Act Number:	09-128	
Bill Number:	6200	
Senate Pages:	4599-4625, 4794-4796	**30**
House Pages:	2634-2667	**34**
Committee:	Public Health: 84-91, 95-97, 217-241, 434-499, 563-564	**104**
	Page Total:	**168**

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CONNECTICUT
GENERAL ASSEMBLY
SENATE

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4324 – 4666

THE CHAIR:

Thank you. You've got to watch those Italian pastries.

Will you remark? Will you remark further on the bill?

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. If there's no objection, I'd move that this matter be put on the Consent Calendar.

THE CHAIR:

Senator has requested House Bill 5635 be placed on the Consent Calendar. Without objection, so ordered.

Mr. Clerk.

THE CLERK:

Calendar page 10, Calendar Number 605, Files Number 583 and 903, Substitute for House Bill 6200, AN ACT CONCERNING THE USE OF LONG-TERM ANTIBIOTICS FOR THE TREATMENT OF LYME DISEASE, as amended by House Amendment Schedule A, favorable report of the Committee on Public Health.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. I move acceptance of the Joint Committee's favorable report and passage of the bill.

THE CHAIR:

Acting on acceptance and approval of the bill, sir, would you like to remark further?

SENATOR HARRIS:

I will, Mr. President, yes, thank you. Mr. President, everybody, I'm sure, around this circle and that's listening has heard now of Lyme disease. It's a disease that has had a dramatic effect on so many citizens, so many families here in the state of Connecticut. Of course it even derives its name from Connecticut, from Lyme where, of course, it was first originated or discovered, I should say.

Mr. President, as a matter of fact, the prevalence of Lyme disease in Connecticut at this point is so high that, in the past couple of years, I believe 2008, we had the highest number per capita of Lyme disease afflictions if you will in this country.

Over the years as people have tried to unlock the mysteries of Lyme disease, and one of the problems here is that it is a mystery. There is not one test,

no one way to see whether somebody actually has it, and it actually can go undiagnosed, untreated for long periods of time as well-intentioned health care professionals and patients struggle to try to figure out why they have joint pain, what's going on internally, why they are fatigued, and numerous other symptoms that are associated with Lyme disease.

Over time, Mr. President, there has been kind of a division that has developed in how medical professionals should treat Lyme disease. In the past it's been deemed to be something that's sort of a short-term. We can treat it. You get cured. That's it. It's over. And recently, in more recent years, there has been a growing group of professionals and evidence that show that Lyme disease actually is a chronic condition, that it actually is not something that is there and can be treated and go away but is there long-term. And to address that long-term, chronic illness, these professionals have begun treating Lyme disease with long-term antibiotics.

And there's some evidence out there that because of this division and things that we know that happen in the world, some of the professionals that believe it is chronic and long-term and should be treated by

long-term antibiotics, have come under attack. And what this bill does, in its very simplest form, is give the medical professionals a safe harbor. No matter which camp you're in, you will be able to, in your professional judgment, determine what you think Lyme disease is, short-term or long-term chronic, and treat it accordingly. So this bill specifically says that long-term antibiotic therapy may be prescribed and that a medical professional physician shall not be disciplined solely, solely for the use or prescription of long-term antibiotic therapy.

Mr. President, this is such an important bill for the health and safety of our families, friends and neighbors out there in Connecticut, and I really urge passage of the bill today.

THE CHAIR:

Senator Debicella.

SENATOR DEBICELLA:

Thank you, Mr. President, and, Mr. President, this is another in a series of bipartisan bills that are coming out of the Public Health Committee. This is an important bill not only for the advocates of it, and there have been many, but for the entire State of Connecticut, because I'm sure that all of us have

family or friends who have contracted Lyme disease at some point in their lives. It is, as Senator Harris said, very prevalent in our state. And having a family member who's gone through this myself, I can tell you that you want to, A, make sure that it's detected early because the treatment is much more effective if detected early, but too, that it's not a one size fits all disease. Is that the way it impacts one person can be very different from how it impacts another, and the path that that disease takes can be very, very different.

And the underlying philosophy of this bill is to give doctors flexibility in how they treat the patients of Lyme disease. We need to be able to allow doctors, if they believe it is the right course for their patients, to undergo a long-term antibiotic treatment. Now, not all doctors think that that's the right way to go, and that's okay. But this bill gives doctors and patients that flexibility to make that decision for themselves.

This is something, you know, on the Public Health Committee we've talked a lot about giving doctors and patients the tools to make better choices. I believe this bill falls into that category by giving the

flexibility of how to attack and treat Lyme disease.

Mr. President, Lyme disease, for people who have it, is a disease that never goes away. It's something that you need to live with for the rest of your life. And by allowing more flexibility with treatment, we can ensure that the patients who have Lyme disease are able to ameliorate the symptoms and ensure there is no long-term lasting health impacts. I urge adoption of this bill, Mr. President. Thank you.

THE CHAIR:

Thank you.

Senator Meyer.

SENATOR MEYER:

Thank you, Mr. President. Thank you, Senator Harris for doing this bill in the Health Committee. I'm a living survivor example. I've had Lyme disease twice. Both times the tick was found early and we were able to do a short-term antibiotics which would restore me to good health. But so many people have had the long-term effects of it, generally when they have not caught the tick, and the fact that this bill does flexibility is just where we should be going.

You know, last year a group of physicians from Fairfield County came to the Environment Committee and

asked us to do what they believe was the cure for Lyme disease. They wanted us to kill every deer in Connecticut, and you know, we were not -- the Environment Committee was not about to go with that, not only because of the killing of deer, but because of the fact that the tick would come on some other animals in some other places, and that was not going to solve -- DEP told us that was not going to solve the problem.

This bill today is going to help solve the problem, and that's why I'm very encouraged by it.

Thanks Mr. President.

THE CHAIR:

Thank you, sir.

Senator Kane.

SENATOR KANE:

Thank you, Mr. President. I too rise in favor of this bill. It was actually a friend of mine that I hadn't spoken to in, God, I want to say 20 years, that brought this to my attention. He suffers from Lyme disease and the chronic illness that it brings. I do know of a number of other people that do suffer the same way, and I think this is a good step in the direction of moving towards a cure and helping people

with Lyme disease in their affliction. So I, too, rise in favor of this bill and look forward to the Chamber's support. Thank you.

THE CHAIR:

Thank you, sir.

Will you remark?

Senator Kissel.

SENATOR KISSEL:

Thank you very much, Mr. President. I also rise in support of the bill. My brother Steven was afflicted for a while with Lyme disease, and my understanding that it was not a pleasant process. In response to Senator Meyer, the notion to kill all the deer, what I was stating to Senator Witkos that I thought that was an enormously drastic response, and hopefully not like your heart attack, you didn't get the Lyme disease on my birthday as well. That would be unfortunate. You and I have to go on a blue fishing trip together, buddy, that's all I can say.

But I will say this, I was listening to National Public Radio the other day, and they were talking about mosquitoes and malaria and how folks that are trying to combat this, when they have tough insecticides, they go through a wave, but then insects

build up resistance, and then they can't combat it. And there was an interesting twist in some of the technology and the science regarding this in that this, almost by accident, and how many great scientific discoveries are stumbled upon by accident, but these folks that are trying to combat these terrible diseases, and I would guess that the ticks associated with the deer, which is associated with the Lyme disease, would be in a similar category, that if you get the appropriate insecticide or repellant or whatever it is for these, my understanding from when I studied the bubonic plague, believe it or not once upon a time, is that these are called vectors.

But when you get the thing to get these insects at the time that they reproduce, you don't even have to necessarily wipe them out because if they build up resistance, if the time that the insecticide and the repellant takes place is at the reproductive stage, you can actually get your arms around the deer tick population.

So I think there's a lot of things a lot less drastic than wiping out the deer population in the state of Connecticut. I am ever amazed at the march of technology and medical discoveries, and I think

that this bill goes a long way towards moving us towards a humane and yet sensitive path towards remedying this really incredible disease that is insidious and a lot of folks don't even know they have it. They get misdiagnosed, and a lot of opportunities to turn their lives around are missed, and so I think it's a good bill.

Thank you Mr. President.

THE CHAIR:

Thank you, Senator Kissel.

Senator Frantz.

SENATOR FRANTZ:

Thank you, Mr. President. I stand in favor of the bill. We all know the symptoms of Lyme disease can be absolutely devastating. There is a range of symptoms, but when you get the worst end of the spectrum it can be absolutely devastating. It's like malaria. It never really goes away; it continues to come back. And I can tell you from personal experience, not my own, but being around people who have had it, it's an unacceptable condition. It's like the worst fever that you've ever had times about five, and that can last for up to a couple of weeks at a time.

I know it's a controversial approach to dealing with the condition. There are two camps, if not three camps, having to do with the long-term use of antibiotics, and we should be sensitive to that. There's no question about that. We've been told that something as mild as antibacterial soap, hand soap, at the kitchen sink is something that we have to watch, no question about it. But I think for anybody afflicted with this disease they should have the chance of going long-term with antibiotics. Lyme disease started here in Connecticut. Let's help end it here in Connecticut.

Thanks, and thanks for your fine work on this, Senator Harris and Senator Meyer.

THE CHAIR:

Senator McLachlan.

SENATOR McLACHLAN:

Thank you, Mr. President, and thank you, Senator Harris and the Public Health Committee, who has worked hard on this. I looked at the bill this morning, and I see that it's almost a hundred Legislators that have cosponsored this bill, and I'm proud to be one of them. Lyme disease has struck my family, and I can say that the experience back in 1995 was a good one

because it was very promptly diagnosed and treated. However, I do have a very dear friend who I went to school with who now is over seven years being treated for Lyme disease, and it clearly is a very challenging, life-changing event for Fran Ryan who -- Fran is from Danbury and somewhat reluctantly became an advocate for Lyme disease public education and for this bill.

And so Fran Ryan is just one of many people, a big group of people, who have worked very hard on this bill. I applaud their efforts. I thank my fellow Legislators who have brought this bill forward and found a way to bring language to us that's acceptable and provides choices for Connecticut's residents.

Thank you, Mr. President.

THE CHAIR:

Thank you, Senator McLachlan.

Senator Boucher.

SENATOR BOUCHER:

Thank you, Mr. President. Mr. President, I rise to support this particular bill and initiative. It is something that is unfortunately necessary. It is a very difficult issue. It's been through many years of evolution. We were at this state at a time when we

tested for this, and then there was another period of time when we didn't provide funding for the testing of Lyme disease, but there's no question that our state and certainly the district that we represent is almost ground zero for this given the -- the amount of education, the number of deer.

You know, it's interesting to note, historically, in our part of the state, when farming was the major activity in our area, most of our land was clear-cut, and there were actually many, many fewer deer, in the thousands. Today when all of the vegetation has grown back, we have more suburban communities, that has risen to the hundreds of thousands of deer and, as a result, the problems with the instance of Lyme disease has probably affected almost every family and certainly most of our constituents.

So there's no question that having a spotlight on it has been very effective, but I do have a question, if I might, through you just to assure those that might say are we creating another health care mandate at a time when we can least afford it, and maybe if we can get some assurance there that that is not the direction that this is going in and if there's any other legal issue that -- that could be discussed.

Thank you. Through you.

THE CHAIR:

Do you have a question?

SENATOR BOUCHER:

Yes, through you, Mr. President.

THE CHAIR:

Of course, Senator Boucher.

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. Through you, there is no health care mandate there -- here and it was actually put on the record in the House, and I do want to thank members of the House who really pushed this bill forward for us, that the fact that we say that a professional may prescribe or administer or dispense long-term antibiotics there was a question as to whether that somehow gave a safe harbor against the negligence action and the answer is no.

There still is a duty of care. Professionals still have to act reasonably. This does not eliminate a negligence cause of action or any other cause of action that might be brought against a medical professional.

THE CHAIR:

Senator Boucher.

SENATOR BOUCHER:

Thank you very much for the answers to any concerns on the financial mandate that might be prescribed or even legal barrier as well. Thank you very much, and I stand in support.

Thank you, Mr. President.

THE CHAIR:

Thank you, Senator Boucher.

Will you remark further on House Bill 6200?

Senator Fasano.

SENATOR FASANO:

Thank you, Mr. President. Mr. President, just a question to Senator Harris, through you if I may.

THE CHAIR:

Senator Harris.

SENATOR FASANO:

Senator Harris, by virtue of being exposed to this issue of Lyme disease, you understand that there is some hardened folks who believe that long-term treatment of antibiotics is not in line with evidence-based medicine. Is that your understanding with respect to some of the evidence that you've heard through your committee?

Through you, Mr. President.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Through you, Mr. President. Yes, there is a camp that I would call the older school of professionals that treat Lyme disease who do believe that there is no evidence that it is a long-term chronic disease that should be treated by long-term antibiotics. So, yes, that is true, Mr. President.

THE CHAIR:

Senator Fasano.

SENATOR FASANO:

Thank you, Mr. President. And through you, Mr. President, and it is my understanding that there are several national societies that have come out and indicated that long-term antibiotic treatment of Lyme disease through the studies and research, they believe, do not back up that that is an appropriate method to cure Lyme disease. Would you agree with that statement?

Through you, Mr. President.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Through you, Mr. President, yes, I believe there is one in particular that does believe that.

THE CHAIR:

Senator Fasano.

SENATOR FASANO:

Thank you, Mr. President. I thank Senator Harris for his answers. And if I can, Mr. President, this is a difficult bill for me as I prepare to vote on it. I know that CDC does not recognize nor support nor encourage long-term treatment by antibiotics of Lyme disease. The National Institute of Health of America does not support it, infectious Disease Society of America does not support it, and American Lyme Foundation does not -- American Lyme Disease Foundation does not support long-term treatment of antibiotics.

And some suggest that long-term treatment by antibiotics, for whatever reason, is not good for a number of reasons: One, bacteria would then accumulate in the colon resulting in infections in the colon. There's other side affects that antibiotics have upon the body that are negative in nature and, over time, can produce secondary health concerns for

those who are being treated with antibiotics long-term.

I'd also like to point out that this would be the first time that the State of Connecticut would be legislating, if you would, in opposite of evidence-based medicine. For those of you who don't know what evidence-based medicine is, evidenced-based medicine is something within the medical community that they recognize that there is support for the treatment that is going on. And if that support is there, even if there is counter support, that is, some trials say A and some trials say B, it's still deemed appropriate treatment because clinical studies can differ.

In this case there's been very little, if any, studies that have indicated that the long-term treatment by antibiotics is, without question, the best way of treating it. In fact, most of the evidenced-based medicine is to the contrary.

Recognizing that issue, I understand that the bill is permissive. The bill says there are some folks who have come and testified in front of this committee, perhaps even some experts who have testified that long-term treatment of Lyme disease

with antibiotics have proved to be effective. I was talking briefly with Senator McKinney who shared with me a story that he had where somebody was treated with antibiotics long-term and helped out that person.

So that's what gives me a little bit of a mixed feelings about the bill. On the one hand, I don't know how the Legislature, who has absolutely no knowledge of antibiotics, medical treatment, long-term effects of antibiotics, or even really understands if, and with all due respect to our circle, understands the medical complexity of Lyme disease and the treatment of antibiotics. And what we're saying is we're going to take it out of the hands of the medical society, and we're going to dictate what treatment is good, and we're going to dictate what treatment is permissible even if you as a medical society determine that it is not, we're going to allow them to do it.

That's a problem I have. I think that the medical society, one way or the other, has got to look at it and say that it is supportive or is not supportive within their community, and the Legislature should not be dipping their hands in and saying, forget about what you're doing and forgetting about your own policing and forgetting about what your

studies or what you say in your area of expertise, we know better. That bothers me.

So, as I said, I'm betwixt and between. Maybe it is cutting edge, and I don't want to discount that. Maybe over the long-term we'll find out that this long-term antibiotic is the way to go, but it's a very difficult vote for me because I don't know if this is where we should be dabbing our legislative authority.

I raise that issue to the folks around this circle because I have done a little bit of research. I have talked to a few doctors about the Lyme disease and got their opinion, but I have read online materials where there are people who are victims of Lyme disease who feel very strongly in this bill, and I hear them. And they're very supportive of this bill, and I don't want to feel like I'm being insensitive to their views. I've not experienced Lyme disease, nor has anybody in my family experienced Lyme disease.

So I guess, Mr. President, I raise these issues. I'm still undetermined how I'm going to vote on this bill. However, I do want to express my views in the event that I do vote no. I thank you, Mr. President.

THE CHAIR:

Thank you, sir.

Will you remark on House Bill 6200?

Senator McDonald.

SENATOR MCDONALD:

Thank you, Mr. President. Through you, just a couple of quick questions to the proponent of the bill.

THE CHAIR:

Senator Harris.

SENATOR MCDONALD:

Senator Harris, in the bill in Section 1.b, it indicates that a licensed physician may prescribe antibiotics. I just want to be clear, that language doesn't require a physician to prescribe antibiotics over an extended period of time, does it?

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Through you, Mr. President, the answer is no. It is permissive, and just to kind of clarify that and to pick up on Senator Fasano's remarks, this is a tough issue from the Legislature's point of view. As a matter of fact, I often joke with people that I'm not a doctor, but I play one on the Public Health

Committee. And we are asked to make some decisions that are beyond the kin of our experience as laypeople. Well, that's why this bill is so important because this bill, as Senator McDonald asked, does not say that a professional should do something. It just says that it is permissive, and they cannot be disciplined solely for doing so.

And it's important here because, unfortunately, in this situation where there are two different camps, if you will, that have their own reasons and evidence, I might add, to support their conclusions, there needs to be a referee, and that's where we as Legislators are called in to arbitrate, just to allow the professionals to do the job that they do. And, actually, the Connecticut State Medical Society was involved in drafting this bill and supports this bill. So sorry for the long answer, Mr. President.

THE CHAIR:

Thank you, sir.

Senator McDonald.

SENATOR MCDONALD:

Thank you, Mr. President. Well, I actually appreciate the long answer, Senator Harris. It was very helpful. Because you've addressed many of the

issues that have been brought to my attention by some of the physicians with whom I'm familiar in my city of Stamford. And I just want to be clear that if a doctor were to prescribe antibiotics over an extended period of time for a Lyme disease patient, would that doctor still have an obligation to explain to the patient the risks associated with extended antibiotic treatment?

Through you, Mr. President.

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Through you, Mr. President, yes, and the bill specifically says that the clinical diagnosis and treatment are documented in the patient's medical record so they would have all of the responsibilities that doctors always have to give informed consent, to diagnose, and keep appropriate records.

THE CHAIR:

Senator McDonald.

SENATOR MCDONALD:

Thank you, Mr. President, and just one final question through you, Mr. President.

Senator Harris, if the doctor were to prescribe

antibiotics for a Lyme disease patient over an extended period of time and that was coupled with other surrounding circumstances that would breech the standard of care for a doctor, that would not preclude the examining board from initiating disciplinary action against that doctor because of a confluence of other events besides just prescribing the antibiotics. Is that correct?

THE CHAIR:

Senator Harris.

SENATOR HARRIS:

Through you, Mr. President, yes.

THE CHAIR:

Senator McDonald.

SENATOR MCDONALD:

Thank you, Mr. President. Mr. President, I support this legislation. I actually wonder what the utility of the first sentence of Subsection B of the bill is because I believe that doctors are required to uphold a standard of care in the treatment of their patients, and why we would be giving them or legislating what doctors can or cannot do in legislation is somewhat questionable. I think the more important part of this legislation is the second

part of Subparagraph B, which would indicate that a doctor could not be disciplined solely for providing that medication to a patient.

So notwithstanding the fact that I may quibble with some of the language, I think the goals are laudable, and I certainly commend Senator Harris and the Public Health Committee for bringing it forward.

THE CHAIR:

Thank you, sir.

Will you remark further on House Bill 6200?

Senator McKinney.

SENATOR MCKINNEY:

Thank you, Mr. President. I rise in support of the legislation before us. Certainly want to thank Senator Harris and Senator Debicella, members of the Public Health Committee, countless numbers of our colleagues in the House, both sides of the aisle, who have worked on this. But most importantly Mr. President, I want to thank the many people in my district and across the state of Connecticut who have advocated for this who have and are still suffering with Lyme disease.

I think it was my first term when I met several people from Newtown, Connecticut, who had started the

Newtown Lyme Disease Task Force. There are sadly similar groups scattered throughout towns across the state of Connecticut because of the prevalence of Lyme disease in our communities. These are people who struggle every day with this disease, and moreover they struggle with the fact that many doctors and many in our society fail to understand just the serious problems that Lyme disease can cause them.

Senator McDonald's questions of Senator Harris, I think, are very appropriate because I sat through, and I think several other Legislators sat through, a lengthy disciplinary hearing where a doctor in Connecticut, a Lyme literate doctor, was disciplined, lost his ability to practice, was suspended, solely because he had administered long-term antibiotics to a child suffering from Lyme disease. That will no longer be allowed to happen.

I have also heard from constituents, doctors, people far smarter than I, who are concerned about the long-term use of antibiotics on any individual, whether it's for Lyme disease or other reasons. But the bottom line here, Mr. President, is this is an issue that people all across the state of Connecticut have been struggling with. It is something we have

struggled with as a Legislature for almost a decade on how to deal with this. I think we have reached a good resolution which will allow Lyme literate doctors to treat and care for patients as they see fit and will finally allow those people who are struggling and suffering with Lyme disease much relief.

So I want to thank Senator Harris and all those who've worked so hard on this. Thank you, Mr. President.

THE CHAIR:

Thank you, sir.

Will you remark further on House Bill 6200?

Senator Harris.

SENATOR HARRIS:

Thank you, Mr. President. If there's no objection, I move that this matter be placed on the Consent Calendar.

THE CHAIR:

The Senator has a motion on the floor to place this item on the Consent Calendar. Without objection, so ordered.

Mr. Clerk.

THE CLERK:

Calendar 607, File Number 635, House Bill 6576,

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SENATOR GAFFEY:

Mr. President, if there's no objection I'd ask that the bill be moved to the Consent Calendar.

THE CHAIR:

The Senator has requested that the bill be placed on the Consent Calendar. Seeing no objection, so ordered sir.

Senator Looney.

SENATOR LOONEY:

Thank you, Mr. President. Mr. President we had one item previously placed on the Consent Calendar that I would move now to remove from the Consent Calendar and to mark it pass temporarily. And that was Calendar page 8, Calendar 582, House Bill 5436.

THE CHAIR:

There's a motion on the floor to remove an item from the Consent Calendar and to PT it. Without objection, so ordered.

SENATOR LOONEY:

Yes, thank you Mr. President. Mr. President, if the Clerk might now call the items on the Consent Calendar.

THE CHAIR:

Mr. Clerk please call Consent Calendar Numero

Uno.

THE CLERK:

Immediate roll call has been ordered in the Senate on the Consent Calendar. Will all senators please return to the chamber. Immediate roll call has been ordered in the Senate on the Consent Calendar. Will all Senators please return to the chamber.

Mr. President the first Consent Calendar begins on Calendar page 1, Calendar 681, House Joint Resolution Number 121; Calendar page 4, Calendar Number 401, Substitute for House Bill 5669; Calendar page 5, Calendar 456, Substitute for House Bill 5019; Calendar page 7, Calendar 532, House Bill 6448; Calendar page 8, Calendar 8 -- correction, Calendar 580, Substitute for House Bill 6531; Calendar page 9, Calendar 597, Substitute for House Bill 6114; Calendar Number 600, House Bill 5635; Calendar page 10, Calendar 605, Substitute for House Bill 6200.

Calendar page 14, Calendar Number 644, House Bill 6391; Calendar 650, Substitute for House Bill 6540; Calendar page 16, Calendar 657, House Bill 6541; Calendar page 29, Calendar 330, Substitute for Senate Bill 954; and Calendar page 34, Calendar Number 504, Substitute for Senate Bill 939.

Mr. President that completes those items placed on the first Consent Calendar.

THE CHAIR:

Mr. Clerk, please call the Consent Calendar again, the machine will be open.

THE CLERK:

The Senate is now voting by roll call on the Consent Calendar. Will all senators please return to the chamber. The Senate is now voting by roll call on the Consent Calendar. Will all senators please return to the chamber.

THE CHAIR:

Have all senators voted? If all senators have voted please check your vote. The machine will be closed. The Clerk will call the tally.

THE CLERK:

Motion is on adoption of Consent Calendar Number 1.

Total Number Voting	36
Those voting Yea	36
Those voting Nay	0
Those absent and not voting	0

THE CHAIR:

Consent Calendar 1 passes.

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Total number voting	127
Necessary to pass	64
Those voting Yea	126
Those voting nay	1
Those absent and not voting	24

DEPUTY SPEAKER KIRKLEY-BEY:

The bill passes.

Will the Clerk please call calendar number 391.

THE CLERK:

On page 13, Calendar 391 substitute for House Bill number 6200, an act concerning the use of long-term antibiotics for the treatment of Lyme disease, favorable report of the Committee on Public Health.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Madam Speaker, I move for acceptance of the Joint Committee's favorable report and passage of the bill. The question before us is unaccepted so the Joint Committee's favorable report and passage of the bill. Will you remark further?

REP. RITTER (38th):

Yes I will, Madam Speaker. Madam Speaker, this bill allows a licensed physician to prescribe, administer, or dispense long-term antibiotic to a patient if the patient has a clinical diagnosis of Lyme disease or has symptoms consistent with a diagnosis and the physician correctly documents the diagnosis and treatment in the patient's medical record.

In addition, beginning July 1, 2009 this bill solely prevents the Department of Public Health from initiating any disciplinary action against a physician and the Connecticut Medical Examining Board from taking any disciplinary action solely because the physician has prescribed, administered, dispensed such therapy. The clinical diagnosis must be documented in the patient's record by the physician.

In addition Madam Speaker, this bill does not limit the ability of the Connecticut Medical Examining Board to take disciplinary action against physicians including entering into a consent order for violations of existing law concerning their practice of medicine. Madam Speaker, the Clerk is in possession of an amendment, LCO-6317. I would ask the Clerk to please call the amendment and I'd be granted leave of the

chamber to summarize.

DEPUTY SPEAKER KIRKLEY-BEY:

Will the Clerk please call LCO-6317 which will be designated House A.

THE CLERK:

LCO number 6317, House A, offered by Representative Ritter, et al.

DEPUTY SPEAKER KIRKLEY-BEY:

The Representative has asked leave to summarize. Is there any objections? Hearing none, please proceed, madam.

REP. RITTER (38th):

Thank you, Madam Speaker. Madam Speaker, this amendment makes a few technical changes to the bill as I originally discussed it. The amendment in -- and I would urge adoption.

DEPUTY SPEAKER KIRKLEY-BEY:

Question before us is on the adoption of House amendment A. Is there any discussion -- is there any discussion regarding House Amendment A? Representative Giegler you have the floor.

REP. GIEGLER (138th):

Thank you, Madam Chair. I too rise in support of the amendment before us. This -- this is a

culmination of a lot of effort on the part of the members of the Public Health Committee. During our Committee meeting there were some points that were brought out that really needed to be concerned. The Chairs promised to make those changes and this is the fruition of those changes that were requested so I urge my colleagues support of the amendment. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, madam. Will you remark -- will you remark further on the amendment that's before us? Representative Chapin you have the floor sir.

REP. CHAPIN (67th):

Thank you, Madam Speaker. Madam Speaker, I heard the Chairman of the Public Health Committee urge adoption. Did she move adoption?

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter, will you please move adoption.

REP. RITTER (38th):

Thank you, Madam Chair. I would move adoption of the amendment please. Thank you.

REP. CHAPIN (67th):

Thank you, Madam.

DEPUTY SPEAKER KIRKLEY-BEY:

The notion before us is on adoption.

REP. CHAPIN (67th):

Thank you, Madam Speaker. And through you a question to the Chair now. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter prepare yourself. Representative Chapin please frame your question.

REP. CHAPIN (67th):

Thank you, Madam Speaker. I had had a conversation with my local director of health who had had a conversation with the chief of infectious diseases at our local hospital and some concern had been expressed about the overuse of antibiotics and the impact that has on other infectious diseases and our ability to combat those. Does this amendment in any way address any concerns in regards to that? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you. Representative Chapin, the purpose of the bill is to very narrowly define this particular instance to be

that surrounding the clinical diagnosis of Lyme disease and the prescription of antibiotics for that specific diagnosis. It does not extend -- it does not discuss the use of a long-term antibiotic treatment for any other purpose.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Chapin.

REP. CHAPIN (67th):

Thank you, Madam Speaker. So, the new language that this amendment would insert in lines two through five in the amendment that more or less narrows the -- the focus of the use of antibiotics is my understanding of that correct? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you, yes that is correct.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Chapin.

REP. CHAPIN:

Thank you, Madam Speaker. And I thank the gentle lady for her answers.

DEPUTY SPEAKER KIRKLEY-BEY:

Will you remark -- will you remark further on House Amendment A? Representative Nicastro, you -- Will you remark further on House amendment A? If not, let me try your minds. All those in favor please indicate by saying aye.

REPRESENTATIVES:

Aye.

DEPUTY SPEAKER KIRKLEY-BEY:

Those opposed nay.

The ayes have it. The amendment is adopted. Will you remark further on the bill as amended? Representative Hetherington, you have the floor sir.

REP. HETHERINGTON (125th):

Thank you, Madam Speaker. If I may address several questions to the proponent.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter, prepare yourself. Representative Hetherington, please frame your question.

REP. HETHERINGTON (125th):

Thank you. Through you, Madam Speaker. Does this bill require a personal, physical examination of the patient before long-term use of antibiotics can be

prescribed? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Through you, Madam Speaker. A diagnosis must be made by the treating physician on the basis of knowledge obtained both by the medical history and a physical examination.

REP. HETHERINGTON (125th):

Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Hetherington.

REP. HETHERINGTON (125th):

Through you, Madam Speaker. Is there any ultimate limit on the length of treatment that can be utilized involving antibiotics? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Through you, Madam Speaker. The length and -- of duration of the treatment by antibiotics would indeed be under the purview of the physician -- the physician's base of knowledge and experience in

dealing not only with the patient and the disease but also the effects of treatment with antibiotics and those decisions would be made by the physician.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Hetherington.

REP. HETHERINGTON (125th):

Thank you. Sounds like a no to me. But through you, Madam Speaker is it -- I don't pretend to have a great deal of medical knowledge. I get most of my medical information from House but I -- it's seems to me at least from what I have read and understand that the unlimited extension of and -- of the application of antibiotics is generally contrary to the way of -- of the substantial way that medical opinion. Is that correct? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you. I'm not exactly sure I understood the question from Representative Hetherington. Could he be a little more clear.

REP. HETHERINGTON (125th):

Certainly. I apologize. Through you, Madam Speaker.

I believe the overwhelming way of published medical opinion is opposed to the unlimited application of antibiotics for any disease. Is that correct? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. No. Long-term antibiotic treatment is used in the treatment with -- of many diseases. Again, under the careful administration of the -- of the prescription by the patient's physician. Diseases for example such as tuberculosis, endocarditis, sickle cell anemia, various other uses of a long-term treatment of antibiotics.

REP. HETHERINGTON (125th):

Thank you. Through you, Madam Speaker. Does this bill contemplate the application of antibiotics both by intravenous means and also by oral means? Through you, Madam Speaker. Or other possible means? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you. It is my understanding that it could include both of those.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Hetherington.

REP. HETHERINGTON (125th):

Thank you. Do you know, through you, Madam Speaker, does our State Medical Association have a position on this bill? Through you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you. Yes, I do, Representative Hetherington. And as Representative Giegler pointed out in her statements, this bill is the result of a lot of work in -- collaborative work between the Connecticut Medical Society, the Department of Health, Advocates for Lyme Victims, and legislators. And it is my understanding the medical society is in very strong support.

REP. HETHERINGTON (125th):

I see. Well I thank the gentle lady and I thank these people.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you. Representative Sawyer, you have the

floor. Representative Nicastro, you have the floor.

REP. NICASTRO (79th):

Good afternoon, Madam Speaker. I rise in strong support of this bill. Madam Speaker for all too long people who suffer with this illness have -- have looked for help. I have several constituents who live in my district who have been diagnosed with Lyme disease and if -- I can't tell you the amount of phones calls, emails that I've received from them over the years asking and begging for help to fight this disease. And that's what it is. And this is a major step forward to help these people.

I've seen a mother and her children all diagnosed with Lyme disease and in the past as you all know if a doctor tried to do something about it, that doctor could be brought up on charges. This bill eliminates it. This bill goes a long way in helping people who have this disease and I think it's a -- something that we should jump on. And we have the chance to do it today. Madam Speaker, and I would strongly recommend passage of this bill as quick as we can get it done. It's a step in the right direction. It's not a perfect cure-all but I think to the people who suffer out there they'll see that we care and that we

have concerns about them. Thank you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you. Representative Bartlett, you have the floor.

REP. BARTLETT (2nd):

Thank you, Madam Speaker. I just wanted to first acknowledge a question by Representative Hetherington and make sure that Representative Hetherington knows that the use of long-term antibiotics is used on a number of diseases such as tuberculosis, Q fever, endocarditis, sickle cell anemia, and quite frankly acne. Oftentimes one -- a patient would need the use of long-term antibiotics. So I just wanted to address that if there were any concerns. Madam Speaker, a couple of questions for the -- for Representative Ritter.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter, please prepare yourself for questioning. Representative Bartlett, please proceed.

REP. BARTLETT (2nd):

For purposes of legislative intent, Representative Ritter testing for Lyme disease is unreliable and it's difficult to diagnose because

there's a broad variety of symptoms that vary from person to person. When these disease symptoms persist they can come and go and due to the difficulty in diagnosis treatment is often delayed requiring longer term antibiotic therapy to eliminate the infection or control a patient's sometimes life-altering symptoms.

Clinical diagnosis and physician discretion is the basis of House Bill 6200, as there is currently no commercially viable or available gold standard test for the diagnosis of Lyme disease. Therefore testing for Lyme disease is unreliable. Representative Ritter, could you please clarify what this means -- what this bill means by clinical diagnosis.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you and I believe we spoke to this point already. A diagnosis made by the treating physician on the basis of knowledge obtained by the medical history and physical examination of the patient.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Bartlett.

REP. BARTLETT (2nd):

Thank you, Representative Ritter for indulging me. Just wanted to make sure that we're clear. Upon passage of the bill physicians will no longer be fearful to treat chronic Lyme disease of potential reprimands from the medical boards, will have the right to choose the best treatment protocol they feel is necessary to follow based on their medical judgment and clinical experience, and that guidelines will not dictate how Connecticut physicians may practice.

This legislation will convey the message to all practitioners that they can now treat how they feel it is best and the possible outcomes for their -- for their patients. I began working on Lyme disease when I was first a freshman and we worked on medical reporting and we have now involved into trying to guarantee medical access for patients across the State of Connecticut because so many are having to leave our state and go to neighboring states to receive -- to receive medical care. And unfortunately the State of Connecticut right now -- the -- the two sets of guidelines that exist for this particular disease, there is a chill effect in that some are afraid that if they stick with the first set of medical guidelines which is the IDSA guidelines which only says you can

have 28 days of antibiotic treatment, that they will be brought up on charges. Many Lyme literate physicians believe in such a thing as chronic Lyme disease which means that you could be bit by a tick and have it in your body for a long period of time and then have the symptoms show themselves later on. It could be a year, it could be two. And in such cases many physicians believe that you need longer term treatment and that's really what the debate has been about coming into this point and time in the chamber.

And so I encourage all of my colleagues to support 6200 to guarantee access to physicians, to guarantee that we have more physicians who are willing to treat and this is quite a debilitating disease and I really appreciate everyone's support. Thank you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, sir. Representative Sayers and I do apologize. Representative Sayers you have the floor, ma'am.

REP. SAYERS (60th):

Thank you, Madam Speaker. Representative Sawyer and I frequently have that problem. Through you, Madam Speaker, a question to the proponent of the

bill.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter, prepare yourself. Representative Sayers, please proceed.

REP. SAYERS (60th):

Thank you. Has the Department of Public Health initiated any disciplinary action against any physician in this state for prescribing long-term antibiotics for the diagnosis of Lyme disease?

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Chair. And through you, Madam Chair, in most recent years I am not aware of any. In previous years there have been several.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Sayers.

REP. SAYERS (60th):

Thank you, Madam Speaker. And could you tell me was that just for the prescription of long-term antibiotics for Lyme Disease because I'm not aware of any official cases that have become -- come before the Department of Public Health.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Chair. Representative Sayers, I know that of the cases there have been several and it's my understanding that in at least one of those cases it was definitely not strictly for the prescription of long-term antibiotics that we had this issue with the Department of Public Health.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Sayers.

REP. SAYERS: (60th):

Thank you, Madam Speaker. While the prescription of long-term antibiotics for the diagnosis of Lyme disease is controversial at best and many of the best physicians of infectious diseases disagree on what should be done and what should be the standard treatment for Lyme disease. For the most part there hasn't really been a lot of disciplinary actions or reprimands in the State of Connecticut because of that.

Many times these cases were brought before the Department of Public Health because the physician in question did not meet other standards of prescribing the medications such as prescribing for a child who is

in another state and the physician had never even seen that child in order to make a proper diagnosis of the child. So I think we still have to be careful.

We know that the effects of long-term antibiotic therapy are always questionable and have created many of the problems that we have to deal with today such as a new and very, very low strain of tuberculosis when we had eradicated tuberculosis altogether. So I just would really urge that as we go forward that there still be some caution in terms of this type of long-term prescribing. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, madam. Representative Scribner, you have the floor.

REP. SCRIBNER (107th):

Thank you, Madam Speaker. I rise in support of House Bill 6200 as a member of the Public Health Committee and want to applaud the Chairs and ranking members and all the other members who are bringing this before us today. And -- and I might say that I would associate some of the concerns and comments of Representative Bartlett, perhaps for the first time -- it is -- it is an issue of very concern and I think a lot of lack of knowledge and confusion out there.

I've been lucky enough to work with a regional task force that's been established in -- in our area of the state who have been diligent about sharing information -- factual information with great accuracy. And -- and it's been very beneficial to the people that we serve because the symptoms of Lyme disease are not always readily apparent and they are often over-looked and misdiagnosed.

I come from personal experience having suffered with Lyme disease myself and in addition to that two of my children have had it; one of them twice. In addition to that our family dog had Lyme disease. And I would tell you I was one of the lucky ones because I was quickly diagnosed because I had that very commonly known target that allowed me to almost self-diagnose and then be treated very quickly.

When my daughter was three years old she was diagnosed with strep and put on a -- a very nominal dose of antibiotic. It was not sufficient to eliminate the Lyme disease that she had contracted so several weeks went by and a horrific experience for a parent to have a three year old child who is normally very astute and very energetic and responsive having been on an antibiotic you have this false sense of

comfort and then all of a sudden she would be sleeping for up to 13 hours at night and she would come out in the morning and fall asleep on the floor an hour later. We were petrified. And so at our insistence we had further testing done. She had to be put on additional antibiotics and typically they will do higher dosage in the beginning of the treatment. I would not have ever wanted her physician to not have discretion to give her that longer term of dose of antibiotics that really got her through that infliction. And -- and so I think it is well thought out. It is not reactionary. We have witnessed many people who have suffered long-term unnecessarily because of the misdiagnosis and perhaps not getting enough antibiotic up front or for the long-term as needed. So I strongly urge all in the chamber to consider supporting this measure which I think is a very responsible measure for passage and for the benefits of all of our constituents. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, Representative. Representative Fawcett you have the floor.

REP. FAWCETT (133rd):

Thank you, Madam Speaker. I also rise in support of House Bill 6200 as amended. One thing I've learned in my three short years of working in this chamber is that nothing good like this occurs without many, many people's input. I just want to extend my sincerest thanks to speaker Donovan, and our majority leader, the co-introducers, and the co-sponsors which there are more than 70, both republican and democratic co-sponsors, also the co-chairs, Representative Ritter and Senator Harris who have gone above and beyond in their first session as our Health Committee Chairs to engage an issue that is difficult and complex. And I commend you and thank you, Representative Ritter for your leadership. I also thank the Department of Public Health and Karen Buckley-Bates who is sitting here with us.

Thank you for working patiently with us through this process. I also extend that thanks to the State Medical Society and all of the activists and advocates out there watching today. We thank you for your testimonies and for sharing your stories. The hundreds and hundreds of emails I received of people impacted by this disease was just overwhelming.

A year ago I can tell you that I thought Lyme

disease was something that started in Lyme, Connecticut and that a lot of people got from a tick bite. I had no idea what last July was going to present to me when my husband was diagnosed with a life-threatening case of Lyme disease. As we go through the process now ten months later he's still struggling to find treatment for this disease. But as I've gone through the process with him I've asked a lot of questions and learned a lot about this very complex disease and the -- the controversy that exists in our own medical community because they can't come to an agreement on how to best diagnose and how to best treat this disease. House Bill 6200 has Connecticut join New Jersey, New York, Rhode Island, and California in saying that we recognize there's controversy in diagnosing and treating this disease.

But let's let our doctors make the decision. Let's give our doctors the freedom and the autonomy to diagnose their patients even if they must diagnose clinically and not always with blood tests -- blood tests. And let's give our doctors -- let's empower our doctors to treat this disease the way they see fit.

And I am so proud to be joining with an

organization in Connecticut called the Turn the Corner Foundation, such an appropriate name today because the Turn the Corner Foundation is working in Connecticut to educate you and I on the impacts of disease -- of Lyme disease, on joining the fight to prevent, and diagnose, and treat Lyme disease. And it's such an appropriate name because today as we pass this legislation and send it to the Senate and look forward to the Governor signing it, we are leading the way and turning the corner on fighting disease. And I thank you so, so very much for your support.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you for those eloquent words. Representative Lyddy, you have the floor, sir.

REP. LYDDY (106th):

Thank you, Madam Speaker. Madam Speaker, I rise in strong support of this legislation as well. I believe that Connecticut's residents both young and old share the commitment and vision of raising healthy children and families. Unfortunately throughout the years especially with this particular disease there have been barriers to developing that backbone that provides the ability for our children and our families to access adequate healthcare regarding this issue.

As a social worker and as a representative, I'm charged with the great responsibility of speaking and fighting for the people who can't fight for themselves or speak for themselves and in this case access adequate healthcare.

So it's an honor to be supporting this bill today and I urge the adoption with the rest of the chamber. Lyme disease and other tick-born diseases have severely impacted communities around the country but more specifically right here in Connecticut including my hometown of Newtown. This bill works to protect the doctor and patient relationship and I'd suggest and argue that that relationship is seriously protecting the basic safety net that allows our children, our adults, and our growing retirement population to access affordable and adequate healthcare around this issue. So again I'd thank the proponents of this bill, the Chairs, and everybody else involved and urge adoption. Thank you so much, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, Representative. Representative Miner, you have the floor.

REP. MINER (66th):

Thank you, Madam. If I might a question through you to a proponent of the bill please.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter, prepare yourself for questioning. Representative Miner go right ahead, sir.

REP. MINER (66th):

Thank you. Thank you, Madam Speaker. Madam Speaker, through you, I like everyone else here in the chamber have a number of constituents who have spoken to me over the years about Lyme disease and the treatment of Lyme disease and in a couple of instance there have been prescriptions of long-term antibiotic treatment that seemed to have had side effects, that there have been other health problems that have resulted possibly through that prescription of long-term intravenous antibiotic treatment.

Is there anything in this bill, if it was determined by someone that perhaps that treatment went on too long that would restrict the Department of Public Health's ability to begin a disciplinary action against a physician if that was in fact the case, through you?

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you, Madam Speaker. The language in the bill speaks solely for the support of a diagnosis of Lyme disease and solely for the purpose of treating those symptoms that have been so diagnosed. So to the extent that something happen outside of that the answer would be yes.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Miner.

REP. MINER (66th):

Thank you, Madam Speaker. No, I'm actually referring to the diagnosis being exactly that and the treatment being exactly long-term treatment through intravenous antibiotic therapy. That it is conceivable and it has been my experience that there have been people who have had some pretty serious digestive side effects as a result of that and in those cases of -- if the Department of Public Health felt that the treatment had gone on too long is it possible with the passage of this that it could still bring an action against the physician, through you?

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. Through you, Madam Speaker. There is nothing in the provisions of this bill that would not prevent such complaints to the Department of Public Health.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Miner.

REP. MINER (66th):

Thank you, Madam Speaker. And once that complaint was initiated is it -- as a result of this legislation, would there -- is it possible that disciplinary action could occur if it was determined that that treatment had gone on too long, through you?

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Thank you, Madam Speaker. The answer to that question is no, provided that the antibiotic is being properly used as a preventative for the symptoms that the patient is presenting.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Miner.

REP. MINER (66th):

Thank you, Madam Speaker. So in that answer, it is conceivable that if there was -- if it was

determined that the treatment went on too long or if the individual felt that there were inappropriate side effects as a part of that treatment they could make a complaint and there could be a cause of action in terms of disciplinary action even in light of this bill if it was solely for the purpose of Lyme disease with long-term therapy.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Say that again. Yeah. Thank you, Madam Speaker. And through you Madam Speaker that would be solely through the -- the evaluation process again with the examination of the effect of the antibiotic and how it's operating on the symptoms in the patient.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Miner.

REP. MINER (66th):

The yes is a hard word to find, Madam Speaker, but I'm -- I'm gathering that that's what that answer is. Is that -- that if everything was as we thought it should have worked and the treatment for whatever reason went on too long, someone still could make a complaint and there still could be a disciplinary

action. But what this does is puts in place a process where just the mere prescription of long-term isn't the threat that some physicians feel they've been operating under over years. And I do thank the gentle lady for her work and her comments. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Ritter.

REP. RITTER (38th):

Was that a question? I apologize.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Dargan, you have the floor.

REP. DARGAN (115th):

Thank you, Madam Speaker. I rise in strong support of the bill. There's been a number of personal stories that have been shared here today. And as they're called the Lymers, this is a small step for them today. My personal story is about my sister who after about 30 doctors was so misdiagnosed and when she was finally diagnosed after four tests for Lyme disease, she ended up with encephalitis of the brain. Every two weeks we travel down the Merritt, get off in Greenwich and go to New York so she can be protected with that antibody.

For us as a state to send people out of the state

for a disease that has been so misunderstood not only by elected officials but by the medical community and for insurance carriers to tell medical doctors what they need to do is wrong. During that time -- we're not sure where she was inflicted either in Guilford or in Block Island, it tore the family apart because we as a family did not know what was wrong with her.

And over those years now, I've been able to get educated on this disease. And the stories that have been shared here today by other legislators, by their immediate families, by constituents that we represent, the Lymers, this is a step in the right direction. But we as a legislative body have to go much further to understand this horrible disease. Thank you.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, Representative. Representative Sawyer, you have the floor.

REP. SAWYER (55th):

Thank you, Madam Speaker. One of the things that I believe when we look at this particular bill it does is talk about medical freedom. The freedom to be able -- for the doctor to be able to make the choice that he was trained to make. So I'll be supporting this and -- and I thank all the proponents for all the work

that they did. Thank you, Madam Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you. Representative Hornish, you have the floor.

REP. HORNISH (62nd):

Thank you, Ms. Speaker. I stand in strong support of this bill and I'd like to briefly share my story as someone who was misdiagnosed for about one year with Lyme disease. And like many people, my symptoms weren't classic which is why I wasn't prescribed antibiotics immediately. And it wasn't until later on, my initial test was also negative. And that's a common problem with this disease it's not -- not a very good lab test. When I was retested about eight months later, I -- that was only after I persisted with the doctor to be -- to be retested after my joints -- I had gotten to the point where my joints started swelling.

And -- and I, you know and I do respect the fact -- I understand the issue of overprescription of antibiotics but I think we really need to focus -- I agree with Representative Sawyer in that we need to give physicians the liberty to practice medicine, the freedom. They know. They're trained. And they need

to make that decision. I'm around ticks all the time.

I live in the woods and I'm in the woods. And I think my physician would have made a different -- might have been more apt to prescribe antibiotics to me early if he could have. So I stand in strong support of this bill. Thank you, Ms. Speaker.

DEPUTY SPEAKER KIRKLEY-BEY:

Thank you, Representative. Will you remark? Will you remark further on the bill that is before us? If not, staff and guests please come to the well.

THE CLERK:

The House of Representatives is voting by roll call. Members to the chamber. The House is voting by roll call. Members to the chamber please.

DEPUTY SPEAKER KIRKLEY-BEY:

Have all members voted? Please check the board to see that your vote's been properly cast. The machine will be locked and the Clerk will prepare the tally. The Clerk will please announce the tally.

THE CLERK:

House Bill number 6200, as amended by House A.

Total number voting	137
Necessary to pass	69
Those voting Yea	137

Those voting nay 0

Those absent and not voting 14

DEPUTY SPEAKER KIRKLEY-BEY:

The bill as amended passed.

Will the Clerk please call calendar 112.

THE CLERK:

On page number 2, Calendar 112, substitute for House Bill number 6302, an act concerning revisions to the utility statute, favorable report of the Committee on Energy and Technology.

DEPUTY SPEAKER KIRKLEY-BEY:

Representative Nardello, you have the floor, ma'am.

REP. NARDELLO (89th):

Good afternoon, Madam Speaker. It's wonderful to see you there. I move acceptance of the Joint Committee's favorable report in passage of the bill.

DEPUTY SPEAKER KIRKLEY-BEY:

The motion report is on the acceptance of the Joint's Committee favorable report in passage of the bill. Will you remark further?

REP. NARDELLO (89th):

Madam Speaker, the Clerk has an amendment, LCL-5538. Will the Clerk please call the amendment and may I be

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what you're saying, Tim -- and thank you for coming and expressing these concerns, because we all want to make this something that's practical and doesn't overburden business unnecessarily -- that you're saying that just by giving access to the public then the ADA just comes into play, is that what you're --

TIMOTHY G. PHELAN: That's what I understand, Senator, yes.

SENATOR HARRIS: Okay. If we can just get clarification on that through you and our attorneys and everyone else, then we can try to figure that out. Thank you.

TIMOTHY G. PHELAN: Sure.

REP. RITTER: Any further questions?

Thank you, Mr. Phelan. As you can see, there's a lot of interest in getting that information.

TIMOTHY G. PHELAN: Yes. Yes. I got that.

REP. RITTER: Thank you very much.

TIMOTHY G.PHELAN: Thank you.

REP. RITTER: Next we have Representative Fawcett together with Representative Reeves.

REP. FAWCETT: Representative Ritter, Senator Harris, and members of the Public Health Committee, I thank you for this opportunity to speak before you today, and for your willingness to hear testimony on HB 6200. I'm joined by 12 additional co introducers and a mounting number of cosponsors to bring this bill before your committee for consideration.

The goal of this legislation is simple, protect doctors who treat Lyme Disease and by -- by doing that, improve patient care and expand options and flexibility in treatment and, yet, this bill is not without controversy. Really how to diagnose and how to treat are at the crux of the conflict in the testimony you will hear today. It is those two questions that are also central to the long-standing controversy in this state, even occurring all over the country when we talk about Lyme Disease.

Every major disease makes advances in how we both diagnose and treat the various conditions. Doctors get smarter by experiencing results from sometimes alternative types of treatment and, ultimately, because of that, patient care gets better. I am completely baffled by how over the nearly 30 years that we've known about and been treating and identifying Lyme Disease, the evolution of care, of patient care, has not similarly occurred.

Now you may hear today about guidelines used for diagnosis and treatment, or about the constantly ongoing and hotly contested controversy over how these guidelines have been written. No one in this room will deny that guidelines are not helpful, but they are guidelines intended to guide doctors treating a complex disease with numerous and diverse symptoms. Common sense would dictate that along with the assistance of guidelines, the art of being a doctor must kick in, and practical knowledge and ability to diagnose a patient clinically become paramount.

For too many patients -- far too many patients have experienced the frightening impact of Lyme Disease, and I would even argue it's life

threateningly irresponsible to not allow doctors to look outside the guidelines to diagnose. Those in opposition will also talk about long-term antibiotic care, and say it's not necessary or even dangerous to patient health. No reasonable patient or doctor wants to prescribe long-term antibiotics. But once again, we have made strides in understanding this disease. Attending doctors and patients have seen results with longer than -- with the longer than recommended 14 to 28 days of treatment.

My own husband required about four months of intensive antibiotic therapy to -- to recover. Today we're asking you to consider supporting this bill because it's an important opportunity to answer the call of thousands and thousands of patients that suffer from this disease each year. It is a bill that simply tells the Department of Public Health, medical practitioners, and Lyme patients that it's okay to diagnose and prescribe treatment while recognizing that each individual patient is experiencing unique symptoms and sometimes requires unique courses of care.

REP. REEVES: Thank you, Representative Ritter, Senator Harris and members of the Public Health Committee. I am the State Representative of the 143rd District representing Wilton and Norwalk.

As you are aware, Lyme Disease got its name from Lyme, Connecticut where arthritis-like symptoms were noted in a cluster of cases among children and adults back in the 1970s, but it could as well be called Wilton Disease or Norwalk Disease or Ridgefield Disease because it is as close to an epidemic among my constituents as I have seen. Whether I am at the local hardware store, whether I am in the

market or a town hall, the topic of discussion is always Lyme Disease, who has it, who's treating you, how are you feeling. If it's a child, how much school have you lost, how much of your college years have you lost because of this insidious disease. And Lyme Disease has not only affected my constituents, but I am here because it has affected every member of my own family, including the family dog. My husband has suffered from chronic Lyme Disease since 1994. He suffers from severe joint and muscular pain in his shoulders, neck, elbows and hands, as well as feverish feelings, night sweats, various neurological manifestation's including anxiety, fatigue, distress and irritability.

His symptoms, because of the fact of these guidelines were very strict in force, and because doctors back in the nineties didn't understand Lyme Disease, his symptoms were misdiagnosed. And because of the misdiagnosis, he underwent painful cortisone shots and finally intensive elbow surgery at Beth Israel Hospital in New York City where a team of surgeons cut and reattached the tendons in both his elbows believing that he had a sports injury.

He has taken lengthy courses of antibiotics over the last 12 years, and although the symptoms never completely go away, these periodic treatments of antibiotics have clearly helped to achieve several lengthy periods of remission. In this regard, the disease often acts like Malaria, and it is often treated with an anti-Malarial drug. My daughter was first diagnosed with Lyme Disease in the early 1990s when she was in second grade. She is now 24 and still suffers with joint and muscle pain, fatigue and neurological symptoms. Like my husband, she

has also been on and off antibiotics. I never wanted her on antibiotics for an extended period of time. I'm aware of the issues with the overuse of antibiotics, but the alternative would have been a reduced quality of life for an active young woman who was captain of her high school cross country team and was the Connecticut scholar athlete of the year.

Other people testifying today will say that there is no such thing as chronic Lyme, that it is some other named or unnamed disease, or they will say that most of these people never had a tick bite or their doctors just invented the diagnosis for want of anything else. In my case, I can say that my husband and my daughter have had on numerous occasions embedded and engorged dear tick. My daughter has also had the classic bulls-eye rash. My husband never did. This proposed bill does not seek to change our insurance laws. We have an excellent statute in place that covers medical costs associated with a diagnosis of Lyme. What we are seeking to do is protect the doctor/patient relationship. We do not believe that public agencies should use their regulatory and licensing powers to punish those doctors who are only seeking the best course of treatment for their patients.

Thank you.

REP. RITTER: Thank you very much.

Are there any questions from the committee for the Representatives?

Senator Debicella.

SENATOR DEBICELLA: Thank you, Representatives, for bringing this forward. Reading the language

of the bill, it seems like a very rational proposal, but my question is what's different from today, and this is just not my understanding of it, it sounds like you're basically saying that a doctor who will be able to diagnose and treat with a variety of antibiotics. Are they restricted today in how they can treat Lyme Disease, and if so, how?

REP. FAWCETT: Yeah. I think that's exactly what we're trying to get at is there is a recommendation in the guidelines that says that 14 to 28 days is sufficient, even completely all that's necessary, and because there's -- and again, a lot of political controversy about these guidelines, but the long and the short of it is that over time they have become more than guidelines, they have become almost set regulation or law, and because of that, doctors feel very worried about treating outside the guidelines.

If they do, there is a tendency to hear from the Department of Public Health that there's word on the street that they are too aggressively treating Lyme Disease, and so as soon as they too often diagnose, too often treat, what has occurred on several -- several times is that the doctors have felt the pressure from the Department of Public Health that possibly their license would be threatened. And so as this over the past ten years, in particular, this has permeated the medical community, what has really occurred is just a long, far reaching feeling among the medical community to just avoid these patients. Doctors really don't want to diagnose Lyme Disease. They don't want to be caught up in the middle of the controversy. They don't want to treat it because they know they can't cure it in less than 28 days a lot of times, so they deflect the patient. So

what you have is patients in Connecticut that can't find doctors that will help them. And it's not that the doctors don't want to, it's that the doctors are just frustrated with the political controversy and unable to get around it.

REP. REEVES: If I could just add something to that, sorry. My own husband now sees a doctor in New York City, as does my daughter, and I have constituents in town who actually travel up to Poughkeepsie, New York, in order to get treated.

SENATOR DEBICELLA: Got it. Great, thank you both. And thank you, Madam Chairman.

REP. RITTER: Further questions?

Representative Lyddy.

REP. LYDDY: Thank you, Representatives, for your testimony. This is a very difficult issue to speak about, and coming from Newtown this has been a huge issue, not only most recently, but for the past ten years. What's really frustrating is this deflection that you talk about of patients from doctors. And I'm wondering if you feel comfortable talking about your experiences, if you've had that experience, if you're hearing from your constituents about them being deflected and what some of those reasons are, if you can expand on that? I know you just commented a little bit about that, but if you can expand on that a little more?

REP. REEVES: Yes, I would just say that, you know, in the beginning what happens to the constituents that I've talked to and also in my own family, is that, again, you go to your local internist or your local pediatrician,

and they don't know how to treat it beyond what they sort of read in the guidelines or what they've been told in medical school, and so what happens is you get so frustrated that you then keep seeking specialists and it just becomes a very difficult, long evolving process.

If you could get on antibiotics right away, I mean, it seems clear that if you find a tick bite right away and you can get on it right away, in fact, you have a much better outcome than when the opposite happens. And so when you're going from physician to physician, and you'll hear from people today, that when they go from physician to physician, all that adds to a delay of time and a delay in getting on the proper treatment, and so that's what we seek to avoid with this bill.

REP. FAWCETT: I'll just add my story real quick with it. My husband was diagnosed last July, and it took about between four and five months for him to recover from the disease, and in that time we had to seek treatment from three different doctors. So each time he had a 28-day course of antibiotics, the doctor said, okay, done with that, you're cured. And then within a week of being off the antibiotics he would get violently sick again, and be on the verge of having to go back into the hospital which is where he started and was diagnosed, and we would be deflected. The doctor would sort of say, Oh, well, I don't know what's going on, so you need to get to a specialist. And as we went through this process, found that it is incredibly hard in Connecticut to find doctors that are willing to treat Lyme patients if you go past that 14- to 28-day threshold. It suddenly becomes incredibly hard to find someone to help you.

of us. And thank you for coming up here, traveling all the way from Danbury and Newtown to do so. I know you're missing work and, you know, that's really appreciated, and doesn't go unnoticed by the committee.

So please, you've already helped your daughters and people struggling with Crohn's disease across the state, helping just educate us all more about what these folks go through, you've already done that already. So please be proud of your advocacy. We appreciate it. Thank you.

REP. RITTER: Any other questions from the committee?

And thank you, I want to echo the sentiments of Representative Taborsak, you're wonderful advocates for your daughters.

REP. RITTER: Next I'd like to see if Representative Linda Orange is present or Representative Mary Mushinsky.

We'll go to our last official, that is Rudy Marconi.

HB6200
HB6262

RUDY MARCONI: Good afternoon. Representative Ritter, Senator Harris, thank you very much, and the rest of the committee, thank you for this opportunity to testify, what I hope would be the morning but it's the afternoon, but nonetheless, I am appreciative.

The residents of Ridgefield who I represent are acutely aware that the controversy surrounding Lyme Disease diagnosis -- diagnoses and treatment put them at risk. I feel confident in saying that most of our citizens know a friend, a neighbor, or family member who has been severely affected by

tick-borne illnesses. We are talking about individuals who have lost their ability to work, children who are out of school and seniors who can no longer live alone. Some are diagnosed late, others appear not to have recovered despite treatment. The reasons why they are unable to resume a normal life are still a mystery to medical science. What is clear, to the average Connecticut resident, is that many people know -- they know are being severely affected by an illness that is supposedly easy to detect and easy to cure.

Ridgefield has taken many measures to ensure the safety of its citizens in regard to tick-borne diseases over the past six years. Frankly, I believe we have done everything a community can do, including forming a task force to address the problem, coordinating prevention seminars, sponsoring a support group by our -- through our local VNA, and developing the blast health promotion effort to facilitate prevention, education, and early symptom awareness through Fairfield County. We have taken tick-borne diseases seriously, and still our residents are suffering. Some drive long distances to find specialists, deplete their savings, and lose jobs and homes in the process of trying to regain their health.

During my tenure as first selectman in Ridgefield, I've had many opportunities to work with our local hospital and physicians in collaborative health promotion and fund-raising efforts. At present, I am actively involved in trying to resolve community concerns regarding the level of care patients afflicted with tick-borne diseases are receiving. The recent information of a ten-town HVCEO Lyme Disease Task Force is a step in the right direction. I encourage our

Department of Public Health to place a priority on tick-borne disease research and prevention. I ask our Governor's support statewide efforts to eradicate tick-borne diseases, and today, I am asking our Public Health Committee to recognize the rights of patients to be informed that multiple standards of care exist and choices are available in Lyme Disease treatment.

That said, I believe it is imperative that doctors be allowed to make decisions based on their best judgment and years of clinical experience. It is not in the best interest of Connecticut residents for physicians to be hindered by guidelines or the fear of recrimination.

Thank you.

I would also like, if I -- if you would allow, for me to comment on Bill 6262. I did not submit written testimony, but I would like a minute just to speak against the bill.

REP. RITTER: Certainly.

RUDY MARCONI: Thank you very much Madam Chair.

Bill 6262, which involves the regionalization of the RACs, from a first selectman municipal perspective, is the wrong direction to take. We work very closely, and I have worked for ten years now in Ridgefield, in trying to bring awareness in many programs to help address substance abuse, beginning in the fifth grade, addressing fifth grade parents. We've developed a program.

It is a very serious issue, and I think to consolidate to reduce the number of RACs in our state is heading in the wrong direction.

REP. RITTER: Okay.

REP. BARTLETT: Would you like to comment?

WILLIAM HANDELMAN: We're testifying on 6310.

REP. RITTER: Right. We're at 6310 right now, so --

REP. BARTLETT: Oh, okay. So we don't -- okay. I'm new to this committee, so I actually when I have questions on each one. Okay.

REP. RITTER: It might be easier to wait until we get the testimony.

REP. BARTLETT: Okay. I'm sorry. I apologize.

REP. RITTER: No problem. Thank you.

Are there any other questions from the committee?

If not thank you very much for your testimony.

WILLIAM HANDELMAN: Thank you.

REP. RITTER: And our next speaker on our next bill which is 6200, let me just -- an Act Concerning the Use of Long Term Antibiotics for the Treatment of Lyme Disease.

And our speaker is Margaret Smith, to be followed by Maggie Shaw.

MARGARET P. SMITH: Good afternoon, Madam Chair, Senator Harris, and members of the Public Health Committee.

My name is Maggie Smith. I am 17 years old, and I live in Lyme, Connecticut. I'm here in

support of physicians being able to clinically diagnose and treat chronic Lyme Disease with long-term treatment as needed.

I was officially diagnosed with Lyme in 2005, but one of my Lyme doctors told me that it was probable that I was born with it. Prior -- prior to a positive diagnosis, I had been to numerous physicians with various specialties who were willing to treat my symptoms but would not address the issue of Lyme itself. Not satisfied with this, my family took me to a Lyme literate doctor out of state. She was astounded that I had not been treated for Lyme, considering how sick I was.

The doctor put me on an antibiotic schedule for the next year. Within weeks, there was great improvement. Unfortunately my doctor was forced to stop treating patients for Lyme, and once my antibiotics ran out, I became ill.

Once again, my family and I had to start looking for a doctor who would be willing to treat me for Lyme. It had been difficult, and I started to lose hope when I was diagnosed with complex partial seizures, and the neurologist claimed that there was no possible way that it was related to Lyme. The medicine he put me on just made me sicker.

I turn 18 next Thursday, and I've been sick most of my life, and most of these doctors have told me I just have to get used to it. I don't understand why it is so difficult. When I am on antibiotics I feel better, and when I am off, I can barely function. When I'm on the medicine I need, I can stay in school. When I am not on it, each day becomes a struggle. I miss an average 30 days a year for the last three years. I believe we need to protect those doctors who are familiar with

the disease, enough to realize that long-term antibiotics are required.

Thank you for your attention to this matter.

REP. RITTER: Thank you very much for your testimony.

Are there any questions from the committee?

I want to thank you for sitting with us through a long day.

MARGARET P. SMITH: Thank you.

REP. RITTER: Our next speaker will be Maggie Shaw and she will be followed by Pat Smith.

MAGGIE SHAW: Good afternoon, Chairman Ritter and Chairman Harris. My name is Maggie Shaw, and I'm with the Newtown Lyme Disease Task Force.

I support the concept of physician protection to diagnose and treat all stages of Lyme Disease clinically protecting the principals of medical ethics of autonomy and informed consent. The Connecticut Department of Public Health sent to me an executive summary of the infectious diseases Society of America guidelines to inform me on how my children should be treated. Opinion within the medical community is deeply divided regarding the best approach for treating Lyme Disease. This split has resulted in the development of two standards of care.

The International Lyme and Associated Diseases Society formulated by physicians. Physicians who see and treat Lyme and tick-borne diseases on a daily basis. These guidelines address treatment which persists beyond a short course of antibiotic treatment, and allow physicians

to exercise clinical judgment. I think we've heard a lot of that today.

The IDSA formulated primarily by academic researchers and physicians address only short-term treatment for Lyme, usually less than 30 days. The IDSA guidelines replace the long-standing policy of allowing physicians to make decisions based on clinical judgment and how to diagnosis and treat Lyme Disease.

Connecticut Public Health Commissioner Galvin stated in a public hearing 2004, that the Connecticut Department of Public Health would not initiate cases against physicians who treat Lyme Disease, and they have no rules about the length of antibiotic treatment. The IDSA guidelines are obliviously not addressing this exploding epidemic rather, they are being used by the Connecticut DPH medical licensing board to curtail treatment threatening doctors who step out of line.

The combination of limited options and the overzealous enforcement of restrictive rules, has managed to instill fear in our local doctors. The practice is severely limiting treatment options for Connecticut families and causing great suffering. Fewer physicians will consider treating Lyme Disease for fear of being charged of malpractice by the Connecticut Department of Public Health. This is especially true with pediatricians and our children here in Connecticut. They run the greatest risk of infection.

Newtown research study shows by the University of New Haven that in Newtown our ticks are 70% infected with Lyme Disease. After finally receiving a diagnosis for my three children who had been sick for years, and my request to address my pediatrician, I was asked to leave

the practice and find another doctor.

HB 62 is an important step towards protecting our doctors ability to use their own clinical judgment for the treatment of Lyme.

Thank you very much.

REP. RITTER: Thank you for your testimony.

Are their questions from the committee?

Representative Lyddy.

REP. LYDDY: Good afternoon, Maggie.

MAGGIE SHAW: Good afternoon, Representative.

REP. LYDDY: Thank you so much for being here. I really appreciate you really advocating on behalf of Lyme patients, and bringing to our attention the widespread issue of Lyme Diseases especially in Newtown.

You just ended, actually, and I'm hoping that you can maybe tell me a little bit more about where you possibly were going with it, in terms of the doctors and how long it's taking for your children to be diagnosed and treated, if you could talk a little bit about what that was --

MAGGIE SHAW: Well, I can go into my children's treatment, but I know you received testimony, I think there's been over 90 pieces of testimony received from people throughout -- throughout the state, and -- and also going into your own communities, you will hear exactly the same thing that I hear as a task force leader and a person with a hotline directly into my home to help people with resources and support for Lyme Disease.

But the fact of the matter is, is that Lyme Disease is a -- there is no perfect testing for it. There are two sets of guidelines which have really created this dichotomy. One set just a strict 30 days and you should be better, and if you're not, then it could be something else or you never had Lyme Disease to begin with.

And with my children, the testing being very unreliable, my son went six years undiagnosed because he never tested positive for Lyme Disease, but I think the most important thing that I try to relay to people about the testing for Lyme Disease is that it was never really meant for diagnostic purposes. It was meant for surveillance purposes. That means in order for our state to count Lyme Disease you have to reach this -- this strict criteria, but physicians in Connecticut have adopted that criteria for diagnostics.

So even if you have symptoms of Lyme Disease physicians are afraid to treat and diagnose without a positive test, which was only meant for surveillance criteria, because of -- of investigations by medical licensing boards, possibly being watched by -- by their colleagues, and so we have a limited amount of -- limited amount of physicians in Connecticut who are willing to address Lyme Disease that -- that was not caught in it's early stages. And that's very easy to do because of the ticks being so small to see, that many people don't get the rash, and -- and the symptoms are not just the IDSA EM rash, swollen knee, bells palsy. They're sub -- they're subjective symptoms as opposed to objective.

REP. LYDDY: Thank you very much.

This is such a confusing topic. So I appreciate you taking the time to --

MAGGIE SHAW: Sure.

REP. LYDDY: -- explain that a little bit more.

The next question I have for you is you mentioned that you contacted the DPH for information regarding Lyme Disease?

MAGGIE SHAW: Yes. I requested information on what the Connecticut Department of Public Health had on Lyme Disease, because when I would go to my health district, there really wasn't much information, and physician's offices, you go to physician's offices and there's no information. So I wanted to see what exactly the Connecticut Department of Public Health had for information on Lyme Disease. And I believe they sent me a website for the Connecticut Agricultural Experiment Station with -- with -- pertaining to ticks. But they also sent me an executive summary of the infectious diseases Society of American Guidelines. Now that really astonished me because in 2004, Commissioner Galvin at the Perspectives on Lyme Disease Hearing that was held here with the Department of Public Health and the Attorney General's Office, stated that they have no standard of care. That they have not adopted -- that they will allow physicians to treat as they seem -- deem appropriately with no restrictions on treatment or how long or the antibiotics. And so I was really shocked when I got that executive summary of the Infectious Diseases Society of America Guidelines. To me, that was almost promoting a standard of care from our Connecticut Department of Public Health. And if they sent that out to other people informing them of how

they should possibly treat Lyme Disease.

REP. LYDDY: Right. So it sounds like just -- I just kind of want to kind of sum up so I can get my head around it. It sounds like our own DPH doesn't have a whole lot of information or accurate information, or is providing information that may be controversial around this issue?

MAGGIE SHAW: Well, I don't think it's up to the Connecticut Department of Public Health to provide or promote any standard of care --

REP. LYDDY: Okay.

MAGGIE SHAW: -- when there are other standards of care.

REP. LYDDY: Right.

MAGGIE SHAW: And -- and I was sent that copy from them, and it just astonished me because I've been involved in Lyme Disease education and prevention and advocacy, and as a task force leader for over 10 years now. And, you know, people are leaving the state for treatment because the climate here is very fearful for physicians who want to treat, beyond that IDSA guideline standards.

REP. LYDDY: And just a quick question, hopefully it'll be a quick answer.

MAGGIE SHAW: Sorry.

REP. LYDDY: You said that you had a Lyme Disease phone line in your house, how many calls do you receive on average? And just quickly, you don't have to tell me about the stories.

MAGGIE SHAW: Hundreds a year. Hundreds from all

over because of the -- Fairfield County is the county that is very well educated on Lyme Disease. We have probably five or six task forces, support groups, and so that's -- that's growing testimony to this disease also.

REP. LYDDY: Thank you so much.

MAGGIE SHAW: Sure.

REP. RITTER: Are there any other questions from the committee?

Thank you very much for your testimony.

MAGGIE SHAW: Thank you very much.

REP. RITTER: Our next speaker is Pat Smith to be followed by Dan Cameron.

PAT SMITH: I'd like to thank the chairman and the committee for this opportunity to testify today. I'm President of National Nonprofit Lyme Disease Association.

And 34 years into Lyme Disease one would expect that the plight of patients would have improved. Numbers are on the rise, culminating with the 38 percent increase nationwide in 2007. All 50 states now have had reported cases, yet, treatment guidelines have become more restrictive. There's no gold standard test, and in 1994 the tests had more restrictions placed on them, so less patients would be reported positive.

In 2000, the Infectious Diseases Society of American issued Lyme treatment guidelines, and then updated them more restrictively in 2006. The guidelines recommend against lists of antibiotics, against alternative treatments, even supplements for Lyme patients, there is

no chronic Lyme in these guidelines. When they define post-Lyme syndrome to explain the symptoms that happen after short-term treatment, it's very carefully crafted, so that somebody who was clinically diagnosed early on with Lyme Disease, can never develop post-Lyme syndrome, and clinical discretion isn't permitted anyway in the guidelines.

Treating doctors who veer from the ISDA guidelines, who have been increasingly brought up before licensing boards for treating outside the IDSA standard of care, often the states say oh, it's not about Lyme. But the charges would reveal, indeed, it was all about Lyme.

Infectious disease doctors would testify against doctors at hearings and cause troubles at hospitals for the treaters, and hospital privileges, and even dismissal being threatened. If they wanted to publish studies to support their viewpoint, they would find that infectious disease reviewers, on most major journals, would reject their submissions.

Doctors had two choices. They could conform to the guidelines and stop treating chronically ill patients, or they could jeopardize their licenses and continue to treat. A small cadbury of doctors nationwide chose to continue to treat patients despite the tremendous pressure they faced to stop treating, often retaining lawyers to protect their autonomy. Their practices are full. Their offices spend half and hour to two hours with a Lyme patient, and often see whole families who are affected. Many times it's the Connecticut family who's packed into their car and travels to New York or New Jersey to seek medical help for their Lyme Disease.

IDSA has chosen to take a hard line against both patients and treating physicians by not allowing any treatment for chronic Lyme. Yet, it appears IDSA has 19 million in assets to carry out their mission, according to their online tax returns. Neither patients nor treating physicians can match resources.

And I just want to say that last year, that IDSA lobbied against a federal bill for research that would look for a gold standard test for $100 million for research, they lobbied against it.

So, in closing, I would like to say until more research can be funded, we need elected officials to protect our doctors rights to determine the most appropriate treatment protocol for their patients. And please fine tune the language in HB 6200 by defining terms in the bill that would give doctors the ability to use their knowledge and skills to diagnose and treat their patients without being subject to medical board actions for simply providing a better quality of life for their patients.

Thank you.

REP. RITTER: Thank you very much for your testimony.

Are there any questions from the committee?

Representative Bartlett.

REP. BARTLETT: Thank you, Madam Chair. Thank you for coming today.

So basically what I'm hearing is there are basically two groups of doctors, two standards

of care guidelines. You mentioned IDSA and I believe the other is ILADS? And so the IDSA group only recommends their guidelines state four weeks of antibiotics and then that's it.

PAT SMITH: That's correct.

REP. BARTLETT: So even if, say, the spirokeet, which is basically what Lyme Disease is, is in the body, and it's in your body which it could happen because not everybody will see a rash, just in that example, and it's in your body for a year, or a couple of years, it's still, with those guidelines, it's only four weeks, is that correct?

PAT SMITH: That's -- that's absolutely correct, yes.

REP. BARTLETT: And the others doctors, the ILADS doctors, say that because of that circumstance and maybe a host of others that a more long-term approach of longer than four weeks. What other -- are there any other kinds of things? I mean -- I'm just trying to get a sense of four weeks of antibiotics, what does that really mean? In dermatology, in other areas, what are some of the uses of antibiotics --

PAT SMITH: Well, I -- I -- for example, tuberculosis and Q Fever, endocarditis, acne, all of these things do allow long-term use of antibiotics. It's only Lyme Disease, and we know doctors that have treated acne patients for two, three and more years with antibiotics. It's only with Lyme Disease where a red flag, across this country and across the world, is raised when doctors attempt to give longer than a standard course.

REP. BARTLETT: So let me ask you about that. So,

you mentioned in your testimony that there were conflicts of interest, you use that word, I believe, and my recollection is that our own Attorney General sued IDSA because he felt that there were some sort of conflicts of interest in terms of how the guidelines came about.

Do you want to expand on that? Because I'm not -- maybe it would help illuminate why this controversy exists.

PAT SMITH: Well basically, what happened is Attorney General Blumenthal issued something called a CID, a Civil Investigative Demand, and asked for all the records surrounding the development of the guidelines because he felt that this could violate anti trust laws in the country, because he felt as though, perhaps, IDSA might have a monopoly.

So basically he did an investigation. And what he indicated in the settlement, they had a settlement, and he did indicate that he found undisclosed conflicts of interest. And as a result of the settlement, the IDSA now has gone back to the drawing board under a new panel, a brand new panel, which they just selected under the auspices of an Ephesus.

The problem, unfortunately is, that this new panel which was just constituted a week ago, still contains no long-term Lyme Disease treating physicians. So now you have a panel, again, that has one viewpoint of this whole situation, and no more. And patients obviously are extremely concerned, which is why this -- we feel this is so important.

REP. BARTLETT: So just one last follow-up. So, again, the conflict of interest could be, for example, somebody is working for a research

institution and is a doctor, may not be practicing and getting -- there is a good word we were using all day today, but Senator Harris used it, what is that word we were using with epilepsy when -- anecdotal. Thank you. That's the word I want -- and not getting the anecdotal evidence, but doing a lot of research and maybe being paid for that research, and so maybe that helped draw some of those conclusions, but some of the doctors that are actually practicing and seeing chronic Lyme patients, and see that anecdotal and the clinical and everything else, recommend longer use of antibiotics. Would that be accurate?

PAT SMITH: I -- I certainly think that that's a possibility. I, by the way, had not mentioned conflicts in my testimony.

REP. BARTLETT: Oh, I'm sorry.

PAT SMITH: But I -- but I will mention the fact that conflicts oftentimes are competing interests, and they can be competing into -- concerning drug company holdings, or vaccination testing, maybe insurance company work, consulting work, things like that are usually construed or can be construed as some type of competing interest.

REP. BARTLETT: Okay. Great. Thank you.

REP. RITTER: Thank you very much.

Are there any other questions from committee?

Thank you for your testimony.

PAT SMITH: Thank you.

REP. RITTER: Thank you.

Our next speaker will be Dan Cameron followed by Jonathan Lyons.

DANIEL J. CAMERON: I'm Daniel Cameron. I'm a physician about 70 miles away in New York, and I'm also a President of ILAD, the International Lyme and Associate Diseases Society, and I'm here to support the bill.

When I was started in treating in Minnesota, and then in New York, is that doctors were pretty excited about Lyme Disease; that there were incidents they could treat these rumatory arthritis-type presentation, neurologic things, and it was pretty exciting. And then in 2000 when the IDSA came along and they said, well, why don't we write guidelines up. And they came to the conclusion that there was no such thing as chronic Lyme Disease, and that set a major divide between physicians.

So the IDSA continues to say it doesn't exist, and the last guidelines said that it was nothing more than aches and pains of daily living, whereas ILADS has continued to say well, Lyme is common, you know, when the epidemiologist of Connecticut said in a testimony that there were 34,000 cases a year in Connecticut, that up to 25 percent of families already have Lyme in Connecticut, during his testimony we -- we agree that many of them get Lyme; many of them become chronic.

I include in the packet a paper I wrote that every trial that's been done by NIH shows severe debilitating symptoms of fatigue, pain and quality of life. There's a -- I also include a packet from the paper of the CDC that said that it could cause up to $17,000 a year per chronic Lyme patient, and two-thirds of it is not anything to do with a doctor. It

has to do with lost opportunities through work, needing other types of support.

So physicians are also divided on treatment. One group says don't treat. ILADS says, Well, we've been treating a long-time effectively, and when we always keep saying the -- the NIH trials are supportive, we read those trials and say at, like at Columbia, that study, people were sick two years before they got in the trials, before they got any treatment. It was nine years of sickness before they got into those trials, and so it the headlines should have been, it was an outrage to have people who were sick that long in the tri-state area with chronic Lyme.

And I wrote an epidemiology review that -- showing how many troubles, there were eight major flaws in those studies, and that's in your packet.

And so just to conclude. Why do we need legislation? The main reason is that so often the ideas -- ideas I view --

Thank you very much for having me.

REP. RITTER: Thank you very much for your testimony.

Are there any questions from the committee?

Thank you.

Our next speaker will be Jonathan Lyons and he will be followed by Karen Forschner.

JONATHAN LYONS: Hi, my name is Jonathan Lyons. I would personally like to thank Senator Harris and Representative Ritter, and the other distinguished members of the Public Health

Committee for giving me a chance to speak on this matter.

I live in a heavily wooded endemic area of Connecticut, in Madison. I first tested positive for Lyme Disease when I was six years old, and I received the standard two-week regimen of oral antibiotics. I was rediagnosed with the disease two more times and, again, received the same regimen. Each time I was treated the initial physical symptoms banished, and my doctor and my parents thought I was cured, however, since then, some doctors have noted that they could have been recurrences of initial infection.

As I progressed through grade school and high school, I began suffering from terrible fatigue and neurological symptoms, and cognitive symptoms such as, attention problems, memory problems, thinking problems, all of which made it very difficult to function. They only grew more severe as I entered college. Finally, in my sophomore year of college, my symptoms became so severe that I could no longer complete my school work. I felt like I was dying, so I checked myself into the hospital. Several confused doctors and misdiagnosis later, blood test for Lyme were taken, and it came back again strongly positive. So I was placed on intravenous (inaudible). My condition improved dramatically, within two months, but I did not recover enough of my energy or my memory to return to school until I had endured another four months of oral antibiotic treatment on Biaxin, Clarithromycin, and Plaquenil hydroxychloroquine which is another antimalarial drug.

Finally after six months of antibiotic treatment, I felt well enough to return to

college. My doctor even thought I was doing well enough to stop taking the antibiotics, but this turned out to be a very bad idea because within two months I was slowing down again. My fatigue returned, and so did all my neurological symptoms with a vengeance.

Just a few months before I had more youthful vitality then I had ever had. Now I was so tired that I had to spent much of my day resting in bed. I barely made it through the next year of college. And finally had to take more semesters of medical leave. It has taken two more years and a long course of oral (inaudible) in order for me to recover enough to be -- to able to come here today.

Let me emphasize that long-term antibiotics are the only reason I am able to come here today to speak to you. If it weren't for this medicine, I would still not be able to get out of bed. After years of struggling with this terrible illness, this medicine is giving back my life.

I just wanted to add that I know that I'm a lucky individual in the sense that my case is pretty clear cut, serologically speaking. My tests always come back strongly positive for Lyme Disease, and so it was much easier for me to find a doctor who was willing to treat me for this disease and give me the antibiotics that I needed.

I know that there are a lot of people who are not so lucky, and they need to be even a wider latitude in order to find the treatment they need.

Thank you very much.

REP. RITTER: Thank you for your testimony.

Are there any questions from the committee?

Representative Lesser.

REP. LESSER: You mentioned -- you mentioned that you first discontinued your studies, do you feel like that the inability -- if being taken off antibiotics would prevent you from getting a job or from contributing to (inaudible) of Connecticut?

JONATHAN LYONS: Yes. Very much, because every time I've gone off of antibiotics my symptoms have returned, and they become so debilitating that I'm unable to really do anything during the day.

But when I'm treated for a while, I become functional again, and I'm able to do my school work and go to college and, generally be, you know, a normal 25-year-old-person. So, yeah, antibiotics have made the difference.

REP. RITTER: Thank you very much.

Are there any other questions from the committee?

Thank you for your testimony.

JONATHAN LYONS: All right.

REP. RITTER: Our next speak will be Karen Forschner followed by Eileen Rice.

KAREN VANDERHOFF FORSCHNER: Distinguished members, Senator Harris, Representative Ritter, the Committee, and especially Representative Bartlett, I am Karen Vanderhoff Forschner, president of the Lyme Disease Foundation, and I strongly, strongly support HB 6200.

This is probably one of the most important pieces of legislation, if passed, that will be passed in the last decade. About 25 years ago, I gave birth to my son, Jamie Forschner. He battled his life against a bacteria inside a little tick the size of what's floating inside here. During his five short years, it was the most painful time of my life, not only because he suffered to live and breathe and eat, he never learned to sit, but because the doctors that tried to treat him, in a world that didn't know about Lyme Disease, harass the doctors that would treat him.

The problems that we had in finding a doctor at a time when we set up the Lyme Disease foundation because there was no place to call, no one -- nothing was out there, that -- you know, since then we've worked with the Federal Government, with State Government, with education, with TV programs, but the point is that the doctors in this state made such a freeze, a chill in the area for treatment, that we could no longer get treatment for him.

Every doctor that treated him in the state was called up by an act of admission, here in the state, and threatened to be turned into the medical licensing board. We eventually had to go outside the state.

At the Lyme Disease Foundation, we get 6,000 calls on our hotline. We get thousands of e-mails. Six million a month on our hot -- our website. The fact is that all of the doctor referrals we give are almost -- almost nonexistent in having physicians that we can refer people to.

And the point of this bill and why it is so important, is because the medical licensing

board turn-in threat is the single most important chill that keeps our doctors from treating, and this bill will kick that problem. You don't need to go to a Lyme specialist, if your family doctors feels free to treat you.

So that I am strongly in favor of this bill and you will thank yourselves in the future for voting for it and passing this bill, because it will open up diagnosis and treatment and keep it private between the doctor and patient until there is a test.

Thank you. Now I'm within the three minutes here.

REP. RITTER: Thank you very much for your testimony.

KAREN VANDERHOFF FORSCHNER: Sorry, it wasn't scripted better. It would have taken much longer.

REP. RITTER: That's not a problem for us.

Are there any questions from the committee?

Thank you very much.

KAREN VANDERHOFF FORSCHNER: Thank you.

Our next speaker will be Eileen Rice, and she will be followed by Dr. William Handelman.

EILEEN RICE: Good afternoon. Thank you for allowing me to testify in support of the Lyme Bill 6200.

Our family's nightmare with Lyme Disease began almost three years ago when our 13-year-old daughter suddenly became disabled with extreme

vertigo and chronic fatigue. Her initial blood test for Lyme was negative, largely because our pediatrician had only administered the Alyssa blood test instead of the more reliable Western Blot test. When she finally got a positive Lyme test from an infectious disease specialist, six weeks later, the damage had been done.

She had already missed the last two months of her seventh grade year, due to chronic fatigue, inability to concentrate, insomnia and vertigo. Following the IDSA guidelines, the infectious disease specialist put her on a three-week course of amoxicillin, telling us that she would be fine, but he was wrong. She relapsed with a high fever, chronic fatigue and dizziness. We went back to our pediatrician who put her on doxycycline and amoxicillin for 30 days, followed by an additional 20 days of amoxicillin.

After returning to her eighth grade classes in September, she relapsed two days later with the same debilitating Lyme symptoms. Our pediatrician then told us that he was out of treatment options. Although he, himself, had been treated with long-term antibiotics for Lyme Disease, he said his pediatric practice didn't advocate this type of protocol.

This was our first introduction into the politically charged and hypocritical world of Lyme Disease. Finally, we saw a pediatric Lyme specialist who asked for a thorough two-and-a-half hour clinical evaluation and consultation, put our daughter on a six-month course of antibiotics.

Fast forward two-and-a-half years: The odyssey has been long and painful, filled with suffering and despair for our entire family.

The long-term antibiotics were not a quick fix, but gradually our child, a former star athlete and conscientious student, began to get her life back together. She returned to school full time in February of her eighth grade year, she was still plagued with chronic fatigue but the long-term antibiotics improved her concentration and energy level to the point where she could do her school work.

Over time, with the help of two Lyme Disease specialists, she finally went off the antibiotics this past December. She's now on herbal remedies indefinitely, and we're hopeful that they will keep her Lyme Disease at bay.
Thankfully, our 15-year-old daughter has resumed the life of a normal teenager. She swims competitively on the high school team, takes challenging academic courses, and has an active social life.

The real tragedy though here, is that hundreds of thousands of patients aren't so lucky. They are being denied successful long-term antibiotic treatment either because they're doctors are Lyme illiterate or they're afraid to prescribe them for fear of harassment. I urge you to please do the right thing and pass this important piece of legislation.

We need to protect and liberate our physicians so that they can once and for all clinically diagnose and successfully treat Lyme Disease by prescribing long-term antibiotics without fear of reprisal.

Thank you.

REP. RITTER: Thank you very much for your testimony.

Are there questions from the committee?

Thank you.

EILEEN RICE: Thank you.

REP. RITTER: Our next speaker is Doctor William Handelman to be followed by David Evans.

WILLIAM HANDELMAN: Thank you, Representative Ritter and the committee, Dr. William Handelman, again I represent the Connecticut State Medical Society.

The Connecticut State Medical Society actually would like -- would support this legislation. We realize that this is a difficult issue and that there's a large dichotomy of physicians between two groups of physicians who treat this condition. We feel that any physician who's acting in good faith and using appropriate diagnostic criteria and evaluation, and treating according to acceptable guidelines should be permitted to practice to his full extent.

We also feel the physicians should not be prosecuted or be subject to licensure restrictions when they're acting in good faith and treating according to acceptable guidelines..

And with that, I'd like to take any questions of the committee.

REP. RITTER: Thank you.

Are there any questions from the committee?

Thank you Doctor Handelman.

The next speaker is David Evans and he

followed by Vernice Jury.

DAVID EVANS: Representative Ritter, and members of the Committee, my name is David Evans, and I'm here to speak on behalf of myself and my family.

Although you've seen me around here in the halls often, this is issue has touched very close to my family. My daughter, 18 years old, was originally infected with Lyme Disease in 2003. Unbeknownst to us, her condition continued to get worse over a number of years, and it wasn't until the last year or two that we recognized what the real cause of the issue was, and she has just gotten off of a six-month PICC line, her gallbladder was removed inexplicably, as having shut down. And what we found out it was a result of the -- of the Lyme Disease. And had she been treated initially, and in long-term, it would have -- it would have prevented the agony and the problems that we've had over the last number of years.

My son has also been infected with it, and is on antibiotics. When the -- when the rash that was originally seen on his hand was very small, and he was refused antibiotics because of the protocol.

I could go on with a number of the issues that have affected our family, but I would sincerely ask that this committee pass this legislation. It's long overdue. And it's needed, and long-term treatment for antibiotics should be an option without any recourse against the doctor, and I would hope that the committee act favorably on the bill.

And thank you very much.

JOINT
STANDING
COMMITTEE
HEARINGS

PUBLIC
HEALTH
PART 2
313 - 623

2009

CTChiro
Connecticut Chiropractic Association

doctor of chiropractic. In fact, recent research in the prestigious "Spine Journal" indicates that the incidence of stroke in the office of a chiropractor is no greater than it is in the office of the primary care physician, indicating that **the incidence of a stroke is temporally related and not causally.** (2)

Another study measured the forces transmitted to the vertebral artery during a cervical manipulation. This study found that the forces transmitted to the vertebral artery are less than 1/9th of the force necessary to stretch or otherwise damage the normal vertebral artery. The study noted that in fact, that manipulation forces were actually less than the forces measured during normal ranges of motion of the neck. Based on these studies, **many experts now believe that it is physically impossible for a competently performed neck adjustment to cause a vertebral artery dissection unless the artery already has a significant pre-existing weakness.** (3)

Chiropractic neck manipulation has been demonstrated to be safe and effective for a variety of conditions from whiplash, to tension headache amongst other conditions. (4,5,6) All healthcare procedures carry a risk, in fact "doing nothing" about neck and back pain carries risks as well. These risks include increased rates of disability, abuse of prescription medication or other non-prescription drugs, disruption from work and activities of daily living as well as well as disruption of social activities.

It is the opinion of the CT Chiropractic Association that SB 90 unfairly singles out a profession that has been proven to be extremely safe and effective in it's delivery of holistic healthcare. We are not opposed to the concept of informed consent. Informed consent is a process that if this committee feels is something that needs to become law, should be applied across the board to all healthcare professions for the good of the public.

Thank you for the opportunity to offer this testimony today,

Respectfully submitted,

Gina M. Carucci, DC, MS, DICCP

1) Basilar artery embolism after surgery; under general anesthesia: a case report. 1993. Neurology.

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2) What are the Risks of Chiropractic Neck Adjustment? 2003 William J. Lauretti, DC
3) Risk of Vertebrobasilar Stroke and Chiropractic Care: Results of a Population Based Case-Control and Case-Crossover Study. February 15, 2008 Spine Journal
4) Internal Forces Sustained by the Vertebral Artery During Spinal Manipulative Therapy. 2002 Journal of Manipulative Physiological Therapeutics.
5) Quebec Task Force Report on Whiplash Injuries. 1995 Spine Journal
6) Rand Corporation Report: The Appropriateness of Manipulation and Mobilization of the Cervical Spine. 1996
7) Duke University Evidence Report. 2001 Evidence Report: Behavioral and Physical Treatments for Tension-Type and Cervicogenic Headache.

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Good Afternoon Senator Harris and Representative Ritter and distinguished members of the Public Health Committee,

My name is Mathew Levy and I am asking you to support Senate Bill 90.

Seven years ago, my mom had a major stroke caused by a chiropractic adjustment. I was only ten years old when it happened, but I remember being so scared that my Mom might actually die. I remember going to visit her in the hospital and I remember how bad she looked. Here was my Mom unable to move, when she had been such an active Mom, always on the go, walking 5 miles a day. I desperately wanted her to be back to being my Mom again.

When she came home from the hospital, every day when I came home from school, I would ask her if she could move yet. Each day we rejoiced over the fact that maybe a toe wiggled or she could lift one finger up, maybe a 1/16th of an inch.

About three years ago, I started helping my Mom with the organization she had founded . She named it VOCA, for Victims of Chiropractic Abuse. She had decided that there were far too many injuries happening to people not that much older than me, as a result of a chiropractic adjustment and something had to be done about it.

I helped her set up computer programs. Then she asked me to help other victims set up their computer programs so that they could write to each other. I spent a lot of time looking up articles that pertained to chiropractic manipulation and stroke.
It is amazing how many hundreds upon hundreds of articles there are which talk about how chiropractic manipulation can cause a stroke. And it is amazing how many hundreds of victims have suffered a stroke after having a chiropractic manipulation.

Yet some chiropractors still deny it even happens, which is just ridiculous if you see the amount of stuff written over the years. In fact, in one article, it says that the first chiropractic stroke incidence was in 1937, and back then they said it was a rare when there were only 5,000 chiropractors. Well today there are over 75,000 chiropractors and many still say it is rare.

This bill should become law to protect the public. People need to be aware of everything that has a risk to it, especially if that risk is so devastating as a possible stroke, permanent disability or even death. It should be our right to know.

When the American Chiropractic Association admits in their own literature that it is true, that neck manipulation is a risk factor for stroke and the American Heart Association has on its web-site articles about how chiropractic manipulation can cause a stroke, and when in Canada there is a half billion dollar class action lawsuit that is suing the Health Minister for not properly informing patients about the risk of stroke with a chiropractic adjustment, and when a well respected chiropractor who teaches at the University of Bridgeport urges all chiropractors to tell their patients about the risks of stroke following

a chiropractic adjustment, it is TIME to let people know. And if certain groups of chiropractors refuse to tell patients, then that is when the government needs to step up and protect people.

After all that has happened to my Mom, she still isn't against chiropractors. She talks to many chiropractors all the time who are in support of this legislation. One chiropractor, in fact, called her yesterday and told her that on the American Chiropractic Association's web-site there was an article talking about the case where a young woman had died in Canada. One of the jury's recommendations was that chiropractic physicians obtain written informed consent from every patient before performing a neck adjustment and that every patient be given an information sheet with risks and stroke symptoms clearly spelled out.

That was in 2004.

RADIOLOGICAL SOCIETY OF CONNECTICUT, INC.
A CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY

Statement of the
Radiological Society of Connecticut
in regard to Senate Bill 406
Public Health Committee
February 6, 2009

Sen. Harris, Rep. Ritter and members of the committee:

My name is Linda Kowalski. I am executive director of the Radiological Society of Connecticut, whose members are Medical Doctors specializing in the field of Radiology.

As the physician professionals who are responsible for medical imaging, the people who will be responsible for supervising radiologist's assistants, and the employers of these professionals, RSC is very interested in Senate Bill 406, ***An Act Concerning Licensure of Assistant Radiologists***. For the record, we reserve judgment on this legislation and cannot support it at this time. The introduction of such a bill should be done with the close collaboration of radiologists. Serious questions of credentialing and patient safety are involved here, including:

- Education and clinical training requirements for licensure;
- Scope of practice responsibilities,
- Prohibited activities;
- Requirements for medical liability coverage;
- Disclosures under the Medical Professional's Profile law;
- Responsibilities of the supervising Radiologist; and
- Fiscal impact of licensure.

These are not frivolous questions—they go to the heart of what qualifies someone to be a Radiologist's Assistant as well as what they are entitled to do, or not do, as a practitioner. We have seen absolutely no information on this—and we cannot support the bill until we have answers to these important questions. We also believe that the appropriate title for these practitioners should be "Radiologist's Assistant."

If you move forward with a fully drafted bill, we urge you to clarify the ability of another class of highly skilled professionals, Physician Assistants, to engage in the use of Fluroscopy for diagnostic and therapeutic procedures. You can do so by adding Physician Assistants to the list of practitioners who are currently exempt from licensure requirements in the Radiological Technologists' statute. This will help ensure that Fluroscopy procedures can be performed in appropriate settings without any confusion or controversy as to who is entitled to assist the Radiologist. If you ultimately decide not to approve the licensure provision in S.B. 406, we would still request that you address this burgeoning controversy by adopting a strike-all amendment as follows:

Section 20-74ee

New subsection (a) 6

Nothing in subsection (c) of section 19a-14, sections 20-74aa to 20-74cc, inclusive, and this section shall be construed to require licensure as a radiographer or to limit the activities of a physician assistant, licensed and supervised pursuant to chapter 370, who is engaged in the use of fluoroscopy for guidance of diagnostic and therapeutic procedures.

As many of you know, an unfortunate clash has erupted between certain members of the Radiological Technologists' profession and Physician Assistants. The former contend that Physician Assistants should not perform Fluroscopy under the supervision of the Radiologist. To make their point, they have sent letters of complaint to hospital executive staff and to the Department of Public Health.

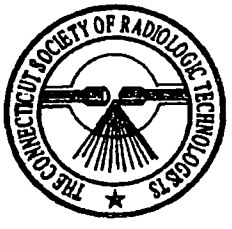
By statute, a Physician Assistant is entitled to undertake such activities as his or her supervising physician direct so long as the activity is not prohibited in their practice statute. Their practice statute contains no prohibition on assisting with Fluroscopy. Since the two professions have not been able to resolve this disagreement, we ask that you step in and do so. We need you to mediate and referee this controversy now before it spirals out-of-control.

Please use S.B. 406 as a vehicle to do so. When you hear all of the evidence, RSC believes you will agree that the education, training and clinical experience Physician Assistants bring to the table eminently qualifies them to assist with Fluroscopy.

Thank you.

The Connecticut Society of Radiologic Technologists

Affiliated with the American Society of Radiologic Technologists



Good Afternoon, Senator Harris, Representative Ritter, and members of the Public Health Committee, I am Diane Kosenko; Chairman of the Board for The Connecticut Society of Radiologic Technologists .The CSRT is the organization that represents the Radiologic Technologist in Connecticut. We are an affiliate of the American Society of Radiologic Technologists.

Our mission is to provide state of the art education, communication, and legislative representation for our society; while creating public awareness of our integrity, professionalism, and humanitarianism. The purposes of the Society is to advance the science of Radiologic Technology, to assist in establishing and maintaining high standards of education and training, to elevate the quality of patient care, and to improve the welfare and socio-economics of Radiologic Technologists.

As the affiliate of the American Society of Radiologic Technologists, CSRT believes in the promotion of, and the elevation of the quality of patient care throughout the state. We are proud to uphold that fine reputation among our medical professional peers and associates.

The CSRT has been involved with updating our state regulations, to keep the laws current with the RT's scope of practice and our continuing education requirements. Some of the over 3,000 licensed Radiographers in CT participate in educational seminars that are offered throughout the year at different locations within the state.

The health of the public can only benefit from properly certified and fully licensed radiologic personnel. No matter what the radiologic procedure, the technologist's detailed knowledge of anatomy, the precise patient positioning, the careful application of radiation and skillful operation of sophisticated medical equipment are the keys to success. All these skills are due to the education Radiographers have obtained. Competence is necessary when one individual is responsible for controlling the intensity of the beam, the duration of exposure, and the shielding of the patient.

There is a delicate balance between the amount of radiation administered in order to correctly diagnose a potential disease and the amount of radiation, which would be more dangerous than the potential disease. The National Cancer Institute estimates that the long-term effects of overexposure to radiation during diagnostic x-ray examinations alone may be responsible for more than 3,500 cancer deaths a year.

The Physician Assistants in this state are going to ask to be excluded from the Radiographers Bill Chapter 376c. The curriculum for Physician Assistants does NOT include any radiation safety, radiation protection, radiation biology, radiation production and characteristics, and patient positioning. These classes are all required of Radiographers. These are the fundamental principals in radiology. Competency in these areas must be shown before graduating, passing the American Registry of Radiologic Technologists Board Exam, and practicing in our state.

Allowing all Physician Assistants the right to operate fluoroscopy machines, which can emit 4 times the radiation of routine radiographs, while they are performing image guided procedures, without formal academic instructions, from an accredited institution of higher learning, could harm not only the patient, but also the Radiographer and other staff involved in the procedure. Having an in-service without showing competency does not prove that anyone has mastered the information.

The American Registry of Radiologic Technologists Code of Ethics. #8 "The Radiologic Technologist practices ethical conduct appropriate to the profession and protects the patients right to quality Radiologic technology care." This Code of Ethics is compromised when Radiographers work with Physician Assistants who administer ionizing radiation to patients when they are not licensed to do so. We must work within our Code and Standard 's of Ethics.

According to the National Academy of Sciences \ National Research Council's Committee on Biological Effects of Ionizing Radiation, or also known as BEIR, medical diagnostic radiology accounts for about 90% of the total man-made radiation dose to the U.S. population. They also released a report "Health Risks from Exposure to Low Levels of Ionizing Radiation" and reconfirmed their previous stance that even very low doses of radiation can cause cancer. Furthermore, they now believe that risks from low dose radiation could be even greater than previously thought.

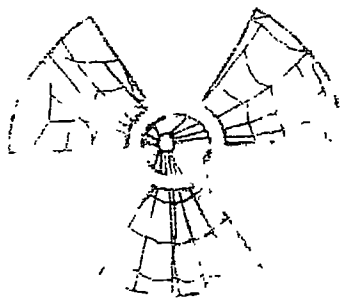
The EPA has stated that medical personnel who are always receiving radiation are also increasing their risk of cancers. The Radiologic Technologist would be in the room while a Physician Assistant utilizes the fluoroscopy equipment during an image-guided procedure. It is the CSRT concern for the well being of everyone in the radiology suite. Fluoroscopic exams are considered "Dangerous or Hazardous Procedures" by the Texas administrative Code, and PA's and RN's are not allowed to perform these procedures.

In fact, in states near us, New York, New Jersey, Delaware, and Massachusetts do not allow PA's to fluoroscope or perform image-guided procedures utilizing radiation. Other states such as Iowa, Kansas, Nebraska, Ohio, Texas, Utah, Washington, West Virginia, Wyoming, also do not allow PA's or RN's to perform diagnostic procedures, including fluoroscopy.

New Jersey has written on their Radiologic Technology Licensure states web site, "Radiation is unique in that it cannot be detected by sight, touch, smell, hearing or taste. It's proper use can save lives but its abuse may ultimately harm patients. Because of this inherent risk, it is every patient's right to have their radiographic procedure performed by licensed, knowledgeable professionals who are aware of the proper techniques and the associated risks involved in these procedures." The American College of Radiologists, states "Modern fluoroscopic equipment is capable of delivering very high radiation doses during prolonged procedures. There have been reports of serious skin injuries in some patients undergoing certain fluoroscopically guided procedures. Management of the use of radiation must also ensure adequate safety of the medical personnel involved in these procedures"

The CSRT exists to ensure that the patients of Connecticut receive the best care possible, with the lowest amount of ionizing radiation, administered by the highest educated and quality professionals. This is not an issue of "A turf war" as some have called it; this is simply an issue of safety for the patient and all personnel involved during these procedures, including the PA.

Sincerely,
Board of Directors
Connecticut Society of Radiologic Technologists



Radiation Safety Office

Henry Ford Health System

4. Case Studies of Radiation Injury

1 Radiation Physics
2 Radiation Biology
3. Fluoroscopy System Description and Operation
4. Case Studies of Radiation Injury
5 Reducing Radiation Exposure
Fluoro Training Exam (12/01)
Fluoro Training References

Chapter 4: Case Studies of Radiation Injury

Non-Symptomatic Skin Reactions

Minor skin reactions caused by X-rays can be easily misattributed to other causes (e.g. sun exposure or rashes). Also, since these skin reactions are delayed effects, they typically would not be be seen in the clinic. Thus, patients and caregivers may not be aware of skin changes that can be caused by lengthy fluoroscopic procedures (Wagner 1999). The following case study is a useful example:

1. Physical examination one year following coronary angioplasty identified a 1 x 2.5 cm-depigmented area with telangiectasia on the patient's left shoulder. Total fluoroscopy time: 34 minutes.
2. One year after PTCA involving 66 minutes of fluoroscopy, a 10-cm diameter hyperpigmented area with telangiectasia was evident on the patient's right shoulder.

The above skin changes were in areas not visible to the patients and were only identified upon physical examination.

Symptomatic Skin Reactions

The circumstances leading to symptomatic radiation induced changes are varied. Case reports are grouped according to common factors in order to identify the reasons for radiation-induced effects.

PA Fluoroscopy

The posteroanterior (PA) orientation of the fluoroscope, when properly

configured with the image intensifier down close to the patient, is probably the least problematic with regard to Entrance Skin Exposure (ESE) rate. However, extended fluoroscopy usage has resulted in reports of skin damage. The following case study, which did not occur at Henry Ford Health System, illustrates this effect (Shope 1995).

On March 29, 1990, a 40-year-old male underwent coronary angiography, coronary angioplasty and a second angiography procedure (due to complications) followed by a coronary artery by-pass graft. Total fluoroscopy time estimated to be > 120 minutes. Figure 4-1 shows the area of injury six to eight weeks following the procedures. The injury was described as "turning red about one month after the procedure and peeling a week later." In mid-May 1990, it had the appearance of a second-degree burn.

Figure 4-1: 6-8 Weeks Post Procedure

Courtesy of Wagner, 1999

Note the square pattern of the injury.

Figure 4-2 shows the appearance of skin injury approximately 16 to 21 weeks following the procedures with small ulcerated area present.

Figure 4-2: 16-21 Weeks Post Procedure

Courtesy of Wagner, 1999

Appearance of skin injury approximately 18 to 21 months following procedures, evidencing tissue necrosis:

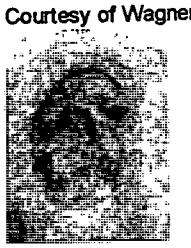
Figure 4-3: 18-21 months Weeks Post Procedure

Courtesy of Wagner, 1999

Figure 4-4 shows a close-up of injury area at 18-21 months:

Figure 4-4: 18-21 Months Post Procedure

Courtesy of Wagner, 1999



Two additional reported cases of radiation-induced injury (Wagner 1999):

1. Following a transjugular intrahepatic portosystemic shunt (TIPS) procedure involving 90 minutes of fluoroscopy, a discharged patient developed erythema and discoloration on his back. One year after the TIPS procedure an ulcer developed, which did not heal, and two years later it was 4-cm in size. A split thickness skin graft from the right buttock was performed.

2. Following a TIPS procedure lasting 6 hours and 30 minutes (no indication of total fluoroscopy time), a 16- x 18-cm hyperpigmented area developed on the patient's back and progressed over a period of several months into a central area with ulceration. After 14 months a split thickness skin graft was performed leaving a depressed scar at the surgical sight.

These case studies indicate that extensive use of fluoroscopy can induce severe skin damage, even under the most favorable geometries.

Steep Fluoroscopic Angles

When the fluoroscope is oriented at a lateral or an oblique angle, two factors combine to increase the patient's ESE rate. The first is that a thicker mass of body tissue must be penetrated. The second is that the skin of the patient is closer to the source because of the wider span of anatomy (Wagner 1999). Example cases are given below:

1. A PA oblique angle using a C-arm involved 57 minutes of fluoroscopy. Twenty-four hours later the patient reported a stabbing pain in his right thorax. Three days later an erythema developed which evolved into a superficial ulcer. At two and half months after the procedure the area was approximately 12-cm x 6.5-cm and described as a brownish pigmented

area with telangiectasia, central infiltration and hyperkeratosis.

4. A PA oblique angle was employed during a catheter ablation procedure involving 190 minutes of fluoroscopy. A symptomatic discoloration was noted several days after the procedure on the patient's left upper back. In the next few weeks the area had become painful and was draining. At seven weeks the area was approximately 7- x14-cm in size and described as a rectangular erythema with ulcers. After treatment, there was a gradual lessening of tenderness with reepitherlialization, leaving a mottled slightly depressed plaque.
5. A steep PA oblique angle through the right shoulder was employed involving 51 minutes of fluoroscopy. Fourteen days after the procedure, an erythema appeared on the right shoulder that progressed into moist superficial ulcer with poor healing. This degenerated into a deep muscular ulcer requiring a myocutaneous skin graft approximately 14 months after the procedure.

The temporal progressions of these effects are consistent with high levels of acute exposure to x-ray radiation. The temporal differences in the responses are due in part to the levels of radiation received, but are also likely due to variations in radiation sensitivity amongst the patients.

Multiple Procedures

Although intervals between procedures should permit the skin to recover, healing might not be complete. This may lower the tolerance of the skin for further procedures (Wagner 1999). Example cases are given below:

1. A patient underwent two PTCA procedures about one year apart. Skin changes appeared approximately three weeks after the second procedure. At seven weeks a cutaneous ulcer had developed over the right scapula and healed without grafting.
2. A patient underwent two unsuccessful cardiac ablations involving approximately 100 minutes of fluoroscopy in a lateral oblique orientation. Approximately 12 hours after the second attempt, an erythema developed in the right axilla. At one month the area was red and blistering. At two years the area was described as a 10 x 5cm atrophic indurated plaque with lineal edges, hyper- and hypopigmentation, and telangiectasia. The patient was described as having difficulty raising her right arm.
3. Three PTCAs were performed on the patient, the last two completed on the same day approximately 6 months after the first procedure. The total fluoroscopy time was approximately 51 minutes. Erythema was noted immediately after the last procedure. This progressed from a prolonged erythema with poor healing into a deep dermal necrosis. The patient underwent a successful split thickness skin graft two years after the last procedure.
4. Past treatment of pulmonary tuberculosis often resulted in many patients undergoing extensive exposure to fluoroscopy. These patients had a demonstrated high incidence of breast cancer.

Previous procedures can lower the skin's tolerance for future irradiation. Prior to commencing any lengthy fluoroscopic procedure, the patient's medical history should be reviewed. The skin of the patient should be examined to

ascertain if any skin damage is apparent should the patient have a history of lengthy fluoroscopic examinations. Direct irradiation of damaged areas should be avoided when possible.

Positions of arms

Keeping arms out of the x-ray beam during some procedures can be a difficult. Careful attention must be given to providing the arms with a resting position that will not restrict circulation but will at the same time maintain the arms in an area that is outside the radiation field (Archer 2000).

A middle-aged woman had a history of progressively worsening episodes of arrhythmia. A radiofrequency electrophysiological cardiac catheter ablation was scheduled to treat the condition. The procedure employed 20 min of beam-on time for each plane of a bi-plane fluoroscope. Prior to the procedure the separator or **spacer cone** was removed so that the fluoroscopic c-arms could be easily rotated around the patient. The spacer cone is a spacer attached to the tube housing designed to keep the patient at a reasonable distance from the x-ray source. This is done specifically to avoid the high skin-dose rates that can be encountered near the tube port.

The patient's arms were originally placed at the patient's side but the right arm later fell into a lower position directly in front of this x-ray tube. However, personnel were not aware of this change because sterile covers were draped over the patient and did not correctly interpret the image (Figure 4-4). The right humerus was directly in the beam at the port. Because the separator cones were removed, the arm was only about 20–30 cm from the focal spot. With the soft tissue and bone of the arm directly in the beam, the automatic brightness control drove the output to high levels at the surface of the arm. The cumulative dose probably exceeded 25 Gy (2500 rad). This procedure was not performed at Henry Ford Health System.

Figure 4-4: Image of Arm resting on X-ray Tube Port

Courtesy of Archer, 2000

The patient was released from the hospital the day after the procedure. At the time there were no complaints regarding her arm and no indication of erythema. About three weeks after the procedure, a bright erythema was demonstrated (Figure 4-5).

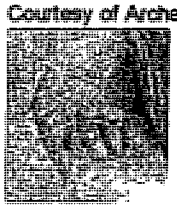
Figure 4-5: Three weeks Post Procedure

Courtesy of Archer, 2000

The condition worsened and at five months a large ulcer the size of the collimated x-ray port developed.

Figure 4-6: Five Months Post Procedure

Courtesy of Archer, 2000



The separator or **spacer cone** ensures that a minimal distance between the X-ray source and the patient is maintained (inverse square law effects). For some X-ray machines, the spacer cone is designed to be removable in order to provide more flexibility in positioning for some special surgical procedures (e.g., portable C-arms). There is a risk of very high dose rates to the skin surface when it is removed.

Skin Sensitivity

Some patients may be hypersensitive to radiation due to pre-existing health conditions (Wagner 1999).

Erythema developed after diagnostic angiography and liver biopsy. Skin necrosis requiring rib resection evolved in the same patient after a TIPS procedure. The wound remained open for five years before a successful cover was put in place. Investigation into the events revealed that the patient suffered from multiple problems, including Sjøgren's syndrome and mixed connective tissue disease.

Injuries to personnel

The following are modern-day examples of how improper use of the fluoroscope can lead to injuries in personnel (Wagner 1999).

1. Hands of physicians have incurred physiologic changes indicative of high cumulative doses of chronic low-dose-rate irradiation. Brown finger nails and epidermal degeneration are typical signs. These changes were the result of years of inserting hands into the x-ray field with the x-ray tube above the patient.
2. Four cases of radiation-induced cataract have been reported in personnel from procedures utilizing the x-ray tube above the patient orientation.

Doses accumulated to hands and eyes from frequently using the fluoroscope with the tube above the patient can be extremely high. Only routine application of proper radiation management techniques will be effective at avoiding such high doses.

Go to Chapter 5_Protection Methods

February 6, 2009

Good afternoon, my name is David Carlson and I am a senior radiologic technology student at Middlesex Hospital and Middlesex Community College. I choose to pursue this highly challenging career path after proudly serving my country for 20 years in the United States Navy. I am now in my 21st month of training of the intensive 27 month program in Radiologic Technology at Middlesex Hospital.

I am here today to show support for SB 406 and have the new field of Radiologist Assistant formally recognized by the state. I ask that you support the admittance of this profession into the Chapter 376c bill, which is the current medical imaging law. Individuals who progress into this field are required to have graduated from an accredited radiographer school, successfully passed the national registry exam, and have already been practicing as a radiologic technologist. The position of Radiologist Assistant has been developed to allow radiographers the ability to advance their education and elevate into positions of greater responsibility while retaining their critical skill and knowledge in the medical imaging field. Radiologist Assistants have completed a master's degree program focused on very specific radiographic curriculum. They are accredited by the American College of Radiology and are experts in medical imaging. Radiologist Assistants have every right to be granted licensure in the state of Connecticut as they have completed very intense and through training in medical imaging.

At this time I am also perplexed about the possibility of the state of Connecticut allowing Physician Assistants to administer ionizing radiation. Physician Assistants have also completed very intensive training However, Physician Assistants have NOT received the necessary training to properly and safely conduct radiographic exams. Physician Assistants should NOT be confused with Radiologist Assistants by any stretch of the imagination. Physician Assistants are not fluent in radiation production and its characteristics, radiation protection and safety, x-ray equipment operation, exposure variables, analysis of image quality, or proper patient positioning, all of which takes extensive training to become certified to administer ionizing radiation.

It is common knowledge that ionizing radiation has the potential to be very harmful if not administered properly. The skills required to safely perform radiographic exams requires long extensive training and is not easily learned. Most accredited radiographic training programs, even "certificate" programs, are a minimum of two years continuous full time training. The programs entail not only human anatomy and physiology, but radiation production, radiation physics, proper positioning protocols, and radiobiology just to name a few. Most importantly, radiologic technologists are well trained in radiation safety as mandated by our Code of Ethics. Performing all exams correctly with accuracy is essential to minimize patient exposure to ionizing radiation. This profession is a learned science and must only be performed by licensed professionals. The technologist know if their patient is properly positioned and what technique to utilize to produce a diagnostically superior image. Additionally, the technologists also know how to adjust exposure factors when sub-optimum results do occur. This IS NOT a "push-button" profession, it is a serious and vital medical profession that must only be conducted by properly licensed professionals.

In conclusion, Radiologist Assistants are the professionals that should be licensed to administer ionizing radiation along with their fellow radiologic technologists They have the experience and the training required to safely perform complex radiographic procedures. I am not implying that Physician Assistants are unimportant or unskilled in medicine. Physician Assistants are however, completely untrained in the field of radiologic science and should be excluded from administering ANY form of radiation to patients as this would be detrimental to public health and safety. Furthermore, if Physician Assistants were granted the right to perform radiographic exams this would immediately make the Radiologist Assistants practically obsolete in addition to the public health and safety risks.

Thank you for your time and attention in this important issue.

Respectfully,

David R. Carlson
Co-President Class of 2009, Radiologic Technology, Middlesex Community College

Testimony regarding
SB 406, *AN ACT CONCERNING LICENSURE OF ASSISTANT RADIOLOGISTS*
Presented before the Public Health Committee
February 6, 2009

Representative Ritter, Senator Harris, and members of the Public Health Committee:

Thank you for the opportunity to speak about Senate Bill 406, which is before the Public Health Committee today. My name is Marc Benjamin, and I am a licensed physician assistant from Farmington, practicing at St Francis Hospital here in Hartford. I am here today representing the Connecticut Academy of Physician Assistants (ConnAPA).

Let me first state that it is not ConnAPA's goal to oppose another profession seeking formal recognition through state licensure. As the Radiologist Assistant profession pursues enabling legislation, the issues of eligibility, scope of practice and licensure are best left to the discretion of the Department of Public Health.

However, ConnAPA respectfully requests that the members of the Public Health Committee consider amending Senate Bill (SB) 406 with language to address the current confusion about physicians delegating the performance of procedures using ionizing radiation, most notably, fluoroscopy to licensed physician assistants. We have attached suggested draft language which recommends amending Section 20-74ee of the Radiologic Technologist (RT) Act to allow qualified, licensed physician assistants to perform procedures which use fluoroscopy, as delegated by their supervising physician.

Physician assistants (PAs) have been performing diagnostic and interventional procedures that use ionizing radiation since the early days of the profession. Most state PA practice laws, including Connecticut, permit supervising physicians to delegate to PAs the ability to order and perform diagnostic tests and therapeutic procedures, presumably including procedures that use ionizing radiation. However, state medical imaging laws permit only licensed RTs to perform procedures utilizing ionizing radiation, such as fluoroscopy. This creates a gap between state PA practice laws and provisions that regulate medical imaging.

Allowing physicians to delegate the use of ionizing radiation to PAs is an urgent matter affecting patient access to care. Some supervising physicians believe PA practice laws already give them the authority to delegate radiological procedures to PAs. It is ConnAPA's goal today to ensure that supervising physicians who are delegating these procedures are doing so safely and legally.

Keep in mind that not every PA in the state performs procedures using fluoroscopy, and ConnAPA's goal is not to usurp an RT's ability to do their jobs. PAs simply want to preserve patients' access to high quality care and use every available diagnostic tool to ensure the safety of the care provided.

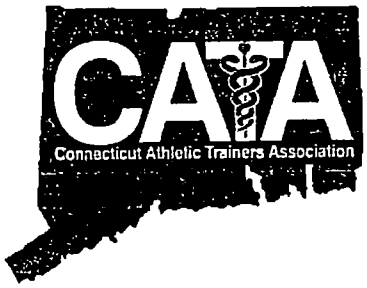
This bill, as amended with the language suggested by ConnAPA, will improve our patients' access to care, decrease hospital lengths of stay, increase efficiency of radiology departments across the state, and help mitigate emergency department overcrowding by allowing licensed physician assistants to assist the radiologists with fluoroscopic procedures.

Thank you for you the opportunity to testify before you today.

Marc Benjamin, PA-C

1 Attachment

Connecticut Academy of Physician Assistants
y Drive · PO Box 30 · Bloomfield, CT 06002 P: 860/243-3977 F: 860/286-0787
connapa@ssmgt.com · www.connapa.org



To: Public Health Committee

From: Vicky Graham, ATC, LAT
Connecticut Athletic Trainers' Association

RE: S.B. No. 755 (RAISED) AN ACT CONCERNING THE USE OF ASTHMATIC INHALERS AND EPINEPHRINE AUTO-INJECTORS WHILE AT SCHOOL.

Date: February 6, 2009

Good morning. I would like to thank Senator Harris, Representative Ritter, and the members of the Public Health Committee for this opportunity to address the committee. My name is Vicky Graham, and I am the President-Elect of the Connecticut Athletic Trainers' Association (CATA). I am speaking today in regard to S.B. No. 755 (RAISED) AN ACT CONCERNING THE USE OF ASTHMATIC INHALERS AND EPINEPHRINE AUTO-INJECTORS WHILE AT SCHOOL.

The Connecticut Athletic Trainers' Association is supportive of this legislation. We believe it essential that students have immediate access to emergency medications, and support their being able to carry asthma inhalers and Epi-pens with them at school, as well while participating in sports and other after school activities. We are requesting that Licensed Athletic Trainers be included in the list of individuals able to administer or assist with the administration of these medications.

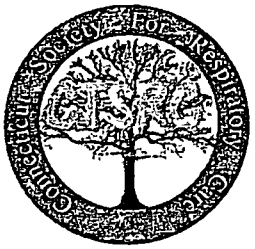
In Connecticut, Athletic Trainers (ATs) are required to work under standing orders from a Physician. ATs very often administer or assist with the administration of asthma inhalers and epinephrine auto-injectors, per standing orders from their supervising Physician. The Licensed Athletic Trainer is responsible for the health and welfare of students participating in sports at the school, and is typically the only trained medical professional on school grounds after classes end. Secondary school athletic practices and events occur after school, well into the evening. The AT is the primary responder to any type of medical problem or emergency that occurs during practices and competition.

ATs are highly qualified, multi-skilled allied health care professionals and have been part of the American Medical Association's Health Professions Career and Education Directory for more than a decade. Athletic trainers are assigned National Provider Identifier (NPI) numbers like all

other health care professionals. In addition, the American Academy of Family Physicians, American Academy of Pediatrics, and American Orthopaedic Society for Sports Medicine, among others, are all strong clinical and academic supporters of ATs. Athletic Training encompasses the prevention, diagnosis, and intervention of emergency, acute, and chronic medical conditions involving impairment, functional limitations, and disabilities. While traditionally practicing in secondary school, college, and professional athletics, the AT also practices in sports medicine clinics, physician offices, the industrial setting, the performing arts, and the military. ATs are required to have received a Bachelor's degree from an accredited Athletic Training Education Program, and to pass a national certification examination. Over 70% of Athletic Trainers have advanced degrees, and all are required to complete ongoing continuing education in order to maintain certification and licensure.

The Connecticut Athletic Trainers' Association is requesting that the language in S.B. 755 be modified to include Licensed Athletic Trainers as individuals who, along with "...the principal, any teacher, licensed physical or occupational therapist employed by a school district, or coach of intramural and interscholastic athletics of a school..." may administer asthmatic inhalers and epinephrine auto-injectors.

Thank you.



STATEMENT OF THE CONNECTICUT SOCIETY FOR RESPIRATORY CARE
Before the PUBLIC HEALTH COMMITTEE
in support of SENATE BILL 755

February 6, 2009

Sen. Harris, Rep. Ritter and members of the committee·

The Connecticut Society for Respiratory Care represents licensed respiratory care practitioners in the state of Connecticut. We strongly support the passage of Senate Bill 755, ***An Act Concerning the Use of Asthmatic Inhalers and Epinephrine Auto-Injectors While at School.***

Nationally, asthma is one of the most common chronic diseases and a leading cause of disability in children. Senate Bill 755 will permit students to possess and self-administer an asthmatic inhaler or automatic prefilled epinephrine injectors at all times while attending school. This will be allowed when a physician, physician assistant, advanced practice registered nurse and respiratory care practitioner make written certification after a comprehensive patient assessment. This practice will ensure prompt treatment of the child's asthma and protect the child against serious harm or death. Under current regulations, local school districts may require that such devices be maintained, stored, and administered by the school nurse or administration. This process can delay or prevent the student from responding immediately to an asthma attack, resulting in serious injury or even death.

Asthma in Connecticut 2008: A Surveillance Report, reported a 10.5% (86,000) incidence of asthma among children ages 0 – 17years. The highest incidence occurred in school-aged children, ages 5 – 12 years (11.6%). This compares to 8.9% of children in the United States. Children have been identified as a priority for asthma intervention in Connecticut. The CT DPH Asthma Program and Connecticut Asthma Advisory Council are in the process of developing a revised statewide asthma plan to address asthma in Connecticut. The plan will focus on expanding asthma interventions. The addition of Senate Bill 755 will be of tremendous assistance in reducing hospitalizations and mortality in children with asthma that cannot receive emergent care in a timely manner. Prompt intervention can reduce hospitalizations and ED visits which are currently averaging at 18 visits per 10,000 and 85.9 visits per 10,000 respectively. This translates into a cost of nearly $14 million dollars per year.

The Healthy People 2010 developed by the US Department of Health and Human Services has identified specific objectives for asthma. Among these are: Reduce asthma deaths, reduce pediatric hospitalizations and emergency room visits, and reduce the number of missed school days related to asthma. Connecticut still falls short of its target based on these objectives.

Asthma prevalence in Connecticut is on the rise. Although there is no known cure for asthma, it can be managed through proper medical treatment. With proper management and prompt access to medications during an acute episode, asthma patients should not have to seek emergency care or be admitted to the hospital because of their asthma. Allowing students to carry and administer these medications independently may prevent these consequences.

The Connecticut Society for Respiratory Care is prepared to assist you in any way to craft statutory language that all entities can accept.

Thank you for permitting me to testify on behalf of this bill. I will be happy to answer any questions you may have.

Respectfully submitted,

Susan Albino, RRT, BSRT

Susan Albino, RRT, BSRT
CTSRC Delegate 2007-2012
CTSRC Past-president 2002-2004
Respiratory Care Department Manager
Hartford Hospital

Mr. Larry S. Berman
1 King Philip Drive Unit 303
West Hartford, CT 06117
(860) 216-4044
lberm@comcast.net

February 6, 2009

Senator Jonathan A. Harris
Chief Assistant Majority Leader
Public Health Committee, Chair
Connecticut General Assembly
Legislative Office Building, Room 3000
Hartford, CT 06106-1591

Dear Senator Harris and Members of the Public Health Committee,

It was about six months ago that I was very surprised to learn that Connecticut is one of the very few remaining states in the country that has not enacted legislation that allows students, with permission from their parents and doctors, to carry their prescribed epinephrine at school. As of today, forty-two out of the fifty states and the District of Columbia have enacted legislation allowing students to carry their prescribed epinephrine at school (please reference The Food Allergy & Anaphylaxis Network (FAAN) link http://www.foodallergy.org/advocacy/advocacy-schools.html and attachment). In addition, legislation has also been proposed in Georgia and New York in addition to here in Connecticut with S.B. No. 755, An Act Concerning The Use of Asthmatic Inhalers And Epinephrine Auto-Injectors While At School.

My fourteen year old son, Marc Berman, has a life threatening allergy to peanuts and tree nuts. Since he was diagnosed at a very young age, his Epipen has always, always, always been nearby. It has to be because we never know what moment it may be essential to saving his life. Despite Marc being acutely aware of his health risk along with his family, friends, coaches, and teachers, and his being extremely vigilant about avoiding exposure to food allergens, he still has had two extremely frightening allergic reactions. His Epipen may very well have saved his life. This school year he began his freshman year in high school and it has become more and more absurd that he is not allowed to carry his Epipen with him where he spends the majority of his day, in school. It is simply unacceptable at his age to have to rely on a teacher or classmate making a phone call to the nurse who we hope is immediately available that then has to get his Epipen out of a locked cabinet and then transport it across a large high school to administer his Epipen... hopefully in time!

Having his Epipen immediately available while at school may make the difference one of these days between my son dying or having the opportunity to live to enjoy the full life that he deserves! If not my son, then it may quite possibly save the life of one of the thousands of food allergic sons and daughters of other parents across the state Connecticut.

I respectfully ask that you please support passage of S.B. 755. Thank you.

Sincerely,

Larry S. Berman

Larry S. Berman

* Source: The Food Allergy & Anaphylaxis Network

[illegible], introduced in Virginia, calls on each local school board to develop and implement a policy for managing public school students with life-threatening food allergies no later than January 1, 2010. The bill also requires appropriate school personnel to receive food allergy management training.

For information on helping pass any of this legislation, please send an email to eweiss@foodallergy.org

*

Carrying Prescribed Epinephrine at School

Below are the states that now have laws or regulations allowing students to carry, and potentially self-administer, their prescribed epinephrine at school (with year of enactment in parentheses):

Alaska (2005)	Maine (2004)	Oregon (2007)
Arizona (2005)	Maryland (2005)	Oklahoma (2008)
Arkansas (2005)	Massachusetts (1993)	Rhode Island (1998)
California (2004)	Michigan (2004)	South Carolina (2005)
Colorado (2005)	Minnesota (2004)	Tennessee (2005)
Delaware (2003)	Missouri (2006)	Texas (2006)
District of Columbia (2007)	Montana (2005)	Utah (2008)
Florida (2005)	Nebraska (2006)	Vermont (2008)
Hawaii (2004)	Nevada (2005)	Virginia (2005)
Idaho (2008)	New Hampshire (2003)	Washington (2005)
Illinois (2006)	New Jersey (2001)	West Virginia (2004)
Indiana (2001)	New Mexico (2005)	Wyoming (2007)
Iowa (2004)	North Carolina (2005)	
Kansas (2005)	North Dakota (2005)	
Kentucky (2004)	Ohio (2006)	

OTHER SCHOOL ISSUES

Statewide Guidelines for Schools

Statewide guidelines to help schools manage students with food allergies have now been published in Arizona, Connecticut, Maryland, Massachusetts, Mississippi, New Jersey, New York, Tennessee, Vermont, and Washington

School Lunch Guidelines

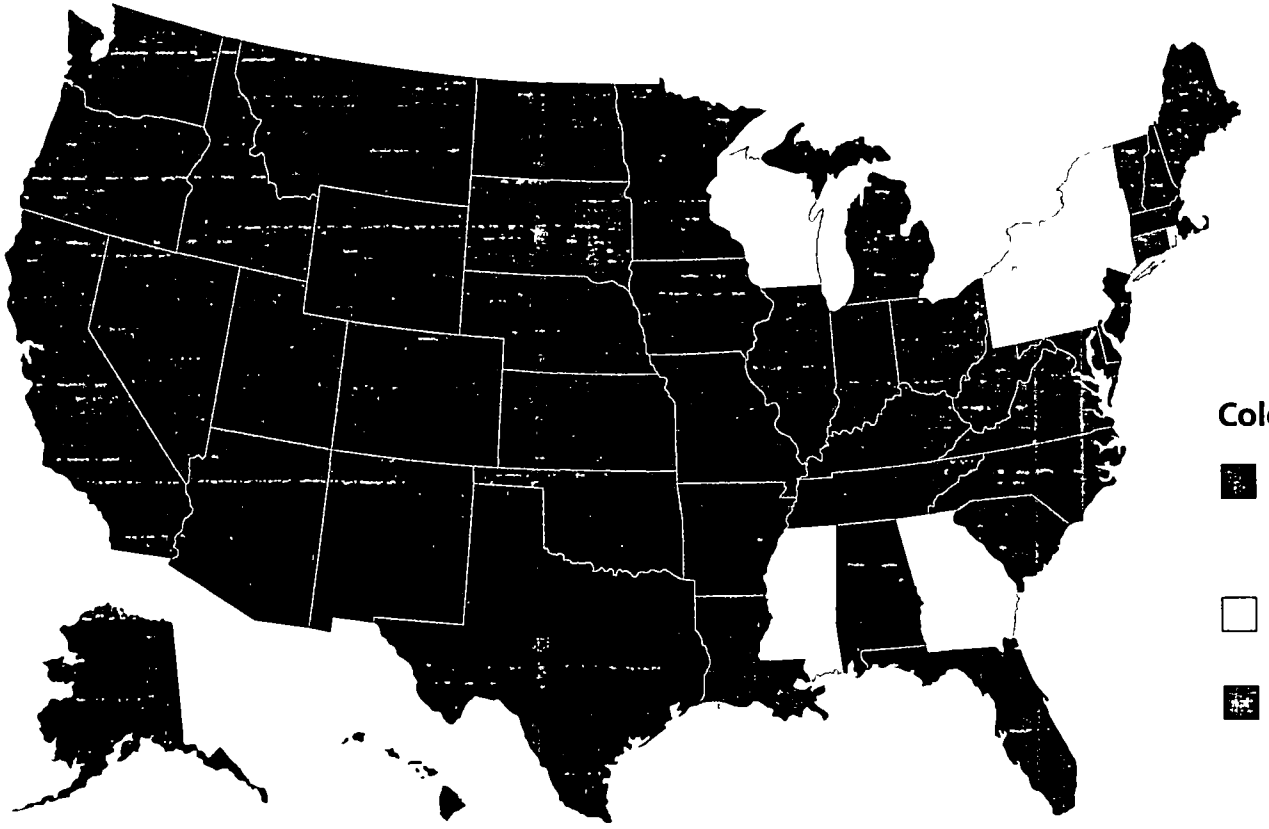
The U.S. Department of Agriculture (USDA), the federal body that oversees the national school lunch program, has a guidance document entitled Accommodating Children with Special Dietary Needs. In this document, the USDA recommends that children with life-threatening food allergies be given a safe substitute meal, based on instructions from the child's physician.

Schools and the Law

It is generally accepted that children with life-threatening food allergies are considered disabled under federal civil rights laws, such as Section 504 of the Rehabilitation Act and the Americans With Disabilities Act (ADA). Section 504 is overseen by the U.S. Department of Education's Office for Civil Rights, and the U.S. Department of Agriculture's Office for Civil Rights. The ADA is overseen by the U.S. Department of Justice.

COMPLICATED ISSUES

State Statutes Protecting Student Rights to Carry and Self-Administer Prescribed Asthma and Anaphylaxis Medications



Color Key:

- States with asthma and anaphylaxis laws
- States with ONLY asthma laws
- States WITHOUT asthma and anaphylaxis laws

000457

Written Testimony of
Linda Wallace, Executive Director
Epilepsy Foundation of Connecticut
February 6, 2009
Public Health Committee

Senate Bill #757, An Act Concerning The Filling of Prescriptions for Antiepileptic Drugs

Good morning Senator Harris, Representative Ritter and members of the Public Health Committee. Thank you for giving me the opportunity to testify in support of Senate Bill 757. My name is Linda Wallace and I am Executive Director of the Epilepsy Foundation of Connecticut. I am also the mother of a young adult who has had epilepsy for 23 years.

For the more that 60,000 people in Connecticut with epilepsy, medication is the most common and most cost effective treatment for controlling and/or reducing seizures. This legislation simply requires pharmacists to receive the consent of a patient and their physician before switching from one manufacturer of a particular medication to another manufacturer of the same medication. Physicians and people living with epilepsy may spend many years finding the right dosage and combinations of antiepileptic medications to prevent the occurrence of seizures. A small change in a patient's blood level of antiepileptic medications could easily upset the delicate balance needed to prevent seizures.

It is important to note that the Foundation is NOT and has never been opposed to the use of generic medications. We understand that epilepsy medication can be costly to people with epilepsy and we welcome generic medicines to lower the cost for individuals. We simply want to ensure that a consistent supply of generic medication for people is dispensed and that the physician and patient are notified when it isn't. Epilepsy is a unique condition. Seizures have the potential to be life threatening and can endanger the individual and others around them. This is true particularly if they occur without warning, while the individual is engaged in the various activities of daily life. To risk the occurrence of seizures by switching products without the guidance of the individual's physician is a matter of both public and patient safety.

Until recently there has been limited data on this issue and most evidence was anecdotal or involved a small patient population. Now there are new study results that estimate the risk of an acute event requiring emergency intervention when switching medications at approximately 5%. (See supporting material attached.)

This is not a new issue, nor is it driven by a desire for anyone to benefit except people with epilepsy. For over a decade now, the Epilepsy Foundation has been opposed to switching medications, brand to generic, generic to brand, or from one manufacturer of a generic to another without the consent of the physician and patient. This protection allows for consistency of a person's medication and does not encourage or promote the use of any particular medication – brand or generic. This legislation has the support of the Connecticut State Medical Society, the Connecticut Neurology Association, the American Academy of Neurology, the American Epilepsy Society, the International League Against Epilepsy, the National Black Caucus of Legislators and the National Hispanic Caucus of State Legislators.

Thank you for introducing this legislation, providing us this time to testify and your thoughtful consideration of this important legislation.

EPILEPSY FOUNDATION®
Not another moment lost to seizures™
8301 Professional Place, Landover, MD 20785

August 4, 2008

ROBERT . BONWETSCH
69 SAND PIT RD STE 300
DANBURY, CT 06810

Re: Breakthrough Seizures Associated with AED Switching

Dear Doctor:

The Epilepsy Foundation has long been concerned about the potential risk of breakthrough seizures or toxicity for some epilepsy patients if there is a formulation change in their anti-epileptic drug (AED). The change could be brand to generic, generic to brand, or between the generic versions from different manufacturers. For this reason we believe you as the treating physician and your patient should decide the best treatment option and the Foundation opposes mandatory substitution without physician / patient consent. Our position is consistent with those taken by the American Academy of Neurology, the American Epilepsy Society, the International League Against Epilepsy and almost all international epilepsy organizations.

Until recently there has been limited data on this issue and most evidence was anecdotal or involved a small patient population. As a clinician who treats people with epilepsy, we wanted to make sure you were aware of what we believe are the first case-control analyses of AED switches. Published in *Epilepsia*, Zachry, et al used the Ingenix LabRx Database (i.e., the United Health Group) to evaluate patients with a claim for ambulance, emergency room or inpatient hospital service with a primary epilepsy diagnosis for patients who were previously well controlled (had not utilized these services for epilepsy in the previous six months). Epilepsy patients who received emergent care for epilepsy had 81% greater odds of exposure to switching prior to the breakthrough event when compared to epilepsy patients not receiving emergent care. This result was highly statistically significant ($p=0.0024$).

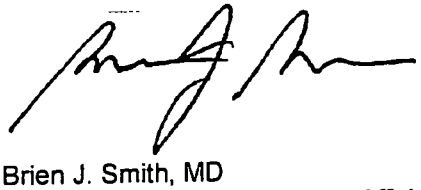
In order to validate the Zachry study, two academic institutions were asked to independently conduct additional case-control studies on other unique nationwide U.S. claims databases. Both studies found almost identical results and are now pending publication. In order to aid clinical application of these studies, each lead author was asked to estimate the attributable risk of an acute event requiring emergent intervention when switching. Based on their study results, each estimated a risk of approximately 5%. It is important to note that these studies only looked at seizures and do not consider toxicity, which anecdotal reports have also linked to formulation changes for some epilepsy patients.

These studies have been shared with the Food and Drug Administration (FDA). Dr. Janet Woodcock, Director Center of Drug Evaluation and Research responded, in part, "We share

your concern that there could be a limited population of epileptic patients who may be at an increased risk of adverse event with even a minor change in AED formulation, but, we currently do not have adequate data to define such a population, or even to be sure that such a population exists. Before FDA can require any labeling changes or issue a public advisory, an objective prospective study is needed to evaluate PK parameters and adverse events simultaneously with switches in formulations while controlling for all the factors relevant to causation."

The Epilepsy Foundation is collaborating with the American Epilepsy Society (AES) and FDA on a prospective trial as described by Dr. Woodcock and her colleagues. However, completion of such a trial may take at least 1-2 years; in the interim the Epilepsy Foundation believes it is important that clinicians are aware of all relevant data available and the potential risks their patients may face. If you would like to read the full text article, it is available via www.epilepsia.com under the "online early" link.

Sincerely,



Brien J. Smith, MD
Chair, Legal and Government Affairs Committee
Epilepsy Foundation

Bruce P. Hermann, PhD
Chair, Professional Advisory Board
Epilepsy Foundation

cc: Epilepsy Foundation Board of Directors
Epilepsy Foundation Professional Advisory Board
Epilepsy Foundation Affiliates

160 St Ronan Street, New Haven, CT 06511-2390 (203) 865-0587 FAX (203) 865-4997

Connecticut State Medical Society Testimony in Support of Senate Bill 757 An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs
Submitted to the Public Health Committee
February 6, 2009

Senator Harris, Representative Ritter and members of the Public Health Committee, my name is Anthony Alessi and I am a neurologist from Norwich Connecticut. On behalf of myself, my patents and the more than 7,000 members of the Connecticut State Medical Society (CSMS) thank you for the opportunity to submit this testimony to you today in support of Senate Bill 757 An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs.

For most patients the substitution of a generic for a name brand and even the substitution of the same medication between two different generic manufacturers are not noticeable. However, the Food and Drug Administration allows variations from one generic medication to the next. Although mainly in the inert ingredients, for people with epilepsy, these variations can have potentially devastating effects. What for most would be an innocuous change from one generic to another is dangerous for patients with epilepsy results in seizures, even on those who have been seizure free for years.

The legislation before you today does not prohibit the switching from one generic to another. It merely requires that the physician provide consent to the change prior such a substitution being made. The requirement is reasonable, in the best interest of the patient and provides for the dispensing of a 72 hour emergency supply in the rare cases where physician consent is not immediately available.

Thank you for the opportunity to submit this testimony to you today. Please support SB 757.

Written Testimony of Dwayne Paul
Friday, February 6, 2009
Public Health Committee

SB 757 An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs

Good morning Senator Harris, Representative Ritter and members of the Public Health Committee.

My name is Dwayne Paul and here with me today is my daughter, Shelby. We are here on behalf of the many people who suffer from Epilepsy and would benefit greatly from your support of Senate Bill 757.

Shelby was diagnosed with Epilepsy NINE years ago. She has absence seizures, which are characterized by a staring episode followed by a period of disorientation. Due to the frequency of seizures that Shelby experiences she will very often lose focus for up to an hour or two

Over the past NINE years we have tried to control Shelby's seizures by utilizing 16 different anti-epileptic medications singularly and in various combinations. These include keppra, lamictal, zonegran, dilantin, pregablin, and others. In addition to these medications not controlling Shelby's seizures they have also caused a number of side effects including rashes, significant weight gain, significant weight loss, tremendous fatigue, and hallucinations! Even Shelby's brain surgery in 2005 has not helped to gain control over her seizures.

To this day we continue to try different Anti-Epileptic Drugs and combinations in the hopes of controlling or minimizing Shelby's seizures. It would be much more difficult to obtain this control when numerous generic manufacturers are added into the AED mix.

In order to help Shelby's doctor gain control we have kept a detailed journal of Shelby's seizures and various medications. During the past month Shelby has had 28 seizures, over the past six months Shelby has had 116 seizures, over the past year Shelby has had 287 seizures. And these are only the ones my wife and I have witnessed.

In short, epilepsy is different than high cholesterol. Because it is different, special precautions should be taken. People living with epilepsy welcome these safeguards and would not find them to be an inconvenience.

In closing I would like to say that if none of you have Epilepsy then:

No, you will never know...how it feels to not be able to get your license when all your friends are getting and talking about theirs,

No, you will never know. .how it feels to experience rapid weight gain due to the Anti-epileptic drugs you are taking,

No, you will never know...how it feels to be so tired in the morning that you have to be physically dragged out of bed for school,

No, you will never know...how it feels to be in the middle of doing something then totally and completely blank out and not remember what you were doing,

No, you'll never know what it is like to experience any of this, but you can know the personal satisfaction that will come by your supporting the Epilepsy Patient Protection Act.

Thank you for taking the time today to consider this important legislation!

CONNECTICUT PHARMACISTS ASSOCIATION
35 Cold Spring Road, Suite 121
Rocky Hill, CT 06067 ▪ (860) 563-4619
Fax: (860) 257-8241 ▪ **Email:** members@ctpharmacists.org
Website: www.ctpharmacists.org

Statement
Before the General Assembly's
Committee on Public Health
Friday
February 6, 2009

Re: Raised Bill 757: An Act Concerning The Filling of Prescriptions For Antiepileptic Drugs

Good morning Rep. Ritter and Sen. Harris. My name is Margherita Giuliano. I am a pharmacist and the Executive Vice President of the Connecticut Pharmacists Association. The Connecticut Pharmacists Association is a professional organization representing approximately 1,000 pharmacists in the state. I am here to oppose Raised Bill 757: **An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs.**

This bill would amend current legislation to mandate that a pharmacist can not substitute a prescription for an antiepileptic drug upon initial filling or refilling to a patient for treatment of epilepsy without obtaining written permission from the prescriber. This legislation is burdensome and costly to pharmacists, patients, taxpayers, and insurance companies.

We appreciate the effort by the Epilepsy Foundation to amend the language this year to include having the ICD codes or diagnoses codes on the prescriptions. As we mentioned previously, many of the antiepileptic drugs are used for other indications besides seizures. This language change will narrow down the number of prescriptions that could be affected by this law. However, our association still opposes this legislation due to the precedent that will be set by carving out a particular therapeutic class of drugs. This legislation has passed in a few states across the country. As predicted, other brand manufacturers are introducing legislation to "carve out" entire therapeutic classes from generic substitution laws. The immunosuppressant drugs are asking to be carved out as well as drugs for Fibromyalgia.

The Food and Drug Administration (FDA) has jurisdiction to identify drugs that are determined to be generically equivalent. In 2008, the FDA stated that they are "aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow up on such reports and interact with those concerned."

I want to stress the statement from the FDA that says they have NO SCIENTIFIC EVIDENCE. Everything we do as healthcare providers is based on best practices and evidence based medicine. To implement burdensome legislation without scientific evidence is unconscionable. We would be more than happy to work with the prescribers and the epilepsy foundation to urge the FDA to do controlled scientific studies to determine if switching manufacturers has a definitive correlation to increased seizures.

The Pharmaceutical Care Management Association published a report in October, 2008 that studied the impact of the generic carve out legislation for the therapeutic classes of brand name drugs – typically anti-epileptics, immunosuppressants, and antipsychotics – from state laws governing generic substitution. The report finds that this carved out legislation will increase prescription drug costs with no clinical benefits to the patient. If carve outs were implemented for the three therapeutic drug classes mentioned, it would cost the State of CT 444.3 million dollars in increased costs over the next 10 years. The anti-epileptic drugs alone would cost the state $275.5 million dollars over 10 years. Can our state afford this – amongst all the cuts you are asking us to take?

Most importantly how is this going to affect the patient? The way this legislation is written patients will have to wait for an unspecified amount of time before the prescriber determines if the pharmacist can substitute or change manufacturers. And if we don't hear from the prescriber or the prescriber says no – we have to turn the patient away.

Pharmacists are allowed to use their professional judgment when it comes to generic substitution. We are the medication experts. We recognize that some of these products are considered to have a "narrow therapeutic index". We weigh this when making generic determinations. This system has worked well for the past 15 years. To place burdensome legislation on pharmacy practice **without the scientific evidence to back it up** is costly to pharmacy, taxpayers and the patients themselves. We urge the committee to oppose this legislation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 11, 2008

Ms. Nicole Schultz
Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, IA 50322

Dear Ms. Schultz:

This is in reply to your correspondence dated November 6, 2007, directed to Ms. Susan Winckler requesting that the FDA provide a statement regarding generic substitution, particularly with respect to anti-epilepsy drugs. It was forwarded to the Office of Generic Drugs for a reply.

The FDA has many years of experience in the review of generic drugs and assures the quality and equivalence of approved generic drug products. FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S., both brand-name and generic, meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires that the proposed generic product is demonstrated to be equivalent to the brand-name drug in both the rate and extent of absorption. As noted in the Preface to the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") (27th Edition),

> FDA classifies as therapeutically equivalent those products that meet the following criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and, (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.
>
> FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and other minor aspects of labeling (e.g., the presence of specific pharmacokinetic information) and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent will produce the same clinical effect and safety profile as the prescribed product.

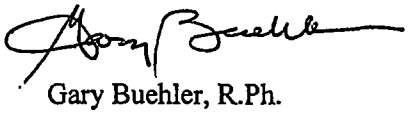
FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned.

If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that:

- Additional clinical tests or examinations by the healthcare provider are not needed when a generic drug product is substituted for the brand-name product or vice-versa.
- Special precautions are not needed when a formulation or manufacturing change occurs for a drug product provided the change is approved according to applicable laws and regulations by the FDA.
- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effects whether the products are brand-name or generic.
- It is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

We continue to monitor, take seriously, and, if indicated, investigate reports of potential inequivalence of all generic drugs. The FDA is committed to approving high-quality generic drug products that can be used with confidence by the American public.

Sincerely,



Gary Buehler, R.Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

cc: S. Winckler
C. Jung

Summary

Visante was commissioned by the Pharmaceutical Care Management Association to study the impact of so called generic carve-out legislation that seeks to exempt or "carve out" certain therapeutic classes of brand name drugs—typically antiepileptics, immunosuppressants, and antipsychotics—from state laws governing generic substitution.

Well-established laws in all 50 states permit a pharmacist to make a generic substitution unless otherwise directed by a prescriber. In fact, laws in fifteen states—including health care bellwethers such as Florida, Massachusetts, New York, and Tennessee—*require* that pharmacists substitute generics for brands unless the prescriber specifically orders the brand to be dispensed. Established laws also allow a prescriber to override a generic substitution by writing "brand medically necessary" or "dispense as written" (DAW) on the prescription.

Proposed carve-out legislation would prevent a pharmacist from substituting a generic for its brand equivalent in certain drug classes unless consent is first obtained from the prescriber, even when the prescriber has given no indication that the brand is medically necessary. Some proposals go further and require pharmacists to maintain written documentation of contacts with prescribers to obtain consent. Such time-intensive requirements could cause harmful delays in the delivery of patient care and impose costly administrative burdens on prescribers and pharmacists alike.

Based on a comprehensive literature review and analysis of sales and utilization data for drugs targeted by carve-out legislation, Visante finds that ***arguments favoring carve-out legislation are not supported by expert opinion and that such legislation would substantially increase prescription drug costs with no clinical benefit to consumers***.

Major Findings

- Generic carve-out legislation runs counter to the opinion of the Food and Drug Administration (FDA), which is that generic drugs can be expected to have the same clinical effects as their brand counterparts and encourages generic substitution across all therapeutic categories, *including* medications in the antiepileptic, immunosuppressant, and antipsychotic classes.

- Carve-out legislation would reduce the percent of prescriptions dispensed with a generic from 90 percent to an estimated 25 percent for targeted drugs, resulting in increased drug costs but no increase in quality of care.

- If generic carve-out legislation were enacted nationally in 2009 in the antiepileptic, immunosuppressant, and antipsychotic therapeutic classes, total prescription drug costs to Medicaid, commercial payors, and consumers would increase by **$29 billion over the 2010–2019 period**.

- Nationally enacted carve-out legislation would increase drug costs to commercial payors by $17.5 billion, Medicaid by $6.2 billion, and consumers by $5.3 billion over ten years.

⇒ **We estimate that carve-out legislation would reduce the market share of affected generic drugs from 90 percent to 25 percent.**

Carve-Out Laws Would Raise Prescription Drug Costs for Payors and Consumers

If generic carve-out legislation were enacted nationally in 2009 in the antiepileptic, immunosuppressant, and antipsychotic therapeutic classes, total prescription drug costs to Medicaid, commercial payors, and consumers would increase by **$29 billion over the 2010–2019 period**.

Table 1 details how nationally enacted carve-out legislation would increase drug costs to commercial payors by $17.5 billion, Medicaid by $6.2 billion, and consumers by $5.3 billion over ten years.

Table 1: Cost of Generic Carve-Outs Applied to Antiepileptics, Immunosuppressants, and Antipsychotics, 2010–2019

(Dollar figures in billions)

Drug Category	Total	State Medicaid	Federal Medicaid	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
Antiepileptics	$18 20	$1.55	$2.16	$11.00	$3.49
Immunosppressants	$4.09	$0.19	$0.24	$3.00	$0.67
Antipsychotics	$6.68	$0.89	$1.17	$3.48	$1.13
TOTAL	**$29.0**	**$2.6**	**$3.6**	**$17.5**	**$5.3**

To be conservative, the above estimates measure only the impact of generic carve-out legislation on new generic drugs introduced during the 2010 to 2019 period. This is because the requirement that the pharmacist call the doctor for consent before dispensing a generic can be expected to have the greatest impact on the use of new generic products that have not yet established a market share. In reality, however, carve-outs could also have an impact on the use of older generic drugs, since the vast majority of prescriptions for multisource products are written using the brand name rather than the generic name.[18]

More detailed data is provided in the Tables 2–5, for all states and for each payor type. New York and California are the states with the greatest drug utilization and costs, and would see the greatest impact. Both states would experience increased drug costs of almost $1 billion if carve-outs were implemented for the three drug categories analyzed.

[18] Steinman, M., et al , "What's in a Name? Use of Brand versus Generic Drug Names in United States Outpatient Practice," Gen Intern Med, 22(5): 645–648, May 2007

Table 3: Cost of a Generic Carve-Out Applied to Antiepileptics by State, 2010–2019

(Dollar figures in millions)

	Total	Medicaid (State)	Medicaid (Federal)	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
US Total	$18,204	$1,549	$2,165	$11,001	$3,489
AK	$28 2	$3 6	$4.0	$15 8	$4 8
AL	$343 5	$21 5	$44 9	$210 0	$67 1
AR	$220 2	$16 1	$43 4	$117 8	$42 9
AZ	$307 3	$16 0	$31 4	$193 9	$66 1
CA	$1,538 6	$133 2	$133 2	$961 2	$311 1
CO	$252 5	$20 0	$20 0	$159 9	$52 5
CT	$275 5	$17 4	$17 4	$181 5	$59 2
DC	$48 6	$3 2	$7 6	$28 7	$9 0
DE	$63 2	$8 0	$8 0	$35 6	$11 6
FL	$989 3	$62 7	$82 5	$618 6	$225 5
GA	$541 2	$40 9	$69 9	$329 4	$101 1
HI	$42 7	$4 7	$6 1	$24 6	$7 3
IA	$172 1	$13 7	$22 1	$102 7	$33 5
ID	$73 3	$5 2	$12 1	$41 6	$14 4
IL	$712 9	$71.6	$71 6	$427 7	$142 0
IN	$417 8	$33 7	$56 7	$246 8	$80 6
KS	$187 8	$15 4	$22 5	$112 0	$37 9
KY	$377 3	$28 6	$66 1	$214 8	$67 7
LA	$289 2	$18 2	$47 9	$165 4	$57 6
MA	$543 3	$61 7	$61 7	$324 0	$95 8
MD	$329 7	$28 2	$28 2	$213 9	$59 4
ME	$99 4	$10 2	$17 6	$56 7	$14 9
MI	$699 7	$41 0	$56 8	$462 2	$139 7
MN	$364 2	$26 9	$26 9	$240 7	$69 8
MO	$483 0	$39 7	$66 0	$282 9	$94 4
MS	$176 9	$8 2	$26 5	$106 0	$36 2
MT	$46 6	$3 4	$7 4	$26 9	$8 8
NC	$629 6	$49 8	$88 8	$378 2	$112 8
ND	$48 0	$3 4	$6 0	$28 8	$9 8
NE	$131 5	$12.0	$16 6	$78 1	$24.7
NH	$85 8	$8 0	$8 0	$54 0	$15 8
NJ	$451 0	$40 0	$40 0	$283 9	$87 2
NM	$93 1	$1 6	$3 9	$65 8	$21 9
NV	$109 6	$7 6	$8 5	$69 8	$23 8
NY	$1,202 1	$153 0	$153 0	$702 0	$194 1
OH	$821 8	$87 8	$136 0	$455 5	$142 5
OK	$198 1	$12 2	$24 9	$120 0	$40 9
OR	$163 4	$12 2	$19 0	$101 2	$30 9
PA	$753 7	$77 2	$90 9	$452 9	$132 7
PR	$127 5	$20 9	$20 9	$62 6	$23 0
RI	$88 4	$7 8	$8 6	$56 6	$15 5
SC	$260 7	$16 3	$37 7	$156 5	$50.2
SD	$44 6	$3 6	$5 4	$27 3	$8 3
TN	$545 2	$44 6	$78 4	$318 3	$103 8
TX	$1,289 4	$113 5	$174 0	$746 1	$255 8
UT	$145 1	$8 1	$20 5	$89 7	$26 8
VA	$424 3	$25 1	$25 1	$288 5	$85 7
VT	$47 0	$6 3	$9 0	$24 7	$7 0
WA	$346 7	$35 9	$38 1	$208 2	$64 5
WI	$361 5	$27 3	$37 2	$228 2	$68 8
WV	$187 2	$18 3	$52 8	$89 8	$26 3
WY	$24 4	$3 0	$3 0	$12.9	$5 5

Table 2: Cost of Generic Carve-Outs Applied to Antiepileptics, Immunosuppressants, and Antipsychotics by State, 2010–2019

(Dollar figures in millions)

	Total	State Medicaid	Federal Medicaid	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
US Total	$28,975	$2,628	$3,581	$17,473	$5,293
AK	$47 2	$6 2	$6 8	$27 0	$7 2
AL	$493 2	$32 2	$67 3	$302 8	$91 0
AR	$337 0	$26 0	$70 0	$179 5	$61 6
AZ	$499 3	$21 6	$42 4	$336 3	$98 9
CA	$2,789 1	$278 8	$278 8	$1,640 5	$591 0
CO	$389 8	$32 7	$32 7	$247 9	$76 4
CT	$444 3	$33 0	$33 0	$287 6	$90 7
DC	$94 6	$6 5	$15 1	$57 8	$15 2
DE	$90 1	$11 9	$11 9	$50 1	$16 1
FL	$1,548 0	$102 5	$135 0	$976 0	$334 5
GA	$800 6	$59 4	$101 6	$499 9	$139 8
HI	$76 8	$9 2	$11 9	$43 4	$12 3
IA	$289 1	$23 9	$38 5	$173 4	$53 2
ID	$109 0	$8 2	$18 9	$61 6	$20 3
IL	$1,156 6	$121 7	$121 7	$701 0	$212 2
IN	$634 8	$52 0	$87 3	$380 1	$115 4
KS	$304 3	$25 4	$37 2	$182 9	$58 7
KY	$528 9	$40 7	$94 0	$303 9	$90 2
LA	$432 3	$28 3	$74 5	$243 1	$86 4
MA	$903 1	$104 4	$104 4	$546 8	$147 6
MD	$541 0	$52 5	$52 5	$346 4	$89 7
ME	$148 1	$16 1	$27 8	$83 0	$21 2
MI	$1,089 7	$80 7	$111 9	$696 6	$200 5
MN	$587 2	$44 2	$44 2	$387 8	$110 9
MO	$734 8	$62 5	$103 8	$429 3	$139.2
MS	$259.3	$13 0	$41 8	$153 5	$50 9
MT	$79 0	$5 8	$12 7	$46 5	$14 0
NC	$941 9	$74 9	$133 5	$574 1	$159 3
ND	$75 9	$5 0	$8 8	$46 8	$15 3
NE	$201.9	$19 1	$26 3	$120 3	$36 2
NH	$127 3	$12 3	$12 3	$80 0	$22 7
NJ	$713 4	$69 7	$69 7	$442 4	$131 7
NM	$156 1	$2 4	$5 8	$111 5	$36 5
NV	$162 1	$12 2	$13 5	$103 8	$32 5
NY	$2,112 7	$309 6	$309 6	$1,189 7	$303 8
OH	$1,260 1	$134.4	$208 3	$712 1	$205 4
OK	$311 5	$21 5	$43 8	$183 8	$62 4
OR	$270 9	$21 8	$33 8	$168 7	$46 6
PA	$1,262 3	$138 8	$163 5	$755 4	$204 6
PR	$198 1	$32 6	$32 6	$95 4	$37 4
RI	$135 9	$13 0	$14 4	$86 1	$22 4
SC	$384 7	$24 5	$56 6	$233 4	$70 1
SD	$70 0	$5 4	$8 1	$43 9	$12 6
TN	$807 1	$65 1	$114 3	$476 9	$150 8
TX	$2,007 4	$176 5	$270 6	$1,182 2	$378 1
UT	$222 7	$12 2	$30 9	$141 2	$38 3
VA	$654 7	$39 5	$39 5	$451 4	$124 4
VT	$69.2	$8 9	$12 8	$37 5	$10 0
WA	$539 7	$57 5	$61 1	$326 3	$94 7
WI	$592 2	$43 8	$59 5	$379 9	$109 0
WV	$253 3	$23 9	$68 9	$125 6	$34 9
WY	$36 4	$4 5	$4 5	$19 6	$7 9

RAISED BILL 757 AAC THE AVAILABILITY OF PRESCRIBED ANTIEPILEPTIC DRUGS

Members of the public health committee, I am Richard Carbray, owner of Apex Pharmacy and Home Care Center in Hamden, Conn. I also serve as co-chairman of the legislative committee of the Connecticut Pharmacists Association, an association which represents over 1000 pharmacists in Connecticut. I am here today to speak in opposition to RAISED BILL 757 as it is proposed and discuss the reasons this legislation is not appropriate

In addition, I would suggest to the committee an alternative solution which would not require new legislation, but would utilize existing legislation that could be amended to accomplish the same intent of the proposed bill and result in a very controlled and patient oriented manner to improve patient outcomes with anti-epileptic medication therapies. Under this amendment, RB 757 would be unnecessary.

RB757 would mandate a pharmacist to obtain physician consent on a new or refill prescription for any brand to generic or generic to generic substitution of epileptic medications. It is important to note that brand to generic substitution has already been addressed Current state statute already exists for a do not substitute (DNS) by the physician. This generic to generic substitution would create barriers to patient access to generic drugs through unnecessary waiting time for substitution approval required from physicians to pharmacists via fax, phone, or written communication. Furthermore, both the AMA and FDA have restated their public policies determining that it is not necessary to approach any therapeutic class of drugs any differently from any other class and that a more stringent generic substitution process for narrow therapeutic index drugs is not warranted If that were the case, the manufacturer could manufacture smaller increments of drug strengths as is currently done with warfarin where the milligram strength can be titrated within a smaller range of drug potency.

This brings us to a very rational solution involving the amendment of the existing Conn Statute Sec 20-631 the Collaborative Practice Act which currently allows a physician to enter into an agreement with a pharmacist to manage a patient's medication through a protocol. Protocols are patient specific and developed by the physician in order to enable the pharmacist to participate in maximizing patient outcomes

In the case of the epileptic patient, if the prescriber wants a pharmacist to inform him/her if a generic to generic substitution is necessary due to a manufacturer change or unavailability of a certain generic drug product, it could be accomplished with the

notification protocol. The protocol could simply state that the pharmacist must notify the physician via fax whenever the generic manufacturer of a patient's epilepsy medication is changed.

The benefit of this collaborative practice amendment is threefold: (1) provides a solution for physicians to manage their patient's medication regimen without carving out one therapeutic class of drugs. All classes of medications could be monitored through this protocol, (2) it focuses the attention to the group of patients who will receive the most benefit from more stringent monitoring, and (3) it encourages collaboration between health care professionals to optimize patient care and therapeutic outcomes

In summary, we as an association are confident that the amendment to the collaborative practice act is the most efficient manner to ensure that the health, safety, and welfare of the patient is not only maintained but enhanced. This in fact was the foundation on which collaborative practice was built when it was first proposed This amendment is a natural addition to that foundation. It was through the leadership of both Sen. Handley and Rep. Sayers that we have this vehicle for health care professionals to interact for the benefit of all their patients. We are grateful for that and look forward to your consideration on this issue. Thank you for the opportunity to present to you today.

TESTIMONY SUBMITTED REGARDING CONNECTICUT SENATE BILL 757

PUBLIC HEALTH COMMITTEE

Submitted by:

Andrew Friedell
Director, Government Affairs
Medco Health Solutions, Inc.

February 6, 2009

State Senator Jonathan Harris, State Representative Elizabeth Ritter and members of the Public Health Committee, my name is Andrew Friedell and I am a Director of Government Affairs for Medco Health Solutions, Inc., which is a pharmacy benefits management company, or "PBM." I would like to thank you for this opportunity to testify today regarding our concerns with Senate Bill 757. We believe this legislation is not needed, that prescribers already have the authority to achieve the underlying intent through existing state law and that the issues raised by this bill can best be addressed by the doctor, patient and pharmacist -- not by the legislature. If enacted, this bill will result in added costs and make it harder for Connecticut patients to receive affordable prescription drug coverage.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. As a PBM, Medco is hired by large employers, unions, health plans and public sector entities to help manage the quality and affordability of the drug benefit these plans offer to their members or employees. Medco provides drug benefits to roughly 60 million people nationwide and about 20 percent of the Connecticut population. In 2008, we mailed approximately 965,000 prescriptions to state residents and we also operate a specialty pharmacy in Vernon, Connecticut.

We have serious concerns about Senate Bill 757 because it seeks to carve one class of drugs -- anti-epileptic medications -- out of the state's generic substitution rules without any scientific evidence supporting such protections. This will drive up costs for patients and payors by making it harder for the patient to obtain a lower cost generic medication and by opening the door to additional legislation in the future seeking similar exemptions for other classes of medication.

The U.S. Food and Drug Administration, charged with approving new drug applications and applications for generic equivalent products, weighed in on similar legislation under consideration in the state of Iowa in a letter dated January 11 of 2008 (copy attached):

> *FDA is aware that certain individuals and groups have expressed particular concern about the switch of anti-epileptic drug products.* ***To date, we have no scientific evidence that demonstrates a particular problem with this group of products.*** *Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned (emphasis added).*

Furthermore, the FDA also noted that when a generic product is deemed to be therapeutically equivalent to the innovator product (as is the case with several drugs that would be subject to the provisions of this bill), there is no need for the prescriber to "approach any one therapeutic class of drug products differently from any other class..."[1]

In addition, the American Medical Association has also looked into this specific issue and determined in a letter dated August 30, 2007 that "After reviewing the scientific evidence, the CSAPH (Counsel on Science and Public Health of the AMA's House of Delegates, 2007)

[1] Letter from Gary Buehler, R.Ph., Director of the FDA Office of Generic Drugs, to Ms. Nicole Schultz of the Iowa Pharmacy Association, dated January 11, 2008

concluded that a separate, more stringent generic substitution process for NTI (narrow therapeutic index) drugs was unnecessary."[2]

Given that both the FDA and AMA have weighed in effectively opposing special rules for this class of medications and given that there is no scientific evidence indicating that such special treatment is warranted, we urge the committee to leave this as a matter best addressed in discussions between the doctor, patient and pharmacist. Clearly, it is critical that physicians educate their patients about these matters and that pharmacists always inform patients when changes are made to their drug therapy.

Prescribers already have the ability to indicate if and when a drug can be substituted and when it should not. They have the right to indicate "dispense as written" on the prescription; *they do not need additional legislation to underscore that authority*. Therefore any risks associated with therapy changes in these medications are easily addressable under current law. In limiting drug substitution, S.B.757 creates new barriers between patients and safe and effective generic alternatives.

In addition, if the legislature decides to step in and limit generic substitution for this particular class of medications, it will no doubt open the door to addition legislation in the future seeking a similar exemption for other classes of medication. We fear that the passage of this legislation would be viewed by some as a "green light" to promote additional carve-out legislation that would further drive up the cost of prescription drug care.

The potential long term cost implications of this legislation are particularly relevant when considering the anticonvulsant class of medications, due to the fact that several significant branded drugs in this category face patent expirations over the next few years. If the pathway to

[2] Letter from Michael D Maves, MD, MBA, Executive Vice President and CEO of the American Medical Association, to Mark Merritt, President and CEO of the Pharmaceutical Care Management Association, dated August 30, 2007

safe generic alternatives is obstructed, patients and payors will end up significantly overpaying for prescription drug care. For example, when the branded drug Zoloft lost patent protection in August of 2006, Medco's mail service pharmacies were able to convert 93% of these prescriptions to lower cost generic alternatives *within the first week following the patent expiration*. These generic products offer both immediate *and* long term savings to patients and payors. In fact, FDA research on competition and generic drug prices found that generic drugs can be 80% less expensive than the brand name equivalent in drug categories that attract multiple generic competitors.[3] Every one-percent increase in generic utilization equates to roughly $4 billion in drug cost savings for this country. Furthermore, the difference in price inflation between brand and generic products can also generate long term savings as well. For example, in 2006 the average price inflation for generic drugs across Medco's book of business was 0.2% while the average price inflation for branded medications was 6.9%. This demonstrates that the higher cost of a branded drug is further compounded over time relative to generics -- thus exacerbating the long term problem for those purchasing the medications.[4]

Without any scientific evidence to justify these new rules, this legislation could result in significant and unnecessary increases in health care costs. In a time of rapidly escalating drug costs, we should be focused on encouraging the use of safe and effective cost control techniques, such as generic drugs, rather than discouraging them.

In summary, S.B. 757 aims to mediate issues which should simply be addressed through the communications that the prescriber and pharmacist have with the patient. No additional legislation is needed at this time. Thank you for your consideration of our views. I would be happy to answer any questions that members of the Committee might have.

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[3] U S. Food and Drug Administration, Center for Drug Evaluation and Research. "Generic Competition and Drug Prices " Available at. http://www fda.gov/cder/ogd/generic_competition htm (last accessed on 3/11/2008).

[4] Medco Drug Trend Report, 2007. Available at http://medco mediaroom.com/file.php/129/2007+DRUG+TREND+REPORT.pdf (last accessed on 3/11/2008).

Written Testimony of Terry Tabler, for Ellen Tabler
Friday, February 6, 2009
Public Health Committee

SB 757 An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs

Senator Harris, Representative Ritter and members of the Public Health Committee, thank you for inviting me to testify before you today, on behalf of my sixteen year-old daughter Ellen, her mother and my wife Ann, and Ellen's two college-aged siblings, Sally and Stewart.

We are residents of Newtown, Connecticut where we own a home, work, worship and play. I am a relatively new member of this club – that is the "Parents of Children with Epilepsy Club". One is not so much invited into this fraternity, as one is shoved. Until two years ago when she was diagnosed with epilepsy, my daughter Ellen was a competitive gymnast and an "A" freshman student. Today she is a junior at Newtown High School, struggling to maintain a "C" average, wondering if she will get into college, and when – or if – she will obtain her driver's license.

Even with the burden of Epilepsy, Ellen for the most part does indeed *appear* to be a "normal" teenage girl. Only her family, teachers and best friends know she has epilepsy, or would even recognize if she had a seizure in their presence. While Ellen did experience two tonic-clonic seizures prior to diagnosis and the initiation of treatment, she has not suffered one since. Ellen does though exhibit simple partial (frontal) seizures. These are relatively mild, brief (3-5 second in duration) epileptic activity with no loss of consciousness…but none-the-less are disruptive. What Ellen's seizures lack in intensity, they often recompense in frequency.

With her current regimen of Lamictal™ (now available as the generic lamotrigrine) and Lyrica™ (pregabalin), we have been mostly successful in reducing Ellen's episodes of simple partial seizures to: on a great day – none, and on a normal day - just a handful. But on a bad day – triggered by test induced stress, menstruation, lack of sleep, or multiple other known and unknown variables – Ellen may suffer 20 to 40 seizures. Often she loses count. During a recent chemistry mid-term, she thinks she had about 30. In a test that most students completed in two hours, Ellen toiled over for three, just to score a 53.

Committee members, you can help Ellen and thousands of other Epilepsy patients in Connecticut control one very important seizure variable – dosage. You heard testimony from Dr. Alessi about the importance of a consistent supply of medication. Control of this single but critical variable may just make the difference between a passing and a failing grade, obtaining a drivers license, or being accepted into a university.

Thank you for you consideration of Senate Bill 757.

National Alliance on Mental Illness

Testimony before the Public Health Committee
February 6, 2009
Support for SB 757

Good afternoon Senator Harris, Representative Bye and members of the Public Health Committee. My name is Amy O'Connor and I live at 504 Whitney Avenue in New Haven. I am here today to testify on behalf of the National Alliance on Mental Illness of CT (NAMI-CT) in support of SB 757, AN ACT CONCERNING THE FILLING OF PRESCRIPTIONS FOR ANTIEPILEPTIC DRUGS.

SB 757 prohibits pharmacists from substituting prescriptions for anticonvulsant medications with generics or other brand names without contacting the patient's physician for approval. In addition to being approved to treat epilepsy, some anticonvulsants are prescribed for people with mental illnesses, specifically bi-polar disorder. Mental Illness is common—one in four adults will experience a mental health disorder, and one in seventeen will have a serious mental illness, like schizophrenia, bi-polar disorder and major depressive disorder. Mental Illness is the leading cause of disability in the US and Canada for people aged 15 – 44. But between 70 – 80% percent of people can be effectively treated and return to their normal daily activities and lives, in large part due to new advances in psychiatric medications, including anticonvulsants. Substantial research shows, however, that these medications are not interchangeable, and that substitutions can be both ineffective and dangerous.

According to the National Institute of Mental Health, individuals have unique responses to psychiatric medications. While psychiatric medications in a class may have similar effectiveness overall, they have specific mechanisms of action that affect each person differently. Proper medications and dosages are determined by a variety of factors, including age, gender, past medication history, and overall health status. Limiting access to necessary medications by not taking into account individual patient characteristics can have devastating, even deadly consequences for people with mental illnesses. It is important to maintain physician and patient choice in order to quickly find the best possible clinical outcome and avoid higher health care costs such as emergency visits, hospital stays, and crisis management. In considering SB 757, it is important to understand that this choice is compromised by allowing critical decisions about a patient's medication to be made by pharmacists. Effective treatment can also reduce the costs related to homelessness and criminal justice system involvement, promote employment and reduce reliance on federal and state funded programs.

Speaking from a personal perspective, it weighs heavily on a person when she or he knows that everything depends on finding the right medication. For my bi-polar disorder, I take six psychiatric drugs, for a total of 11 pills taken at five times throughout the day. The thought of not having even one of these medications terrifies me. It has taken me years to find the right combination and I've come a long way from when I started taking them— relying on state heath care, deeply depressed, unable to keep a job, isolated, and in poor physical health. The last time I stopped taking my anticonvulsant, Lamictal, I was nearly hospitalized but thanks to my family, my doctor allowed me to be treated on an out-patient basis. Although I only missed a few doses of Lamictal then, I felt the emotional, mental and physical side effects of this mistake for the next six months. I know from experience that biologic differences among patients mean medications that treat these disorders work differently for each person, since I've tried dozens of them. I lost years of my life to an illness that I finally found out is treatable with the right medications, and so I urge you to support HB 757 and keep those who rely on anticonvulsants safe and give us an opportunity to fulfill our potential.

Thank you.

NAMI-CT 241 Main Street, 5th Floor, Hartford, CT 06106
PHONE: 860-882-0236 FAX: 860-882-0240 www.namict.org

Statement of Carol Allocco before the Public Health Committee
in support of Senate Bill 781 – February 6, 2009

Sen. Harris, Rep Ritter and members of the committee·

My name is Carol Allocco. I am the Senior Director of Government Affairs for Johnson & Johnson Today, I represent one of our Operating Companies - VISTAKON, a division of Johnson& Johnson Vision Care, Inc. I am here today to offer comments in regard to Senate Bill 781, **An Act Concerning Therapeutic Contact Lenses**

New technology, in the form of contact lenses that emit therapeutic pharmaceutical agents, is emerging to treat eye disorders Under current US state optometry, medical and pharmacy practice act statutes, these combination contact lens/drug products would be available immediately for prescription and dispensing by vision care professionals in 34 states (see attached table), which represents an increase of 13 states since this issue was heard in Connecticut last year. Connecticut remains a state that requires clarification, through the introduction of this bill, of the language surrounding the abilities of vision care professionals to prescribe and dispense this technology to their patients I would like to make the following points

- This is about an emerging technology, not a single product The technology is described as using a contact lens as a drug delivery device. This device will provide therapeutic pharmaceutical agent directly into the eye
- Optometrists, where the majority of patients seek vision care, would not be able to dispense these products to their patients under current law.
- Optometrists can currently prescribe and dispense contact lenses in their practice.
- Optometrists, as per statute (Chapter 380, Sect 20-127(5)), are able to prescribe therapeutic pharmaceutical agents to their patients
- Pharmacies in the State of Connecticut are prohibited from dispensing contact lenses. The definition of "device" (which pharmacies are legally allowed to dispense) in the pharmacy statute specifically excludes "contact lenses" from the definition.
- Only those lenses with pharmaceutical agents that are within scope of practice would be available to the optometrists. **Nothing in this legislation alters the scope of practice of the profession.**
- If no change is enacted, patients will either have to seek to have their prescriptions filled at an ophthalmologist's office or through a licensed provider on the Internet.
- Most consumers in Connecticut have their vision tested and contact lenses prescribed by an Optometrist If this bill is not passed, we fear the marketplace as it now exists in Connecticut will dramatically change and confuse consumers.
- Nothing in this law circumvents the authority of the FDA and its approval of drug products. This law is intended to ensure that these products are available to the people of Connecticut once FDA approved
- The first of the products combines a vision correction device (Acuvue Contact Lens) with an over-the-counter anti-allergy product (ketotifen) When combined together, there is a restricted ability for patients to access this technology.
- It is important to note that this same bill was raised in last year's Session as HB 5811. HB 5811 was raised out of committee, passed the House unanimously and was not raised by the Senate prior to the expiration of the Session

I would like to conclude by thanking the Committee for hearing this issue. VISTAKON and I stand ready to work with you on this legislation as the 2008 session proceeds I would be happy to answer any questions you may have.

VISTAKON Division of Johnson & Johnson Vision Care, Inc
7500 Centurion Parkway
Jacksonville, FL 32256

VISTAKON
Division of
Johnson & Johnson Vision Care, Inc.

Table 1 – Status of US States on Vision Care Professionals Ability to In-Office Dispense Therapeutic Contact Lenses

STATUS	States
States That Required No Changes (20)	Pennsylvania, Indiana, Alabama, Oklahoma, South Dakota, Wyoming, Montana, Idaho, Utah, New Mexico, North Carolina, Missouri, Florida, Michigan, New Mexico, Arizona, Washington, Hawaii, Delaware, District of Columbia
States That Still Require Legislative Changes to Be Made (17)	Connecticut, Maine, New Hampshire, Massachusetts, New York, New Jersey, West Virginia, Maryland, Arkansas, Wisconsin, Iowa, Kansas, Nebraska, Texas, Colorado, Mississippi, North Dakota
States That Required Clarification Through Enacted Legislation, Board Rules or Interpretation of Existing Language (14)	Ohio, Kentucky, Minnesota, Louisiana, California, Oregon, South Carolina, Nevada, Virginia, Illinois, Vermont, Rhode Island, Tennessee, Georgia

Testimony of the Connecticut Society of Eye Physicians

On SB 781; AAC Therapeutic Contact Lenses

Before the Public Health Committee

February 6, 2009

Good afternoon, Senator Harris, Representative Ritter, and members of the Public Health Committee. I am Dr. William Ehlers, a corneal specialist and Past President of the Contact Lens Association of Ophthalmologists. I am here today representing the Connecticut Society of Eye Physicians to speak in opposition to HB 781, AAC therapeutic Contact Lenses as it is written.

I want to make it clear that we are here today to oppose HB 781 as written, but not the principle of optometrists being allowed to sell and dispense contact lenses that contain antihistamines or specific other drugs, once the safety of such lenses has been proven. We feel, as we did last year, that in the absence of any publicly reviewable data on the safety and efficacy of these lenses, and with FDA approval at least a year off, it is premature to be considering statutory changes to allow their distribution. More importantly, though, we feel the language of the amendment as proposed is vague, and improperly placed. We would recommend that the term "therapeutic drug" be defined as those agents allowed for topical administration in Section 20-127 (5) and designated as "ocular agent T" drugs, which have already been agreed to by both optometrists and ophthalmologists in a compromise in 2007, as the scope of advanced optometric prescribing. Our specific suggestions regarding language changes can be found appended to our written testimony.

This legislation is similar to legislation introduced last year because a completely new type of contact lens may become available next year. The K lens – under development by Vistakon incorporates an anti-allergy medicine, ketotifen, into the matrix of the lens. It is intended to provide contact lens wearers who suffer from seasonal allergies with relief of symptoms. According to information received from Vistakon and available on the website clinicaltrials.gov, these lenses are in Phase III testing. Phase III testing involves healthy volunteers who wear the lenses to determine their safety. The information that I have received is a description of the study design only. To date, I have seen no data regarding either the efficacy or the safety profile of these lenses.

The issue of contact lens safety is one that is near and dear to my heart. I have lectured and published peer-reviewed articles on this subject, and personally conducted comparative studies on contact lens safety. Although contact lenses are an exceptionally safe means of vision correction, several news

stories in recent years have underscored the fact that contact lens wearers can experience serious complications and loss of vision. Despite the efforts of the best minds in Ophthalmology, Optometry, and the contact lens industry, a small number of wearers experience sight threatening complications each year, and the percentage of people experiencing the most feared contact lens related complication – microbial keratitis, a bacterial infection of the cornea – hasn't changed in 20 years.

The causes of contact lens related complications are complex. Contact lenses are a foreign body that has to interact with the ocular surface and the tear film. Although ketotifen has an excellent safety profile and is available as an over-the-counter allergy drop, it is certainly possible that incorporating this drug into a contact lens that will be held right against the eye for hours - or even days - may alter the safety profile. It must also be remembered that patients don't always follow directions exactly, and that places them at risk for complications. Adding a chemical, such as a medication, to that equation increases that risk.

A valid concern has been raised about the limited distribution infrastructure for a lens of this type, and I thank Linda Kowalski, Vistakon, and Connecticut Optometrists for bringing this matter to public attention. Although the need for a distribution system for these lenses is an important consideration, it is not a critical need. It is, in fact, a business consideration – not a public welfare concern. If this matter is considered and approved in the next legislative session, when we will presumably have more information regarding the safety of these lenses, any new legislation would go into effect on October 1, 2010. The earliest anticipated time frame from Vistakon for FDA approval would be late spring or early summer of 2010. Perhaps they will be approved in that time frame – and perhaps not. Perhaps they will be the best treatment for contact lens wearers with allergies, and perhaps they will be a disappointment. We will have more of these answers in one year. In the interim, it must be remembered that there are treatment options in place to meet the needs of contact lens wearers with allergies.

It will be said today that as long as FDA approval is stipulated in the language of this legislation, we need not concern ourselves with whether this combination of a drug and a medical device is safe – that is the job of the FDA. Although the FDA certainly bears the major responsibility for determining the safety and efficacy of drugs and devices, everyone in this room can think of instances where the FDA got it wrong. In addition, I will argue that the overall safety of this new and exciting modality should be the concern of everyone in this room. You became legislators because of your concern for public welfare. Physicians

have a long history of public service and concern over public welfare. I am here today – as are others to express that concern. I believe in the area of contact lenses, safety is the shared responsibility of the FDA, the contact lens industry, eye care professionals, legislators, and even patients.

This lens is apparently the first in a series of lenses under development by the contact lens industry for drug delivery. We have attempted to satisfy our concerns regarding the safety and efficacy of these lenses in several conference calls with Vistakon, but they have chosen not to share data with us, despite our offer to sign any confidentiality agreement they might require. We also believe this legislation is premature as the earliest anticipated date for approval is early 2010.

Although the concerns we expressed on this matter both last year and this year are valid, we are not opposed to the concept of Optometrists dispensing this lens - or any other lens - that contains a therapeutic agent within the scope of their practice. For this reason, we will not oppose this legislation if the minor changes suggested are made in the language. In addition, optometrists who dispense such lenses will be required to meet the same record keeping requirements and requirements of notification to the Commissioner of Consumer Protection regarding their intent to dispense drugs other than professional samples. We also feel Ophthalmologists should have language added to Connecticut Statutes on Medicine and Surgery that specify the same rights to dispense contact lenses that contain medications but such medications will be consistent with the prescriptive limits of medical practice, and ophthalmologists will have the same record keeping and reporting responsibilities.

We hope to continue the good faith efforts we have made over the last year to work with optometry to resolve this matter and craft language acceptable to everyone. Thank you for your time and attention.

Raised Bill No. 781

January Session, 2009 LCO No. **2671**

*02671_____PH_*

Referred to Committee on Public Health

Introduced by:

(PH)

AN ACT CONCERNING THERAPEUTIC CONTACT LENSES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Subsection (f) of section 20-127 of the general statutes is
2 repealed and the following is substituted in lieu thereof (*Effective*
3 *October 1, 2009*):
4 (f) [No] Except as otherwise provided in this subsection, no licensed
5 optometrist authorized pursuant to this section to practice advanced
6 optometric care shall dispense controlled substances under schedules
7 II, III, IV and V or under section 21a-252, to any person unless no
8 charge is imposed for such substances and the quantity dispensed does
9 not exceed a seventy-two-hour supply, except if the minimum
10 available quantity for [said agent] such substances is greater than a
11 seventy-two-hour supply, the optometrist may dispense the minimum
12 available quantity. A licensed optometrist authorized pursuant to this
13 section to practice advanced optometric care may acquire, prescribe,
14 dispense and charge for contact lenses that provide vision correction
15 and contain a therapeutic agent as defined in Section 20-127 a 5 A "Ocular Agents T" for topical administration, and are ~~"a therapeutic drug agent~~ approved by the federal Food
16 and Drug Administration.

This act shall take effect as follows and shall amend the following sections:

Section 1 *October 1, 2009* 20-127(f)

Statement of Purpose:

To allow a licensed optometrist to acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain a therapeutic drug agent approved by the federal Food and Drug Administration.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it

Raised Bill No. 781

January Session, 2009 LCO No. 2671

*02671_____PH_*

Referred to Committee on Public Health

Introduced by:

(PH)

AN ACT CONCERNING THERAPEUTIC CONTACT LENSES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a 1 ~~f~~) of section 20-127 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2009*):

~~(f) [No] Except as otherwise provided in this subsection, no licensed optometrist authorized pursuant to this section to practice advanced optometric care shall dispense controlled substances under schedules II, III, IV and V or under section 21a-252, to any person unless no charge is imposed for such substances and the quantity dispensed does not exceed a seventy-two-hour supply, except if the minimum available quantity for [said agent] such substances is greater than a seventy-two-hour supply, the optometrist may dispense the minimum available quantity. A licensed optometrist authorized pursuant to this section to practice advanced optometric care may acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain "Ocular agents Da therapeutic drug agent approved by the federal Food and Drug Administration.~~ (1) The "practice of advanced optometric care" means any one or more of the following practices and procedures: (A) Measuring, examining, diagnosing, preventing, enhancing, managing or treating visual functions, defects of vision, muscular functions or anomalies, or other conditions or diseases of the visual system, the eye and ocular adnexae; (B) the prescribing, supplying, adjusting, fitting or adapting of ophthalmic devices and lenses, spectacles, prisms, orthoptic therapy, visual therapy, visual rehabilitation, oculomotor therapy, tinted lenses, filters, contact lenses, diagnosing, preventing, enhancing, managing, treating or relieving visual functions, defects of vision, muscular functions or anomalies, or diseases of the visual system, the eye and ocular adnexae; (C) the administration or prescription of any pharmaceutical agents related to the diagnosis and treatment of conditions and diseases of the eye and ocular adnexae, excluding nonemergency oral glaucoma agents but

including controlled substances under schedules II, III, IV and V in accordance with section 21a-252, subject to the limitations of subsection (f) of this section relating to quantities dispensed, performance or ordering of procedures or laboratory tests related to the diagnosis and treatment of conditions and diseases of the eye and ocular adnexae; these procedures include, but are not limited to, removal of superficial foreign bodies of the cornea, ultrasound and topical, oral or injectable medication to counteract anaphylaxis or anaphylactic reaction; (D) the prescribing, supplying, adjusting, fitting or adapting of contact lenses containing therapeutic agents as defined for ocular agents - T for topical use per subsection (a) 5 A of this section, (E) [(D)] the nonsurgical treatment of glaucoma consistent with subsection (k) of this section; or [(E)] (F) the use of punctal plugs. The "practice of advanced optometric care" does not include surgical treatment of glaucoma, treatment of ocular cancer, treatment of infectious diseases of the retina, diagnosis and treatment of systemic diseases, use of therapeutic lasers, use of injectable medications other than to counteract anaphylaxis or anaphylactic reaction, surgical procedures other than noninvasive procedures, use of general anesthesia, use of intravenous injections, procedures that require the cutting or opening of the globe, enucleation of the eye, extraocular muscle surgery or any invasive procedure performed on the human body other than noninvasive procedures performed on the eye or ocular adnexae.

And

Section 1 Subsection (e) of section 20-127 of of the general statutes is
2 repealed and the following is substituted in lieu thereof (*Effective*
3 *October 1, 2009*):

(e) No licensed optometrist authorized pursuant to this section to acquire, administer, dispense and prescribe an ocular agent-T shall dispense such agent to any person unless no charge is imposed for such agent and the quantity dispensed does not exceed a seventy-two-hour supply, except if the minimum available quantity for said agent is greater than a seventy-two-hour supply, the optometrist may dispense the minimum available quantity, or except if the

agent is a contact lens that provides vision correction and contains a therapeutic drug agent consistent with sec 20-127 a 5.

This act shall take effect as follows and shall amend the following sections:

Section 1 *October 1, 2009* 20-127(f)

Statement of Purpose:

To allow a licensed optometrist to acquire, prescribe, dispense and charge for contact lenses that provide vision correction and contain a therapeutic drug agent approved by the federal Food and Drug Administration.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it

Statement of Brian T. Lynch, OD
Before the Public Health Committee
In Support of #SB781
Sen. Harris, Rep. Ritter and Members of the Committee:

My name is Dr. Brian T. Lynch. I am an optometrist who has practiced in Branford for 27 years. Currently I serve as legislative chair for the Connecticut Association of Optometrists. I appear before you today to urge your support of SB781, An Act Concerning Therapeutic Contact Lenses.

All healthcare providers practice legislated professions. Simply put, how we practice and care for our patients is defined by statutes. In 1996, this committee defined the practice of "advance optometric care" as what it is today. The statutes adopted by the general assembly were based on public safety and need, provider training, and available technologies at that time. As these factors change, we periodically find ourselves needing to "tweak" our statutes to address advances in healthcare and patients' requirements.

In 1996 the concept of a contact lens impregnated with a pharmaceutical to treat a patient's allergy symptoms wasn't on the horizon. Thanks to Johnson and Johnson it will soon be available. However, patients in Connecticut will have very limited access to it.

Currently, optometrists who are the primary suppliers of contact lenses are prohibited from supplying any more than a 72-hour supply of a pharmaceutical to their patients. Pharmacies in Connecticut do not sell contact lenses. Opticians can't supply any pharmaceuticals to their customers, leaving only one supplier: ophthalmologists, whose statutes don't prohibit them from dispensing.

Contrary to what you may have been told, this is not a "scope of practice" issue. Once the FDA approves this product, Connecticut optometrists will be able to sample patients and prescribe for them without any statute change. It is, however, an "access issue." Limiting a patient's access to this revolutionary product and restricting a patient's freedom to choose where they want to purchase this product is not sound policy.

Please support SB781 and empower patients to choose.

Testimony of the Connecticut Society of Eye Physicians

On SB 781; AAC Therapeutic Contact Lenses

Before the Public Health Committee

February 6, 2009

Given by Jamie Weisz

Good afternoon, Senator Harris, Representative Ritter, and members of the Public Health Committee. I am Jamie Weisz,M.D. a retina specialist and Secretary of the Connecticut Society of Eye Physicians. I am here today representing the Connecticut Society of Eye Physicians to speak in opposition to HB 781, AAC therapeutic Contact Lenses as it is written.

I want to make it clear that we are here today to oppose HB 781 as written, but not the principle of optometrists being allowed to sell and dispense contact lenses that contain antihistamines or specific other drugs, once the safety of such lenses has been proven. We feel, as we did last year, that in the absence of any publicly reviewable data on the safety and efficacy of these lenses, and with FDA approval at least a year off, it is premature to be considering statutory changes to allow their distribution. More importantly, though, we feel the language of the amendment as proposed is vague, and improperly placed. We would recommend that the term "therapeutic drug" be defined as those agents allowed for topical administration in Section 20-127 (5) and designated as "ocular agent T" drugs, which have already been agreed to by both optometrists and ophthalmologists in a compromise in 2007, as the scope of advanced optometric prescribing. Our specific suggestions regarding language changes can be found appended to our written testimony.

This legislation is similar to legislation introduced last year because a completely new type of contact lens may become available next year. The K lens – under development by Vistakon incorporates an anti-allergy medicine, ketotifen, into the matrix of the lens. It is intended to provide contact lens wearers who suffer from seasonal allergies with relief of symptoms. According to information received from Vistakon and available on the website clinicaltrials.gov, these lenses are in Phase III testing. Phase III testing involves healthy volunteers who wear the lenses to determine their safety. The information that we have received is a description of the study design only. To date, we have seen no data regarding either the efficacy or the safety profile of these lenses.

Although contact lenses are an exceptionally safe means of vision correction, several news stories in recent years have underscored the fact that contact lens wearers can experience serious complications and loss of vision. Despite the efforts of the best minds in Ophthalmology, Optometry, and the contact lens industry, a small number of wearers experience sight threatening complications each year, and the percentage of people experiencing the most feared contact lens related complication – microbial keratitis, a bacterial infection of the cornea – hasn't changed in 20 years.

The causes of contact lens related complications are complex. Contact lenses are a foreign body that has to interact with the ocular surface and the tear film. Although ketotifen has an excellent safety profile and is available as an over-the-counter allergy drop, it is certainly possible that incorporating this drug into a contact lens that will be held right against the eye for hours - or even days - may alter the safety profile. It must also be remembered that patients don't always follow directions exactly, and that places them at risk for complications. Adding a chemical, such as a medication, to that equation increases that risk.

A valid concern has been raised about the limited distribution infrastructure for a lens of this type, and CSEP thanks Linda Kowalski, Vistakon, and Connecticut Optometrists for bringing this matter to public attention. Although the need for a distribution system for these lenses is an important consideration, it is not a critical need. It is, in fact, a business consideration – not a public welfare concern. If this matter is considered and approved in the next legislative session, when we will presumably have more information regarding the safety of these lenses, any new legislation would go into effect on October 1, 2010. The earliest anticipated time frame from Vistakon for FDA approval would be late spring or early summer of 2010. Perhaps they will be approved in that time frame – and perhaps not. Perhaps they will be the best treatment for contact lens wearers with allergies, and perhaps they will be a disappointment. We will have more of these answers in one year. In the interim, it must be remembered that there are treatment options in place to meet the needs of contact lens wearers with allergies.

It will be said today that as long as FDA approval is stipulated in the language of this legislation, we need not concern ourselves with whether this combination of a drug and a medical device is safe – that is the job of the FDA. Although the FDA certainly bears the major responsibility for determining the safety and efficacy of drugs and devices, everyone in this room can think of instances where the FDA got it wrong. In addition, I will argue that the overall safety of this new and exciting modality should be the concern of

everyone in this room. You became legislators because of your concern for public welfare. Physicians have a long history of public service and concern over public welfare. I am here today – as are others to express that concern. I believe in the area of contact lenses, safety is the shared responsibility of the FDA, the contact lens industry, eye care professionals, legislators, and even patients.

This lens is apparently the first in a series of lenses under development by the contact lens industry for drug delivery. We have attempted to satisfy our concerns regarding the safety and efficacy of these lenses in several conference calls with Vistakon, but they have chosen not to share data with us, despite our offer to sign any confidentiality agreement they might require. We also believe this legislation is premature as the earliest anticipated date for approval is early 2010.

Although the concerns we expressed on this matter both last year and this year are valid, we are not opposed to the concept of Optometrists dispensing this lens - or any other lens - that contains a therapeutic agent within the scope of their practice. For this reason, we will not oppose this legislation if the minor changes suggested are made in the language. In addition, optometrists who dispense such lenses will be required to meet the same record keeping requirements and requirements of notification to the Commissioner of Consumer Protection regarding their intent to dispense drugs other than professional samples. We also feel Ophthalmologists should have language added to Connecticut Statutes on Medicine and Surgery that specify the same rights to dispense contact lenses that contain medications but such medications will be consistent with the prescriptive limits of medical practice, and ophthalmologists will have the same record keeping and reporting responsibilities.

We hope to continue the good faith efforts we have made over the last year to work with optometry to resolve this matter and craft language acceptable to everyone. Thank you for your time and attention.

Testimony
Submitted to the
Committee for Public Health

February 6, 2009

Proposed H.B.# 5599 An Act Concerning Licensure Exemption for Magnet Schools That Administer Day Care Services

In support of H.B. # 5599 An Act Concerning Licensure Exemption for Magnet Schools that Administer Day Care Services

Good Afternoon Senator Harris and Representative Ritter.

My Name is Bruce Douglas and I represent the Capitol Region Education Council (CREC). I am here to speak in support of H.B. # 5599 An Act Concerning Licensure Exemption for Magnet Schools that Administer Day Care Services.

Key Points:

1. CREC supports DPH license exemption for charter schools and would like to supplant the term "magnet" with "charter" for this act and will highlight key points for charter schools.

2. CREC provides early care and education to our young and often, most at risk population.

3. Charter schools have been able to provide unique educational experiences for a diverse population in a stimulating environment where students are engaged in theme-based education.

4. This year and in the future, many charter schools have and will continue to focus on early childhood education- providing quality, educational opportunities for our youngest school population.

5. High quality early childhood educational opportunities have not been universally available across the state of Connecticut. Charter schools have begun to meet the need for these services especially in urban settings. In Connecticut, most families bear the burden of finding and paying for preschool education.

6. As **public schools**, charters are required to abide by guidelines established by the State Department of Education (SDE). Those include health and safety measures. The Department of Public Health (DPH) insures that facilities like **daycare facilities and nursing homes** are providing safe and healthy environments. These are different programs than public schools such as charters.

7. The duplication of two very similar and very lengthy processes is a burden on the charter schools, and the public health license does not fit.

8. It is important to note that quality education for students is at the forefront for both departments (SDE and DPH) and early childhood public schools and that they are obviously invested in providing quality care and education to our youngest students. The duplication of oversight is what is in question.

9. That said DPH requirements for ratio and group size are important standards – with an adult to child ratio of 1:10 with no more than 20 children per preschool or kindergarten classroom. This ensures that a proper adult to child ratio is preserved in charter school classrooms.

10. Our goal is quality education for all Connecticut preschool children. It is not to avoid regulation, but as stated before, to avoid duplicative and burdensome regulation

Conclusion:
The language of H. B. # 5599 removes the redundancy of duplicative oversight.

We respectfully request that the language in H.B # 5599 be accepted with the term, "magnet" changed to "charter."

Respectfully submitted,
Bruce Douglas Ph.D.
Executive Director

Capitol Region Education Council

LYME DISEASE FOUNDATION HB 6200

P.O. Box 332, 384-z Merrow Road, Tolland, CT 06084
860-870-0070 Fax: 860-870-0080 www.Lyme.org 501(c)(3) Est. 1988

Mission:
To protect people and pets from illness caused by Lyme disease and *other* vector-borne disorders.

Janis Boasso, MS
Educator

Dr. Karen Vanderhoof-Forschner, LLM, BS, MBA, CPCU, CLU
President & Founder
JD - General & Health Law
LLM - Insurance Law
Doctor of Humane Letters
Author

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Family Medicine
Webmaster

Karen Vanderhoof-Forschner
Author, Founder

Feb. 5, 2009

Dear Public Health Committee :

I commend you on the introduction of H.B. 6200.

The Lyme Disease Foundation, which represents 100,000 families and businesses, is strongly in favor of this legislation. I am enclosing suggested changes that will help strengthen and clarify the bill.

As you know, there is a great need for this legislation because of the fatal flaws in the state of the art in Lyme disease testing. The largest Lyme clinical trials ever conducted, managed by academics using the highest scientific technology in the world, proved that *at best* only 64% of *proven* Lyme infected patients tested positive for their Lyme infection. That means that 36% of clearly Lyme-infected patients continued to have a negative blood test ("seronegative") throughout the life of their disease, despite infection. While the pharmaceutical's Medical Director freely disclosed this finding in an accredited scientific conference, the study's investigators have consistently failed to include this data in subsequent diagnosis and treatment guidelines. (*see* Illinois Dept. of Health Satellite Medical Conference, 1998. http://www.lyme.org/movies/seroneg.mov). The group of seronegative patients will continue to be ravaged by their bacterial infection unless they receive curative antimicrobial treatment. The only way to measure success, is to for the practitioner to evaluate the patient's response to therapy – which makes diagnosing and treating Lyme disease a clinical judgment.

The flaws in testing have resulted in polarized medical views with some practitioners being obsessed with ending the debate by eliminating those with opposing viewpoints. These attacks have appeared in medical publications, crept into insurance health guidelines, turned up in grant reviews, and have even involved accusations made to medical licensing boards in order to launch license reviews of their fellow competitors. As astonishing as it may seem, I was contacted by a doctor seeking a lawyer to sue a fellow doctor for the sin of simply treating patients with antibiotics for longer than 30 days.

Until there is a perfected direct detection test, patients need to be able to get treatment from their *family* doctor who is free to diagnose and treat the patient, without fear of being hauled before a medical review board. This bill is not about one specific doctor, it is about creating a climate in Connecticut so that *all* of our practitioners can treat their own patients. Indeed, maybe the prime result of this bill is that there will no longer be a need for "Lyme Literate" specialists, because *all* of our doctors will hereafter be free to become *Lyme aware*, without fear of reprisal.

Please vote yes for this bill!

Sincerely,

KV-Forschner

Karen Vanderhoof-Forschner

HB 6200 - Lyme Bill - *Submitted by the Lyme Disease Foundation* *Feb. 5, 2009.*

www.Lyme.org 860-870-0070

The Lyme Disease Foundation is strongly in favor of this bill and asks that the following wording changes to HB 6200 be made for clarification purposes.

A. HB 6200 WITH PROPOSED CHANGES

- **AN ACT CONCERNING THE USE OF LONG-TERM ANTIBIOTICS FOR THE TREATMENT OF LYME DISEASE.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That the general statutes be amended to provide that:

(1) [*Proposed*] A **Practitioner** may prescribe, administer, or dispense antibiotics that the **practitioner determines** is in the best interest of the patient when the **practitioner** makes a **clinically-based** or **laboratory-based diagnosis** that the patient has a **tick-borne** disorder, documents that diagnosis and the treatment plan in the patient's medical record, and obtains **informed consent** (agreement) from the patient or the patient's legal representative for the documented diagnostic and treatment plans.

(2) [*Proposed 2*] no **practitioner** may be subjected to disciplinary action from any source when adhering to Section 1 of this bill.

B. CURRENT BILL & EXPLANATION OF THE PROPOSED CHANGES

(1) **[Current]** ~~A physician may prescribe, administer or dispense antibiotic therapy for therapeutic purpose to a person diagnosed with and having symptoms of Lyme disease if a diagnosis and treatment plan has been documented in the physician's medical record for that patient;~~

(1) **[Proposed]** A **Practitioner** may prescribe, administer, or dispense antibiotics that the **practitioner determines** is in the best interest of the patient when the **practitioner** makes a **clinically-based** or **laboratory-based diagnosis** that the patient has a **tick-borne** disorder, documents that diagnosis and the treatment plan in the patient's medical record, and obtains **informed consent** (agreement) from the patient or the patient's legal representative for the documented diagnostic and treatment plans.

- **Explanation of Changes**:

a. **Practitioner** – This clarifies that the protection extends to the full range of medical professionals, including Nurse Practitioners and Physician's Assistants, who treat patients with Lyme and other tick-borne disorders.

b. **Tick-borne Disorder** – Because Connecticut ticks carrying Lyme disease also other pathogens, there is always the difficulty of selecting an antibiotic to treat more than one disease in the patient. Since the patient's practitioner is treating all of these disorders, it is logical this bill's protection should apply to all of those illnesses.

c. **Choice of Antimicrobial** – The patient's healthcare provider is vested with the authority to determine which drug and method of administration to use because that practitioner is in the best position to make those choices.
The term "antimicrobial" is broader than the term "antibiotic" and gives the practitioner more "tools" in the infection control "tool-box" to help the patient.
According to the CDC:
- **Antimicrobial agents** - A general term for the drugs, chemicals, or other substances that either kill or slow the growth of microbes. Among the antimicrobial agents in use today are antibacterial drugs (which kill bacteria), antiviral agents (which kill viruses), antifungal agents (which kill fungi), and antiparisitic drugs (which kill parasites).
- **Antibiotic** - *Type* of antimicrobial agent made from a mold or a bacterium that kills, or slows the growth of other microbes, specifically bacteria. Examples include penicillin and streptomycin. (Source – CDC)

d. **Diagnosis** – This clarifies that the patient's practitioner is vested with the authority to make the diagnosis of a tick-borne disorder – whether laboratory or clinically based.

e. **Patient Informed Consent** – This bill provides extraordinary equal protection for *all* practitioner's ability to avoid liability for decisions made in the diagnosis and treatment arena for tick-borne disorders, including those that treat by short, medium, or long term methods. Therefore, the patient needs to receive informed consent about how the diagnosis was reached and what treatment plan is. This way the patient knows the options and can make the choice to stay with the practitioner or seek treatment elsewhere.

(2) [**Current**] ~~no physician may be subject to disciplinary action solely for prescribing, administering or dispensing long-term antibiotic therapy for a therapeutic purpose for a patient clinically diagnosed with Lyme disease, if a diagnosis and treatment plan has been documented in the physician's medical record for that patient.~~

(2) [**Proposal 1**] no **practitioner** may be subjected to disciplinary action [] for prescribing, administering, or dispensing **antimicrobial** therapy for a patient diagnosed with a **tick-borne** illness, if the **practitioner** makes a **clinically-based** or **laboratory-based diagnosis** that the patient has a **tick-borne** disorder, documents that diagnosis and the treatment plan in the patient's medical record, and obtains **informed consent** (agreement) from the patient or the patient's legal representative for the documented diagnostic and treatment plans.

- **Explanation of Changes**:
  The wording mirrors the changes listed in Section 1.

(2) [**Proposal 2**] no **practitioner** may be subjected to disciplinary action from any source when adhering to Section 1 of this bill.

02/06/09

Written testimony to the Public Health Committee by Jonathan Lyons, 55 Sheep Pasture Rd. Madison, CT 06443 regarding H.B. 6200

I would first like to thank Senator Harris and Representative Ritter, distinguished members of the Public Health Committee, for giving me a chance to speak on this matter. I live in a heavily wooded area of Madison, CT. I first tested positive for Lyme Disease when I was 6 years old, and received the standard two week regimen of oral antibiotics. I was re-diagnosed with the disease two more times, and again received the same regimen. Each time I was treated the initial physical symptoms vanished, and my doctor and my parents thought that I was cured.

However, as I progressed through gradeschool and high school, I began suffering from terrible fatigue and neurological symptoms that made it difficult to function. They only grew more severe as I entered college. Finally, in my sophomore year of college, my symptoms became so severe that I could no longer complete my schoolwork. I felt like I was dying, so I checked myself into the hospital. Several confused doctors and misdiagnoses later, blood tests for Lyme Disease were taken, and since it came back strongly positive, I was placed on intravenous Rocephin(ceftriaxone).

My condition improved dramatically within two months, but I did not recover enough energy to return to school until I had endured another 4 months of oral antibiotic treatment on Biaxin(clarithromycin) and Plaquenil(hydroxychloroquine). Finally, after 6 months of antibiotic treatment, I felt well enough to return to college. My doctor even thought I was doing well enough to stop taking the antibiotics.

This turned out to be a bad idea. Within 2 months, I was slowing down again. My fatigue returned and so did neurological problems, with a vengeance. Just a few months before, I had more youthful vitality than I had ever had; now I was so tired that I had to spend much of my day resting in bed. I barely made it through the next year of college and finally had to take more semesters of medical leave. It has taken two more years and a long course of oral minocycline in order for me to recover enough to be able to come here today. Let me emphasize that: long-term antibiotics are the only reason I am able to come here today to speak to you. If it weren't for this medicine, I would still not be able to get out of bed. After years of struggling with this terrible illness, this medicine is giving me back my life.

Public Health Committee
House Bill #6200
AN ACT CONCERNING THE USE OF LONG TERM ANTIBIOTICS FOR THE TREATMENT OF LYME DISEASE

My name is Karen Gaudian; I am co-chair of the Ridgefield Lyme Disease task Force and I also represent the town of Ridgefield on the Housatonic Valley Council of Elected Officials' Lyme Disease Task Force.

My family has been dealing with Lyme disease for almost 9 years. I would like to give a brief over view of my daughter's life since she was infected in the spring of 2000.

I thought we were lucky, our pediatrician recognized her symptoms and treated her for Lyme disease without a positive blood test; I thought we were done. She relapsed shortly after finishing treatment. In the fall she developed a positive test and went back on oral antibiotics but kept getting worse. She missed more and more school until her physician felt she needed to be put on homebound status; we were horrified. After fighting with our insurance company for 6 months she was put on IV; but the damage was already done. She was homebound unable to function, unable to read, with short term memory loss, cognitive problems and a constant headache. With 6 weeks of IV treatment we thought she would be cured, get back to school and her friends and move on with her life; but after treatment was stopped she relapsed again. Unable to get more treatment with IV she was placed on oral antibiotics; slowly she improved and went back to school part time. We could see the light back in her eyes, but again she was taken off antibiotics and again relapsed. This cycle of partial treatment and relapse has gone on for almost 9 years.

Each time her treatment is stopped her symptoms come back with a vengeance. She is currently unable to read, do schoolwork, see her friends and has to travel hours out of state to see physicians willing to help her. If treatment was continued until symptoms resolved the chance of relapse would be greatly diminished.

Over the years the CT Department of Public Health has received millions in funding for prevention and research for Lyme disease. This money has gone to only three health districts in CT to study and develop prevention programs. In spite of this money, and the fact that most residents surveyed by state officials report they are using preventative measures, each day 83 more people in CT become infected with Lyme and other tick-borne diseases. Prevention alone has not been able to stop this exploding epidemic and the numbers continue to rise at alarming rates.

In the wake of the Department of Public Health's failed prevention approach, we must turn to physicians across the state to properly address this dire situation. Health care professionals must be given the ability to diagnose Lyme disease clinically. There are no "Gold Standard" tests available for Lyme disease and available tests miss 50% or more of those infected. Physicians must be allowed to treat until symptoms resolve or go into remission, and retreat when or if necessary, using all treatment options available as we would in the event a cancer were not eliminated or returned. Citizens can no longer afford to be forced to follow a totally unsuccessful 'cost effective' limiting treatment protocol which has allowed up to 20% or more of those exposed to Lyme to become chronically ill or disabled due to lack of adequate treatment.

Karen Gaudian
Co-chair Ridgefield Lyme Disease Task Force
Ridgefield, CT 06877

Madam Chair/ Mister Chairman, my name is Maggie Smith, I am seventeen years old, and I live in Lyme, CT. **I am here in support of house bill # 6200.** I have been tested for Lyme numerous times since I was 6 years old but wasn't officially diagnosed until 2005. Prior to that I had been diagnosed with Rheumatoid Arthritis, Relapsing Polychondritis, migraines, and numerous allergies. Not satisfied with these improbable diagnoses, my family and I went to Rhode Island to a Lyme literate doctor who we had heard of who also took insurance. After listening to our story and conducting a few tests, including a CD-57, she told me I was so sick and that it was very possible that I had suffered with Lyme since birth. I was put on antibiotics and felt a difference within weeks. I continued therapy with varied success for about a year. It was suggested that I go on IV treatment since my Lyme was very resistant to the drugs. At this time the doctor I was seeing was forced to stop treating Lyme or the insurance companies would back out. My doctor was very upset but felt she had no alternative.

We started our search once again. My family can't afford the out-of-pocket expenses that most Lyme literate doctors require, so we had to try to find a way around the system. Next, we went to see a neurologist, since most of my symptoms are nerve based. Perhaps he could be convinced that it was Lyme related. Tests revealed that I was having complex partial seizures. The doctor told me that it couldn't be Lyme, despite the fact that I have a positive test! That did it for me. I gave up.

I turn 18 next Thursday, and I've been sick most of my life, and like most of these doctors have told me, "I just have to get used to it". For me, that means I have electric shocks down my arms and legs, I become so dizzy and disoriented that I can barely walk. I have a high temperature, my ears will be ringing making it hard to hear, I'll have a headache, and my eyes sting and become blurry making it hard to see, my whole body will be shaking, and on occasion I have difficulty breathing because my airway starts to swell. I learned how to manage going to school even when I was sick. I would hold on to the walls to get to class without falling, and once there I would not be able to see the board or hear what was being said, but at least I was at school. Not many people know about the effects my Lyme has on me, and they do not understand how severe it is. What's worse, I am not alone. If doctors were able to properly treat Lyme patients with the antibiotics they need without fear of reprisals, many more people would get the help they need. I am sick of going to doctors who think Lyme disease does not exist and that tell me it is all in my head. Worse than that, I hate that fact that those doctors told me that I would just have to live with it. I refuse to believe that I will have to live the rest of my life like this because I can not be properly treated. I believe this bill should be passed to protect those doctors who are familiar with the disease enough to realize that long-term antibiotics are required. Even if people get the opportunity to be properly treated, not all of them can afford it. For this reason it is also critical that the insurance companies are involved with treatment. Thank you for your attention to this situation.

Margaret Smith
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Lyme, CT 06371

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Connecticut State Medical Society Testimony
Presented to the Public Health Committee on
House Bill 6310 An Act Concerning Direct Access to Laboratory Results
House Bill 6200 An Act Concerning the Use of Long-term Antibiotics for the Treatment of Lyme Disease
Senate Bill 6265 An Act Concerning Speech and Language Pathology
Senate Bill 406 An Act Concerning Licensure of Assistant Radiologists
SB 781 An Act Concerning Therapeutic Contact Lenses
February 6, 2009

Senator Harris, Representative Ritter and members of the Public Health Committee, my name is Dr. William Handelman and I am currently the President of the Connecticut State Medical Society (CSMS). On behalf of our more than 7,000 members thank you for the opportunity to submit this testimony to you today on various pieces of proposed legislation that would in some way impact the healthcare system in Connecticut and the health of our patients.

House Bill 6310 An Act Concerning Direct Access to Laboratory Results would require physicians ordering certain medical tests to authorize the entity conducting the test to communicate the results to the patient unless the physician reasonably determines that the communication may be detrimental to the physical or mental health of the patient, or may result in the patient hurting himself, herself or another.

CSMS believes that every patient not only has a right to access his or her medical record, but along with the treating physician owns it. However, the complexity of many medical services and testing require communication and explanation from the treating physician in order to convey a true understanding of the results. Furthermore, the results of testing for many conditions are difficult to interpret and can lead to unnecessary concern and anxiety for a patient prior to a discussion with the treating physician. While it may not elevate to the level of a patient being harmed mentally or physically, such premature access to records may have an unneeded negative impact on the patient.

While we welcome the opportunity to work with members of the committee to ensure that patients have appropriate access to medical test results at the appropriate time, we are obligated to raise the concern about mandating physicians to require access to test results prior to interpretation of such results by the ordering physician. Despite advances in internet, web based information, the best information on medical treatment and care, as well as evaluation and interpretation of test results rests with the treating physician.

House Bill 6200 An Act Concerning the Use of Long Term Antibiotics for the Treatment of Lyme Disease (1) allows physicians to prescribe administer or dispense

antibiotic therapy for therapeutic purposes to a person diagnosed with and having symptoms of Lyme disease and (2) protects against disciplinary action when doing so.

CSMS supports this legislation to protect physician treating Lyme disease with long term antibiotics provided that the diagnosis and treatment fall within acceptable medical guidelines. Antibiotic therapy is a proven treatment for Lyme disease. A physician utilizing such therapy should in no way be disciplined or persecuted when reasonably determining that such a treatment is medically necessary for the benefit of the patient.

CSMS joins the Connecticut ENT Society in support of **House Bill 6265 An Act Concerning Speech and Language Pathology.** There is a distinct difference in medicine between the terms "diagnose" and "evaluate." Diagnose is medical in nature and requires the training and education of a physician. We do not believe that it was the intent of the legislature or the sponsoring organization to permit non physicians to medically diagnose.

CSMS supports the concerns raised by the Connecticut Radiological Society (CRS) on **Senate Bill 406 An Act Concerning Licensure of Assistant Radiologists** and does not support the bill at this time with no specific drafted language. CRS has raised serious questions in its testimony regarding credentialing and patient safety. We agree that these questions and the lack of answers to them in the legislation go to the heart of what qualifies someone to be a radiologist's assistant.

Also, any legislation impacting healthcare professionals who assist radiologists should clarify the ability of physician assistants to engage in the use of Fluoroscopy for diagnostic professionals exempt from requirements of the Radiological Technician Statutes. This will ensure that fluoroscopy procedures can be performed in appropriate settings without any confusion or controversy as to who is entitled to assist the radiologist.

Finally, CSMS respectfully asks the committee to oppose **Senate Bill 781 An Act Concerning Therapeutic Contact Lenses.** Currently no publicly reviewable data on the safety and efficacy of these lenses currently exists. Furthermore, these contact lenses have not been approved by the Food and Drug Administration (FDA) at this time. The legislation before you stipulates FDA approval prior to granting optometrists the ability to dispense such contact lenses. We disagree with this approach. Legislating prescriptive authority pending the potential approval of the lenses is premature and not in the best interest of the health and safety of Connecticut citizens. Not only is it the responsibility of this committee to ensure FDA approval, but it also must review data on safety and efficacy to determine whether certain classes of health care providers have the level of training and skill necessary to safety prescribe and dispense.

Thank you for the opportunity to submit this testimony to you today. We look forward to working with committee members on this and other significant legislation that will impact the health and well being of our patients.