NY– Assembly Health, Education & Codes Committee Lyme Hearing

PAT SMITH'S, PRESIDENT, LYME DISEASE ASSOCIATION, TESTIMONY TO NEW YORK ASSEMBLY HEALTH, EDUCATION & CODES COMMITTEE, JANUARY 31, 2002

(Note: after a brief history of the Lyme disease situation, I will be primarily discussing questions 7, 8, and 9)

(Testimony included in parenthesis was spoken testimony added at the hearing and thus just summarizes these comments)

The Honorable Chairmen Gottfried, Sullivan, & Lentol, and Members of the Committees,

Thank you for inviting me today. Besides president of the Lyme Disease Association, I serve on the Board of Director of ILADS, International Lyme and Associated Diseases Society, a professional medical society, am former chair of the (NJ) Governor's Lyme Disease Advisory Council and former president of the Wall Township Board of Education.

The Lyme Disease Association is in all volunteer nonprofit 501 (c) 3 organization dedicated to prevention, education and raising funds for research for Lyme and other tick-borne diseases, TBD's.[1] In March, with our affiliate, the Greenwich Lyme Disease Task Force, we will be presenting a check to Columbia for the establishment of an endowed research center for Lyme and other TBD's to be opened at Columbia University.[2] (At this time, I invite Chairman Gottfried, Assemblyman Miller, and Assemblywoman Mayersohn to attend the opening celebration on March 21.)

Lyme is the fastest growing vector-borne disease in this country with New York State reporting the highest number of cases followed by Connecticut, New Jersey, and Pennsylvania. The Centers for Disease Control & Prevention, CDC, announced last week that cases increased by 8 percent in the year 2000.[3] Reported cases represent about 1/10th of actual reportable cases. The Northeast region constitutes about 90 percent of the cases in the country. There are thousands of patients in these states that require doctors to treat them for chronic disease–symptoms that last longer then a typical 28-day treatment and may include ophthalmologic, cardiac, and central nervous system problems including seizures, depression, and psychiatric manifestations. [4]

To prevent chronic disease, individuals must be diagnosed early and treated adequately. Lack of effective tests and physician education combined with the increase in other TBD's is contributing to late diagnoses and often, undertreatment. The CDC has criteria for Lyme disease meant for surveillance purposes only, not for diagnostic purposes.[5] Many people do not meet the surveillance criteria set up by the CDC, but some doctors are only diagnosing using

that criteria and insurance companies are often only paying for treatment based on those criteria. [6]

Lyme literate physicians, LLMD's, often treat patients who do not fit that surveillance criteria, and therefore, they frequently find themselves in the difficult position of battling with their insurance providers and also with their state licensing boards. LLMD's generally base their treatment regimen on clinical findings and sometimes use testing to support those findings.[7] In NY, a small number of physicians are willing to take the risks associated with treating chronic patients, and we estimate that 60% of our LLMD's have been investigated for treatment practices by the OPMC.

New York, recognizing the significance of clinical practice issues states that in clinical practice cases, "Experts may be made available by the state medical society of the state of New York, by county medical societies and specialty societies, and by New York state medical associations dedicated to the advancement of non-conventional medical treatments." [8]

The law does not, however, define "expert," so individuals who have little or no clinical experience treating chronic Lyme disease can be called to testify as experts in cases involving physicians treating chronic Lyme disease. Plus, the OPMC process does not include a disclosure mechanism for the expert witness or discovery proceedings. Thus, witnesses who may have significant vested interests may provide information to an OPMC committee or testify against doctors without ever disclosing these interests unless or until the doctor's attorney elicits them during the hearing. Since no discovery proceedings are available, it can't be determined if, for example, an expert against the doctor may have used the exact same practice or procedure for a patient in the same circumstance in his own practice, yet he is now testifying against the doctor for that same practice—a circumstance, which we know, has already arisen.

The initial interview the doctor has with the OPMC is an extremely important one in the process. This meeting is the basis for the determination of charging or not charging the doctor, yet no official transcript is kept of that meeting, thus, the doctor's attorney has no way of subpoenaing the record of this interview, if said interview results in the doctor being charged. An official transcript should be made of this meeting.

In clinical practice cases, the role played by supportive evidence is crucial. Currently, in New York State, evidence is only admissible after two tiers are satisfied. First, the hearing officer rules whether evidence is/is not admissible. Second, if evidence is ruled admissible, upon cross-examination, the state expert is asked to recognize the authoritativeness of a particular journal. That same expert has usually been involved in making the initial recommendations that the doctor be charged, and now he/she is deciding on the evidence to be admitted. If he/she refuses to recognize the journal, it cannot be admitted as evidence. In one instance, evidence was allowed to be introduced in a case in defense of the doctor, yet in another case, the same evidence was not allowed to be entered. The first doctor was able to support his practices and was vindicated on most charges, while the second doctor was unable to admit the same evidence and his case was not so favorably disposed. There is existing federal case law, which New York does not recognize, that says the judge may take judicial notice and allow the literature to be presented. [9] A summary of the case is included.

Due Process is often an issue. The Federation of State Medical Boards states on its website "Whatever the complaint, physicians are afforded the rights of due process as the board investigates a complaint of misconduct. The tenants of due process state that an individual is innocent until proven guilty and apply to formal hearing/judicial procedures, which the medical board carries out by following established rules and principles, to ensure that a physician is not treated unfairly, arbitrarily or unreasonably." [10] It seems that the literature standard results in unfair treatment of certain doctors since "hostile" experts solely determine which particular peer reviews qualify as evidence.
Rules of evidence, such as bringing in outside evidence such as decisions from another case, need to be modified. Currently, precedence is not set, so that the hearing committee may conclude in one case, for example, that Lyme disease is indeed mired in scientific controversy and should not be the basis for OPMC investigation, yet the next doctor can be similarly charged and may not be able use that previous finding.

Secrecy surrounding the process should be examined. Currently, doctors are never told the original complainant or complaint. It puts the doctor in the position of not being able to confront his/her accuser. While some secrecy is understandable, the legislature might consider a more equitable practice, perhaps following New Jersey's example with a form which clearly states on the application cover letter that "a copy of the complaint will be forwarded to the licensee with a cover letter from the Board requiring a detailed written response to the allegations in the complaint…. the complainant should understand that any information supplied on the complaint form may be subject to public disclosure." [11] Another option is to have the OPMC use a form, which states that all complainants and complaints will be released to the doctor unless the complainant specifies why that disclosure could be harmful to him/her.

At the least, complainants could be separated by category, e.g., patients, insurance companies, peers, other entities. Patient complainant identities could always remain confidential if that is felt necessary, but other complainants would need to give a reason if they felt their identity should be kept secret. A peer's reason to remain anonymous could be evaluated by the OPMC and a determination made based on the reason(s) provided. Insurance companies or other entities most likely to have vested interests could be identified immediately to the charged physician and hearing committee. As expressed in a letter addressed to Assembly Health Chair Dick Gottfried by Congressman Christopher H. Smith, Chairman of the US House of Representatives Veterans Affairs Committee, "While it is the job of state boards of medical examiners to review complaints logged against doctors and to take action when needed, a concern that was expressed in my state was that some of the complaints were filed not by patients, by but insurance companies (and entities associated with them) who did not want to pay for the costs associated with treating Lyme patients under an aggressive antibiotic regimen. Using a state panel that is supposed to investigate malpractice to help achieve financial gain is simply wrong."[12]

Secrecy has also perpetuated some questionable viewpoints. Officials have been publicly adamant in the cases of several of our treating physicians who were charged that the charges were unrelated to Lyme disease treatment. A few advocates, including me, and some NY assembly people attended a series of meetings with OPMC, health department, and other NY State officials. We were repeatedly told at these meetings that the Department of Health was not targeting Lyme doctors, nor were they soliciting complaints against them, and that charges against them were unrelated to Lyme disease treatment.

According to an NY assemblyman present at the last meeting we attended, the charges are indeed, directly related to Lyme disease treatment. We also subsequently discovered the word “Lyme” appears a total of 41 times in the factual allegations against two of the doctors. As for not soliciting complaints, a patient letter suggesting otherwise details her call to the NYDOH and two subsequent calls from them to her. Only seeking information on Lyme and other TBD’s from the DOH, she was subject to her diagnosis being questioned, told to see another physician other than her own, received an unsolicited complaint form in the mail from the DOH, and was pressured to file a complaint against her treating doctor. The DOH doctor told her that he and the DOH could obtain anyone’s record that they chose, including hers. She never filed a complaint; however, her medical records were pulled soon after the call, and she never heard from that DOH doctor again. [13] Her treating physician was eventually charged, despite the fact that the patient never filed a complaint against him. (What concerns me about this morning’s testimony relating to whether the OPMC solicits doctor complaints is that they appear not to be aware of what their employees are doing. I brought the above example to their attention at the first meeting in New York with health department and OPMC officials and Assemblypeople. Now at today’s testimony, the OPMC indicated in response to Chairman Gottfried that the individual(s) mentioned have not been disciplined, despite the fact they appear to have violated the confidentiality of that doctor. They not only told a patient on the phone that she should file complaints against her doctor, whose indentity she had not revealed according to her, but also told her that other complaints had been filed against her doctor, which appears to violate NY confidentiality laws.)

We in the Lyme community believe the targeting of NY Lyme physicians began in 1993, when U.S. Senator Edward Kennedy heard a prominent New York physician testify in his DC Senate hearing concerning the problems facing Lyme treating physicians: “…a few state health departments have now begun to investigate in a very threatening way, physicians who have more liberal views on Lyme disease diagnosis and treatment than they do… And indeed, I have to confess that today I feel I am taking a personal risk, a large one, because I am stating these views publicly.”[14] Two weeks after that hearing, that physician received a notice that an investigation was begun by New York State.

Even after he was cleared by the OPMC on initial complaints, his lawyer informed him his case was kept open, something the lawyer had never seen in his 30 years of experience. The investigation continued with more charts pulled. Although chart selection was supposedly random, only charts of chronic Lyme patients were kept for further review. He was eventually charged. In 2001, eight years after the initial investigation, he was exonerated on most of the charges against him. Incredibly, the OPMC then filed an appeal of that decision rendered by its own hearing committee. Ironically, one of the OPMC officials told us at a meeting that New York State provided the best example of due process for doctor disciplines in the nation.

Targeting physicians and rendering discipline in a scientific controversy are not the role of the OPMC or any state licensing review board. Comments from numerous officials nationwide support this statement: Office of US Congressman Joseph Pitts, PA, to Health Committee Chair Dick Gottfried, “We believe Lyme disease is a scientific controversy and, consequently, medical boards should not prosecute physicians based on their long term treatment of this devastating illness.”[15]

Congressman Christopher Smith, NJ, to Chairman Gottfried: “Lyme disease is unique because debates among the medical and scientific community often revolve not only around treatment, as is the case for other diseases, but around diagnosis as well. Two well-trained and well educated physicians could review identical patient symptoms and make a different diagnoses….I do not want anyone…to suffer because the doctor they were depending on for treatment has decided to stop seeing Lyme patients out of fear that aggressive therapy will result in an investigation of their practice. The investigatory “chilling effect could have a real impact on the ability of patients to receive quality health care when seeking assistance with this disease.” [16]

From Connecticut Attorney General Blumenthal at his state hearings on Lyme disease: “Different people at various stages of the disease may need different treatments, and my own basic philosophy is that decisions about diagnosis and treatment ought to be made by the treating physician and the patient, and those decisions ought to be respected by insurance companies, by government officials and ought not to be governed by arbitrary artificial dictates or regulations.”[17]

From the interim report *The prevalence of Tick-borne Illnesses in Texas* from the Texas Senate Committee on Administration “The Committee has concluded from this study that insufficient information on how these diseases should be identified and managed over the long term exists for ANYONE [their emphasis] to make a definitive determination of appropriate diagnostic or treatment guidelines.” Furthermore, a report recommendation “Directs the Board of Medical Examiners to develop guidelines in reviewing and investigating medical care providers when treatment of tick-borne illnesses is involved.”[18]

A letter to U.S. Senator Rick Santorum, PA, from the PA Commissioner of the Bureau of Professional and Occupational Affairs: “Regarding your inquiry into whether the office is conducting any investigations into the medical practices of Pennsylvania licensed physicians who treat Lyme disease…anecdotal responses indicate that there may have been one or two such complaints in recent years, which were closed without any action by the Prosecution Division because of lack of consensus in the medical community as to the appropriate standard of care made it difficult or impossible for a prosecutor on behalf of the Commonwealth, with an expert’s opinion in support, that a particular method of treatment did not meet the standard of care.”[19]

The ultimate irony is embodied in my last quote, which also appears to hint at a double standard for Lyme disease treating physicians. In a letter to a Lyme patient who filed a complaint against a doctor **opposed** to long term treatment, Dr Ansel Marks, MD, JD, Executive Secretary for the NY Board of Professional Misconduct states: “As defined by law, a difference of medical opinion, in and of itself, is not medical misconduct.” [20]

The secrecy surrounding the OPMC process combined with the power of the agency is a concern for legitimate physicians and patients alike, since there appears to be little or no oversight of the OPMC. Through their actions, they have the power to bring New York physicians and consequently, patients, to bended knee, but where is the authority that can bring them to their knees? Even at the first hearing before the Health Committee in November, no one from that office appeared. I wondered what message that sent to the legislators. I know what message it sent to me—we are not accountable to you in the actions we have taken against Lyme disease treating physicians.

After hearing today's testimony, I ask that you find a way to rein in the power of the agency without losing site of its mission to protect the patients. Please remember Lyme disease patients

- are not being protected when their treating physicians are afraid to treat in New York and patients have to travel elsewhere to get treatment,
- are not being protected when their doctors must spend half their practice time defending their right to practice medicine according to their best clinical judgment, and
- are not being protected when their already small number of doctors become smaller because their licenses are revoked for treatment of a debilitating illness, Lyme disease, about which the then Commissioner of the New York State Department of Health, David Axelrod, MD said in a 1988 communication to all New York Physicians, "Treatment of secondary and tertiary LD may require prolonged therapy with intravenous antibiotics."[21]

(Before ending, I would ask that the committee to ascertain when the OPMC changed their policies regarding Lyme disease treatment guidelines. This morning they testified that they did not use treatment guidelines in cases of Lyme disease physicians. Yet we have many letters, I would hesitate to say dozens, but probably dozens, to patients and Lyme disease groups which state the guidelines the OPMC said they used.

Chairman Gottfried, in response to your question as to whether an increased use of lay people on the committees would help, I would like to say it could be a factor, but it is my personal opinion as an outside observer studying this process these past few years and speaking with doctors, lawyers, and patients on the issue, I believe the most important change which could be made would be to lift the veil of secrecy surrounding the process. I think almost all the speakers here today have agreed that that aspect is necessary. It has been my experience in government, 12 years on the board of education, that government agencies are only accountable when you hold them accountable. I see very little accountability here for the OPMC due to the vast secrecy involved. When you lift that veil, as was begun today, I do not think you will like what you see, I know I haven't liked it.)

Thank you.

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[1] LymeR Primer, The ABC's of Lyme Disease
[2] Letter to LDA & GLDTF from Gerald Fischbach, MD, Dean of the Faculty of Medicine, Columbia University
[3] AP online January 17, 2002
[4] http://columbia-lyme.org/dept/nyspi/flatp/lymeoverview.html
[5] http://www.cdc.gov/ncidod/dvbid/lyme/casedef2.htm
[6] Aetna guidelines http://www.aetnaushc.com/cpb/data/CPBA0215.html, Prudential Guidelines, March 1995
[7] http://www.cdc.gov/ncidod/dvbid/lyme/diagnosis.htm
[8] Section 230 10(a)(ii) State Board for Professional Medical Conduct Proceedings

[9] Daubert vs. Merrell Dow Pharmaceuticals (92-102), 509 U.S.579, 1993
[10] http://www.fsmb.org/
[11] NJ State Board of Medical Examiners complaint form
[12] Congressman Christopher H. Smith letter to Chairman Richard Gottfried, November 27, 2001
[13] K.M. letter To Whom It May Concern, about experiences calling NY Department of Health July 2, 1998
[14] *Lyme disease: A Diagnostic and Treatment Dilemma* Hearing of the Committee on Labor and Human Resources United State Senate, August 5, 1993
[15] Office of Congressman Joseph Pitts to Health Committee Chair Dick Gottfried, November 23, 2001
[16] Congressman Christopher H. Smith letter to Chairman Richard Gottfried, November 27, 2001
[17] http://www.cslib.org/attygenl/mainlinks/tabindex6.htm
[18] [Texas] Senate Committee on Administration, *The Prevalence of Tick-Borne Illnesses in Texas*, Interim report, 77th legislature, November 2000
[19]Pennsylvania Commissioner Bureau of Professional & Occupational Affairs Dorothy Childress letter to U.S. Senator Rick Santorum, April 26, 2000
[20] Executive Secretary, NY BPMC Ansel Marks, MD, JD letter to Joseph Burke, December 29, 1999
[21] Commissioner of Health David Axelrod, MD, to all NY doctors, October 6, 1988