California Senate Business, Professions and Economic Development Committee, January 9, 2012. SB 352

Chiropractors using lasers to treat food allergies (The California Channel Website)

Senator Bob Huff: . . . I bring before you today SB 352. Over a year ago I became aware of an issue that there were some chiropractors using laser to treat food allergies. Having some awareness of food allergies through former colleague Dennis Hollingsworth, as well as my own staff, this seemed like a significant issue. So I did some inquiry and approached the Board of Chiropractic Examiners with my concerns regarding their involvement with the diagnosis and treatment of what can be life-threatening allergies. And while allergies can be a nuisance in some instances, actually practically every instance; in others they can be dangerous and life-threatening if not handled properly.

So if person who is allergic to nuts, for example, were to eat them the outcome can be fatal. The board was open to looking into regulations. That was about a year ago. To date there are no approved regulations and I have been trying to understand the process a little bit more and I understand it does take time. But it seems like it's taking longer than it should be and that, again, may just be part of the time, but I am up against the deadline on my bill so that's why I am here today just to move it forward to the next step.

With the health issue's seriousness I believe we need to be proactive and not reactionary. So I am moving this in effort to bring resolution to what I believe may be a dangerous issue that doesn't seem to have regulations. SB 352 states that chiropractors are prohibited from engaging in the act of treating and diagnosing patients with hypersensitivity to allergies. This measure also prohibits them from advertising they can do these things; Finally it gives the board disciplinary rights should their licensees choose not to follow the law.

The FDA and the California Department of Public Health have been engaged in this issue and are pursuing the manufacturers of many of the devices. Witnesses here today in support of the bill, starting with one of the leading physicians in our state on allergies, Dr. Travis Miller; and after Dr. Miller we move onto Dena Robertson who has a personal family experience from the treatment.

Dr Miller: Thank you senators for being here. As Senator Huff said, my name is Travis Miller. I am a board-certified physician and licensed by the state of California. I practice allergy and immunology in the Sacramento area. I am also board-certified in pediatrics and internal medicine. At the same time I was approached by many patients of mine who have allergies who had been asking me if they should take the advice of a chiropractor who they had come in contact with regarding laser treatment for their allergies. And I made it very clear to the patients who in fact asked me that question that I thought that was not a good idea as allergies can be life-threatening.

Fifty million people in the United States with allergies. It's probably 12 million with food allergies. There are about 5,000 allergists. I don't expect that all patients with allergies will get care from a specialist, but
nevertheless it can be a potentially extremely dangerous issue. I wanted
to bring some examples of food allergies—and this is a patient who has
given me written consent to be able to distribute his information. He has
life-threatening food allergies as you'll see. He was actually approached
as well, and in discussion we agreed that he not go down this road.

For the group of the senators here I just wanted to define what's the
difference between an intolerance and an allergy. I took my definitions
from Wikipedia. Intolerance are negative reactions, often delayed, to
food, beverages, additives, or compounds that may produce unwanted
symptoms. They might include bloating, cramping, belching, nausea, gas,
diarrhea, constipation, or rash. That was one of the discussions that I've
read from the groups who oppose this measure is that this will not allow
them to diagnose intolerance, it's quite the opposite. Intolerances and
allergies are very different.

[0:05:23]

Allergies are hard-wired immunologic responses to environmental or
food substances we call allergens. They are inflammatory and they can
range from uncomfortable to life-threatening, as we've said. I have never
read anything to date to suggest that lasers have anything to do with
either the diagnosis or treatment of food allergies—and I read a lot of
literature regarding allergies.

The next thing I wanted to share with you is actually our federal
government spent money to establish the diagnosis and treatment of
food allergies and actually published those in December of 2010. These
are guidelines which I think are fairly concise, and I'll draw your attention
to the fact that diagnosis has nothing to do with lasers. In fact, blood
testing and skin testing are the only methods by which they endorse, in
addition to a food challenge.

Once a patient has been diagnosed with food allergies, avoidance is the
primary measure of treatment at current time. They can have things
such as epinephrine should they have life-threatening symptoms. We
give them anaphylaxis action plans, but unfortunately there is no
definitive treatment at the current time.

I believe the chiropractors have an important role in treating our mutual
patients. However, I think that when it comes to allergies and potentially
life-threatening food allergies, there lacks not only a scientific
background for the use of this therapy but it also violates the Hippocratic
oath which I took specifically, which discuss non malfeasance or do no
harm. And that's why I am here today. I want to thank you for your
attention, and if you have any questions, I would be happy to answer
them for you at the end.

Senator Price: Any other witnesses in support?

Dena Robertson: My name is Dena Robertson. Thank you very much for having me here
today to share my story, and I appreciate Senator Huff in your support on
this issue as well. I have two small children who both have severe
allergies. I also have the history of losing a sister to an asthma attack and
so I realize very clearly that sometimes you can get to a certain point
where nothing more can be done to save someone. And I live with that fear every day with my own children because Haley my oldest does have asthma and my youngest daughter Abby does have a nut allergy. And if Abby were to ingest a nut she would be in risk of having an anaphylactic reaction.

I was given a flyer advertising the local chiropractor, the services for the laser allergy and on September 2010 I did take my oldest daughters Haley in to be treated and we went approximately eight times. We were told anecdotally about patients that would have one treatment that were severely allergic to animals that then we were able to go to an animal, vigorously pet the cat, rub on its face and would have virtually no reaction. So after my daughter was treated for cat and dog hair, we went to a friend’s house, my daughters did pet a cat, and she began to develop a severe reaction with her allergies and her asthma.

So we immediately gave her pill, her inhaler, her nasal spray, had her take a hot shower and she was able to recover from that. We did let the chiropractor as well as Dr. Miller know what had happened, and I let them know also that the reaction almost seemed to be more severe than it had in the past. They did refund my money at that point, but they did ask to continue providing the service because they were confident that it would still work.

Prior to this event, I had also taken in my youngest daughter Abby to undergo treatments for her nut allergies. And I brought in actual nuts, cashews, walnuts, pecans, almonds and it was explained to me that the laser would work in conjunction with these and that it would recondition her body to not react inappropriately if she were to ingest the allergen. I was surprised at that point that she was basically free to go and walk out of the office and be able to eat a nut. And I did share with them that from my history and the fear for my own daughter, that if someone were to experience an anaphylactic reaction, that they could get to that point where there is no saving them. And that is why the majority of food challenges are instructed to be done right outside of the doors of an emergency room, and I still was not instructed to do so.

So I was already hesitant to the process. I was very conservative for the sake of my own daughter’s health and my goal in the treatment was never to suddenly be able to have Abby have a peanut butter and jelly sandwich. But instead that if she were to accidentally be in a situation and ingest a nut, that perhaps best the reaction would be less severe and we would have more time to save her.

So on a trip to Monterey we had a frightening experience on New Year’s Day 2011. Abby wanted to bite of a . . . candy and so my husband opened it up saw visibly that there was not a nut but did not read the ingredients to see that’s it did contain almond oil in the chocolate. So Abby took a little bite she spit it out and she began to have an anaphylactic reaction right in front of our eyes, which means that her face began to develop hives, she began to swell, her lips began to swell and her right eye began to swell and disfigure as well. And she became very lethargic, which are all very common reactions to ingesting an allergen.
We rushed her to the emergency room, which luckily was right down the street from where our home is and they took one look, they rushed her in and admitted her immediately where she was given an IV. And when the doctor asked me does Abby’s voice sound like its getting higher, I knew that that was the way they were asking to know because her throat was beginning to shut at that point. So they put an emergency rush onto the medicine, they were able to get the medicine to the emergency room stop the reaction, and after hours of observance at the emergency room, we were able to head home.

I alerted the chiropractor’s office to what had happened so that they would be aware and that hopefully no other children or their patients would be affected by this. For this reason, I am in strong support of SB 352. I’m very concerned that patients with children that have an allergies and food allergies are a group that does look for some kind of help and if they go out and find this, they may not be as conservative and skeptical as I was. And that their children or themselves are currently at risk, thank you so much.

Senator Price: Thank you. Any other witnesses in support? Come right up, make room.

Ryan Spencer: Ryan Spencer with the California Medical Association. Just like to thank the senator for his leadership in this particular issue dealing with life-threatening diseases such as food allergies and allergies to medications, bee stings, and whatnot. Also for the reasons stated by the previous speakers, California Medical Association supports this information.

Senator Price: Other witnesses in support? Any witnesses in opposition? Can we make some room at the table, please. We’ve got a little opposition.

Fred Lerner, DC I am Dr. Fred Lerner DC. I am chair of the Board of Chiropractic Examiners. I would like to say first, starting off, that we also share the same concern about our licensees treating anaphylactic reactions with food allergies. The only difference here is we have been promulgating a regulation on this for about the past year. And we have been working very diligently with senator Huff’s office. We’ve spent about a year listening to stakeholders, but these things do take time and some things we can’t change about that. We voted our final language in at our last board meeting, we have to give a 45-day notice to go to a public hearing which should take place in March. At that point, we have to give a 45-day hearing period for opposition. We then have about a month to prepare the regulation that goes to the office of the administrative law, and they have another month. And there is just nothing we can do about speeding that up.

There are some aspects of this bill language that gives us great concern. One is by limiting or removing ability to diagnose conditions it jeopardizes consumers. We are also concerned about the necessity, because we already have several regulations in place that could regulate this and we have actually a disciplined several chiropractors who have created those advertisements that the senator was first concerned about.

So we are doing everything we absolutely can and as quickly as we can, and we anticipate we will have the regulations then probably within about a six months period if my timeline is correct.
Senator Price: Okay other witnesses please.

Cathy Donahue, DC: Good afternoon. I am Dr. Cathy Donahue with the California Chiropractic Association. We are also opposed to this bill. Our scope of practice right now requires that we differentially diagnose every condition [so] that we can appropriately refer for those patients that should be referred, co-manage those who should be co-managed, and treat the ones that we can treat individually in our office.

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On one the things that is our biggest concern with limiting our ability to diagnose is that that takes away our ability to appropriately refer. Most of our . . . a number of our patients that come in to see us do so because they choose not to take a medical route with regard to treatment of their condition. And just as an example, if I have a mother bring in their child who is complaining of neck pain and headaches and two watery eyes right now I can differentially diagnose that child as perhaps having some sort of environmental allergen, and we would refer them to their allergist. If that mother though chooses not to take that route at this time I would do trial of treatment to see if the child responded and . . . if the watery eyes continued, then I would again refer that patient to see the appropriate medical doctor. Not being able to diagnose the condition would really cause public safety issues because I wouldn’t be able to . . . appropriately refer the patient.

Senator Price: Other witnesses in opposition please.

Howard Maize, DC: Good afternoon. Thank you for being here this afternoon. My name is Dr. Howard Maize. I work with I have worked with two of the chiropractic colleges. I work on staff as clinical staff with USC University Health Center. To this point none of our students, internning in any of our classes are allowed to use any modalities that have not been taught in our classrooms. Every one of the therapies that we use, including laser therapy, the students, the interns, the chiropractors who are using them they understand how they are used, why they are used, and physiologic effect. And to this point I have never seen anything that’s been any negative reactions to this, so I am highly opposed to this bill.

Senator Price: Any other witnesses in opposition? Members any comments?

Senator Corbett: Yes. I am sorry. I did step in a little bit late and didn’t get all of your testimonies. But I was interested in knowing I understand you just said you have been working by about a year on this regulation. Help me understand the process of a year, seeing is a little long but if you could help me understand the process maybe that would be helpful. And if you could also sort of give the committee an idea as to how much time you think you still need to continue to move forward on this on a regulatory basis.

Dr. Lerner: I think you will find senator most regulations take about three years on the average to get through the process. We hear a lot of testimony from different stakeholders on issues. We may or may not agree with them, just like you. And we look at the danger to the public, of course, because that’s our primary reason for being is to protect the public. I do need to
point out to you we have never had a single complaint filed with the board for treatment of lasers or treatment of allergies and, as far as we know, in its existence.

But we do take things very seriously. We certainly took Senator Huff’s concerns seriously. We meet about every two months as a board. I don’t think we can meet much more often than that just because of the cost to the state and other concerns. And we spend hours and hours on this, trying to vet and clarify the language that we wouldn’t have opposition at the back end. We find that it actually works more expediently to get this out of the way first, and once we send it to OAL often it’s just a 30-day approval period, sometimes even less. And so we try to clean things up on the front end rather than waits till everybody files complains and then we have to start all over again.

What that looks like is after the initial 45-day comment period, we have to go back and amend the language at a board meeting and then send it out for another 15-day comment period and another 15-day comment period and it just keeps going like this until we get a regulation done. So to avoid that, we held this up front in the first place. As far as what’s left, I described that we voted the final language in at our last board meeting in November. It requires a 45-day notice, which will take us from March to have a public hearing, which we have to do. Once the public hearing is convened, we go through the 45-day comment period, or anyone in opposition or regulation can send in written or verbal complaints.

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We then meet as a board again to see if we have to address the opposition. If there is none, which I don’t think there will be at this point, then our office takes about roughly 30 days to put the regulation packages together with all the reasons for the regulation. And we submit it off to the office of administrative law. From there they have 30 business days to accept the regulation or send it back. So if you add that up 45 days, three months, four months, about five to six months more and this should be done. And we are just asking to be able to continue with our task. I think we are moving very well this will about a year and a half to get leg through you are not used to taking this long I understand that in the legislature but so . . .

Senator Corbett:: Oh no we take our time sometimes too.

Dr. Lerner: Well for us that’s pretty high speed.

Senator Corbett: People get this in front of....

Dr. Lerner: Much faster than the 405 anyway.

Senator Corbett: But do you think another five to six months?

Dr. Lerner: It would have to be that way no matter how quickly we want to move on this.

Senator Corbett: But that will be after we conclude our legislative session for this year or before?
Dr. Lerner: I don’t know the answer to that, but, okay.

Senator Corbett: Okay.

Dr. Lerner: Hopefully before.

Senator Corbett: Hopefully before, that would very helpful I think if it happens before we conclude our session. Thank you.

Senator Hernandez: Yes thank you very much. And you are the president of the board?

Dr. Lerner: The chair yeah.

Senator Hernandez: The chair, are you a chiropractor as well?

Dr. Lerner: Yes sir.

Senator Hernandez: Okay you had made a comment about the effects of what this particular bill would have your ability to diagnose. Can you kind of explain to me what your comment meant.

Dr. Lerner: Well it’s the language of the bill, where you are limiting our ability to diagnose food allergies where you want and the bill does and so...

Senator Hernandez: So that currently is in the chiropractic statute or the—

Dr. Lerner: No that’s in SB 352.

Senator Hernandez: But if you are limiting the ability to diagnose. Your ability to diagnose I am assuming is in your act is that correct?

Dr. Lerner: Yes.

Senator Hernandez: But my understanding—Correct me if I am wrong—Isn’t your act, wasn’t that an act of the people?

Dr. Lerner: Yes sir.

Senator Hernandez: So in order for us to do that don’t we have to have the voter, the people to eliminate what you can do as far as your diagnosis?

Dr. Lerner: Yes.

Senator Hernandez: . . . I am just raising the question because that was your concern about the elimination of the diagnosis portion.

Dr. Lerner: What we believe this has go out to if this makes it through the legislature and the governor signs, it there would then have to be a proposition to the people, who would have to vote on it. So we would to open up the initiative act to make this sort of change.

Senator Hernandez: And I am not really familiar with your act, and that’s why I was just curious. I do know that the Chiropractic Act was an act of the people, so this bill would alter your Chiropractic Act, correct?

Dr. Lerner: Yes, potentially.
Senator Hernandez: So according to the act at this point, can a chiropractor diagnose allergies?

Dr. Lerner: Yes.

Senator Hernandez: Okay.

Senator Huff: On that point, the testimony raised a good issue. I am willing to take out the restriction on diagnosis. I think that’s a valuable part that they could contribute in. So I have no problem with striking that. As far as the legality of you make a good point let’s...

Senator Emerson: Dr. Lerner.

Senator Hernandez: And that was just my question because I know that he had a concern and I will be honest with you I haven’t read and Senator [0:23:30][indiscernible] pointed out to me. . . .

Senator Hernandez: It hasn’t been a long day. It just started. But it just struck me that even if this law were to be signed by the governor because it’s an act of the people I don’t know if we can do that.

Senator Huff: Unless council was inconclusive in how they looked a,t it they thought there may be some merit there. But it’s probably something that we get taken care in the court so it would ultimately decide. The scope of chiropractic and medicine has changed quite a bit since you know original time. But just for clarity, I am not trying to prevent them from diagnosing, and I am willing to fix that.

Senator Hernandez: And that’s what my concern about is this particular bill but and I understand that the scope of all the practices have to change, but the big difference between medicine, dentistry, optometry is that they are through the will of the legislature as opposed to the chiropractic is to through the will of the people. So that’s my biggest concern for this particular piece of legislation. I don’t know if the lasers are an appropriate form of treatment. What my concern is that the piece of legislation is going to change the act, which I don’t know we have the ability to do, so that’s just my question that I’m raising.

Senator Price: Good question. Senator Emerson.

Senator Emerson: Dr. Lerner, as chair of the board, can you cite a specific scientific article stating that laser is an effective treatment for allergy treatments?

[0:25:08]

Dr. Lerner: No sir. We have investigated this pretty thoroughly and we are convinced that you can’t treat allergies with lasers. We don’t disagree with Senator Huff on that at all. We haven’t seen a shred of evidence. I agree with the previous doctor’s testimony about that. We certainly don’t want to advocate that as board and we have actually disciplined people for those ads we have managed to get. I think all those ads or most of them pulled, so I think we have done some good there. Now as far as we know the only use of lasers is treatment of chronic and acute musculoskeletal pain. And these aren’t the lasers that burn people. I don’t want to get into whole technical things but we are just talking about what we would call a
low-level laser or a cold laser that is good for acute and chronic musculoskeletal pain. That’s what the FDA does accept it for, and that’s what we would be limiting the scope to with this regulation that we have.

Senator Emerson: Because I do have concerns as an healthcare provider that if a modality is being used, and that there should be some pathway for discussion about that and in protecting the health and safety of patients, that we should not be in any way not disciplining or eliminating that treatment modality.

Dr Lerner: In our opinion claiming that sort of thing violates truth-in-advertising laws as well. So we already have the ability to discipline our licensees for that.

Senator Emerson: Thank you.

Senator Price: Any other discussion? Senator Corbett?

Senator Corbett: I have a question for Senator Huff. Senator Hernandez and I were having a little sidebar here. There is conflicting issues raised by this measure. One is – is the regulatory process the more appropriate forum for taking a look at this issue. The other is this whole issue of what authorities or legislature has when a profession is provided with the rules for a particular profession resides in an act by the people. And that is a little disconcerting as well. And then there is this issue if making sure that an issue of concern is addressed, which Senator Huff has very appropriately raised.

And I guess a question I would have is: Senator Huff if you do see that ... this issue will be addressed in a regulatory way before the end of session would you be willing to you know appropriately hold the bill or you know take notice of the work that’s being done. So I am having the same confusion and conflict with regard to whether it’s appropriate for us to deal with this issue, and because of the act, because of the unique circumstances of chiropractic and how they authorized. But also I certainly understand Senator Huff what you are trying to do to ensure that the regulatory process does work and does move along and does address this issue, which I believe the board is also very sincerely concerned about as well so.

Senator Huff: Right, and thank you for the question. The short answers is yes, I will pull it back. What we are up against this legislative deadline, and to be fair they have been working cooperatively. The timeline I have expressed the same frustration you did. You originally articulated and I don’t know how much this process versus just inertia. But nevertheless if we can get this through I will totally drop the bill because it was always just to make sure and the best is that it’s self-monitored and that it takes care of it without legislative action. Because there is a legal question. Senator Hernandez brings up a pretty good question and ... it’s possible that is something that would be decided in the court should it go forward.

For my part, if you have chiropractors—I will call them rogue chiropractors because I don’t think it represents the nucleus of the industry. I certainly have benefited and I am a constant user of chiropractors. But to treat potentially life-threatening allergies with a treatment that has no scientific base and in fact—as we had some testimony here today—is just the opposite, where you have a false sense
of security and then you ingest some nuts and go onto anaphylactic shock that could exacerbate the problem. If you have somebody that hasn’t disclosed that this may or may not help and they feel that it has.

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And that’s really what’s driving this in and so they are working well I think they will get it taken care of, I am willing to take out the diagnosis out right now because that’s a very legitimate question that’s been raised. But if the committee could just move to the step forward, and if they get it done it six months this pulls back and we have the regulations in place.

Senator Price: Okay well it’s clear that we are all moving on two tracks—obviously the legislation and the regulatory approach—in an effort to address the issue. I think overriding it is the potential legal challenge as it moves forward. There is a recommendation that it move forward to props and hopefully continues the discussion as it progresses. Madam chair I am sorry madam secretary read the roll. Is there a motion, is there a motion?

Male Speaker: Is there an amendment, is there an amendment?

Senator Huff: Yeah I would do it as amended to strike the in fact to be specific it’s listed on Page Two line 20 where it reads “the Practice of chiropractic does not include the treatment and strike “or diagnosis”. So it just wouldn’t allow the treatment of hypersensitivity to food medication . . .

Senator Price: Okay all right let’s move to pass as amended.

(The roll was read and the amendment passed 6-0.)