective and timely federal actions, CanLyme recently created its own research organization to focus on independent, evidence-based research into Lyme disease.

One serious concern that arises, given the "conflicts" experience in the U.S., is whether or not Canada should continue its present approach to health research funding since that often channels government spending into private, for-profit activities and ultimately into corporate hands (that being the locus of all of the problems uncovered by the A-G for the State of Connecticut.). Given the nature of Canada's system of public health care through non-profit insurance, surely it is more logical and reasonable to argue that the public health system in Canada and, thus, the Canadian government, should itself directly undertake and support and oversee research into Lyme disease as a major public health issue. New research should lead to licensing arrangements to permit re-capture of some public research spending, rather than simply having our federal government giving up or handing over proprietary rights that may come from

such research and the public expenditures on health research. New and better avenues of Lyme disease research must be undertaken in the interests both of Canadians now diagnosed with Lyme disease and of countless others who may, unsuspectingly, have acquired the disease but (given our failed testing protocols) have no confirmation of that. We are at this moment truly at a crossroads in Canada in regard to research on Lyme disease.

The 2007 Canadian *Guidelines* are being surpassed and overtaken by other developments that could simplify or lead to better results in serological testing for Lyme disease. In 2006, as an example, the U.S. Food and Drug Administration approved a new test[21] that enables veterinarians to screen dogs for several tick-borne diseases, including Lyme disease, through a simple blood test that also simultaneously screens for heartworm and, in addition to Lyme disease, can uncover canine forms of anaplasmosis and ehrlichiosis. Surely, one must ask: Why is not the same type of testing and measurement technology capable of being adapted and put to use for human testing? On February 23, 2009, as another example, the *Journal of Clinical Pathology* first published an on-line report concerning a Scottish research project that resulted in increasing the sensitivity of testing for Lyme disease through the use of a "single mixed antigen" for IgG Western blot testing, which improved the predictive value of that test.[22] Such information holds out hope and promise for the initial diagnosing of Lyme disease and for tracking long-term sufferers from chronic Lyme disease because

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[21] See report: http://www.dogflu.ca/03012007/15/new_tick_test_available_for_dogs.

[22] See: http://dx.doi.org/10.1136/jcp.2008.063461.

it apparently improves accuracy in testing for both sero-positivity and sero-negativity.

What has been written thus far in this Brief makes it appear that the status quo (the doctor "do-little" and "do nothing") current approach to Lyme disease diagnosis, treatment and research is ineffectual. Those activities that have been undertaken through research agencies that report to the Public Health Agency of Canada to date achieved very little. Through the development, publication and dissemination of the Canadian *Guidelines,* physicians have not been assisted but rather (because their professional governing bodies have relied on that document) they are being inhibited in regard to vigorously and actively treating Lyme disease patients without fear of being investigated and prosecuted for doing so. One other major problem in Canada is that no single, comprehensive, accurate and up-to-date source of information exists, such as a clearing house for physicians, to which they and others can turn for accurate, current and complete practice information or reports of research. If, as the *Guidelines* purported, the intention was to provide information and content to be used by physicians and relied upon for clinical diagnostic and treatment purposes, such content and information must surely be in the form of a document that is accurate, comprehensive, evidence-based and reliable. But, as the foregoing critique suggests, the Canadian *Guidelines* document deserves a failing grade because it is little more than a political and polemical piece designed to support a particular point of view that is apparently intended to downplay the prevalence and risks of Lyme disease in Canada, and, as well, its effect has been to sow seeds of doubt and confusion. If our Canadian public health officials are intent upon and serious about offering support and guidance, they must be compelled to act and be allowed to fulfill their duties and responsibilities to

produce and deliver what is now needed in Canada if only because the issue of potential risk of harm to patients with Lyme disease (those diagnosed and persons yet undiagnosed) is grave and serious. Rather than allowing for any open-ended debate or professional dialogue, the normative, or prescriptive and mandatory, approach the *Guidelines* process to date has taken, instead of assisting physicians, really acts as an unnecessary impediment, and, indeed, it threatens physician-patient relationships by withholding access to and even ignoring results from recent reliable research and evidence that could assist doctors. In Canada, the genie is now out of the bottle, and there is a growing awareness and concern about the spread and prevalence of Lyme disease among members of the Canadian public.[23] If our public health institutions honestly and genuinely mean to fulfill the statutory duties and responsibilities with which they are charged, and if there is to be any reasonable hope of either arresting or coping with the spread of chronic Lyme disease in Canada, those agencies must reform their practices and undertake a true leadership role and provide guidance for Canadian professionals and the public, as well as undertaking research and the delivery of the full array of health services that are needed by Lyme disease patients.

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[23] In part, that can be attributed to numerous screenings across Canada of the award-winning film documentary entitled, "Under our Skin".

PART TWO

Canadian Health Care Structures and Organizations Need Reform

Canada's health care system involves both the federal and provincial levels of government, but the Lyme disease *Guidelines* process described earlier, that is, the process of preparing and disseminating information about Lyme disease, in this instance, originated with the Federal Government at Ottawa. Such an activity eventually reaches the hands of provincial health authorities, as well as doctors, nurses, and other hospital-care personnel who work in each province. There is a complex legislative framework and, at the federal government level, everything begins with and follows from what our federal Parliament has determined in different statutes to be the fundamental principles and governing framework for the Canadian system of public health care. The system in Canada, as most people know and understand, is entirely different and distinct from the manner in which health services are organized and structured in the U.S.A. where the system is essentially based on the provision of private and, most often, "for profit" health care services. To understand the differing principles that operate here in Canada and to understand how distinctive our publicly funded health care system is from that in the U.S.A., it is worthwhile to begin by looking at the *Canada Health Act* ("the Act").[24]

The governing principles stated as the legislated aims and objectives of the Canadian health care system are outlined in a long preamble to the *Canada Health Act,* and it refers specifically to some of the guiding principles and objectives that Parliament

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[24] R.S. C.1985, c. C-6, as amended.

has recognized, among which are the following:

> – that Canadians can achieve further improvements 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 . . . .

The fundamental underpinning for achieving those public health initiatives and objectives is our fiscal system involving federal-provincial transfer arrangements for funding our public health care facilities and services as those are laid out in that statute. The *Canada Health Act's* "program criteria" are stated as principles to be adhered to as part of the fiscal transfer arrangements, and those, too, are intended to guide the administration and the operation of our provincial insured health care systems on the basis of not-for-profit and public administration. Those criteria declare that the Canadian health care system that operates in each province must follow the principles of "comprehensiveness," "universality," "portability" and "accessibility," as those characteristics are defined in the *Act*.[25] The *Canada Health Act* also clearly identifies and specifies as the principal goals of the Canadian health care system these objects:

> 3. It is hereby declared that the primary objective of Canadian health care is *to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health*

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[25] R.S. C.1985, c. C-6: S 8, 9, 10, 11, 12.

services without financial or other barriers. (Emphasis added.)

Those goals describe what are the objective, program or task-oriented actions and outcomes that are to be undertaken and achieved. That is, the *Act's* objective is not just philosophical or idealistic but is directed to creating services and structures capable of achieving practical, program- or action-oriented results through systemic measures that foster and support those objectives. Those are, in summary, the bedrock principles that underlie measures to be taken to implement the objects and intentions of our Canadian Parliament.

One can say that any activities or undertakings that foster those goals are desirable and consistent with the principles of the *Canada Health Act,* which would be a good thing, but that any activities that run counter to, or serve to undermine, hinder or thwart the achievement of those objectives would lead to bad outcomes which, at all times, should and must be discouraged and avoided as leading to unacceptable and unworthy results. The words Parliament chose to use in s.3 to describe the objects of our Canadian health care system are mandatory and also serve as directives that must be read as being the underpinnings for other agencies or institutions and the programs and activities that are undertaken by those bodies to serve the purposes and objects of the *Canada Health Act.* The *Canada Health Act* also defines in s.2 what are "insured health services," meaning "hospital services," which are defined to include both in-patient and out-patient "services that are medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability". Among such services are listed "laboratory, radiological and other diagnostic procedures, together with the necessary interpretations". The *Act* also defines

"physician services" to mean "any medically required services rendered by medical practitioners". The *Canada Health Act* also names "the Minister of Health" as the person ultimately in charge of and responsible for the operation and administration of the Canadian health care system and, thus, the *Act* charges the Minister of Health with the oversight of all of the *Canada Health Act's* provisions and other related legislation passed by Parliament.

A separate statute, the *Department of Health Act, 1996* also specifically and more particularly defines various "Powers, Duties and Functions of the Health Minister," among which are the following:[26]

> 4(1) The powers, duties and functions of the Minister extend to and include all matters over which Parliament has jurisdiction relating to the promotion and preservation of the health of the people of Canada not by law assigned to any other department, board or agency of the Government of Canada.
>
> (2) Without restricting the generality of subsection (1), the Minister's powers, duties and functions relating to health include the following matters:
>
> . . .
>
> (a. 1) the promotion and preservation of the physical, mental and social well being of the people of Canada;
>
> (b) the protection of the people of Canada against risks to health and the spreading of diseases;
>
> (c) investigation and research into public health, including the monitoring of diseases;
>
> . . .
>
> (h) subject to the *Statistics Act,* the collection, analysis, interpretation, publication and distribution of information relating to public health; and
>
> (i) cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

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[26] C.8, s.4.

The responsibility last-listed clearly is to be seen as intended to encourage and permit federal-provincial collaboration in programs aimed at addressing emergent public health issues, which would include issues such as the spread of Lyme disease in Canada. In that regard, the *Department of Health Act* also specifically states, in s. 4.1., that "the Minister shall coordinate the activities of, and establish strategic priorities for, any board or agency for which the Minister is responsible," and it states, as well, that "those powers, duties and functions" may (subject to the Minister's terms and conditions) be delegated to the Deputy Minister of Health. In other words, that *Act* indicates that the duties of the Minister and Deputy Minister encompass and include oversight of all activities of the Health Department, which, presumably, must include the federal government's obligation to acknowledge and respond to emergent issues, such as to address the expanding scope of and managing of acute and chronic disease in Canada and the need for developing adequate and effective diagnostic and treatment protocols to undertake measures necessary to address any situation that creates a health risk for Canadians.

Similar duties and responsibilities are acknowledged and identified in the *Public Health Agency of Canada Act, 2006.*[27] The responsibility for and the administration of that *Act* (in s.4) is also invested with the Minister of Health:

> 4. The Minister presides over the Agency and has the management and direction of it.

Save for "the power to make regulations," the Minister may delegate other functions, "subject to any terms and conditions that the Minister specifies" (s.5). The "Chief Public

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[27] S.C., c.5

Health Officer" is designated in the *Act* as the deputy head of the Agency, and the person so appointed must be "a health professional" who has qualifications in the field of public health.

In the preamble of the *Public Health Agency of Canada Act, 2006,* Parliament specifies clearly that the Canadian Public Health Agency is intended to function as a "hands on," actively participating body in the fulfilment of all measures and programs to be undertaken by the federal government in the public health field. For example, the program purposes and objectives specified in the preamble to the *Public Health Agency Act* are stated in the following terms:

> . . . the Government of Canada wishes to take public health measures, including measures relating to health protection and promotion, population health assessment, health surveillance, disease and injury prevention, and public health emergency preparedness and response;
>
> . . . the Government of Canada wishes to foster collaboration within the field of public health and to coordinate federal policies and programs in the area of public health;
>
> . . . the Government of Canada wishes to promote cooperation and consultation in the field of public health with provincial and territorial governments;
>
> . . . the Government of Canada also wishes to foster cooperation in that field with foreign governments and international organizations, as well as other interested persons or organizations;
>
> . . . the Government of Canada considers that the creation of a public health agency for Canada and the appointment of a Chief Public Health Officer will contribute to federal efforts to identify and reduce public health risk factors and to support national readiness for public health threats.

Sadly, as this Brief concludes, not all of those objects have been or are being served in respect of the growing prevalence of Lyme disease, and, particularly, its spread among growing numbers of patients living with chronic Lyme disease in Canada. The further

sad fact is that chronic Lyme disease was, at one time, never even recognized, but, now, is probably being under-recognized. The *Guidelines* for Lyme disease in Canada were expediently borrowed and copied from the U.S. But, the U.S. standards have been found to be corrupt, that is, flawed and tainted by third-party influences. Also, by covertly appropriating a known, identifiable bacterial protein assay capable of eliciting a human immune response, the same flawed U.S. guidelines process, which Canada adopted, hid a reliable diagnostic model and bacterial identification test. All of the same deficiencies cast doubt on the credibility and reliability of Canada's *Guidelines.* The effect is that, in both Canada and the U.S., there is currently no universally accepted, credible and reliable protocol on which patients or their physicians can rely as a basis for properly diagnosing and treating Lyme disease. In the three-year period since the establishment of the Canadian Public Health Agency, it seems that very little else has been done or achieved that can count as a success in regard to diagnosing and treating Lyme disease, and in particular, chronic Lyme disease, or in meeting Parliament's stated objectives in the field of public health care in relation to that disease.

The final piece of relevant legislation is the *Canadian Institutes of Health Research Act, 2000,*[28] which statute establishes the model and approach for medical research undertakings for Canada (previously under the auspices of the Medical Research Council). The present *Act* allows for the creation of new research institutes to be set up through a corporation whose president is appointed by the Governor-in-Council. The research functions are farmed out and funded through a 20-member

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[28] S.C. 2000, c.6

"governing council". The *Act* also allows for inter- and intra-corporate research undertakings, each with separate advisory boards, whose members and their staffs may be paid through the public purse. That *Act* specifies that research activities should be undertaken with "a transparent approach" so as to "facilitate accountability to Canadians" and must take "ethical issues" into consideration. The statute's aims, as stated in the preamble, are for "the creation of new scientific knowledge based on research that meets the highest international standards of excellence" and "the development and implementation of innovative policy and practice". The "objectives" stated in s.4 of the *Act* suggest that the research to be undertaken will pertain to all aspects of health and "include bio-medical research, clinical research ... environmental influences on health, and other research as required". All of that effort is to be directed to "addressing emerging health opportunities, threats and challenges and accelerating the discovery of cures and treatments and improvements to health care, prevention and wellness strategies".

Aside from the very thorough recent vector surveillance field studies and research analyses undertaken with cooperation by the Public Health Agency, the Canadian Wildlife Centre, participating zoonotic diseases agencies and university biology and entomology research departments,[29] no other kind of public research activity has to date offered hope or measures that would hold out possible relief and treatment success for Canadians suffering with Lyme disease. In spite of what may appear as

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[29] See, for instance: Ogden, N.H. *et al.* "*Ixodes scapularis* Ticks Collected by Passive Surveillance in Canada: Analysis of Geographic Distribution and Infection with Lyme Borreliosis Agent *Borrelia burgdorferi* in J. Med. Entomol. 43(3) 600-609 (2006); and see: Ogden, N.H. *et al.* "Role of Migratory Birds in Introduction and Range Expansion of *Ixodes scapularis* Ticks and of *Borrelia burgdorferi* and *Anaplasma phagocytophilium* in Canada" in Applied and Environmental Microbiology, Mar. 2008. p. 1780-1790.

necessary major reforms in health research services and activities in Canada, and what was promised at the time, the spread of Lyme disease, with each passing year, is emerging as a major threat to public health in this country, as well as in the U.S., Europe and Asia. But, Lyme disease, it seems, is not yet seriously "on the radar" for our institutional research bodies in Canada. Where is there any posting of Lyme disease research being undertaken, or of any articles or research abstracts to give up-to-date information and reporting about diagnosing and treating Lyme disease that would indicate that diagnosing and treating and halting the spread of that disease is going to receive the attention it needs in Canada? The Public Health Agency's activities in the case of Lyme disease treatment seem to extend no further than having issued and published the Canadian Lyme disease *Guidelines.* But, those, like the U.S. diagnostic and treating protocols, are disgraced and have had little or no positive impact for Lyme patients. Also, it is clear that the *Guidelines* document downplays and discounts the seriousness of the spreading in Canada of the Lyme bacterium, contrary to the approach that is needed today. Those *Guidelines,* if only because they aped the disgraced U.S. standards, need to be discarded and be replaced immediately.

Now is the right time for action and attention by the Minister of Health. The need for measures to arrest the threat to public health from the spread of Lyme disease is growing. We know the Public Health Agency convened a meeting in March of 2006, at which CanLyme experts and representatives were also present, for the purpose of establishing criteria to be used for a made-in-Canada diagnostic and treatment protocol for Lyme disease. That, it appears, was the specific mandate given to public health officials prior to that meeting. The March, 2006, conference did not result in agreement

on either diagnostic criteria or treatment modes. From a set of notes subsequently made public by PHAC attendees, it seems there was to have been a continuing dialogue, through committees, on the establishment of criteria for diagnosing and treating Lyme disease. But, the Public Health Agency's post-conference notes appear to indicate that there was agreement at the March, 2006, meeting only about the need for continuing surveillance of Lyme disease. It seems that was then taken up by the authors of the *Guidelines* document to mean that surveillance information and studies on tick habitats and their prevalence in Canada was to be given emphasis. Sadly, in the absence of agreement on the real areas of need, including developing practice information that physicians could rely on for diagnostic and treatment purposes, the authors simply adopted the flawed IDSA/CDC guidelines criteria developed and now disgraced in the U.S.A. The Canadian version was issued without any hesitation or any further consultation with organizations such as CanLyme. The consequences have been that patients and physicians still do not have any appropriate needed guidance relating to diagnosing and treating Lyme disease. For reasons difficult to understand, responsible public health officials have remained silent on those matters ever since. It is plain and obvious from all of the preceding that the Minister of Health and representatives of the Public Health Agency of Canada owe an explanation to Canadians as to what went wrong, and, especially, to those persons who may be suffering silently and needlessly with Lyme disease symptoms but without receiving treatment, including persons suffering today who may be undiagnosed largely as a result of the fact that the *Guidelines* document has downplayed the scope and significance of Lyme disease in Canada. Those Canadians, too, are owed an explanation, and they need to see action

taken. In this Brief, the writer is seeking and asking for an undertaking from the Minister of Health that this situation of neglect through inaction can and will be remedied immediately and will never be repeated. What can be done? How can that be assured?

The Minister of Health should assume responsibility, first, to intervene and investigate to discover why it has taken so long in Canada to advance the cause of properly diagnosing and treating Lyme disease in all of its manifestations. Senior Health Department officials should then be directed to re-open and re-establish communications with professional research bodies and representatives of the Canadian Lyme Disease Foundation (CanLyme) with the intention and objective of empanelling a new committee, to include representatives from patient-related groups like CanLyme, and other interested and knowledgeable professionals and individuals for the purpose of establishing a new set of "made in Canada" practice standards and criteria for diagnosing and treating Lyme disease, through investigation into all the known and possible manifestations of Lyme disease. The Minister must, as well, begin by adopting and directing attention to treatment and diagnostic methods known to be effective and worthy of promotion through scientific, evidence-based research that is reported as being underway in Canada, the U.S. and E-U countries. As one example, the Minister of Health, through the public health laboratory and other reporting agencies, should immediately order adoption of Western blot testing that uses and relies on the IgG/IgM bands specific to "Osp A". Without sounding unduly alarmist, physicians, the provincial colleges and other medical and nursing associations should be alerted to the potential that Lyme disease in Canada is likely far more prevalent than earlier indications have suggested, and, simultaneously, those groups should be informed about newer, better

and more accurate diagnostic and treatment procedures to be introduced as soon as possible. As well, high-level representatives designated by the Minister of Health should immediately undertake to consult and collaborate with representatives of provincial health ministries to undertake appropriate professional information programs and options to introduce programs to train, as quickly as possible, every physician who wishes to learn about known best-practice approaches and techniques for diagnosing and treating Lyme disease, including exposure to teaching methods offered through ILADS and by affording them opportunities for accreditation. The current small number of "Lyme literate doctors" (LLDs) practising in Canada are the persons most likely to have access to, and to have with them to bring, the most up-to-date knowledge and experience. Those LLDs should be asked or recruited to undertake to write curricula for such programs of training for Canada. Rather than seeking to harass and prosecute our Lyme-literate doctors, the provincial colleges should look to those physicians as the key resource personnel for the interim. But, that is not all, since those steps alone may not be enough to bring about all needed and immediate changes. The Minister of Health must, finally, undertake also to retain personal oversight or create a specialist national oversight body for managing research on all of the public health issues surrounding the emergence of Lyme disease in Canada.

PART THREE

The Role of Canada's Attorney General

The federal response also needs to address and recognize numerous medico-legal issues that arise as a result of the sorry history of managing chronic Lyme disease in Canada up to this point.

The Minister of Justice is also Canada's Attorney General, pursuant to the *Department of Justice Act, R.S.,* c. J-2 ("the *Act*"). The Minister is also "the legal member of the Queen's Privy Council for Canada" and, as such, is empowered to "see that the administration of public affairs is in accordance with the law," and the Minister also is vested with authority to exercise "the superintendence of all matters connected with the administration of justice in Canada, not within the jurisdiction of the governments of the provinces".[30] In cases where there are or may be legal issues pertaining to any other government departments, the *Act* says the Attorney General of Canada "shall advise the heads of the several departments of the Government on all matters of law connected with such departments". In addition, the Attorney General is empowered in subsection 5(d) to undertake "the regulation and conduct of all litigation for or against the Crown or any department, in respect of any subject within the authority or jurisdiction of Canada". The conflicts that have already been mentioned concerning the Canadian experience with the *Guidelines* and its problems in relation to diagnosing and treating Lyme disease outlined earlier undoubtedly disclose a variety of legal issues, some of which are subtle and some others that are obvious and potentially

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[30] Department of Justice Act, ss.4(a) and (b).

litigious in nature. The apparent arrogance of officials linked to the adoption and unilateral publication of the Lyme disease *Guidelines* document, for example, appears to have shown little regard for the fate of patients in this country suffering with Lyme disease from the fact of having hastily adopted and borrowed information from U.S. treating guidelines. Those are now disgraced and defunct because of conflicts of interest. In Canada, too, many related questions arise and corrective measures are needed.

The weight of all the evidence arising from and underlying the preceding critique of the *Guidelines* helps to shed light on "who's wrong" and "who's responsible" for the continuing conflicts in viewpoints, rather than adopting and embracing the better approach involving collaboration among all groups concerned about Lyme disease in Canada. But, some questions of a legal nature need answers. Were there any links or interests on the part of Canadian officials who unilaterally took over the responsibility for publishing the Canadian *Guidelines* akin to the kinds of personal and professional conflicts of interest discovered in the U.S. situation? And, in turn, that kind of question invites others: Are there any legislated conflict of interest rules in place to require full disclosure of personal interest or professional ties on the part of persons who may not be public office holders in Canada but are influential participants in federal public health policy initiatives and activities? Where persons or agencies who report to the Minister of Health or the Department of Health may be examined or questioned, it is surely within the purview of the Attorney General of Canada to investigate and give advice to that other ministry on such matters.

The situation here is one in which there is a conflict and controversy concerning

appropriate treating and diagnostic services in respect of persons with Lyme disease. But, the situation here is also one which sees the Department of Health and the Public Health Agency failing or being unwilling or unable to provide accurate, up-to-date and unbiased guidance, support and direction for physicians and health practitioners in diagnosing and treating patients with Lyme disease. That situation raises many kinds of medico-legal issues. Because the Canadian *Guidelines* are so deficient and incomplete, persons diagnosed with Lyme disease, particularly chronic Lyme disease, have in fact been denied adequate health services because physicians and clinicians are lacking the kinds of specific, accurate and complete information they need in order to offer competent and timely treatment. In one sample case referred to (that of patient "H"), the testing system in this country failed and that person continues in a chronic state, no doubt owing to a botched Canadian ELISA test result, without any recommendation for an initial screening with a Western blot test. There may be other persons who were initially tested and diagnosed as negative for Lyme disease but who, in fact, are positive but were missed because the present-day testing protocol is deficient and inadequate. There is voluminous information and evidence that is ignored or not provided to physicians in the *Guidelines,* such as the fact that Lyme disease sometimes can be refractory, and that *Borrelia burgdorferi* is a polymorphous micro-organism that is able to hide itself in human tissue in a cystic form, rather than a spirochetal form, all of which simply means that Lyme disease, in its differing manifestations, can be persistent and

chronic and very difficult to detect and treat.[31] Surely, for most Canadians, it is preferable, and their choice would be, that all persons suffering with Lyme disease should be returned to health, to be able to lead productive lives and to be self-supporting and able to care for themselves, rather than to remain chronically ill. It is also likely to be far less costly for our public health system to provide effective diagnosis and treatment than it is to pay for the costs of long-term, chronic care.

The Canadian *Guidelines* document merely duplicates the CDC/IDSA protocol. But that fact alone raises other difficult legal questions: Was the U.S. guideline model chosen for reasons of expediency? Was that done unwittingly or was that a result of wilful action or blind neglect of duty and was that choice taken without regard to potential harm to individual Canadians? There is in this instance an obvious duty of care because, through publication of the *Guidelines,* the Public Health Agency of Canada made the choice to implement a protocol for the purpose of addressing the case requirements for diagnosing and treatment of persons infected with the Lyme disease bacterium. But, as this Brief points out, the chosen *Guidelines* obviously failed to do that in any adequate or effective way. That same choice (the decision to adopt the U.S. standards and the situation that created) also brings to the forefront the fact that there is a public (institutional) as well as an individual duty of care in this set of circumstances. The Canadian *Guidelines* document was intended and written and adopted as a

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[31] For a scientific description of the morphology and investigational complexities of the cystic form of *Borrelia burgdorferi,* see: Brorson, S.H., *"Invitro* Conversion of *Borrelia burgdorferi* to Cystic Forms in Spinal Fluid and Transformation to Mobile Spirochetes by Incubation" in Infection 26 (1998) No. 3. Also, for example, as early as April of 1911, Balfour, A. in the British Medical Journal reported "dark-field" microscopic views of spirochaetes discharging spherical granules and "morphing" in liver tissue (See and go to: http://www.drerniemurakami.com/attachments/DCysts.pdf.)

definitive, prescriptive and detailed directive for physicians, to which at least two of the provincial colleges have chosen to adhere in the course of investigating doctors who have undertaken to treat chronic states of Lyme disease. The Canadian *Guidelines* were intended and written as if they contained, and were to be relied upon as containing, complete and determinative statements about diagnosing and treating Lyme disease. The *Guidelines* document's many ascertainable shortcomings and failings as a diagnostic and treating protocol have already been commented on and noted earlier in this brief. To what effect?

In his report made following the investigation into the U.S. treating protocols, the Attorney General for the State of Connecticut suggested that the U.S. guidelines had "sweeping and significant impacts on Lyme disease medical care," and it observed that the U.S. guidelines panel had "undercut its credibility" when it stacked the panel membership with individuals who had financial interests linked to pharmaceutical companies and insurance companies in what we now know are the key areas of Lyme disease conflicts. The A-G for Connecticut went so far as to say, "Medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.[32] As in the U.S., the situation here in Canada begs similar kinds of questions: Who's interests were served? Was any third-party interest served, and was there any improper conduct on the part of anyone in Canada? How (assuming there may be a finding that there were no improprieties) is anyone able otherwise to account for the Canadian *Guidelines'* fiasco outlined in this Brief?

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[32] *Supra,* footnote 17, *supra.*

Other questions concern the matter of the nexus, or relationship, between persons with Lyme disease who may be or were or are at risk of harm and the agencies who created the *Guidelines* and who owed a duty of care in the circumstances. The persons actually or potentially at risk of harm are those with Lyme disease, whether diagnosed or not, including persons who may yet be found to be in need of treatment for Lyme disease. In the circumstances here, the diagnosis and treatment of Lyme disease is the very subject-matter chosen and intended to be addressed by the Public Health Laboratory Network through its authorship and by the Public Health Agency through its adoption of the *Guidelines.*

In recognizing and acknowledging in Canada the need for adequate and proper diagnostic and treatment services to combat chronic Lyme disease, one is confronted with the case circumstances of all individuals whom the *Guidelines'* fiasco has potentially negatively affected. Every Canadian has equality rights that are guaranteed under the Canadian Constitution. In particular, the *Charter of Rights and Freedoms,* in the two following *Charter* sections, declares unequivocally:

> 7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

and

> 15. Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination, and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental of physical disability.

The Supreme Court of Canada in one recent case provided the following interpretation to indicate what it is that would amount to an infringement upon those equality rights:

> If a benefit program excludes a particular group in a way that undercuts the overall purpose of the program, then it is likely to be discriminatory: it

amounts to an arbitrary exclusion of a particular group.[33]

The *Public Health Agency Act* allows for the introduction of a variety of programs and measures that could apply for all Canadians, but, in the situation here, the denial of such rights occurred because the *Guidelines* were intended to introduce detailed information and measures specific to the diagnosing and treatment of one group of Canadians: persons with Lyme disease. But, as this Brief indicates, the Canadian *Guidelines* are too minimalist, inaccurate and insufficient, as well as ineffectual and prospectively harmful to achieve that purpose. If there is any doubt or question as to whether or not the stated *Charter* protections could apply in the case of Lyme disease patients, and, in particular, those with chronic Lyme disease, one need only contemplate and imagine the degree of outrage and the levels of public outcry that would arise in Canada if patients suffering with cancer, diabetes, heart disease, or other debilitating and potentially terminal illnesses were to be denied access to accurate and appropriate diagnostic and treatment services. This has been a disgraceful chapter in our history. The Canada *Health Act's* promises and the duties it and related statutes create in the case of Canadians with Lyme disease have not yet been met or fulfilled.

This brief ends with a direct appeal to the Attorney General and Minister of Justice of Canada to intervene officially and formally. That intervention must include a full investigation into the circumstances that led to implementing the inapt and ineffective Canadian Lyme disease *Guidelines.* Canadians then need the Minister's intervention to promote and recommend measures to ensure that all of the applicable

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[33] *Auton (Guardian ad litem of) v. British Columbia (Attorney General),* [2004] 3 S.C.R. 657; (2004), 245 D.L.R. (4th) 1; [2005] W.W.R. 189; (2004), 124 C.R.R. (2d) 135; (2004), 34 C.B.L.R. (4th) 24.

and referenced governing legislation will be fully understood, followed and applied properly for the future benefit of all Canadians. The objectives must also be to restore all persons suffering with Lyme disease to their proper status as persons for whom medical-health services are at least equivalent to the levels and kinds of services received or offered and available to other Canadians with a serious disease. This would mean ensuring that all Canadians, as well as persons with Lyme disease, will be able to benefit from the availability of enhanced diagnostic and treatment services and methods. A further aspect of such legislative objectives should be to restore physicians and others providing health services to their proper role of primary clinical case managers with freedom to choose, from within available, tested and reliable guidelines, the best diagnostic and treatment methods that can be offered, and, ultimately, to give recognition of the right for them to assert and fulfill their professional practice responsibilities by allowing them to offer services that best benefit and will promote the health and well being of all Lyme disease patients whom they may be called upon to treat without any fear of reprisals.

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