

March 8, 2013

Honourable Deborah Matthews
Minister of Health and Long-term Care
10th Floor, Hepburn Block
80 Grosvenor Street
Toronto ON M7A 2C4

Dear Minister:

RE: Two-stage Serologic Testing for Lyme Disease in Ontario

This is an “open letter” to the Ontario Minister of Health. It is also being shared with other persons and groups interested in the issues described herein.

You may know from participation in the affairs of the Pan-Canadian Public Health Network that the issue of laboratory testing for Lyme disease was raised again by Health Canada in its publication entitled “Canadian Adverse Reaction Newsletter,” vol. 22-issue 4, October 2012. In it Health Canada issued the following warnings:

Lyme Disease test kits and limitations

Key Points

- Serologic test results are supplemental to the clinical diagnosis of Lyme disease and should not be the primary basis for making diagnostic treatment decisions.
- Lyme disease test kits have sensitivity and specificity limitations.
- Health care professionals should be aware of these limitations and are encouraged to report suspected incidents, including false-positive and false-negative results, to Health Canada.

The Newsletter states unequivocally that “false” testing results have occurred as a result of using the two-tiered Canadian laboratory blood-testing protocol as the basis for detecting Lyme disease. It goes on to say that those false reports likely result from the failure to address the “genetic diversity of *B. burgdorferi*” (the bacterium known to cause Lyme disease) and from failing to consider “*cross-reacting antibodies due to other conditions or infections.*”

Health Canada’s warnings are clear “admissions against interest” and offer evidence that our federal public health officials now recognize and acknowledge the failings of two-tiered Lyme disease testing. That recognition undermines any belief in the integrity of the 2007 federal Lyme disease guideline (referred to below).

Yet, MOH put out a guideline in which it says “PHOL (Public Health Ontario Laboratories) will continue to use two-tiered testing as recommended by the Canadian

Public Health Laboratory Network” (CPHLN). The latter comment relates to the (above referenced) previous Lyme disease guideline published nationally in 2007 by CPHLN (under the aegis of the Public Health Agency of Canada). But, Health Canada’s “Adverse Events” newsletter suggests that is no longer apposite. The MOH guideline published in October 2012 came out after Health Canada’s “Adverse Events” newsletter was published. The newsletter apparently intends to alert the medical community and give notice to our provincial public health establishment that “the Feds” are making a clean break from their previous policy position on serological testing for Lyme disease.

Health Canada’s “Adverse Events” newsletter as well refers to the fact that, in a large sample cohort study that included “well-characterized Lyme disease patients,” it was found that “the sensitivity of the two-tiered approach was as low as 38% for patients who had erythema migrans [the ‘bull’s eye’ rash] during the acute phase” of a Lyme disease infection. Conversely, Health Canada’s statement concerning low-level sensitivity from the Lyme cohort study is clear evidence that two-tiered testing in fact yields inaccurate and/or “false” results more than 60% of the time.

Obviously, the system of two-tiered testing for Lyme disease is to be viewed as fatally flawed and unreliable. That conclusion holds up because the current testing approach detects only a single strain (B31) or a narrow spectrum of closely related strains of the bacterium known to cause Lyme disease, and, therefore, is not able to capture enough of the *borrelia* genus to yield a valid test result. But, there is published Canadian research that shows infected ticks are being widely dispersed into most areas of the country by migratory birds and that some ticks are infected with and carry multiple strains, including local strains, of bacteria that are not being detected using the current (B31) strain, two-tiered testing approach. [See enclosed articles: Morshed, M. J. et al.; Ogden, N., et al.; Scott, J. D., et al.; and Shah, J. S., et al.] Morshed (2006) reports finding four (4) different genospecies of *Borrelia* across Ontario, and Shah (2010) outlines an “improved” antibody testing protocol using two (2) strains of bacteria. It appears that none of that research information reached the attention of MOH staff prior to publishing the October 2012 guideline.

The failure to detect differing strains of bacteria likely explains why so many “false negative” test results are put out by Canadian testing laboratories. The other conclusion from the failure to address the issue of species diversity is that the sensitivity and specificity of two-tiered testing is likely to be much lower than was referenced by Health Canada in the “Adverse Events” newsletter. All of that information undermines any claim of credibility asserted by MOH staff as to the validity of the October 2012 Lyme disease testing guideline.

In view of the foregoing, the action taken by MOH in publishing the October 2012 guideline is rash. It is unreasonable in the circumstances and, in the writer’s

opinion, constitutes an act of gross negligence. That action shows evidence of a complete disregard for the lives and well-being of those persons who have and who suffer with Lyme disease, as well as those who may not yet experience negative consequences from the two-tiered testing system failures. Indeed, considering that a duty of care arises in the Lyme disease case, the action taken by MOH may even border on criminality, subject to finding evidence of improper or untoward intention. The obvious harm from the flawed two-tiered testing system and the guidelines is that they can jeopardize and threaten the health and safety of Ontarians. That is a foreseeable consequence. It comes from the fact that hundreds of Ontario families (perhaps thousands of other Canadians) because of a failed, “false negative” test have been denied accurate, effective and timely diagnostic and treatment services.

The result for patients is that a Lyme disease infection can lead to “chronic Lyme disease,” or a “persistent” state of illness that will lead ultimately and inevitably to “chronic Lyme disease” when left untreated.

The continued operation of the fatally flawed two-tiered system of laboratory testing for Lyme disease in Canada creates a class of persons who are “victims” of negligence and victims of the disease. That opens up the possibility for claims- seeking damages by patients and families who support them. There are likely to be other uncounted victims of chronic Lyme disease where the bacterial infection becomes persistent (i.e., late-stage or chronic) by virtue of the misleading information (i.e., misinformation or disinformation) that has been distributed by our public health officials. That, in turn, has led to delays in recognizing and responding to the spread of Lyme disease and withholding and not disseminating essential pathological treatment information about Lyme disease needed by physicians. Through withholding or not disseminating available and essential pathologic and treatment information about Lyme disease and now by holding onto the flawed two-step Lyme disease testing system, the essential legal requisites are in place to sustain a negligence action. In a class action, the legal requisites may be met where the facts identify a class of claimants, within a “Lyme disease negligence action,” that is ascertainable and where individual factual circumstances bring forward identical or common case facts, leading to similar patterns of claims and heads of damages. That action could be described as a “Constitutional Torts” case since there are also *Charter* issues that come into play.

Information from MOH about Lyme disease introduced at the “Rounds” session in April 2012 as well as in other MOH documents about Lyme Disease (“Diagnostic and Treatment Challenges;” “Technical Report :Update” and the October 2012 guideline), when read together show MOH staff are uncritically following and eagerly promoting what is all too often inaccurate, incomplete and inadequate (i.e., misleading) information about Lyme disease from the U.S.-based Infectious Diseases Society of America (IDSA). Members of that organization say, and apparently believe, there is no such thing as “chronic” Lyme disease; that the two-tier serologic (laboratory) testing approach is adequate and effective to identify cases of Lyme disease; or that the potential risk of

acquiring the tick-borne infection known as Lyme disease is small, not often serious and most often results from a person's having been bitten by an infected tick after visiting what are referred to as tick "endemic areas" (so called as a result of a period of continuous habitation by infected ticks carrying the Lyme disease bacterium *Borrelia burgdorferi*). The IDSA's denials of chronic Lyme disease continue today despite the overwhelming weight of evidence that chronic Lyme disease exists widely.

The MOH Lyme disease papers elaborate upon an IDSA concept they now call "endemicity" to suggest that physicians could somehow compute a "pre-test probability" for an infection and could then base a clinical decision to diagnose and treat for Lyme disease upon learning of such an exposure. MOH information does not indicate by what "calculus" a doctor could determine the level of "probability." The "endemicity" concept is "silly pseudo-science" because common sense alone suggests there is now a likelihood or probable risk of infection from a tick bite anywhere in Canada. The "endemicity" notion presupposes that a census exists and that all of Ontario's endemic areas have been identified. Another fallacy is the assumption that rates of infection and infectivity among ticks and their hosts in such areas are also known. That is simply not the case.

One yet more serious issue is that the weak Lyme "guidelines" that follow the IDSA's restricted approach are being used by the provinces' physicians' governing bodies, the Colleges, as a basis to investigate and, at times, discipline doctors known to be openly treating Lyme disease patients. Some physicians base their approach to treating Lyme disease using other practice guidelines and training available through the International Lyme and Associated Diseases Society (ILADS). One-hundred percent of all Ontario doctors who were openly clinically diagnosing and treating Lyme disease outside of the IDSA guidelines have been subjected to practice scrutiny from the governing colleges. Most have now discontinued treating Lyme patients to end what they see as "harassment." Such harassment has left a "chill" in the medical community such that very many doctors want nothing to do with diagnosing and treating Lyme disease. Such actions by the colleges have achieved that result, whether intended or not. But, that leaves patients to fend for themselves and has forced many to seek help outside Canada. We need, as several of the U.S. states recently enacted, new "protection" legislation to allow physicians to treat Lyme disease patients based on known clinical best practices and to allow that to occur without any fear of reprisals -- which can and will fulfill what Health Canada now recommends and has proposed in the "Adverse Events" newsletter.

It seems MOH staff never considered that the use of the "gatekeeper" ELISA first-stage test is the root factor and lies at the core of all of the "false negative" testing controversies that have forced many hundreds of Canadians to travel to the U.S. at their own expense to get help and find answers about a disease for which they cannot be treated in Canada. Several reputable and accredited Laboratories in California and New York State test for multiple strains of Lyme bacteria and also test and report on Lyme-specific Western Blot ("WB") bands. That can explain why many who receive a "false

negative” test result in Ontario subsequently show “positive” for a Lyme disease infection when tested outside of Canada. [See the enclosed article, Shah et al., “European Infectious Disease” on testing sensitivity for two strains of *B.burgdorferi*.]

Ontario public health officials have been heard to refer to out-of-country testing as being done in labs without accreditation and have even gone so far as to intimate that those labs are unethical and may be acting fraudulently in diagnosing Canadians. The truth of the matter is that we as Canadians have been witnessing and experiencing the effects of a massive fraud perpetrated by persons who blindly adopt and rely on the IDSA approach on both sides of the international boundary. The IDSA’s approach is to limit and restrict Lyme disease awareness -- for “reasons unknown.” The cynical viewpoint is that the two-stage Lyme testing system is ineffectual and wasteful but can serve to transfer the burden of the costs to those affected by Lyme disease. Persons who are treated outside of Canada then do not “count” as Canadian citizens with Lyme disease infection and, thus, are not as “burdensome” for our provincial health-care systems.

As Health Canada urges in the “Adverse Events” newsletter, the question of whether or not a patient has a Lyme disease infection at first instance must be determined on the basis of a differential clinical diagnosis made by trained doctors using current information distilled from valid evidence-based and up-to-date research and who are trained to apply known, best-practice treatment approaches. Such an approach is one that is decidedly patient-centred, physician-directed (if there is full and open access to the kinds of information just referred to) and could suffice to satisfy all voices engaged in current debates over best methods for detecting and treating Lyme disease.

Much of what the IDSA’s members say about Lyme disease has been “debunked” through publication of alternative research and information that is openly available and readily accessible. Nearly a decade ago, the IDSA’s critics brought forward evidence that persons responsible for creating the IDSA’s 2006 Lyme disease guideline should not have participated because of conflicts of interests and bias. In recent years, some IDSA members narrowly avoided prosecution after a State of Connecticut (“combines”) investigation found that the IDSA’s 2006 Lyme-treatment guideline-publication process had been tainted by interest and bias when the IDSA deliberately excluded and refused to hear from persons with alternative and differing points of view about Lyme disease. That is precisely the situation in Ontario when the MOH guideline on Lyme disease was published without consulting interested and “connected” Canadian Lyme disease organizations.

There was never any prior consultation between MOH staff and representatives of the Lyme Disease Association of Ontario (LDAO) or the Canadian Lyme Disease Foundation (CanLyme). Both groups have a history of published Lyme disease research and information. Both have links to international organizations involved in Lyme disease research such as ILADS, which offers physician training and accreditation and also

publishes a clinical symptom guideline to enable physicians to diagnose and treat Lyme disease comprehensively.

The choice of MOH to ignore and neglect consulting with other “Lyme-literate” groups means there is no indication that MOH considered the possibility of abandoning and eliminating the flawed ELISA first-stage test in favour of other better tests. Such a “better” test would be to use only the second-stage “Western Blot” (WB) test, but modified to require our testing laboratories to report all results from serologic testing (IgG and IgM) at all relevant bands, including those that are known “marker” bands for Lyme disease. That approach would restore WB testing to the “pre-Dearborn, Michigan,” protocol for WB testing. That would significantly benefit patients and the physician community. There is now an abundance of credible, current and historical data to show the higher power, i.e., greater accuracy (specificity and sensitivity) and efficacy, of an extended WB Lyme disease testing approach in contrast to the two-tiered system. The MOH Lyme disease documents focus on the possibility of having “false positive” testing results from the system of two-tiered testing. Most Ontarians living with Lyme disease whose diagnoses were “missed” because of a “false negative” test would emphasize the latter result.

Health Canada’s latest announcement about Lyme disease represents a bold move forward, and our national and Ontario’s public health establishments are now confronted with an opportunity to admit and acknowledge unequivocally that the inadequacies arising from the two-tiered system of Lyme disease testing warrant abandoning that approach.

The most egregious action taken in the October 2012 guideline debacle is the insistence by MOH that patients and doctors, as a condition precedent to requisitioning a test, must furnish patient history and treatment information to the testing facility. That aims at compelling disclosure of privileged and private information and is an unwarranted and unlawful invasion of the patient’s personal privacy rights and intrudes upon the “privileged” (doctor-patient) privacy relationship. There is no rationale and no conceivable “need to know” reason that could justify or allow MOH to step so far into what is and must remain “forbidden territory,” an area of protected privacy. The compulsory approach MOH attempts to introduce would likely vitiate the whole notion of consent. If such information were needed for Lyme disease surveillance purposes that type of data should be gathered only after issuing a test report of a “positive” result and by allowing only the collection of minimal data sets such as geographic location and tick species identity when known.

The question arises as to whether the guideline writers overreached and exceeded any authority or mandate they had by attempting to legislate and “regulate” in the Lyme disease sphere. If so, MOH staff invaded the “legislative” sphere in which only a Minister or the Legislature in committee are competent to act. It seems the MOH guideline was

published with no legislative oversight since, during this period, the Ontario Legislature was “prorogued” and no government business was being done.

Ontarians have a right to expect high levels of accuracy and competence in matters relating to public health care and, thus, much more is expected from those who are elected or appointed to enact policies and administer programs and who are entrusted to operate and manage emerging threats to public health and safety. The task left to our public health laboratory staffs is to provide accurate, complete and objective reports based on effective and appropriate testing.

The possibility of a Lyme disease negligence action gains support and weight because each Canadian has guaranteed *Charter* rights. The Canadian *Charter of Rights and Freedoms* highlights concerns about issues and effects of the flawed testing system for Lyme disease. The two-tiered testing system and the guidelines debacle likely infringe the section 15 “equality rights” of Lyme disease patients and, obviously, interfere with the protections in section 7 guaranteeing the “right to life, liberty and security of the person.” It is obvious to all Lyme disease patients in Canada that they do not have access to diagnostic and treatment facilities equal or equivalent to what is allowed to persons suffering from other acute or chronic and debilitating illnesses; nor have they been offered the same assurances about personal protection and security of person that our health care system is designed to deliver and does offer to other ill and disabled individuals. More often than not, Lyme disease patients’ hopes of pursuing their right to gain access to timely and effective medical diagnostic and treatment support for Lyme disease are being thwarted through dissemination of misleading or inaccurate information, or withholding relevant treatment information, and leaving only limited diagnostic and treatment options, with the result that doctors have little ability to help their patients.

The Attorneys-General in our federal, provincial and territorial jurisdictions have oversight of all *Charter* matters. To that end, they are invested with the duty and powers to effect and ensure that measures are in place to monitor governmental acts (or omissions to act), including reviewing all legislative matters in order to ensure that governmental activities conform to and support the rights and freedoms accorded to Canadians under the *Charter of Rights and Freedoms*. In the Lyme disease case, the fundamental rights guaranteed in sections 7 and 15 have been systematically ignored, and measures for redress need to be put in place. When domestic government bodies fail to act to protect the human rights of their own citizens, there is one remaining venue for seeking recourse. It is widely known that the U.N.’s Universal Declaration of Human Rights, which is administered by the United Nations Human Rights Council, allows for its receiving, investigating and deciding human rights’ complaints on a world scale. That means those U. N. bodies have the jurisdiction to investigate cases and restore social equality and personal security rights analogous to those that are enshrined in the Canadian *Charter of Rights and Freedoms*, sections 7 and 15.

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The adjudicative and legislative facts in the Lyme disease case are straight-forward enough. But, “access to justice” is a real concern to victims of Lyme disease. Such persons often are too ill to consider legal actions, or they are deterred by cost implications, since they already must pay personally for medical care and treatments not provided under our current provincial health care system. But, other, less costly, legal avenues could potentially be undertaken for seeking redress. In the Lyme disease case, the process of judicial review allows for filing an application to the courts to seek “injunctive relief” aimed, initially, at temporarily prohibiting use of the October 2012 MOH Lyme disease testing guideline. Subsequently, a court application would allow receiving evidence in the form of documentary submissions and reasons for seeking permanent orders. Such orders would serve to prohibit (“prohibition”) permanently using the guideline and to compel (“mandamus”) and order other remedial steps. Those could include ordering MOH to consult with Lyme disease advocacy and support organizations, such as LDAO, CanLyme and other patient groups.

But you, Minister, could order redress and undertake such consultation by simply agreeing to withdraw the MOH guideline and by undertaking to re-visit this matter.

I would be pleased to provide you with any needed further information on any of the above matters.

Yours sincerely,

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