

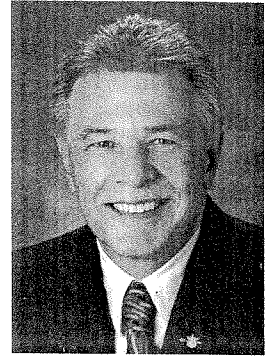
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**Province of
British Columbia**
Legislative Assembly



David Cubberley, MLA
(Saanich South)

March 2, 2009

Dr. A Dodek, President and Members of the Council
College of Physicians and Surgeons of British Columbia
400 858 Beatty Street
Vancouver, BC V6B 1C1

Dear Dr. Dodek and Council Members:

Thanks for your response to my December 18th letter regarding comments on Lyme disease diagnosis and treatment in the October 2008 College bulletin. I expressed concern that your advice to doctors was at odds with advice to patients from the B.C. Centre for Disease Control and the Ministry of Health's Healthguide. Both state that Lyme disease is to be diagnosed from symptoms and is not dependent upon either a detectable rash or a positive blood test; they also tell patients that B.C. doctors are equipped to provide this diagnosis. Your response states that I missed the point of your article, i.e. that "uncommon, even rare, conditions do occur and hence physicians should always be considering uncommon and rare diseases as part of their differential diagnosis". I suggested that calling Lyme 'rare' tells doctors they're unlikely to see it, while advising them that diagnosis and treatment require both a bull's-eye rash and a confirmatory ELISA test means that a majority of infected patients go undetected and untreated.

Your letter did not respond to the substance of mine, and you did not comment on the disparity between your position on Lyme diagnosis and that of the BC CDC and the Ministry of Health. This is a significant problem for patients in B.C., because the College's guidelines determine whether and when patients with Lyme are diagnosed and effectively treated. If these guidelines are flawed (as your advice about rash and test indicate they are) many patients will not receive diagnosis and the medically necessary care they're entitled to. If doctors are uninformed about Lyme symptoms, causes, and the unreliability of tests like the ELISA, they are more likely to diagnose Fibromyalgia, MS, CFS or any of a number of other illnesses sharing some symptoms with Lyme. These diagnoses would all miss the opportunity to treat Lyme infection effectively in its early stage when it's most curable. There is ample evidence that infected B.C. patients are not being diagnosed and treated when they present with Lyme symptoms, meaning they are doomed to untold horror and suffering from living with chronic Lyme disease.

Is characterizing Lyme disease as "uncommon, even rare" appropriate in light of the 20,000 new cases a year reported in the U.S.A., which the U.S. CDC says understates actual incidence by a factor of ten? Even the paper you sent me arguing against 'chronic' Lyme disease begins by

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recognizing Lyme as ‘the most common tick-borne infection in the North American hemisphere’ and ‘a serious public health problem.’ Lyme is the fastest rising infectious disease in North America and – unless ticks, deer and birds are somehow held in check by guards at the Canada/US border – it cannot be ‘uncommon, even rare’ here in B.C. Given that many British Columbians have acquired it walking the West Coast Trail, vacationing at Shawnigan Lake, or gardening in the suburban savannahs of Saanich, it’s hardly rare or uncommon. The number of cases reported annually in B.C. is absurdly low given the incidence in Washington and Oregon – epidemiologically this fact alone should pique our concern and trigger a review of clinical practice guidelines and test regimes in B.C.

My central point was that Lyme will be under-diagnosed if physicians are told to rely on seeing a bull’s-eye rash (not present in many cases of infection) and a positive ELISA test, which is inaccurate at the outset of infection and gets worse over time as bacteria leave the bloodstream for better hiding places. What happens to all those people who lack the rash and therefore don’t even get to the inaccurate test, or those who have the rash but test negative when they’re in fact positive? This inevitability appears to be of no concern to the College, but it is a serious public health issue with an untold number of victims. My offer to acquaint you with a few of the cases I’ve come across would include examples of BC doctors refusing to consider Lyme diagnosis even when a tick bite and EM rash are present, at times defiantly telling patients “there’s no Lyme in British Columbia!” Sadly, this is not an “uncommon, even rare” event, but rather reflects what many see as a systemic bias against clinical diagnosis and effective treatment of Lyme disease.

The article you sent me – A Critical Appraisal of ‘Chronic Lyme Disease’ – argues there’s no such thing as a ‘chronic’ phase of Lyme disease and claims there’s no evidence that long-term antibiotic treatment can be justified as therapy. This is consistent with beliefs embedded in the 2006 Infectious Disease Society of America (IDSA) guidelines, which under your aegis govern patient access to care in B.C. These beliefs are actively enforced by our Infectious Disease Specialists, who refuse to permit long-term or IV antibiotic treatment of patients even when there is serological and/or symptomatic evidence of persistent Lyme disease. This denies Lyme-sufferers access to the only clinically effective response to a debilitating infectious illness, forcing them outside public healthcare in Canada and into for-profit care in the USA – where they must pay out-of-pocket for treatments that often prove effective in restoring their health over the long term.

I was surprised to note that the article you sent was coauthored by (among others) Doctors Gary P. Wormser, Eugene D. Shapiro, and Allen C. Steere, former Chair and members respectively of the IDSA panel that drafted the 2006 IDSA guidelines. I wonder if you’re aware that these guidelines are now subject to complete review by an entirely new panel whose work is to be ‘refereed’ by medical ethicist Dr. Howard A. Brody? This unusual step follows a lengthy antitrust investigation by Connecticut Attorney General Richard Blumenthal, which unearthed conflicts of interest and serious breaches of procedure and guidelines. Blumenthal concluded that **“the IDSA’s 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests – in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies – to exclude divergent**

medical evidence and opinion” (emphasis added). The new panel is mandated to include members representing the entire spectrum of opinion on Lyme disease diagnosis and treatment, because the previous panel’s composition reflected only the beliefs of chronic-Lyme deniers. Time will tell whether the IDSA will see fit to meet ethical and scientific standards in generating future guidelines. However, in the current circumstances, is it appropriate for the College to circulate conjectural articles co-authored by persons who failed to meet their own professional society’s procedural standards for generating clinical practice guidelines?

Given the tainted process and bias against considering the supporting science and clinical practice experience of physicians who treat chronic Lyme with longer term antibiotic therapies, I wonder if the College has informed B.C. doctors of the guideline review and alerted them to their opportunity to participate? Given that British Columbia doctors are bound by guidelines created in another country, it would seem important to participate openly in any process affecting them. I would hope that a self-governing professional body like the College would ensure its members knew about the investigation and the mandated review of the guidelines.

I also think it’s important that the College consider the substance of Blumenthal’s findings, as they speak directly to the issue of whether confidence in the 2006 guidelines is warranted, and to the diligence and duty of care owed citizens of B.C. and Canada. Blumenthal summarized the public interest by noting that the guidelines have “sweeping and significant impacts on Lyme disease medical care” and “are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.” He also notes that “**medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards**” (emphasis added). The investigation found the IDSA and its panel deficient, even derelict in meeting this legal and moral duty.

The 2006 IDSA guidelines tightly restrict a for-profit insurer’s obligation to pay for patient treatment. Blumenthal notes that “insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification” and that “the guidelines are also widely cited for conclusions that chronic Lyme disease is non-existent”. These guidelines serve the same function in Canada’s public healthcare system – although the insurers here (i.e. the governments and people of Canada) have never promoted chronic-Lyme denial and remain financially responsible for the serial misdiagnoses that ensue when doctors are taught not to see Lyme.

Science cannot be said to support the contention that chronic Lyme doesn’t exist, because as Blumenthal’s investigation showed, the IDSA panel simply refused to consider any science or clinical experience that didn’t confirm a conclusion it had already drawn. The guidelines are, in fact, tendentious claims not substantiated by the panel’s deliberations, nor are they confirmed ‘scientifically’ by the material presented in the article by Drs Wormser et al (which is, to be kind, ‘selective’). Of the over 19,000 articles on Lyme disease, the panel cited just 405, nearly half of which were written by the guidelines authors! Given the divergence of medical and scientific opinion on these matters, a society creating clinical practice guidelines has an ethical obligation to ensure a very ‘clean’ and transparent process in working them up. Blumenthal’s investigation

determined there was anything but a defensible process behind the writing of these guidelines.

Rather, he found that “the IDSA’s guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease.” The IDSA’s Lyme guideline process also “**lacked important procedural safeguards**”. Among the most troubling of the flaws and manipulations tolerated or endorsed by the IDSA are the following:

“The IDSA **failed to conduct a conflicts of interest review** for any of the panelists prior to their appointment”. Several members had undisclosed financial interests.

“The IDSA **failed to follow its own procedures** for appointing the 2006 panel chairman and members, **enabling the Chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA’s oversight committee**”.

“The IDSA’s 2000 and 2006 Lyme disease panels **refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease**”.

“The IDSA **blocked appointment of scientists and physicians with divergent views on chronic Lyme** who sought to serve on the 2006 guidelines panel”.

“The IDSA **portrayed another medical association’s** [American Academy of Neurology (AAN)] **Lyme disease guidelines as corroborating its own** when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, **IDSA violated its own conflicts of interest policy**.”

The impropriety of doing these things will surely be evident to members of the College of Physicians and Surgeons in British Columbia. The IDSA compounded its failure to complete ‘due diligence’ by further attempting to promote the idea of an independent confirming opinion.

“When IDSA learned of the improper links between its panel and the AAN’s panel, instead of enforcing its conflict of interest policy, it aggressively sought the AAN’s endorsement to ‘strengthen’ its guidelines impact. The AAN panel – particularly members who had also served on the IDSA panel – worked equally hard to win AAN’s backing of IDSA’s conclusions.”

“**The two entities sought to portray each other’s guidelines as separate and independent when the facts call into question that contention.**”

(All of the above quotes are drawn from Attorney General Richard Blumenthal’s May 1, 2008 news release, copy appended, emphases added).

An abject lack of process-integrity on the part of the IDSA panel and the numerous failures by the IDSA to exercise ethical oversight of a committee operating in its name cast serious doubt on the 2006 IDSA guidelines. They raise questions about trusting this organization to develop any guidelines with the necessary respect for science and an appropriate degree of objectivity. As these guidelines affect the practice of doctors and lives of patients in B.C., should the B.C.

College not be treating them with a greater degree of caution and skepticism? In the College's view, should any individual consulting with private insurers regarding Lyme treatment, or holding patents on particular tests or treatments for Lyme infection, be allowed to participate in developing guidelines? Perhaps a crisis of organizational ethics of this kind should lead a self-governing professional body in a separate country to undertake its own review of clinical practice guidelines for Lyme diagnosis and treatment? Perhaps the least-substantiated parts of the guidelines should be subject to a College initiated review, given the likelihood of systemic error: i.e., making an erythema migrans rash (only present sometimes) a precondition for allowing an ELISA test (flawed) as a further precondition for doing a Western blot test (also flawed) as a further precondition for even considering Lyme diagnosis, leading at best to approval of a one-size-fits-all course of antibiotic therapy (contradicted by science and evidence).

I would urge that, in the public interest, the College distance itself from the many scientifically unsupported components of the 2006 IDSA guidelines, and that it mandate made-in-Canada guidelines formulated from fair consideration of all scientific evidence – including the clinical practice experience of physicians who treat Lyme beyond the existing guidelines. As the 2006 guidelines remain in force, some steps could be undertaken in the interim in order to ensure more prompt diagnosis and effective treatment of infected patients:

- Make diagnosis from symptoms the recommended approach and treat tests as confirmatory only. Comprehensively review whether the ELISA test should be retained as an initial screen for Lyme infection given its inaccuracy. Implement an appropriate test regime and ensure that doctors understand the limitations of all tests for detecting Lyme infection. Ensure doctors understand that ELISA reliability decreases the longer after initial infection it is used. Refocus physician attention on symptom awareness and draw on the extensive experience of doctors with enough experience in Lyme diagnosis to develop skill among those who lack it.
- Revise the guideline mandating a fixed course of antibiotic therapy in every diagnosed case to mandate a variable course (based on monitoring) with a set minimum length. This would take account of patient variability in response due to personal health and differing levels of infection, and it would recognize the rising incidence of co-infections, such as babesia, bartonella, Rocky Mountain spotted fever, and others that often complicate treatment.
- Initiate training for GP's to increase their knowledge of Lyme and co-infection signs and symptoms and to assist with their differential diagnosis, so that diseases without known cause or cure like Fibromyalgia, MS, or Parkinson's aren't the default option. Ensure that doctors understand that a bull's-eye rash doesn't occur in all cases of Lyme, and that proof of being bitten by a tick isn't a necessary condition for diagnosis. Ensure doctors understand their reporting obligations under public health legislation. And invite B.C. doctors with experience and skill in diagnosing Lyme and co-infections from symptoms to assist in developing and delivering the training.

- Initiate a colloquium on the issue of chronic Lyme disease and the effectiveness of long-term antibiotic therapy. Allow the clinical practice experience of doctors treating patients with longer courses to be part of the discussion. Publish the results and invite comment from those who have received such treatments.
- Work with public health agencies to develop and implement a public education program focused on school-aged children, to raise awareness of the spread of tick-borne infection and the safeguards useful in protecting children when they play in areas inhabited by ticks. Develop a protocol for what parents should do when a child has a tick attached to the body and what doctors should do when encountering ticks on the body. Ensure that under no circumstances is the tick just thrown away or Lyme diagnosis summarily rejected.

Action in these areas might begin to reverse the damage being done under the flawed IDSA guidelines, which miss so much Lyme infection by design, and risk so much Lyme relapse due to a non-patient-specific prescription for antibiotic treatment. I would once again offer to work collaboratively with you in raising the College Board's awareness of the under-diagnosis and ineffective treatment of early-stage Lyme disease in B.C., and of the horrendous consequences of categorically refusing antibiotic therapies for patients with persistent Lyme disease. Many people, young and old, are having to exhaust their family's life savings to buy therapies in the United States that should be supplied here under Medicare. Interestingly, most if not all of these patients find improvement when they have access to antibiotic and other therapies not allowed under the current guidelines. As agencies and decision makers responsible for the public interest, should we not be learning from the experience of doctors in supplying care to patients?

Sincerely,



David Cubberley
MLA, Saanich South

DC/ljn
pc/files

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Dr. Perry Kendall
Hon. Leona Aglukkaq
Dr. R Brunhan, BC CDC
Denise Savoie, MP
Dr. Keith Martin, MP
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Connecticut Attorney General's Office

Press Release

Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbitrator

May 1, 2008

Attorney General Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America's (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbitrator.

The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.

Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is nonexistent.

"This agreement vindicates my investigation -- finding undisclosed financial interests and forcing a reassessment of IDSA guidelines," Blumenthal said. "My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists. The IDSA's guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science.

"The IDSA's Lyme guideline process lacked important procedural safeguards requiring complete reevaluation of the 2006 Lyme disease guidelines -- in effect a comprehensive reassessment through a new panel. The new panel will accept and analyze all evidence, including divergent opinion. An independent neutral ombudsman -- expert in medical ethics and conflicts of interest, selected by both the IDSA and my office -- will assess the new panel for conflicts of interests and ensure its integrity."

Blumenthal's findings include the following:

- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;
- 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;
- The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

IDSA has reached an agreement with Blumenthal's office calling for creation of a review panel to thoroughly scrutinize the 2006 Lyme disease guidelines and update or revise them if necessary. The panel -- comprised of individuals without conflicts of interest -- will comprehensively review medical and scientific evidence and hold a scientific hearing to provide a forum for additional evidence. It will then determine whether each recommendation in the 2006 Lyme disease guidelines is justified by the evidence or needs revision or updating.

Blumenthal added, "The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests -- in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies -- to exclude divergent medical evidence and opinion. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result,

medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.

"Our investigation was always about the IDSA's guidelines process -- not the science. IDSA should be recognized for its cooperation and agreement to address the serious concerns raised by my office. Our agreement with IDSA ensures that a new, conflicts-free panel will collect and review all pertinent information, reassess each recommendation and make necessary changes.

"This Action Plan -- incorporating a conflicts screen by an independent neutral expert and a public hearing to receive additional evidence -- can serve as a model for all medical organizations and societies that publish medical guidelines. This review should strengthen the public's confidence in such critical standards."

THE GUIDELINE REVIEW PROCESS

Under its agreement with the Attorney General's Office, the IDSA will create a review panel of eight to 12 members, none of whom served on the 2006 IDSA guideline panel. The IDSA must conduct an open application process and consider all applicants.

The agreement calls for the ombudsman selected by Blumenthal's office and the IDSA to ensure that the review panel and its chairperson are free of conflicts of interest.

Blumenthal and IDSA agreed to appoint Dr. Howard A. Brody as the ombudsman. Dr. Brody is a recognized expert and author on medical ethics and conflicts of interest and the director of the Institute for Medical Humanities at the University of Texas Medical Branch. Brody authored the book, "Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry."

To assure that the review panel obtains divergent information, the panel will conduct an open scientific hearing at which it will hear scientific and medical presentations from interested parties. The agreement requires the hearing to be broadcast live to the public on the Internet via the IDSA's website. The Attorney General's Office, Dr. Brody and the review panel will together finalize the list of presenters at the hearing.

Once it has collected information from its review and open hearing, the panel will assess the information and determine whether the data and evidence supports each of the recommendations in the 2006 Lyme disease guidelines.

The panel will then vote on each recommendation in the IDSA's 2006 Lyme disease guidelines on whether it is supported by the scientific evidence. At least 75 percent of panel members must vote to sustain each recommendation or it will be revised.

Once the panel has acted on each recommendation, it will have three options: make no changes, modify the guidelines in part or replace them entirely.

The panel's final report will be published on the IDSA's website.

ADDITIONAL FINDINGS OF BLUMENTHAL'S INVESTIGATION

IDSA convened panels in 2000 and 2006 to research and publish guidelines for the diagnosis and treatment of Lyme disease. Blumenthal's office found that the IDSA disregarded a 2000 panel member who argued that chronic and persistent Lyme disease exists. The 2000 panel pressured the panelist to conform to the group consensus and removed him as an author when he refused.

IDSA sought to portray a second set of Lyme disease guidelines issued by the American Academy of Neurology (AAN) as independently corroborating its findings. In fact, IDSA knew that the two panels shared key members, including the respective panel chairmen and were working on both sets of guidelines at the same time -- a violation of IDSA's conflicts of interest policy.

The resulting IDSA and AAN guidelines not only reached the same conclusions regarding the non-existence of chronic Lyme disease, their reasoning at times used strikingly similar language. Both entities, for example, dubbed symptoms persisting after treatment "Post-Lyme Syndrome" and defined it the same way.

When IDSA learned of the improper links between its panel and the AAN's panel, instead of enforcing its conflict of interest policy, it aggressively sought the AAN's endorsement to "strengthen" its guidelines' impact. The AAN panel -- particularly members who also served on the IDSA panel -- worked equally hard to win AAN's backing of IDSA's conclusions.

The two entities sought to portray each other's guidelines as separate and independent when the facts call into question that contention.

The IDSA subsequently cited AAN's supposed independent corroboration of its findings as part of its attempts to defeat federal legislation to create a Lyme disease advisory committee and state legislation supporting antibiotic therapy for chronic Lyme disease.

In a step that the British Medical Journal deemed "unusual," the IDSA included in its Lyme guidelines a statement calling them "voluntary" with "the ultimate determination of their application to be made by the physician in light of each patient's individual circumstances." In fact, United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the guidelines as justification to deny reimbursement

for long-term antibiotic treatment.

Blumenthal thanked members his office who worked on the investigation -- Assistant Attorney General Thomas Ryan, former Assistant Attorney General Steven Rutstein and Paralegal Lorraine Measer under the direction of Assistant Attorney General Michael Cole, Chief of the Attorney General's Antitrust Department.

[View the entire IDSA agreement - \(PDF-2,532KB\)](#)

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