

PA 11-172

SB0021

House	9367-9399	33
Insurance	508, 510, 612-613, 617-618, 628, 630, 637, 721, 722, 753- 755, 758-768	25
<u>Senate</u>	<u>4044-4079</u>	<u>36</u>
		94

H – 1119

**CONNECTICUT
GENERAL ASSEMBLY
HOUSE**

**PROCEEDINGS
2011**

**VOL.54
PART 28
9295 – 9634**

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

72
June 8, 2011

Those voting Yea	142
Those voting Nay	0
Those absent and not voting	9

SPEAKER DONOVAN:

The Bill is passed.

Will the Clerk please call Calendar 571.

THE CLERK:

On Page 25, Calendar 571, Substitute for Senate
Bill Number 21 AN ACT CONCERNING HEALTH INSURANCE
COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN
CLINICAL TRIAL PATIENTS. Favorable Report of the
Committee on Appropriations.

SPEAKER DONOVAN:

Representative Bob Megna.

REP. MEGNA (97th):

Thank you, Mr. Speaker. Mr. Speaker, I move the
Committee's Joint Favorable Report and passage of the
Bill in concurrence with the Senate.

SPEAKER DONOVAN:

The question is on acceptance and passage. Will
you remark?

REP. MEGNA (97th):

Yes, Mr. Speaker. This Bill expands health
insurance coverage for routine patient care costs

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

73
June 8, 2011

associated with clinical trials currently under statute. I believe just cancer is mandated. This will expand it on to life-threatening and disabling diseases.

Mr. Speaker, the Clerk is in possession of LCO 6727. I ask that it be called and I be permitted to summarize.

SPEAKER DONOVAN:

The Clerk please call LCO 6727 which is designated Senate "A".

THE CLERK:

LCO Number 6727, Senate "A", offered by Senators Looney, Crisco and Representative Megna.

SPEAKER DONOVAN:

The Representative seeks leave of the Chamber to summarize. Any objection? Hearing none, please proceed, sir.

REP. MEGNA (97th):

Thank you, Mr. Speaker. Mr. Speaker, essentially this Amendment is the Bill. It expands it from cancer, it actually expands the coverage for cancer in clinical trials to life threatening and disabling chronic diseases.

What's coming up, Mr. Speaker, under the Affordable Healthcare Act is another expansion. So this is in conformance with the Affordable Healthcare Act, which will require cancer and life-threatening diseases to be covered by insurance companies in clinical trials, and I move adoption of that Amendment, Mr. Speaker.

SPEAKER DONOVAN:

The question is on adoption. Will you remark further? Will you remark further on the Amendment?

If not, let me try your minds. All those in favor of the Amendment please signify by saying Aye.

REPRESENTATIVES:

Aye.

SPEAKER DONOVAN:

Those opposed, Nay. The Ayes have it. The Amendment is adopted. Representative Megna.

REP. MEGNA (97th):

Thank you, Mr. Speaker. Mr. Speaker, this is a wonderful Bill. It represents hope for a lot of people that have life-threatening diseases, cancer and disabling diseases facing them.

It actually also encourages research and to cures for these types of diseases, and with that, I would

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

75
June 8, 2011

urge my colleagues to support this Bill, Mr. Speaker.

Thank you.

SPEAKER DONOVAN:

Thank you, Representative. Representative Coutu.

REP. COUTU (47th):

Thank you, Mr. Speaker. Mr. Speaker, I rise today with some concerns and I have a few questions, through you to the proponent of the legislation.

SPEAKER DONOVAN:

Please proceed.

REP. COUTU (47th):

First, is there other states that have this expansion on covering clinical trials? Through you, Mr. Speaker.

SPEAKER DONOVAN:

Representative Megna.

REP. MEGNA (97th):

Through you, Mr. Speaker, yes, there are several states, and I believe one state that is actually broader than our definition would be Colorado.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Thank you, Madam Speaker. And through you, is Colorado the only state, or is there multiple states that are doing this? Through you, Madam Speaker?

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam speaker, there are several states, or many states, that do require coverage for clinical trials. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

During the testimony and talking to the industry, I know they have concerns relating, excuse me, Madam Speaker, to this expansion of these clinical trials, the potential costs associated, and them having to extend these costs to their clients, and those who have insurance.

Do we know how much of an impact this will have on the market with costs to, in general, to patients, people who have health insurance? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Thank you, Madam Speaker. Madam Speaker, we're hopeful that if there is any incremental cost as a result of the clinical trials, at anything it would be minimum because quite often when these patients enter clinical trials, they forego medications and care that are covered and are being paid for by the insurers.

So there's actually an offset when they go into this and we believe that any incremental cost would be minimal. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Through you, Madam Speaker, during testimony was there a lot of people who came in and said that we should expand these clinical trials? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

I believe so, through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

78
June 8, 2011

And within this Amendment, could the good gentleman repeat the conditions that would be covered?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, the definition would be life-threatening condition, which would essentially mean any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted through this process.

And with disabling and chronic condition would mean any disease or condition likely to cause disability to the individual unless the disease or the condition is interrupted.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Madam Speaker, disability is a term that has a broad spectrum. You can have a scar on your finger and in the military, potentially, get one percent or some percentage of disability.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

79
June 8, 2011

When I was in the military, I injured my hand. I got a scar. I'm zero percent disabled this time, but the reality is, there's always the concern that it's a very vague and loose term that could be abused and potentially open up to many illnesses, many diseases, and many, any disability condition anyone can determine.

And my concern is that when you do these clinical trials, the reason they're clinical is because many times they're not proven.

But, at the same time, they're expensive and I think this could become a large burden on customers of insurance companies.

Through you, Madam Speaker, was there any discussion on clarifying disabling conditions? Through you.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, actually it's disabling chronic condition and we felt that that was proper in describing what some of these patients enter these clinical trials with. Through you, Madam Speaker.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

80
June 8, 2011

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And is there some examples of disabling and chronic conditions? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, I believe MS would be one.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And I believe on line 21 it does have cancer, Parkinson's and a few other diseases, and as I stated, I understand where we're coming from with this piece of legislation. We all do have concerns on how these people can get the medical attention that they need.

But the question is, should it be a mandate that all clinical trials are covered with these conditions?

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. COUTU (47th):

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

81
June 8, 2011

No question, through you, Madam Speaker. I'm just kind of clarifying in my head.

DEPUTY SPEAKER ORANGE:

Please proceed.

REP. COUTU (47th):

Thank you, Madam Speaker. On line 38 there's, relating to, would this make it where all insurance companies are mandated to cover these clinical trials?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

I don't believe so, Madam Speaker. It would be just individual and small group.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And why would we not include large groups or? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

82
June 8, 2011

Through you, Madam Speaker, I believe because they are self-insured and this mandate would not apply to them.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And through you, Madam Speaker, is there any conflict with the President's Healthcare Plan in 2014 with the essential benefit package?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, no. In fact it's in conformance with the Affordable Healthcare Act.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And who has stated that it's in conformance?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

83
June 8, 2011

Through you, Madam Speaker, it's actually set forth in the federal act that it will be required.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And that's, it will be required to all life-threatening clinical trial and potential current disability trials? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, I believe it would be cancer and life-threatening and our Bill here would extend it to chronic disabling.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Madam Speaker, that's really the gist of why I'm concerned. Specifically, the Healthcare Act that's coming in 2014, it may say that life-threatening diseases, there will be potentially more coverage, and it may be a mandate at that time.

But we're extending this into other conditions, and as I've stated, and as many people know, healthcare costs in our state are very high compared to some other states that have less mandates. Some cases, 30, 40 percent higher.

And every time we have a mandate, and it's hard not to classify this as a mandate just because it's going to cost a lot of funds, and those funds are paid by the clients, the individuals and small companies. It's going to go through them to their employees and their premiums will go up.

And, as many people know, I'm often very critical of these health insurance mandates, not only because we have the most or we're one of the top few states in America with the most insurance mandates, but I believe there's a direct correlation between the number of mandates and the cost of healthcare.

And with it consistently going up, we have a problem, and when our state is being questioned as, are we business friendly, one of the first things that any business in the state will talk about is healthcare costs. It's right up at the top along with energy, and just other mandates related to our employers.

So they're asking us, please, be very diligent when you're looking at these mandates and use caution. And if we're going to be probably one of, if one or two states in America that's really going to expand these clinical trials, I think we're putting ourselves in a position where the companies are going to see the consequences from this legislation.

Through you, Madam Speaker, down in line 194 it starts talking about clinical trials in the Insurance Department. Can the proponent of the legislation just expand on what that first sentence is trying to comprehend?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, yes, that's the Department of Insurance establishing guidelines with respect to the Bill. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And it goes on and it talks about the Connecticut Association Health Plans, Anthem Blue Cross of

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

86
June 8, 2011

Connecticut. Just to verify one more time. Will this mandate apply for individual, small groups on all health plans that are not self-insured? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, it would apply to individual and small group.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And on the OLR Bill analysis, it starts discussing how an HMO must pay out of network and the potential fee schedules. I'm not exactly sure where that's in this piece of legislation, but I'm trying to determine what exactly that means?

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, could he please repeat the question?

DEPUTY SPEAKER ORANGE:

Representative Coutu.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

87
June 8, 2011

REP. COUTU (47th):

I found the answer, Madam Speaker, so I'm okay. Just go back one more time and one more clarification relating to extending this mandate to things beyond life-threatening diseases and potential disabling diseases and conditions.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. COUTU (47th):

The question is, is there any perimeters in here that really clarify the specific conditions that this will cover, or is this really going to open up a Pandora Box for any condition that could be classified as life threatening.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

No, I don't believe so, Madam Speaker. It would be routine patient care costs associated with diseases, chronic disabling or life-threatening diseases or cancer.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

88
June 8, 2011

Representative Coutu.

RPE. COUTU (47th):

And would this cover, in a clinical trial we know there's many levels of those trials. They might have Stage 1, Stage 2, Stage 3 and the conditions, the perimeters within those trials may change.

Does this cover a patient from the start of the trial all the way through the evolution of the disease, or is this only set for a certain period time?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, it would only be while in the clinical trial.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And does that mean there's a time restraint? Because I've read in a few different sections it seems to me it's flexible and there may be, if there's a gap in the condition, you may be able to come back for a second cycle in that trial.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

89
June 8, 2011

I'm trying to get clarification if it covers over a certain time period or multiple trials for one patient.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, we would hope that normally when people enter these clinical trials, they don't really want to but the current care is not helping them.

So when they enter this clinical trial with cancer or a life-threatening disease or a chronic disabling disease, we're hoping that they will come out of that clinical trial alive with the cancer under control or gone, or, and not being permanently disabled. So that's really the goal of it. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Thank you, Madam Speaker. And I assume that this piece of legislation has a lot of support from the

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

90
June 8, 2011

pharmaceutical industry. Did we get testimony in support from them? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

I don't recall. Testimony many have been submitted, but I don't recall. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Madam Speaker, I have recognized that this, what I've witnessed is the pharmaceutical industry, they're being innovative and trying to determine new ways and new cures to help save lives.

And these clinical trials are sometimes the last resort, but I think the success rate of these clinical trials, we don't know. We really don't know how often these new clinical trials succeed.

Things like cancer. There has been thousands of clinical trials, new drugs, new solutions, and often because it's a very small scale that it's tried on, these new ideas and new solutions, it's often that they don't work. But they're very expensive because

it's the economy of scale. There's not that many patients.

Now, with some of the larger conditions, multiple sclerosis, cancer, there's more patients, and these trials can get rather large so the costs can decrease slightly.

But the bottom line is, clinical trials can be very expensive.

And one of my concerns revolves around the idea that if we are mandating that our insurance companies cover costs for many conditions and what may be a Pandora Box, the cost could go up drastically because it's then funded by insurance companies under a mandate.

And I think now some pharmaceutical companies and some organizations and biotech, they're coming up with solutions. They don't know if it's going to work, but sometimes they invite people to join the clinical trial with no cost, and I think there's a chance that this may open up where all clinical trials will have more costs and drastically lead to an increase in insurance.

On line 293 it starts covering about Medicare coverage of its routine costs under the Medicare

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

92
June 8, 2011

Clinical Trial Policy established on September 19,
2000.

I just want to know, was that previous
legislation at the federal level that started to
implement funding for these clinical trials? Through
you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, currently there is
coverage and it's much, I believe much broader through
Medicare so that's probably what that section is
about.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And I would assume that could be somewhat true.
The coverage, as far as I can tell, is life-
threatening diseases and conditions but I'm not sure
if they've expanded it as broad as we are today, and
that's once again my primary concern.

On line 449 it starts once again talking about
the Insurance Department, and how at least one state

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

93
June 8, 2011

nonprofit research or advocacy organization. I'm just trying to figure out. Is this common practice that the Insurance Department's working with advocacy organizations to determine legislation around something like a mandate?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, that mirrors the language in statute with regard to cancer clinical trials.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

Thank you, Madam Speaker. And is, does there, is there any potential conflict in 2014 when the new federal healthcare system is mandated to our state and citizens across America where this could end up costing the State of Connecticut because it doesn't fit within the perimeters of the essential benefit package? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

94
June 8, 2011

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, we have really no knowledge of what any kind of incremental or increased costs may result from this expansion.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Coutu.

REP. COUTU (47th):

And Madam Speaker, that once again is a major concern for me. I stated repeatedly there's always the potential for unintended consequences especially with insurance.

Many of the times we pass legislation relating to mandates. It comes down to an emotional feeling we have inside. We have an attachment to somebody who has a life-threatening disease. We have a connection with somebody who has cancer. We have a connection with somebody who has an illness and it's very hard to say no.

But the problem is, when you do a blanket policy for companies out there that have to buy these insurance plans, they can't opt out.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

95
June 8, 2011

It used to be you buy health insurance and it depended on how much money the company had, how profitable they were, and if they could afford to purchase a great healthcare plan like we have for our State of Connecticut employees. That would in many ways be a gold plan.

But if your company is struggling to survive, and we've heard time and time again all the companies in Connecticut that are really struggling to survive, they are in a position where they may have to get what would be classified in 2014 as a bronze plan, something lower on the totem pole but we would classify as coverage covering all those conditions that we would all like to have, just in case something happens, minimal deductibles and that's where this mandate, I believe, will put us, in the expansion of this mandate, will put us above 60 mandates.

I'm not sure if 2014, how many of these mandates will be accepted by the federal government in the Essential Benefit Package, and if they're not in that package, we will be responsible for them.

With that, I'll strongly urge my colleagues to think about this vote and understand there's

unintended consequences. We may be on the hook in 2014 for a massive obligation at the state level.

There may be unintended consequences for the Governor and his SEBAC Agreement because we already have one of the least funded pension plans in America.

And to put it in perspective, when I say pension plan, I also mean healthcare plan. We're at 42 percent we found out this week, Madam Speaker. Other states like Rhode Island are somewhere around 60 percent, and 90 percent of the states above 80, 90 percent.

So this obligation on our 25, actually 250,000 beneficiaries of our state healthcare plan, could result in a massive tax on the rest of the people because after 2014, it's the people that are going to pay that bill if it's not in the Essential Benefit Package.

So please use caution. I recommend a no vote to my colleagues. Expanding these clinical trials beyond their true intentions, which was for life-threatening conditions, we're opening up, and I believe this may be a Pandora's Box where you could have court cases questioning, well, I believe I had skin cancer. It was evolving and that could be a life-threatening

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

97
June 8, 2011

disease. There's thousands of life-threatening diseases.

And this could end up being the largest mandate in our history. Thank you, Madam Speaker. I appreciate the gentleman's answers and his leadership.

DEPUTY SPEAKER ORANGE:

Thank you, sir. Would you care to remark?
Representative Srinivasan.

REP. SRINIVASAN (31st):

Thank you, Madam Speaker. It's great to see you there. Good afternoon to you.

Through you, Madam Speaker, to the proponent of the Bill.

DEPUTY SPEAKER ORANGE:

Please proceed, sir.

REP. SRINIVASAN (31st):

Thank you, Madam Speaker. Clinical trials are extremely important. It is through clinical trials that we know what needs to be done, what needs to be taken away in terms of treatment, what needs to be added. So clinical trial is extremely, extremely essential in terms of managing our patients more effectively and more efficiently.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

98
June 8, 2011

My questions to you, sir, are, would you in your Committee meetings or in the public hearing, assuming that there was a public hearing on this, did you have examples of what kind of medical trials, without going into details (inaudible) or expected. Like just if you could give us one or two examples of what was done or is being planned to be done as a clinical trial? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Through you, Madam Speaker, these are, I guess the standard, systematic clinical trials that meet all federal guidelines and statutory guidelines.

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Thank you, Madam Speaker. And that is where I have a little difficulty, because clinical trials are extremely complicated. You are changing one parameter and you're seeing the impact of that parameter over a period of time. That is the sense of a clinical trial.

We do clinical trials in our practice. We've been doing that for the last 20 plus years. They are very time involved, consuming. We need to be extremely meticulous, because remember, the results of your clinical trial is the basis of recommendations a) for patients not only in your own practice but across the scope of the land. That is the whole idea.

I am learning from your clinical practice. You are learning from your clinical practice, and that is the whole intent.

Given that, my question to you is, somehow I get the feeling that this may be just a minor change of this or that. Is that the scope of the trial we'll be talking about or are we talking about adding a medication, eliminating a medication for a period of time?

Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

No, I don't believe so. Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Srinivasan.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

100
June 8, 2011

REP. SRINIVASAN (31st):

And so that is where I get into this not understanding, comprehending what you mean by a clinical trial. Because we say clinical trial in the medical field, which is what you're alluding to, we are changing something and seeing its impact over six months, one year, many, many years down the line.

And as you know, the clinical trials have become so complex, so complicated, that usually a single group of people are not even able to do clinical trials any more. It is a team. It is a team of people across the nation so we have enough patients, enough patient information to make an important difference in what the recommendation is.

At the end of the day when we do a trial, we're doing a trial so that we can learn something from that trial, glean something from the trial, which we can use for our patients.

So through you, Madam Speaker, do you see these trials that you are talking about as, where a lot is involved and who is going to be conducting the trial.

Typically you have a group of people that are in charge, monitoring, they come to your site, as I'm sure you're well aware of, look through our records,

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

101
June 8, 2011

go through every I that we have dotted, every T that we have crossed, make sure all the parameters are met.

Are we talking about a trial to that extent, and who is going to be making sure that the trial is run adequately? Through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Megna.

REP. MEGNA (97th):

Thank you, Madam Speaker. This will just be routine patient care costs that would normally be covered if it were not in a clinical trial, and some companies already do this.

But it's just normal, routine patient care costs. I don't know the procedure or the guidelines, the federal guidelines, statutory guidelines on the exact nature of clinical trials and how they qualify lawfully, but, through you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Through you, Madam Speaker, and that is my concern, that we want to make sure that we do a trial, we do it effectively so the end of the day we have information that we would be able to share.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

102
June 8, 2011

My concern is very much what is this encompassing as far as these trials are concerned.

And thank you, Madam Speaker, and I want to thank the proponent of the Bill for bringing up this very important issue to the floor so we have an opportunity to debate that. Thank you, Madam Speaker.

DEPUTY SPEAKER ORANGE:

Thank you, sir. Will you care to remark further? Representative Laura Hoydick, you have the floor madam.

REP. HOYDICK (120th):

Thank you, Madam Chair. Just a few, quick comments about this Bill. In Committee, it barely passed, and one of the reasons was not only is it very expensive and undetermined the costs, but we weren't really sure of the results that would be beneficial.

And with the new healthcare legislation nationally coming down in two years, some of these clinical trials would not have been completed, and we would have to possibly stop paying for those hospitalization costs for the people who were currently in the trials.

And now with the expanded scope of this Bill, I just have to say I cannot support it.

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

103
June 8, 2011

Thank you very much, madam.

DEPUTY SPEAKER ORANGE:

Thank you, madam. Will you care to remark further? Will you care to remark further?

If not, staff and guests please come to the Well of the House. Members take your seats. The machine will be opened.

THE CLERK:

The House of Representatives is voting by Roll Call. Members to the Chamber.

The House is taking a Roll Call Vote. Members to the Chamber, please.

SPEAKER DONOVAN:

Have all the Members voted? Have all the Members voted? Please check the Roll Call board to make sure your vote has been properly cast.

If all the Members have voted, the machine will be locked and the Clerk will take a tally.

Will the Clerk please announce the tally.

THE CLERK:

Senate Bill 21 as amended by Senate "A" in concurrence with the Senate.

Total Number Voting 141

Necessary for Passage 71

pt/tj/lxe/gbr
HOUSE OF REPRESENTATIVES

104
June 8, 2011

Those voting Yea	96
Those voting Nay	45
Those absent and not voting	10

SPEAKER DONOVAN:

Representative Villano, for what reason do you rise?

Representative Villano.

REP. VILLANO (91st):

In the affirmative, Mr. Speaker.

SPEAKER DONOVAN:

The Transcript will so note. Representative Clemons.

REP. CLEMONS (124th):

A vote in the affirmative, Mr. Speaker.

SPEAKER DONOVAN:

Representative Clemons in the affirmative. The Transcript will so note.

The Bill passes as amended.

Are there any announcements or introductions?

Any announcements or introductions? Representative, Deputy Speaker Joe Aresimowicz, you have the floor, sir.

REP. ARESIMOWICZ (30th):

**JOINT
STANDING
COMMITTEE
HEARINGS**

**INSURANCE AND
REAL ESTATE
PART 2
339 – 666**

2011

11
jr/gbr INSURANCE AND REAL ESTATE
COMMITTEE

February 3, 2011
1:00 P.M.

DEBRA POLUN: Thank you so much.

SENATOR CRISCO: Representative Morin. Is
Representative Morin here?

Vickie Veltri on Senate Bill 17.

VICTORIA VELTRI: Good afternoon, Senator Crisco,
Senator Kelly, Representative Sampson.

SB18 SB21

For the record, I'm Vickie Veltri, and I'm the
acting healthcare advocate for the State of
Connecticut, and I'm here to testify on Senate
Bill 17.

OHA -- OHA endorses Senate Bill 17. It's fair
to say that the consumer protections that
we've enacted in our statutes are a reflection
of the state's public policy to ensure
coverage for medically necessary care.

That said, as you know, OHA has long supported
independent cost-benefit analysis of the
consumer protections included in our health
insurance statutes.

As part of a larger discussion on healthcare
reform, this type of analysis is obviously
helpful.

We support the reviews as an objective method
to assist policymaker, so concerns about costs
are valid.

But OHA notes that the review of the consumer
protections contained in Senate Bill 17
concluded that adding those protections put
the estimated cost of covering these services
at about 71 cents per member per month, plus
about zero to three percent of premium cost

13
jr/gbr INSURANCE AND REAL ESTATE
COMMITTEE

February 3, 2011
1:00 P.M.

SENATOR CRISCO: Thank you. Thank you.

Any questions? Don't go away. How about
Senate Bill 21.

VICTORIA VELTRI: Okay.

Senate Bill 21, OHA supports Senate Bill 21.
We have limited coverage for routine patient
care costs to clinical trials for cancer for a
long time.

However, there are -- there are treatments for
diseases other than cancer, other disabling,
progressive life-threatening medical
conditions that also undergo clinical trials.

With rapidly advancing medical technology,
it's likely that clinical trials for the
treatment of illnesses other than cancer will
be available to those who cannot succeed on
approved treatments.

This bill appropriately limits the coverage to
the routine patient care costs to individuals
with disabling progressive or life-threatening
medical conditions. We believe that this is a
fair and overdue extension of our current
statutory scheme.

SENATOR CRISCO: Thank you, Vickie. Any questions?
Any questions? Thank you very much.

VICTORIA VELTRI: Thank you.

SENATOR CRISCO: Is Representative Morin here yet?
No? Senator Prague? Don't hear her, so we'll
just go right into (inaudible) council.

We'll go right into the public session until

115
jr/gbr INSURANCE AND REAL ESTATE
COMMITTEE

February 3, 2011
1:00 P.M.

healthcare.

We strongly urge the Committee to reject this legislation.

SENATOR CRISCO: Thank you, Christine. Thank you very much.

Dina?

DINA BERLYN: Good afternoon, Senator Crisco, Representative Megna and members of the Insurance and Real Estate Committee. My name is Dina Berlyn. You may know me as Senator Looney's counsel and executive aide, but I'm here now as a patient with multiple sclerosis to testify on Senate Bill 21, An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients, and Senate Bill 18, An Act Concerning Appeals of Health Insurance Benefits Denials.

I have researched and written on the issue of routine patient care in clinical trials, and what I have found out about the issue is that the cancer-only provision in our statutes doesn't make a whole lot of sense.

In 2001, the General Assembly passed 01-171, which required coverage of routine patient care for cancer. And they're great goals, but the bill in its final form required coverage only for cancer trials, and a number of insurers also covered these expenses for cancer.

And for rare -- trials for rare diseases, if insurers deny coverage of these costs, which is not asking insurers to cover anything that they shouldn't be asked to cover, it's just

the routine care that they would have to cover patients if they weren't in a clinical trial. It's covering the standard of care. So if they -- if costs are denied for rare diseases, then -- for trials of rare diseases, then there's no way that any of the trials are going to happen.

There's also evidence that routine patient care costs for clinical trial patients are essentially equivalent as routine patient care costs for patients not in clinical trials.

And I believe that in many -- for many patients with diseases such as multiple sclerosis, the routine care costs are actually less, because -- like the drug I take is \$3,500 a month, and there's no way that I would have an increased routine care cost of \$3,500. And of course the insurer would not have to pay for the experimental drug.

So, you know, it -- is that my beep? So anyway, some of this is dealt with in the Affordable Care Act but only for cancer or life-threatening disease, very narrow definition of life-threatening to leave out all the chronic disease.

Section 15 is also great, which was expanding the ability to use off-label drugs. And in terms of Senate Bill 18, the -- there's a lot of problems in the process of denials, which is one is that you don't get the -- the complete record of your case, in which case then the insurance company is the one that has all the information which generally the burden of proof lies with the party who has all the information.

And since they don't and will refuse to give

120
jr/gbr INSURANCE AND REAL ESTATE
COMMITTEE

February 3, 2011
1:00 P.M.

want to comment again on 21? You included in
your original --

DINA BERLYN: (Inaudible.)

SENATOR CRISCO: Okay. I understand. Susan?

Just as long as you had additional comments,
Dina. That's all.

SUSAN HALPIN: Good afternoon, Senator Crisco,
Representative Megna, members of the
Committee, Representative Sampson, I'm Susan
Halpin. I'm here on behalf of the Connecticut
Association of Health Plans.

We'd like to respectfully urge a rejection of
Senate Bill 21. The Connecticut Association
is very proud of the work that we've done
previously on this issue with the American
Cancer Society and the leading Connecticut
oncologists cooperatively developing a model
of coverage for routine costs of cancer
clinical trials.

That bill took a long time to create. It was
a process where all parties agreed that
coverage for routine care expenses was the
right thing to do and that patient safety and
sound medical research protocols were
paramount to providing the health benefits.

The most encouraging thing about this process
was that there was no argument about the
fundamental principle of the bill, patient
safety and sound medical research protocols.

The bill before you seeks to expand coverage
for research trials to the arena of disabling
progressive or life-threatening illnesses.
This is a very challenging area to define.

121
jr/gbr INSURANCE AND REAL ESTATE
COMMITTEE

February 3, 2011
1:00 P.M.

Thousands of clinical trials exist on almost any medical condition, ranging from nearsightedness to cholesterol management.

The issue of whether a condition is disabling, progressive or life-threatening would be difficult or impossible to determine.

Just quickly, one additional matter that I'd like you to consider -- you also have my testimony in front of you -- is that the federal healthcare reform covers trials for cancer and other life-threatening diseases; but to be eligible, trials must be funded by NIH, CDC, AHCRO, CMS, CODBA, cooperative group, or an NIH-qualified research entity, or in certain cases via the FDA.

Additional conditions require that any study be subject to certain peer-review systems and ensure an unbiased review of the highest scientific standards.

Any clinical trial in excess of these standards will be ineligible for federal subsidy and therefore any additional costs will be borne by taxpayers -- Connecticut taxpayers again.

And I think one of the fundamental questions around this issue of clinical research is really who should fund it. It's necessary, but who should fund it? Should that cost be borne by the research entities and the -- and the manufacturers or should that be funded through the insurer?

So I leave you with that question and thank you for your time.

SENATOR CRISCO: Thank you, Susan. Questions?



STATE OF CONNECTICUT

INSURANCE DEPARTMENT

Testimony of the Connecticut Insurance Department

Before
The Insurance and Real Estate Committee

February 3, 2011

Senate Bills:

No. 10 – An Act Concerning Insurance Coverage for Breast Magnetic Resonance Imaging

No. 12 – An Act Prohibiting Copayments for Preventive Care Services

No. 17 – An Act Concerning Wellness Programs and Expansion of Health Insurance Coverage

No. 21 – An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients

The Connecticut Insurance Department would like to offer the following general comment regarding the potential budgetary impact of the above referenced health insurance mandates, as well as some specific comments on SB 12 and 17.

When considering the enactment of new or additional health insurance mandates, the Department respectfully urges the Committee to understand the future financial obligations they may place on the State of Connecticut and taxpayers.

The Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) (PPACA), as amended, requires that by January 2014, each state shall establish an American Health Benefit Exchange (Exchange) that facilitates the purchase of qualified health plans. Qualified health plans will be required to offer an essential benefits package as determined by the Secretary of Health and Human Services (HHS). PPACA Section 1311(d)(3) provides that a State may require that qualified health plans offered in the State offer benefits in addition to the essential health benefits, but, if the State does mandate additional health benefits be provided, the States must assume the cost of those additional benefits by making payments to an individual enrolled in a qualified health plan offered in the State or, to the qualified health plan on behalf of the enrolled individual to defray the cost of the additional. **In simple terms, all mandated coverage beyond the required essential benefits (as will be determined by HHS) will be at the State's expense. Those costs may not be delegated to the individual purchaser of insurance or the insurer.**

Essential benefits have yet to be defined by HHS; therefore, there is no mechanism for determining if these proposed mandates will fall within the definition of essential benefits or not. However, should they be passed into law and be determined to exceed the essential benefit requirements, the State will have an immediate financial obligation to pay the cost of each of those mandates to the individual or to the insurers effective in 2014.

We would also like to offer additional comments regarding two specific proposals:

No. 12 – An Act Prohibiting Copayments for Preventive Care Services - PPACA Sec. 1001 mandates coverage for preventative services without cost sharing for plan years beginning 9/23/10 for all non-grandfathered plans; therefore, this will unnecessarily duplicate federal law which already has addressed this issue.



**Statement
 Of
 Anthem Blue Cross and Blue Shield
 On
SB 10 An Act Concerning Insurance Coverage for Breast Magnetic Resonance
 Imaging
 and
SB 17 An Act Concerning Wellness Programs and Expansion of Health Insurance
 Coverage
 and
SB 21 An Act Concerning Health Insurance Coverage for Routine Patient Care Costs
 For Clinical Trial Patients
 and
SB 848 An Act Concerning Breast Ultrasound Screenings**

Good afternoon Senator Crisco, Representative Megna and members of the Insurance Committee, my name is Christine Cappiello and I am the Director of Government Relations for Anthem Blue Cross and Blue Shield in Connecticut. I am on testifying on SB 10 An Act Concerning Insurance Coverage for Breast Magnetic Resonance Imaging; SB 17 An Act Concerning Wellness Programs and Expansion of Health Insurance Coverage; SB 21 An Act Concerning Health Insurance Coverage for Routine Patient Care Costs For Clinical Trial Patients and SB 848 An Act Concerning Breast Ultrasound Screenings..

We are concerned about SB 10, SB 17 and SB 21 because they seek to add a new mandate for all individuals and group policies, including the State of Connecticut State Employees Health Insurance Plan. Mandates remove any choice that employers or individuals might have in purchasing health care. Our goal as a managed care organization is to provide a comprehensive meaningful set of benefits to individuals and employers purchasing our product. How we accomplish this goal changes as the needs and desires of the market changes. Mandating benefits take away the flexibility insurers have in developing products in response to the needs of the marketplace. The cost of mandates may cause the purchasers of health care, specifically employers to stop offering health insurance all together.

I would also like to add that SB 21 has a potentially large cost because of the number of clinical trials that are currently underway and that people are enrolled in disabling, progressive or life-threatening diseases. An argument could be made that almost every disease could fit into these categories and subsequently substantially increase the cost of this mandate.

Anthem Blue Cross and Blue Shield is the trade name for Anthem Health Plans, Inc. Independent licensee of the Blue Cross and Blue Shield Association. ® ANTHEM is a registered trademark of Anthem Insurance Companies, Inc. The Blue Cross and Blue Shield names and symbols are registered marks of the Blue Cross and Blue Shield Association.



TESTIMONY
of the
CONNECTICUT CONFERENCE OF MUNICIPALITIES
to the
INSURANCE & REAL ESTATE COMMITTEE
February 3, 2011

CCM is Connecticut's statewide association of towns and cities and the voice of local government - your partners in governing Connecticut. Our members represent over 93% of Connecticut's population. We appreciate this opportunity to provide testimony to you on issues of concern to towns and cities.

- S.B. 10 "An Act Concerning Insurance Coverage for Breast Magnetic Resonance Imaging"
S.B. 17 "An Act Concerning Wellness Programs and Expansion of Health Insurance Coverage"
S.B. 21 "An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients"
H.B. 5448 "An Act Requiring Health Insurance Coverage for Breast Thermography"

These proposed bills would mandate insurance policies cover certain new medical procedures/items. Some of the costly new procedures and items mandated in these bills include: weight loss programs, breast thermography, breast magnetic resonance imaging, hearing aids, routine patient care costs for clinical trial patients, and certain prostate cancer treatments and prescription drugs.

The expansion of insurance coverage will increase insurance costs and thus premiums, which will eventually be borne by policy holders - municipalities to name one. This would result in increased insurance costs statewide.

While all of these have their merits, the bottom line is that they will increase insurance costs across the board at a time when local budgets can least afford it.

CCM urges the committee to **take no action** on these proposed mandates

##

If you have any questions, please contact Bob Labanara of CCM at rlabanara@ccm-ct.org.

**JOINT
STANDING
COMMITTEE
HEARINGS**

**INSURANCE AND
REAL ESTATE
PART 3
667 – 987**

2011



Office of the
Healthcare
Advocate
STATE OF CONNECTICUT

**Testimony of Victoria Veltri
Acting Healthcare Advocate & General Counsel**

**Before the Insurance and Real Estate Committee
In support of SB 12, SB 15, SB 17, SB 18 and SB 21
January 27, 2011**

Good afternoon, Representative Megna, Senator Crisco, Senator Kelly, Representative Coutu, and members of the Insurance and Real Estate Committee. For the record, I am Vicki Veltri, Acting Healthcare Advocate and General Counsel with the Office Healthcare Advocate ("OHA"). OHA is an independent state agency with a three-fold mission: assuring managed care consumers have access to medically necessary healthcare; educating consumers about their rights and responsibilities under health insurance plans; and, informing you of problems consumers are facing in accessing care and proposing solutions to those problems.

OHA supports SB 12, AN ACT CONCERNING COPAYMENTS FOR PREVENTIVE SERVICES. OHA has supported this measure in the past. While the Patient Protection and Affordable Care Act (ACA) prevents non-grandfathered plans from applying copayments to preventive services, grandfathered plans are not subject to this provision of the ACA. Passage of SB 12 will ensure that Connecticut residents covered in any type of plan have access to preventive services, encouraging better health care. SB 12's list of preventive services appears to be more comprehensive than the list under the ACA. The committee may wish to consider aligning the definition of preventive services in SB 12 to that in the ACA.

OHA supports the concept of SB 15, AN ACT CONCERNING RATE APPROVALS FOR LONG-TERM CARE INSURANCE POLICIES. It is past time to ensure the availability of public comment and transparency in the long-term care insurance market. Individuals who are subject to repeated double digit rate increases in the long-term care market deserve the chance to scrutinize and comment on proposed rate increases.

OHA supports SB 18, AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS. This bill contains provisions consistent with our recent proposals that provide deference to a provider's medical judgment. No reviewer in a utilization review company can ever truly step completely into the shoes of a provider in the application of medical judgment in a specific case. Every year, the utilization review companies, many of whom are subsidiaries of the insurers themselves, are making medical determinations. In our experience, the insurers are going beyond medical necessity coverage determinations to substitute their medical judgment for that of the providers. This happens in surgical cases and behavioral health cases more and more frequently. An insurer may determine that a service is not medically necessary, but it is not the insurer's role to practice medicine on a patient they have never examined – suggesting an alternative, lower-level of care or a different kind of surgery, for example. While the insurers might argue that the decisions they are making are merely coverage determinations, more often than not, they are de facto denials of services or treatment. In most cases, consumers cannot afford to go ahead with a medical treatment that has been denied.

The insurers will undoubtedly testify that to provide a presumption of medical necessity for a provider's judgment will destroy managed care. We reject that notion. Insurers can still subject a service to prior authorization or post-service utilization review. The only change this bill makes is to shift the burden to where it properly belongs, onto the insurers. It is not unheard of for provider's decisions to be accorded deference. Such deference exists in Medicaid and in Social Security for disability determinations. We've witnessed a significant level of second guessing of providers; MCO peer reviews that are not based on a complete record; and, arbitrary limitations made on approved services. We need to restore deference to the providers who actually examine and treat the patient.

OHA supports the provisions of SB 18 requiring the utilization review company to furnish a provider and an enrollee with the information the company used to make its determination. This information is crucial for the preparation of an appeal.

OHA also supports SB 21, AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS. The limitation of coverage for routine patient care costs to clinical trials for cancer is not allowable under Connecticut law. However, there are treatments for other disabling, progressive or life-threatening medical conditions that also undergo clinical trials. With rapidly advancing medical technology, it's likely that clinical trials for the treatment of illnesses other than cancer will be available to those who cannot succeed on approved treatments. The bill logically links eligibility for reimbursement to Medicare clinical policy in addition to the existing options. The bill appropriately limits coverage of routine patient care costs to individuals with disabling, progressive, or life-threatening medical conditions. This is a fair and overdue extension of our current statutory scheme.

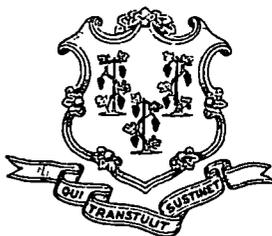
Finally OHA supports the common sense proposals of SB 17, AN ACT CONCERNING WELLNESS PROGRAMS AND EXPANSION OF HEALTH INSURANCE COVERAGE. OHA has testified in favor of this bill in the past. UConn analysts put the estimated cost of covering these services at about \$.71 per member per month plus 0-3% of premium costs for wellness programs. The analysis deemed these costs would not impact the existing health care financial burden of enrollees.

Thank you for the opportunity to submit this testimony. If you have any questions, please contact me at victoria.veltri@ct.gov or 860-297-3982.

FTR

SENATOR MARTIN M. LOONEY
Majority Leader

Looney@senatedems.ct.gov
www.senatedems.ct.gov



Legislative Office Building, Room 3300
Hartford, CT 06106-1591
Telephone (860) 240-8600
FAX (860) 240-0208

State of Connecticut

SENATE
11th District

January 27, 2011

Good afternoon Senator Crisco, Representative Megna and members of the Insurance and Real Estate Committee. I am here to testify in support of two bills that are on the agenda today: S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS and S.B. No. 18 AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS

S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS would expand coverage of routine patient care costs for clinical trial patients to clinical trials for serious or life threatening diseases and ensure that third party payers retain their responsibility to patients. In 2001 the Connecticut General Assembly passed PA 01-171 which required insurers to sustain their responsibility to patients who participate in clinical trials for cancer. At that time I expressed my

belief that this coverage requirement should not be limited to cancer but rather should apply to clinical trials for all serious or life-threatening conditions. These courageous patients are willing to take a risk by participating in a clinical trial that is attempting to find more effective treatment for a specific disease. They enter the trial with no expectation that the new treatment will cure their disease. Usually, since most clinical trials are double blind and placebo controlled, patients do not even know if they are receiving the experimental drug or a placebo until the results of the trial are known. These patients are, in a profound sense, heroes and heroines. They are taking a risk to help others who share their particular condition. These patients deserve our encouragement and support. They do not deserve to be billed for procedures that their insurers would cover if they were not in a clinical trial.

The proposal before your committee does not ask insurance companies to cover more than they should expect to pay. It would only require that insurance companies cover standard of care treatment for patients who are enrolled in clinical trials as they would for patients who are not enrolled in clinical trials. The language in the bill states that routine patient care is care "that would otherwise be covered if such services were not rendered pursuant to a clinical trial." Insurers vary significantly in how they cover these costs. This legislation would create a more rational outcome for patients.

Under President Clinton, Medicare made the common sense change to cover routine patient care costs for clinical trial patients. The Medicare coverage is, sensibly, not limited by disease. I believe that the Connecticut General Assembly should make this same change.

The recently passed landmark Affordable Care Act requires coverage of routine patient care costs but only in trials for cancer or other life-threatening diseases. It then provides an extraordinarily narrow definition for 'life-threatening' which does not include the majority of chronic and disabling diseases. This is in conflict with the thoughtful policy developed by the Centers for Medicare & Medicaid Services. While I am also urging our Congressional delegation to take the lead in proposing legislation to expand the scope of coverage under federal law, I believe that state action this year is necessary and desirable.

In addition, section 15 of this bill would allow greater use of drugs off-label. There are a number of drugs that have been shown to be effective against rarer diseases in small trials, but which will never be approved for those diseases because there is no way to do the large multi-center trials. These are drugs with known safety profiles that are already approved for specific diseases. Our state currently requires coverage for off-label use of cancer drugs; it is illogical to deny this coverage for other diseases.



**Insurance and Real Estate Committee
February 3, 2011**

Testimony of the American Cancer Society

SB 21 – An Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients

The American Cancer Society is in strong support of SB 21. This legislation would assure privately insured cancer patients access to the full range of clinical trials.

Clinical trials are a critical treatment option for current cancer patients and are also essential in our nation's efforts to win the war on cancer. Without clinical trials, new or improved treatments would languish in the laboratory, never reaching the patients who need them. Unfortunately, only a very small percent of cancer patients currently enroll in clinical trials. Part of the problem is that many health insurers refuse coverage for a patient's routine care costs if the patient enrolls in a clinical trial – effectively denying access to possibly life saving treatment.

SB 21 would remove this financial barrier by requiring health insurance plans to cover the same routine patient care costs that they would cover if the patient were receiving standard therapy. This bill does not require the health plans to cover the cost of the drug under investigation or research-related costs. The American Cancer Society strongly supports this legislation as it will provide cancer patients with the assurance that their health plan benefits and services – items which are covered under their monthly premiums – will not be taken away simply because they have enrolled in a clinical trial.

Since 2000, Medicare beneficiaries with serious and life threatening diseases have had access to the full range of clinical trials. We are pleased that this legislation will mirror the Medicare benefit in that it covers the full range of cancer clinical trials and relies on the Medicare definition of routine patient care costs.

The diagnosis of cancer is devastating – patients must not only confront an array of medical decisions, they must cope with the financial and emotional burdens as well. Once again, we commend the members of this committee for your leadership on this critical issue, by seeking to reduce some of the financial worries of cancer patients as they consider their treatment options. We look forward to working with you to assure that these barriers are removed this year.

Please support SB 21.

####

TESTIMONY OF DR. JOHN BOOSS

88 Lacey Road
Bethany, CT 06524
203-393-2288

January 27, 2011

Good Morning Sen. Crisco, Rep. Megna and members of the Insurance and Real Estate Committee. My name is Dr. John Booss and I reside in Bethany Connecticut. In 2005 I retired as the National Director of Neurology for the Department of Veteran's Affairs. I remain on the staff of the VA Medical Center in West Haven in an unpaid capacity and am Professor Emeritus at the School of Medicine at Yale University. I am on the Government Relations Committee of the CT Chapter of the National Multiple Sclerosis Society, have served as a volunteer Neurologist at the Hill Health Center in New Haven, served as a volunteer Neurologist at the Nathan Smith Clinic [for persons with HIV] at the Yale New Haven Hospital, did pro bono consults at the medical students free clinic, Haven, in Fairhaven, and serve on the Board of Directors for Leeway, the long-term care facility in New Haven for persons living with HIV.

I want to offer my support for S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS. I have been involved in numerous clinical trials throughout my career, and I understand that patients need to be sure that their participation in a clinical trial will not threaten the health insurance coverage that they have without participation in the trial.

The need to find new and better treatment options for many devastating and chronic illnesses seems an obvious one, and it is clear that clinical trials are an important part of this process. Coordinating third party payer coverage for routine patient care costs in clinical trials is a sensible step. This issue determines which diseases will be the subjects of clinical trials and the willingness of patients to enter clinical trials (by alleviating fear that they will be left with costs that they would not have to pay in standard treatment). While this coverage would be good policy for all clinical trials, it is crucial in clinical trials for less common diseases because if insurers deny coverage for these costs in that setting, no sponsor will undertake the research. There is evidence that routine patient care costs for clinical trial patients is roughly equivalent to routine patient care costs for patients in standard treatment.¹

¹Bennet et al., *Evaluating the Financial Impact of Clinical Trials in Oncology: Results from a Pilot Study From the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project*, 18 J. OF CLINICAL ONCOLOGY 15, 2805-10 (2000).

¹*Id.*

¹Bruce H. Firemen, et al., *Cost of Care for Patients in Cancer Clinical Trials*, 92 J. THE NAT'L CANCER INST. 7, (2000.).

¹Wagner, et al., *Incremental Costs of Enrolling Cancer Patients in Clinical Trials: A Population Based Study*, 91 JNCI 10, 847-53 (1999).

The insurance companies are not being asked to pay for other than standard of care services -- they are not being asked to pay for any of the costs of the clinical trials themselves. The precedent has been set and widely accepted in clinical trials to treat cancer.

As the rules stand now, only pharmaceutical companies can afford the costs (with the exception of very few government sponsored trials). Pharmaceutical companies are not going to bear these costs unless there will be enough sales of the drug after approval to make it worthwhile. One cause of high study costs is the need to find research funding for activities that would normally be standard of care. If third party payers sustained their responsibility for those aspects of the study that were within standard of care, then funds could be raised for more research to pay for new medicines, or procedures required only by the study protocol.

The position that cancer trials have obtained has greatly facilitated research in those diseases. Very common diseases are also generally adequately covered. But many diseases are relatively uncommon and not profitable for the large pharmaceutical companies. Patients with these diseases would benefit tremendously if the same rules that exist in many states for cancer applied to all serious diseases. Some states have in fact required coverage beyond cancer to all serious or life-threatening diseases. Now we in Connecticut should expand on the work that oncology advocates have done and move this coverage beyond cancer.

Much research needs to be done and much of it will be physician initiated research; patients with uncommon diseases (that are not the subject of sufficient research because discovering treatment will not produce sufficient profits for the drug companies) should also benefit from sustained insurance coverage of routine patient care costs. The wording of the legislation should be careful not to shift costs that are rightfully borne by the trial sponsor to others. Having said this, it would be useful to allow for well controlled and supervised studies on drugs used off label in so-called orphan diseases.

Medicare, due to an executive order by President Clinton, offers carefully crafted language to create broad coverage of routine patient care costs for clinical trial patients. The Patient Protection and Affordable Care Act passed by Congress requires coverage of routine patient care costs but only in trials for cancer or other life-threatening diseases. Sadly, the definition of life-threatening in this act is extraordinarily limited and would not include coverage in clinical trials for diseases such as lupus, multiple sclerosis, epilepsy, or any of the devastating chronic illnesses. Although it is possible that Congress will revisit this issue in its current session, I believe the best option now is state action.

¹Goldman et. al, *Incremental Treatment Costs in National Cancer Institute-Sponsored Clinical Trials*, 289 J. OF THE AM. MED. ASSOC. 22, 2970-77 (June 11, 2003). Note that the date used in this study was compiled before Medicare began paying routine patient care costs in clinical trials.

Sustained coverage is sensible, just, and would create good public policy. It is important that patient protection remain the top priority in Connecticut in what could be an increased number of trials. It is important that all the citizens of Connecticut have access to clinical trials relevant to their disease, that they not be denied access because of the fear that their insurance coverage will be abrogated.

Let me reiterate that patients at risk for loss of coverage of standard medical costs in clinical trials will decline participation. This results in a great sense of frustration and injustice. We should not continue to impose this grave injustice on our friends and neighbors in Connecticut.

Thank you for this opportunity to express my views as a citizen of Connecticut. I have spent my career working with patients with illnesses that would benefit from the advances from clinical trials. I urge you to pass legislation that will encourage clinical trials in all types of illnesses by assuring responsible insurance coverage of standard medical costs.

John Booss, MD
Bethany, CT
27 January 2011



CONNECTICUT BUSINESS & INDUSTRY ASSOCIATION

TESTIMONY
BEFORE THE
INSURANCE AND REAL ESTATE COMMITTEE
LEGISLATIVE OFFICE BUILDING
FEBRUARY 3, 2011

My name is Eric George and I am Associate Counsel for the Connecticut Business & Industry Association (CBIA). CBIA represents approximately 10,000 businesses throughout Connecticut and the vast majority of these are small companies employing less than 50 people.

While the federal government has passed health care reform, more needs to be done to lower costs. More needs to be done to improve the health of our citizens. Employers find health care costs rising faster than other input costs. Some providers are unable to generate sufficient patient revenue to cover costs. Some patients cannot get timely access to optimal care. And too many individuals remain without health insurance, engage in unhealthy behaviors and live in unhealthy environments.

For the business community, the issues of health care quality, cost and access are critical. After numerous years of double-digit and near-double-digit increases, health insurance has quickly become a product that many people and companies find they can no longer afford. In addition, the cost of health care directly affects businesses' ability to create new jobs.

Therefore, CBIA asks this committee to reject **SB 21, AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS**. The business community and other stakeholders are calling for significant reforms to Connecticut's costly and inefficient health care system. As you consider the various proposals to reform the state's health care system, CBIA asks you to refrain from making the already high cost of health care even more unaffordable for the state's companies and residents.

Every health benefit mandate, while providing a benefit to the individuals who utilize those services, increases health insurance premiums for all state-regulated group and individual policies. In fact, the Council for Affordable Health Insurance (CAHI) has reported that health benefit mandates increase health insurance premiums between less than 20% to more than 50%. According to

CAHI, Connecticut's mandates increase group and individual health insurance premiums by as much as 65%.

Connecticut's employers are already struggling to afford health insurance for their employees. The hardest hit among these companies are small employers whose revenues and operating budgets make affording employee health insurance extremely difficult. However, when the legislature adopts new health insurance mandates, it makes affording health insurance particularly difficult for these small employers. This is because state mandated benefits only impact plans that are subject to state regulation. If a company has the financial ability to self-insure, then that company's health plan is governed solely by federal law, including the Employee Retirement Income Security Act (ERISA), and does not have to comply with state health benefit mandates. Companies that are able to self-insure (and therefore not subject to Connecticut's health insurance mandates) are typically larger companies that can afford taking on such risk. Smaller companies usually cannot and are forced to be fully insured and subject to state regulation.

So, Connecticut's health insurance mandates impact smaller employers in the state to a greater degree than larger employers. When the legislature either creates a new mandate or expands an existing mandate, it is making health insurance less affordable for those small companies that can least afford to shoulder these cost increases.

CBIA asks this committee to reject all new or expanded mandate proposals and to enact a moratorium on health insurance mandates. It is crucial that as the state moves forward toward major health care reform, that the General Assembly refrain from taking any actions that would increase the cost of already skyrocketing health insurance premiums.

Again, please reject **SB 21** thank you for the opportunity to offer CBIA's comments on this legislation. I look forward to working with you on this and other issues related to the reforming Connecticut's health care system.



Quality is Our Bottom Line

**Insurance Committee Public Hearing
Thursday, February 3, 2011**

**Connecticut Association of Health Plans
Testimony in opposition to**

SB 21 AAC Health Insurance Coverage for Routine Patient Care Costs for Clinical Trial Patients

The Connecticut Association of Health Plans is very proud of the work we've done previously with the American Cancer Society and leading Connecticut oncologists to cooperatively develop a model on coverage for the routine costs of cancer clinical trials. That bill took 12 months to craft, for a single area of care where all parties agreed that coverage for routine care expenses was the right thing to do, and that patient safety and sound medical research protocols were paramount to providing meaningful health benefits for members' health care dollars. The most encouraging thing about the process surrounding the cancer clinical trials bill was that there was no argument about the fundamental principle of the bill: patient safety and sound medical research protocols.

The present bill seeks to expand coverage for research trials to the arena of "disabling, progressive or life threatening" illnesses. This is a challenging area to define. Thousands of clinical trials exist on almost any medical illness ranging from near sightedness to cholesterol management. (ClinicalTrials.gov) The issue of whether a condition is "disabling, progressive or life threatening" would be difficult or impossible to determine. Any disease an individual has could meet this definition. "Life threatening" could mean that an individual's cholesterol level might some day lead to a heart attack. Clinical trial coverage could very well be opened up to every medical condition. Trying to determine which trials meet a given set of criteria for a given patient for an infinite number of diseases would be an impossible medical task.

To demonstrate the complexity of this issue, please note that this bill deviates from the cancer clinical trials law in that it limits cancer trials for the prevention of cancer to Phase III trials approved by one of the listed expert entities that are conducted at multiple institutions – but there is no such limit for trials for prevention of any other illness. We question why other diseases would have preventive trials covered when cancer would not. This would mean that for all conditions other than cancer, insurers would have to cover even Phase I and Phase II trials for prevention, even though Phase I trials study the safety of an intervention (i.e., to determine whether it is lethal), and Phase II trials which are not yet proven therapies. This would be enormously costly.

p 16

Ln 4

Susan H.

Productive clinical research on disease treatment is a laudable goal for society to support, but the question of how to pay for it is much more difficult. We need to ask what the responsibility of insurers should be for subsidizing medical research? Many of the thousands of trials conducted by NIH and other bodies are well-researched; however, many others are neither well-established nor subjected to rigorous scientific protocols. Forcing insurers to cover expenses for the latter would clearly be a mistake, but even requiring coverage for the former begs the question: "Why is health insurance paying for research?" Privately purchased health insurance is paid for by employers, employees and individuals who are having a hard time shouldering the cost of their coverage in an environment where premium increases are escalating. Adding to this financial burden the cost of care for a broad range of unproven treatments would add to the health care affordability crisis, pricing health insurance out of reach for more people. Cost is always a difficult issue, and it's an unfortunate thing, but a policy that covered everything imaginable would only be affordable to a very few. We believe that private employers, employees and individuals should not be required to fund medical research with their premium dollars.

On additional matter to consider with respect to this proposal is the cost it imposes in the context of the Patient Protection and Affordable Care Act of 2010 (PPACA). PPACA covers only trials for cancer and other life-threatening diseases. To be eligible, trials must be funded or approved by NIH, CDC, AHCRO, CMS, DOD/VA cooperative group, or an NIH-qualified research entity - or it can be a drug trial being reviewed by the FDA or that is exempt from such FDA review. Additional conditions require that any study be subject to certain peer-review systems and assure an unbiased review of the highest scientific standards. Any clinical trial coverage in excess of these standards will be ineligible for federal subsidy and therefore any additional costs will be borne by Connecticut taxpayers alone.

We respectfully request that you oppose SB 21. Thank you for your consideration.

Dina Berlyn
30 Morris Street
Hamden, CT 06517 (203) 776-3869

PLS
Ln 18

January 27, 2011

Good morning, Sen. Crisco, Rep. Megna and members of the Insurance and Real Estate Committee. My name is Dina Berlyn. Some of you might recognize me at the LOB as State Senate Majority Leader Martin Looney's Counsel and Executive Aide, which I am, but I am not here in that role. I am a patient with multiple sclerosis. I am here to testify on two healthcare policy issues of deep personal interest to me: coverage of routine patient care costs in clinical trials and the burden of proof in appeals from benefit denials. Both S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS and S.B. No. 18 AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS would make our healthcare coverage more rational and compassionate for patients.

I have researched, written, and been published on coverage of routine patient care in clinical trials, and I want to share with you my discoveries about this matter -- particularly the irrational nature of the for-cancer-only provision in our statutes.

In 2001, the Connecticut General Assembly passed PA 01-171 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR CANCER CLINICAL TRIALS, HEARING AIDS FOR CHILDREN AGE TWELVE AND YOUNGER, PAP SMEAR TESTS, COLORECTAL CANCER SCREENING AND MAMMOGRAMS, PSYCHOTROPIC DRUG AVAILABILITY AND MEDICAID COVERAGE FOR

MAMMOGRAMS¹. The bill started with a more conventional title: AN ACT CONCERNING HEALTH INSURANCE COVERAGE DURING CLINICAL TRIALS. This legislation had laudable goals – to require insurers to sustain their responsibility to patients who participate in clinical trials by covering standard of care treatment for clinical trial patients. Unfortunately, this bill in its final form required coverage for cancer clinical trials only. Many insurers already covered these expenses for cancer due to the high visibility and influence of cancer care and the use of NIH cooperative groups. While this coverage would be good policy for all clinical trials, it is crucial in clinical trials for rare diseases because if insurers deny coverage for these costs in that setting, no sponsor will undertake the research. Note that there is evidence that routine patient care costs for clinical trial patients are essentially the same as routine patient care costs for patients in standard treatment². In fact it is my belief that for many patients with diseases such as multiple sclerosis that have high standard treatment costs, the routine patient cost of clinical trial patients would likely be lower. In MS, for example, the cost of the approved drugs is quite high -- I take Tysabri now but have taken Betaseron in the past. Both drugs cost my insurer over \$3000 per month. Were I in a clinical trial, the trial sponsor would cover the cost of the investigational drug and I would cease taking the approved therapy. It is unlikely that my routine patient care costs would increase by \$3000 per month.

The denial by insurers of routine care costs that they would be obligated to pay absent a clinical trial by claiming that the costs are ancillary to the trial can be devastating

¹ In 2007 PA 07-67 made some changes regarding required coverage for out of network costs in cancer clinical trials

² Bennet et al., *Evaluating the Financial Impact of Clinical Trials in Oncology: Results from a Pilot Study From the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project*, 18 J. OF CLINICAL ONCOLOGY 15, 2805-10 (2000)

³ *Id.*

⁴ Bruce H. Firemen, et al., *Cost of Care for Patients in Cancer Clinical Trials*, 92 J. THE NAT'L CANCER INST. 7, (2000).

to medical progress. President Clinton changed Medicare Policy so that Medicare covers routine care costs for clinical trials. In the Affordable Care Act Congress requires coverage of routine patient care costs *but* only in trials for cancer or other life-threatening diseases. The definition for 'life-threatening' is extraordinarily narrow and thus will not include the majority of chronic and disabling diseases. I do hope that Congress will act to make the language in the Affordable Care Act consistent the rational and enlightened policy developed by the Centers for Medicare & Medicaid Services. However, since the prospects for Congressional action are unclear, Connecticut should pass this legislation. I strongly urge you to require that insurers sustain their responsibility to patients who enter clinical trials.

In addition, I applaud the inclusion of section 15 which would expand the off-label use of drugs beyond the use of such drugs for cancer. There are many drugs which, although they have been shown to be effective for diseases other than the one for which they were originally approved to treat, are technically not approved for these other diseases. This is the situation I encountered that led to my experience with the system for appeal of a healthcare denial. Doctors, not insurers should engage in the practice of medicine.

Most unfortunately, I have experienced first hand the appeals process for healthcare coverage denials. This experience is why I believe that S.B. No. 18, AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS, is needed. At the beginning of the process in my case it was unclear that the denial was

S - 623

**CONNECTICUT
GENERAL ASSEMBLY
SENATE**

**PROCEEDINGS
2011**

**VOL. 54
PART 12
3674 - 4044**

mhr/gbr
SENATE

190
May 31, 2011

All right. Have all members voted? Have all members voted? The machine will be closed; all right?

And the Clerk will call us the tally.

THE CLERK:

Motion is on passage of Senate Bill 921, as amended by Senate Amendment Schedule "A."

Total number voting	36
Those voting Yea	23
Those voting Nay	13
Those absent and not voting	0

THE CHAIR:

The bill has passed.

Mr. Clerk.

THE CLERK:

Calendar page 27, Calendar Number 45, File Number 15 and 801, substitute for Senate Bill 21, AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL PATIENTS; Favorable Report on the Committee on Insurance, and Appropriations.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Thank you, Madam President.

S - 624

**CONNECTICUT
GENERAL ASSEMBLY
SENATE**

**PROCEEDINGS
2011**

**VOL. 54
PART 13
4045 - 4358**

mhr/gbr
SENATE

191
May 31, 2011

I move for acceptance of the Joint Committee's
Favorable Report and passage of the bill.

THE CHAIR:

The motion is on adoption.

Will you remark further, sir?

SENATOR CRISCO:

Yes, Madam President.

Madam President, the Clerk has an amendment, LCO
6727. I ask that it be called.

THE CHAIR:

Mr. Clerk.

THE CLERK:

LCO 6727 should be designated Senate Amendment
Schedule "A." It is offered by Senator Crisco of the
17th District, et al.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Thank you, Madam President.

Madam President, I move its adoption and I'll be
given permission to summarize.

THE CHAIR:

The question is on adoption.

mhr/gbr
SENATE

192
May 31, 2011

Will you remark, sir?

SENATOR CRISCO:

Thank you, Madam President.

Madam President, LCO 6727 replaces the disease-specific language from the Appropriations Committee language and replaces it with cancer, life-threatening and disabling chronic disease.

THE CHAIR:

Senator, will you remark further? Will you remark further?

Senator Kelly.

SENATOR KELLY:

Thank you, Madam President.

Through you to Senator Crisco, with --

THE CHAIR:

Please proceed --

SENATOR KELLY:

-- regard --

THE CHAIR:

-- sir.

SENATOR CRISCO:

With regards to the -- the amendment, is this going to -- right now when the bill left the Insurance Committee and went to Appropriations, they identified

mhr/gbr
SENATE

193
May 31, 2011

six conditions that the bill would cover. Is this going to remove those six and go back to the original definition of a disabling, progressive, or life-threatening -- threatening conditions? Through you --

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you to the Senator, yes.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Thank you.

So is disabling, progressive, or life-threatening defined specifically in the amendment, through you?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, no, but if one was referred to a federal bill, which defines -- life-threatening condition means any disease or condition for which the likelihood of death is probable unless the course of the disease or condition is interrupted.

THE CHAIR:

mhr/gbr
SENATE

194
May 31, 2011

Senator Kelly.

SENATOR KELLY:

What about disabling and/or progressive? Through you, Madam President.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you. Madam President, through you, this is just disable or chronic condition.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Okay. Would diabetes be a chronic condition?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

I -- I -- Madam President, through you to the good Senator, not having an M.D., I -- I would say -- no, I -- I can't answer that one.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

mhr/gbr
SENATE

195
May 31, 2011

Would dementia or Alzheimer's be a disabling condition?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you to the good Senator, you know, it -- it all depends upon the stage of disease; you mentioned two. Diabetes, I know my father had seven amputations from diabetes before he passed away. And, you know, regards to Alzheimer's and dementia, again, it depends upon the stage. So one could interpret that as disabling.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Would -- would a condition like glaucoma fit within the definition? Through you, Madam President.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through my very limited medical knowledge, no.

THE CHAIR:

mhr/gbr
SENATE

196
May 31, 2011

Senator Kelly.

SENATOR KELLY:

Now, I know if we were to have -- and -- and the American Cancer Society testified at committee that when you deal with issues such as cancer, there's already protocols in place that are necessary to fulfill before we would get to clinical trials. My concern is that when we open this up to conditions beyond conditions such as cancer, that do not have those clinical trials, that we're starting to get on a slippery slope as to where do we define what is going to be covered and what is not.

If we have a situation such as that, you know, for instance dementia, glaucoma, and diabetes, what -- what protocols are we going to follow and how are we going to know whether or not it's -- it's something that's going to be covered? Through you, Madam President.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you, if the good Senator will allow me some leeway, I think it's important to mention the origin of this legislation. It, you know,

it started several years ago when, before the Insurance Committee, a young man named Matt, who spent all of sixth grade in Boston trying to find a cure for his cancer. What happened was that the insurance company did not provide for coverage out of network, so that gave us the impetus to adopt the original legislation in regards to clinical trials and then in regards to the specific diseases that we added.

We find that in today's world, that diseases are -- are extremely, you know, certain diseases are extremely life-threatening, and disable. And clinical trials have certain requirements in regards to be classified as a clinical trial. And we are hoping that this legislation, this amendment will, you know, will meet certain criteria as defined in -- in our -- in our -- in Senate Bill 21. It is defined in Senate Bill 21.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Thank you, Madam President.

Well, as defined, it talks about disabling, progressive or life-threatening medical conditions in human beings. Now the bill coming out of -- I believe

it was Appropriations -- limited that to cancer, MS, Parkinson's, Lou Gehrig's disease, AIDS, and muscular dystrophy, which I believe would all have those protocols that the American Cancer Society spoke about at -- at the public hearing and before the Insurance Committee.

But what my concern is here, as was with the bill in Insurance, is that when we just talk about disabling, progressive, or life-threatening conditions and we don't define them as those six conditions, that we now get on the slippery slope of do we cover cholesterol. You know, in and of itself, it doesn't seem that bad; it seems pretty innocuous. Both we all know that increased levels of cholesterol can lead to coronary problems, heart disease, and death.

Now, I don't believe there's -- there's a protocol in place, like those that are in place with cancer, for cholesterol. So my question is: How does this address those situations, and how are we going to define what is included in this bill and what's not included in this bill? Through you, Madam President.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, I believe in -- in the main bill there are certain protocols that are established and clinical trials are established. And it, again, depends upon the stage of the disease. Like if we do not, you know, adopt this amendment, then we leave many, many individuals without any hope of a clinical trial.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Well, I understand we could leave many people without clinical trial. And I think the bill that came out of Appropriations limiting it to the six was a good bill in doing that, but I think when we draft legislation that goes beyond that and to those conditions that are not well defined in the bill, then we run the risk of -- of including people in and conditions in that may or may not have been contemplated by those looking at was bill today. I think when we look at legislation like this, we should look at -- at drafting legislation that is narrowly tailored to -- to accomplish what we want it to accomplish.

mhr/gbr
SENATE

200
May 31, 2011

Through you, Madam President, to Senator Crisco, in your -- where in the proposed bill does it give us the protocols for conditions such as cholesterol?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you to the Senator, it does not specify the specific disease, but there are protocols that are established for an approved clinical trial.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Okay, Madam President. Could -- could we find in -- in the proposed legislation where that would be?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, we just would appreciate a few minutes.

THE CHAIR:

Well, the Senate will stand at ease, sir.

(Chamber at ease.)

mhr/gbr
SENATE

201
May 31, 2011

SENATOR CRISCO:

Madam President, thank you for the courtesy.

THE CHAIR:

The Senate will come back to order.

SENATOR CRISCO:

It's through you to Senator Kelly. If he will look at File 801, in the lines 26 to 38, I believe he will find his answer.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Through you, Madam President, to Senator Crisco, will this be applicable to the state employee health plan?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

I believe so. Through you, Mr. -- Ms. -- Madam President, to the Senator, I believe so.

THE CHAIR:

Senator Kelly.

SENATOR KELLY:

Okay. Thank you, very much, Madam President.

mhr/gbr
SENATE

202
May 31, 2011

I have no further questions at this time.

THE CHAIR:

Thank you.

Will you remark further?

Senator Looney.

SENATOR LOONEY:

Thank you. Thank you, Madam President.

Madam President, speaking in support of the amendment, I wanted to thank Senator Crisco for bringing forward this -- this bill and the amendment.

One of the -- the key issues in the -- the amendment, Madam President, that changes from the -- the file that was considered in the Appropriations Committee, the issue of -- of cancer, life-threatening, and disabling, chronic disease. One of the fundamental problems about enumerating particular diseases is the fact that -- that currently we -- there are a number of -- of advanced drugs that may be in clinical trials that may actually be simultaneously tested for more than one disease, at the same time. And we could possibly run into the problem of having someone who was tested for -- for one disease.

So, for instance, there is currently one of the biologic drugs, Tysabri is now approved for both

multiple sclerosis and Crohn's disease, so that if there were simultaneous trials going on, potentially you would have coverage for MS, but a Crohn's patient would not have coverage, and in the same clinical trial. And that is the problem with -- with narrowing exclusively to disease-specific conditions. And that's what the -- the amendment seeks to -- seeks to address.

In terms of -- of defining what is likely to be covered or not, obviously looking at a -- by analogy, the federal definition of "life-threatening condition," is any disease or condition for which the likelihood of death is probable unless the course of the disease or condition is interrupted. So a disabling, chronic condition, which would be provided for in the amendment -- or disease -- would be a disease or condition likely -- likely to cause disability unless the condition or condition would be interrupted by -- by treatment. So we're talking about -- clearly the issue is that it is a -- a disease that is serious enough to cause, to likely cause disability, should its course not be interrupted by treatment.

And the -- and the -- the reason for the amendment, Madam President, is to provide flexibility, because of the situations I cited. Often clinical trials may be going on with the same drug for different diseases at the same time, and you would have a completely untenable situation if one were covered and another were not in the very same trial at the same time.

Thank you, Madam President.

THE CHAIR:

Will you remark further?

Senator Crisco.

SENATOR CRISCO:

Madam President, I'm not sure. I -- I would like to request a roll call vote.

THE CHAIR:

A roll call vote will be ordered, sir.

Will you remark further? Will you remark further?

Senator Witkos.

SENATOR WITKOS:

Thank you.

I didn't -- I apologize if by Senator Looney speaking was signaling the end of the debate.

mhr/gbr
SENATE

205
May 31, 2011

Just a question, if I --
to, if I may, to Senator Crisco.

THE CHAIR:

Please proceed, sir.

SENATOR WITKOS:

Thank you.

Through you, Madam President, a few years ago I served on the Insurance Committee with you, Senator. We did pass, I know out of that committee, the first step of the clinical trials when we heard that somebody had to travel out of state, and I guess it was out of the service area, too, to receive the medically necessary treatments to -- in order to survive. And through you, Madam President, do you know if that legislation became law? I -- sometimes you lose track of them, in between the two Chambers; I'm not sure if -- if that passed or not. And you had referenced, I think, that earlier in the debate.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you to the Senator, yes. That was the Matt legislation; that did become law.

THE CHAIR:

mhr/gbr
SENATE

206
May 31, 2011

Senator Witkos.

SENATOR WITKOS:

Thank you, Madam President.

And through my understanding of what the amendment that's here before us, part of the impact is -- and I, you know, that we have to -- it's to an exchange program. We had that debate on an earlier bill. If we don't have an exchange program in the state, then we must adopt the federal exchange program. And we don't know what those benefits are going to be required as of now in the federal benefit, but we are determining what our state benefits are.

And we heard that there was a reimbursement from the federal government for a certain percentage of the benefits that are identified in their exchange program, but if the State of Connecticut exceeds those benefits that are in the federal program, we, as the State of Connecticut, are responsible for paying those increases in our own exchange program. Is that correct, through you, Madam President?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

mhr/gbr
SENATE

207
May 31, 2011

Madam President, through you to the Senator, if I heard him correctly, I say yes.

THE CHAIR:

Senator Witkos.

SENATOR WITKOS:

Thank you, Madam President.

And if you are self-insured, as the State currently is, we are not required as a self-insured to adopt all of the mandates that -- health insurance mandates, yet we routinely do, as a matter of course of business.

So through you, Madam President, if this amendment is adopted, are we mandated by law to adopt this benefit or is it a decision made by those in the insurance plan or those that administer the self-insured plan of the -- for the State of Connecticut to adopt it? Is it required by law, yes or no? Through you, Madam President.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Madam President, through you to the good Senator, if he's referring to state law, of course it is.

But as I stated earlier in our deliberations, we will not know for another two years what the federal lists will include. They may be 40 percent of our preventions; they may be 50; they may be a hundred percent; we just don't know.

We have time to review those recommendations from the federal government and decide as a body whether we should retain what we have on our books, get rid of them all, or get rid of some of them. So we do have a period to evaluate that, and it's something that this body will -- will have to do, one way or the other.

THE CHAIR:

Senator Witkos.

SENATOR WITKOS:

Thank you, Madam President.

I wasn't clear on my question, then. Under our current practice, since the State of Connecticut is self-insured, we follow the ERISA regulations and we are not bound by any mandates placed on insurance policies by this Legislative body. Is that correct, through you, Madam President?

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

mhr/gbr
SENATE

209
May 31, 2011

Madam President, no, we are not required under ERISA law, if that's the question that the Senator was asking.

THE CHAIR:

Senator Witkos.

SENATOR WITKOS:

Thank you, Madam President.

And, you know, when we never -- whenever we talk about -- and I found this as I go out in the district -- the folks that are advocating for enhancements of insurance coverage, they believe that, oh, great, the Connecticut General Assembly; we passed this mandated insurance coverage. But yet they may be part of a group that is not covered under that mandate, because if you're self-insured, you follow under a different set of rules, where you don't have to provide that coverage, as many municipalities fall under. And we, as the State of Connecticut, have now moved to a self-insured plan. So we also are not required to provide the mandated benefits that this body passes.

However, I am to understand that we routinely adopt those mandates, since we're making them, but we're not required to do that. So we're setting ourselves up for two, separate playing fields, those

mhr/gbr
SENATE

210
May 31, 2011

towns that are privately insured, they pay an insurance company to run their claims and to -- to do all the administrative costs. They are required, if we pass this, to provide those benefits. And there is a cost factor, and those costs will go up because this is an additional benefit that we're requiring. Yet we, in the General Assembly, are not mandating this upon ourselves. We generally accept it and we provide that benefit, but we don't mandate that because we're exempt under our statute, as is most self-insured plans or large-group plans. The larger the company, the better benefit it is to you to self-insure your plan, so you're not required to do that.

And when I thought about the cost of a life-ending disease that people have reached out and are -- are at their last hope of being able to extend their livelihood, why shouldn't we -- or mandate that the insurance companies pay to do anything that they -- they can, just to prolong their life on this planet? Because we're certainly paying for that.

But then I read in the fiscal note that it's not the insurance company that pays, it's the State of Connecticut that pays. It doesn't say the insurance company. So folks that are saying, oh, those

mhr/gbr
SENATE

211
May 31, 2011

insurance companies, you know, they're paying their executives a million dollars, they're paying -- they -- record profits of billions of dollars, they're the ones that aren't paying for this, it's the State of Connecticut is going to be paying for the mandate, and the out -- it's listed in the out years, under the -- in the fiscal note.

So I have some reservations of -- with that, especially if the benefits aren't defined by the federal government of what we're going to have to cover. We are not in the economy right now to be making these judgment calls or guesses to see if this is the direction that we want to go in, and especially we don't know the cost of what we're going and what we're going to be required to cover.

So I would urge the Chamber to bring this back next year or the year after, when the federal government says to us, You must cover these benefits, so we know a hard-cost figure that the State of Connecticut is going to be responsible for paying for. Otherwise, open your pocketbooks and pay up, because there's no raw or rough data to determine the costs.

So, reluctantly, Madam President, I will be voting against the bill because there's -- there's too

mhr/gbr
SENATE

212
May 31, 2011

many unknowns for me to make an educated decision on the bill.

Thank you, very much.

THE CHAIR:

Thank you.

Will you remark further? Will you remark further?

If not, Mr. Clerk, will you call for a roll call vote, and I will open the machines.

THE CLERK:

Immediate roll call has been ordered in the Senate. Will all Senators please return to the Chamber. An immediate roll call has been ordered in the Senate. Will all Senators please return to the Chamber.

THE CHAIR:

Have all members voted? All members have voted? The machine will be locked.

Mr. Clerk, will you call the tally.

THE CLERK:

Motion is on adoption of Senate Amendment Schedule "A," LCO 6727.

Total number voting 36

Those voting Yea 22

mhr/gbr
SENATE

213
May 31, 2011

Those voting Nay	14
Those absent and not voting	0

THE CHAIR:

The amendment has been adopted.

Will you remark further? Will you remark further?

Senator Fasano.

SENATOR FASANO:

Thank you, Madam President.

Madam President, I voted against the amendment because of the issue of chronic pain. I felt that was very broad in its nature, and therefore it did not have a bound for which could limit the prospects of this bill.

But now that the amendment is the bill, I just want to share with the Circle. About a year ago, my father had a heart problem and a clinical study was being done at Columbia Presbyterian. And absent this surgery, exactly a year ago, he would have died because his heart would have failed.

Because he was 82, they wanted to increase the number of people surveyed for this clinical study; they accepted him, and he had the operation which is a very evasive operation, going through a vein, coming

mhr/gbr
SENATE

214
May 31, 2011

up, going in through the heart and repairing a valve. He would not have survived open-heart surgery, and he would have died absent the surgery.

Well, his heart is very strong, extraordinarily so. Unfortunately, the program is no longer funded through the federal government, but we go down -- I think he was asked to testify in Washington twice on this procedure, because of what it did to save a life.

So when you look at that issue, you tend to think he could have gone to the hospital, which he did on a number of occasions, for heart failure, for shortness of breath, and each time he went in, they would take the fluid out, send him home, and two or three weeks later he'd be back, take the fluid out, send him home. Now with this, he hasn't been back for the heart at all. That's a savings. It's a savings is what it is.

And we talked a couple days ago about Margaret Oblito, who passed. She was given the ability to look at cancer-related treatments which were making their way through various systems. Unfortunately, based upon time and her heart, she did not -- she could not fall into that category. But the issue is there is other treatment.

mhr/gbr
SENATE

215
May 31, 2011

It makes no sense. If someone has got cancer, it makes no sense. And the chemotherapy, which is an expensive and an ordeal nobody wants to go through and keep doing it, and you know it's not going to help. And you're spending all that money just because you have to -- his insurance company -- when there could be another way of achieving the end. It worked in my father's case; it can work in other cases.

And therefore, although I am concerned about the chronic part of the bill because I think it is too broad, and it's going to lead to a lot of issues -- and perhaps we have to revisit that -- I think the intentions for what the bill has put forward is something I can support.

Thank you, Madam President.

THE CHAIR:

Thank you, Senator.

Will you remark further?

Senator Looney.

SENATOR LOONEY:

Thank you. Thank you, Madam President.

Speaking in support of the bill, I again wanted to commend Senator Crisco and the Insurance Committee for bringing this forward. The key here, Madam

President, as Senator Fasano very, very aptly has said, is that the issue here is trying to find ways to find improved treatments for -- for life-threatening and serious diseases, often leading to disability.

And we have history. Ten years ago, the General Assembly passed Public Act 01171 that required insurers to sustain their responsibility to patients who participate in clinical trials for -- for cancer only. And ever since then, it has become increasingly clear that -- that the -- that more clinical trials for other diseases need to have this kind of protection and coverage, because it's important to keep in mind that the courageous patients who were willing to take a risk by participating in a clinical trial is the way in which medical science is advanced.

And these patients enter the trial with no -- no expectation that the new treatment will necessarily cure their disease or enhance their own particular circumstances, because most of the time the clinical trials are -- are double-blind and -- and placebo-controlled, so the patients often don't even know if they are the ones actually receiving the experimental drug or placebo until the results of the study are known. But they are taking a leap of faith,

mhr/gbr
SENATE

217
May 31, 2011

knowing that it may not benefit them but it may benefit someone in a situation similar to theirs.

So in a profound sense, these are -- are really heroic people, and they're taking a risk to help others who share their own particular condition. And -- and it really is -- is sort of untenable that in many cases they might wind up being billed for procedures that their insurers would actually cover if they were not in a clinical trial. And that's the -- the kind of incongruous reality that -- that they face.

And -- and what the -- the bill provides is that the insurance coverage would cover the standard care of treatment for patients who are enrolled in clinical trials, as they would for patients who are not enrolled in clinical trials. And it just means that -- and the routine patient care is care that would otherwise be covered if the services were not rendered pursuant to a clinical trial. So it just makes -- makes fundamental sense to -- to deal with this so that -- so that we don't have the -- the untenable situation of people actually, in effect, being punished financially for their courage in participating in the clinical trials.

mhr/gbr
SENATE

218
May 31, 2011

So I urge passage of the bill as amended, Madam President.

Thank you.

THE CHAIR:

Thank you, Senator Looney.

Will you remark?

Senator McKinney.

SENATOR MCKINNEY:

Thank you, Madam President.

If I could -- or earlier I heard Senator Kelly ask Senator Crisco a question about what -- what the confines, what the definition of chronic disease was. And I -- I -- I think Senator Crisco's answer was that he did -- was not aware. If I could, through you -- I know Senator Looney's name is on the amendment -- ask if the Majority Leader has the answer.

The reason -- and I'll tell you the reason why I ask the question. Several years ago, I put in a very similar bill, not -- not expanded to chronic diseases but limited to cancer, for some of the same reasons that Senator Fasano said. It became clear to me that insurance companies would pay for treatment for people who were sick with cancer, even when the person's doctor knew the probability of success of that

mhr/gbr
SENATE

219
May 31, 2011

treatment was either limited or of no success. So they'd be willing to pay money to give this standard of care that the doctor said it's not going to work, but they wouldn't pay for something that the doctor said I know that's not going to work; I don't know if this will, but it's your only hope. It makes no sense. If they're going to pay for something, pay for what the doctor thinks might work.

The fear, I think some of us have on this side is the -- is the extraordinary breadth of a term "chronic disease," and what does that mean. I mean could -- could it mean something like chronic back pain or, you know, I mean to -- to have it amended before us, which strikes specific diseases, whether it's AIDS or cancer or et cetera, and to put in generic language, and to have Senators, I think in good faith, ask what does this mean and be told I don't know, is frustrating.

So I'm just curious if -- I support this. I support the intent of this. This is a good direction, but it's frustrating to have Senators ask a question and have the person offering the amendment not know the answer.

So I'm just wondering if Senator Looney could give us a better definition of what chronic diseases

mhr/gbr
SENATE

220
May 31, 2011

are and what the limits of this additional coverage would be, through you, Madam President.

THE CHAIR:

Senator Looney, will you accept that?

SENATOR LOONEY:

Thank you, Madam President.

Yes, and I thank Senator McKinney for the -- for the question.

And in researching this, we looked at some of the -- some of the federal language, and I think that it might be -- be helpful by analogy because the -- the language of the amendment relates to -- to not just any chronic disease but disabling chronic disease. And that is, I think, a significant, limiting factor that will limit it to -- to more serious conditions so that -- I said earlier in -- in the federal definition, the definition of life-threatening is a disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. So I would say that arguing by analogy, a disabling, chronic condition would be a disease or condition likely to cause disability unless the disease or condition is interrupted by effective treatment, so that it would be -- would be a disease

mhr/gbr
SENATE

221
May 31, 2011

tending toward the causing of disability rather than just any chronic disease that might not serious impair someone's enjoyment of life or -- or full use of -- of his or her health and -- and faculties.

So I think that that disabling, the language of limiting it to disabling conditions, disabling, chronic conditions, as opposed to any chronic conditions is a -- a significant, limiting factor.

And I certainly appreciate Senator McKinney's concern about necessarily expanding too wide the universe, but I think it is worth pointing out that -- that Medicare, in effect, does cover clinical trials without that limiting factor, that the Medicare coverage is not limited by disease at all and has much more -- more comprehensive language than -- than what we're attempting in this bill.

Thank you, Madam President.

THE CHAIR:

Senator McKinney.

SENATOR MCKINNEY:

Thank you.

And -- and hence my concerns, since Medicare and Medicaid are due to go broke in 2024. But -- and I

mhr/gbr
SENATE

222
May 31, 2011

don't mean to make light of that. It's a serious issue that our country needs to deal with.

So through you, Madam President, is -- is -- disability, then, is if someone were to -- were to go to a doctor and be deemed disabled. So it would have to be a disease that -- that would lead to or could lead to a disability, not that it has to in that individual person's case, but a disease that leads to a disability.

So, for example, diabetes, I believe Type I diabetes is or -- or maybe Type II -- is one of the leading causes of blindness in men. That's a disability. Through you, is that the type of thing we're talking about, Madam President?

THE CHAIR:

Senator Looney.

SENATOR LOONEY:

Yes. Through you, Madam President, that, I believe, is exactly the kind of thing, a disease that is serious enough that without effective treatment it is likely to be not just chronic but disabling.

THE CHAIR:

Senator McKinney.

SENATOR MCKINNEY:

Thank you.

And -- and my last question is since we're -- since we are self-insured, and I'm going to assume -- and I know Senator Witkos asked these questions, but I'm -- we -- we have, as a state, since self -- becoming self-insured, adopted the policy of assuming all mandates. So are -- are we, as the state, the one who is -- or is it the third-party administrator who would -- administrator of our plans who would determine whether or not something is eligible for a critical -- clinical trial? Through you, Madam President.

THE CHAIR:

Who was answering that? I guess you're delegated, Senator Looney.

SENATOR LOONEY:

Madam President, I would -- I would yield to the -- to the Chairman of the Insurance Committee, if he has a -- a more specific response.

I -- I would think that -- that perhaps unless there were a particular additional specificity provided in statute, it would probably be in the hands of the -- the plan administrator, in the absence of that.

mhr/gbr
SENATE

224
May 31, 2011

SENATOR CRISCO:

Thank you.

Thank you, Senator Looney for your answers.

THE CHAIR:

Will you remark further? Will you remark further?

If not, the -- Mr. Clerk, will you call for a roll call vote, and the machine will be open.

THE CLERK:

Immediate roll call has been ordered in the Senate. Will all Senates please return to the Chamber. Immediate roll call has been ordered in the Senate. Will all Senators please return to the Chamber.

THE CHAIR:

All members voted? Senator Kelly? All members -- Senator Duff.

If all members have voted, all members have voted, the machine will be locked.

And, Mr. Clerk, will you call the tally, please.

THE CLERK:

Motion is on passage of Senate Bill 21, as amended by Senate Amendment Schedule "A."

Total number voting 35

mhr/gbr
SENATE

225
May 31, 2011

Those voting Yea	32
Those voting Nay	3
Those absent and not voting	1

THE CHAIR:

And the bill has passed.

Mr. Clerk.

THE CLERK:

Calendar page 28, Calendar Number 57, File Number 42, Senate Bill 312, AN ACT ELIMINATING THE AGE CAP FOR HEALTH INSURANCE COVERAGE FOR SPECIALIZED FORMULA; Favorable Report of the Committee on Insurance, and Appropriations.

The Clerk is in position of an amendment.

THE CHAIR:

Senator Crisco.

SENATOR CRISCO:

Thank you, Madam President.

Madam President, I move for acceptance of the Joint Committee's Favorable Report and passage of the bill.

THE CHAIR:

Acting on approval of the bill, will you remark further, sir?

SENATOR CRISCO: