

Legislative History for Connecticut Act

PA 14-224

HB5262

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**CONNECTICUT
GENERAL ASSEMBLY
HOUSE**

**PROCEEDINGS
2014**

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DEPUTY SPEAKER RITTER:

Absolutely, please proceed.

REP. NOUJAIM (74th):

Thank you, Madam Speaker.

I have here standing next to me a dear friend to all Republicans and Democrats who have served with us for quite some time, and he left us about four years ago. It is so nice to have him come back. One of the nicest, most wonderful, faithful gentleman you want to meet, former State Representative Sean Johnson. Let's give him around of applause. Thank you.

DEPUTY SPEAKER RITTER:

Representative Johnson, it is -- it is wonderful to hear you receive the acclaim that those of us that have been around are used to hearing you receive on a regular basis.

Are there any other introductions? No. We'll return to the business of the Calendar.

Will the Clerk please call Calendar 150.

THE CLERK:

On page 34, Calendar Number 150, a favorable report of the Joint Standing Committee on Judiciary, Substitute House Bill Number 5262, AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.

DEPUTY SPEAKER RITTER:

Representative Baram.

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REP. BARAM (15th):

Thank you, Madam Speaker.

I move for acceptance of the Joint Committee's favorable report and passage of the bill.

DEPUTY SPEAKER RITTER:

The question is acceptance of the Joint Committee's favorable report and passage of the bill.

Representative Baram, you have the floor, sir.

REP. BARAM (15th):

Thank you, Madam Speaker.

The Clerk has Amendment LCO 5519. I would ask the Clerk to call this amendment, and then I be granted leave of the Chamber to summarize.

DEPUTY SPEAKER RITTER:

Will the Clerk please call LCO 5519, which will be designated House Amendment Schedule "A."

THE CLERK:

LCO Number 5519 designated House Amendment "A," and offered by Representative Baram.

DEPUTY SPEAKER RITTER:

The Representative seeks leave of the Chamber to summarize the amendment.

Is there objection to summarization? Is there objection to summarization?

Hearing none, Representative Baram, you may proceed with summarization.

REP. BARAM (15th):

Thank you, Madam Speaker.

Madam Speaker, this is a bill that has great importance to the State of Connecticut because it intends to govern and regulate what we call sterile compounding pharmacies.

A sterile compounding pharmacy is a pharmacy that mixes drugs that are sold on the market at the request of a doctor or a hospital, and sometimes these are patient-directed drugs where they're specified and requested by a doctor and sometimes they're mass produced.

But they are drugs that are not typically produced by a general manufacturer for production because they are so specialized to a patient's illness and particular needs.

In 2012, in the state of Massachusetts, there was an outbreak of fungal meningitis. And a compounding pharmacy, which was producing specialized medications to deal with this -- this illness, mass produced those and sold them. And there were about 14,000 patients that were impacted by this drug. And actually 48 people, I believe, passed away and died as a result of a contamination of the drug.

So this serves as the impetus for the State of Connecticut to get involved and try and regulate

this industry known as compounding pharmacies.

This is a very long and technical bill, that's some 25 pages in length. And it gives the Department of Consumer Protection the right to regulate these pharmacies and also has various other parts.

And what I'd like to do is briefly summarize the bill in a general concept so that my colleagues understand the intent of what we're trying to do.

The first part of the bill deals with prescriptions that are given by physicians. And what the bill does is it indicates that if a physician gives a written prescription and they want a brand-named drug to be used, they must either put "brand medically necessary" or "no substitution" for the drug -- brand-named drug that they've identified.

If on the other hand, a doctor transmits a prescription by telephone, the bill makes it the obligation of the pharmacist to make notes about who transmitted the prescription and also put on their notepad "brand medically necessary" or "no substitutions."

And there is a new method of transmitting prescriptions through electronic transmission, and those use codes. And the codes used by the physician would, again, have to correspond to the

fact that this was brand medically necessary or no substitutions. So that is the first part of the bill.

The second part of the bill talks about the actual regulation of the sterile compounding pharmacies. And it indicates that all such pharmacies must comply with all medical laws and regulations of the state of Connecticut, as well as the United States Pharmacopeia chapter that governs drugs and regulates these pharmacies.

It also indicates that a pharmacy that is filing or registering for certification in the state of Connecticut must amend its application to include the fact that it is a sterile compounding pharmacy if that's the kind of work that it intends to do. And if they're applying for the first time in Connecticut, there would be a special addition to the application where they would list all the information required.

If they're an out-of-state pharmacy that is providing these sterile compound drugs to residents in Connecticut, they would also have to provide the same kinds of information.

The DCP is required to inspect these pharmacies to make sure they comply with all health codes and all regulations that are promulgated, not only by this act, but by existing statutes and regulations

that I cited a moment ago.

If a compounding pharmacy exists outside the state of Connecticut, they would have to have that state inspect the pharmacy or some independent contractor who is licensed in the area to do so and they would have to provide proof to the State of Connecticut that they are meeting all requirements.

There are also numerous reporting requirements by these sterile pharmacies, and those requirements are dictated by not only when they apply for certification or registration but also if there is a legal action taken against them, if there is a recall, or some kind of an error with the drugs.

There's also a required reporting, an annual reporting, and a reporting if there's any remodeling or moving of a facility so that the state DCP can go ahead and inspect and make sure that the facility meets the health code and also supports the drug regulations, again, promulgated by the state and the federal government.

If the pharmacy has been disciplined, they have to notify the state within ten days of any disciplinary action.

There are a host of penalties that are -- are also included in this bill. There are civil penalties of up to \$1,000. And there are also criminal penalties that are also associated with

violating this -- this act.

The -- again, the intent here is to make sure that we regulate these compounding pharmacies to make sure that as they mix drugs and they prescribe -- honor prescriptions for patients, that these drugs are not contaminated, they're not mixed in a way that are going to cause a threat to public health and safety. And, again, these are pharmacies that not only work to help a specific patient, what we call patient direct, but they're also pharmacies that may mass produce. And if they mass produce, then they have to acquire a pharmaceutical manufacturing permit which is another set of regulations. So the State has attempted to regulate and make sure that these pharmacies are fully compliant with law.

Also, there is a section to the bill that governs counterfeit drugs, that there cannot be any counterfeit drugs that are facsimiles or replicas of real approved drugs or devices that dispense these drugs into the human body. And there are fines and violations and penalties for anybody attempting to counterfeit a drug as well.

Again, there's quite a bit of detail and regulation in this bill, but I think, in terms of general intent, that the idea is to make sure that the residents of Connecticut are well served and

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that when they do receive these drugs that they know that they can assume that the estate -- the State of Connecticut has regulated them, has inspected the pharmacies, and made sure that what they're taking is -- is safe.

So, Madam Speaker, I would move adoption of this amendment.

DEPUTY SPEAKER RITTER:

The question before the Chamber is on adoption of the House Amendment Schedule "A."

Will you remark on the amendment?

Representative Carter.

REP. CARTER (2nd):

Good evening, Madam Speaker.

DEPUTY SPEAKER RITTER:

Good evening, Representative. You have the floor, sir.

REP. CARTER (2nd):

Thank you very much.

I'll make some comments. I've got to say I would thank the good Chairman of General Law for the most thorough briefing of this bill because I think he was right on the mark with everything he said.

I would like to address the first section and the last section prior to talking about compounding pharmacy. The "brand medically necessary" language that you see in the bill is very important because,

right now, if -- if you want a physician to be able to prescribe something and once the brand -- no matter what, then they have to write that on the brand medically necessary. That's the way it works in current law. And if you don't have that, then, they -- of course, they can utilize the generics which is -- which is very good.

We wanted to make sure there was something in -- in the statute that also covered telephonic communication and also electronic communication. So, in the bill, what it does is it talks a little bit about a "dispense as written" code, which the person -- the physician, when they're writing the prescription electronically, can check a box and then it sends the information over to the pharmacy and says, Hey, this is exactly what I want for that patient. Meanwhile, the patients are able to use generics, as to the max extent possible, and save the -- save themselves some money. So that section is a very good section. And it's about time we do that.

The -- the last part of the bill is where we're talking about counterfeit drugs. And, of course, counterfeit drugs are important because, not only with the new world of compounding pharmacies, but obviously, there are plenty of people trying to defray the cost of drugs by getting them through

other means. So we want to make sure we're very careful by putting something out there in statute that covers that and, also, with some of the newer devices available.

For instance, there's some patented devices that will actually deliver medication within the eye. And it's -- it's actually a device. So we want to make sure that those things aren't counterfeited as well, and what that could do to, you know, our public.

Regarding the compounding pharmacy, which is the -- the largest middle section of the bill, as my good colleague from General Law mentioned, back in Massachusetts, we all heard of, you know, what had happened with respect to the sterilization of the pharmacy. And, you know, the Department of Consumer Protection has come to us with this need to say that these pharmacies really need to be looked at more closely, they need to be inspected, and that's what we're trying to do with this bill, because the compounding pharmacies are almost like a mini manufacturer of their own. So we need to make sure that they're doing that in the right way. And they have these pharmacies in institutions. They have them in different businesses around the state. It's actually a -- I would say a growing industry for that matter.

And, in fact; more and more different companies are representing compounded pharmacy products around the state, which actually gives physicians and health care practitioners a little more latitude in what they prescribe. So it's a good thing to do, but we just need to make sure that those places are inspected.

So this is a very, very good bill. Again, it's highly technical, but this is something that we definitely need to be ahead of. So with that I urge its adoption.

Thank you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Will you remark further on the amendment before us? Will you remark further on the amendment before us?

If not, let me try your minds.

All those in favor of the amendment, please signify by saying aye.

REPRESENTATIVES:

Aye.

DEPUTY SPEAKER RITTER:

All those opposed, nay.

The amendment is adopted.

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

Representative Srinivasan, you have the floor,

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sir.

REP. SRINIVASAN (31st):

Good afternoon, Madam Speaker.

DEPUTY SPEAKER RITTER:

Good afternoon.

REP. SRINIVASAN (31st):

Through you, Madam Speaker, just a few questions to the proponent of the bill.

DEPUTY SPEAKER RITTER:

Please proceed.

REP. SRINIVASAN (31st):

Through you, Madam Speaker.

The bill as amended, as was said by my Ranking Member, is a wonderful piece of legislation, something that our state definitely needs. And I want to thank the good Chair for his very thorough and extensive description of what this bill does. Technical as it is, you made it very simple so all of us could understand what the purpose of this bill is.

Through you, Madam Speaker.

On the first section -- through you, Madam Speaker, to the proponent of the bill as amended, if I can look at lines 28 and 29, where we talk about a brand that's medically necessary or no substitution. Through you, Madam Speaker, does that substitution refer only to generic drugs?

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Through you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Representative Baram.

REP. BARAM (15th):

Through you, Madam Speaker, that is correct.

DEPUTY SPEAKER RITTER:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Through you, Madam Speaker, as we all know, multiple pharmaceutical companies make the same product. And so if in the prescription written or in the electronic prescription if a drug, let us say, in the management of hypertension, one drug is mentioned by name and another drug that is also a brand name only -- it is not a generic -- by this piece of legislation, would the pharmacist have any reason not to substitute one prescription for another but they're all in the same category, they are not generic drugs.

Through you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Representative Baram.

REP. BARAM (15th):

Through you, Madam Speaker.

That's a great question. And I suppose that if there were like-kind brand drugs that could be exchanged, that might be a possibility. I'm not

going to represent that exactly how the DCP would interpret that provision. I can only explain that the DCP felt strongly that if you use a brand-name drug, a pharmacist, without permission, should not be allowed to substitute a generic drug for that. So that is a question that, you know, we'll have to get clarification on from DCP, but I certainly understand the intent. And it might make sense to give some flexibility if brand names drugs were identical in constitution and whatnot to allow for some exchange.

DEPUTY SPEAKER RITTER:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Thank you, Madam Speaker.

And I do want to thank the good Chairperson for that answer. Because as you can see with our insurances, we do not know what particular brand is covered by that particular insurance. So when a physician writes a particular brand that he or she is familiar with, but when the patient goes to the pharmacy, you know, that particular brand is not covered or has an extensive -- excessive copay, but they can be substituted by another brand, not generic, and obviously, the copay is in a different scale altogether. So it would be -- as we move forward, get the clarification from the Department

of Consumer Protection that will -- or can the pharmacist switch one brand name for another and not break any laws.

Through you, Madam Speaker, just a few questions on the compounding part of this bill.

Through you, Madam Speaker, does the good Chair know as to how many such compounding pharmacies we have in our state?

Through you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Representative Baram.

REP. BARAM (15th):

Through you, Madam Speaker.

I remember during, public hearings the number of about 40 were mentioned, but I can get that information specifically.

DEPUTY SPEAKER RITTER:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Through you, Madam Speaker. I want to thank the good Chairman for getting the information at a later point. That's -- that's more than adequate for us.

Through you, Madam Speaker.

Have -- are we aware of any grievances, any complaints that have been officially filed through the -- have been filed by -- by, obviously, patients

who have used these compounding pharmacies to any authority?

Through you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Representative Baram.

REP. BARAM (15th):

Through you, Madam Speaker.

No such complaints were brought to my attention by DCP. I think that the real concern is not so much the patient-specific prescriptions, but more the compounding pharmacies that mass produce these, where they think they may have a new drug combination that they're using that would be popular and effective to the mass population. Those are the drugs that I think the DCP is particularly concerned about. But I'm not aware that there have been any incidents in Connecticut. But again, we have to look at what happened in Massachusetts. Something terrible could happen, and it is now time that Connecticut stepped up and make sure that we properly regulate these pharmacies.

DEPUTY SPEAKER RITTER:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Madam Speaker, I definitely agree. You know, I'm glad we have not had any such incident in our state, but learning from what happened from our

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neighboring state is important and for us to act in a proactive way and make sure, especially the compounding pharmacies that produce these products in large scales, that the proper precautions are there so that we do not have something happening in our state similar to what happened in Massachusetts.

Through you, Madam Speaker, my final question.

For clarification purposes, the role of the Department of Consumer Protection, is it -- will they be issuing some licenses to these compounding pharmacies, or will just -- they will be regulating, you know, overseeing and seeing what happens ever so often to make sure that they are following what the appropriate laws of our state?

Through you, Madam Speaker.

DEPUTY SPEAKER RITTER:

Representative Baram.

REP. BARAM (15th):

Through you, Madam Speaker.

Yes, the state of Connecticut will be licensing these facilities. And there will be, as I explained before, an application, an addendum, that covers the specific aspect of sterile compounding facilities. There is also an inspection that's required.

And if the facility is out of the state of Connecticut, there has to be proof presented to Connecticut that the foreign state has properly

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inspected according to the regulations that we have adopted. And if that state does not do inspections, the pharmacy will have to hire an independent party that's properly licensed to inspect and provide that proof to the State of Connecticut:

DEPUTY SPEAKER RITTER:

Representative Srinivasan.

REP. SRINIVASAN (31st):

Thank you, Madam Speaker.

I want to thank the good Chair for his very -- for the various answers for my questions and being very thorough in when he answered all those questions as well.

And, as my good Ranking Member said, this is a wonderful piece of legislation. We definitely need that, and I'm hoping that both sides of the aisle will join us all in making sure that this becomes a reality.

Thank you, Madam Speaker.

DEPUTY SPEAKER RITTER:

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

If not, will staff and guests please come to the Well of the House. Will members please take their seats. The machine will be open.

THE CLERK:

The House of Representatives is voting by roll.

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

(Speaker Sharkey in the Chair.)

SPEAKER SHARKEY:

Have all the members voted? Have all the members voted?

Will members please check the board to make sure your vote is properly cast.

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

Clerk, please announce the tally.

THE CLERK:

Mr. Speaker, House Bill 5262 as amended by House "A,"

Total Number Voting	148
Necessary for Passage	75
Those Voting Yea	148
Those Voting Nay	0
Those Absent and Not Voting	3

SPEAKER SHARKEY:

The bill, as amended, passes.

Ladies and gentlemen of the Chamber, we are about to embark on a tradition that we do every two years towards the end of the biennium to which we've

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The second, Calendar 590, House Bill 5262, move to place on the Consent Calendar.

THE CHAIR:

So ordered, sir.

SENATOR LOONEY:

The third item, Madam President, Calendar Page 29, Calendar 587, House Bill 5377, move to place on the Consent Calendar.

THE CHAIR:

So ordered, sir.

SENATOR LOONEY:

Moving to Calendar Page 30, Madam President, where there are two items, Calendar 593, House Bill 5526, move to place on the Consent Calendar.

THE CHAIR:

So ordered, sir.

SENATOR LOONEY:

And Calendar 591, House Bill 5537, move to place on the Consent Calendar.

THE CHAIR:

So ordered, sir.

SENATOR LOONEY:

Thank you, Madam President. Moving to Calendar Page 33, Madam President, Calendar 215, House Bill 2, excuse me, Calendar 215, Senate Bill 243, move to place this item on the Consent Calendar.

THE CHAIR:

So ordered, sir.

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On Page 27, Calendar 574, House Bill 5564.

House Bill 578, House Bill 5220.

On Page 28, Calendar 580, House Bill 5310.

Calendar 584, House Bill 5334.

Calendar 585, House Bill 5586.

Calendar 583, House Bill 5289.

On Page 29, Calendar 586, House Bill 5402.

Calendar 589, House Bill 5550.

Calendar 590, House Bill 5262.

Calendar 587, House Bill 5377.

On Page 30, Calendar 593, House Bill 5526.

Calendar 592, House Bill 5476.

On Page 33, Calendar 215, Senate Bill 243.

On Page 39, Calendar 387, Senate Bill 432.

On Page 40, Calendar 475, House Joint Resolution
Number 20.

Calendar 476, House Joint Resolution Number 26.

Calendar 532, House Joint Resolution Number 42.

THE CHAIR:

Mr. Clerk, can you please check on Consent Calendar
House Bill 5593. I don't see if you called that, on
the top.

THE CLERK:

That's on the previously adopted Senate Agenda House
Bill 5593.

THE CHAIR:

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SENATOR LOONEY:

If we might pause for just a moment to verify a couple of additional items.

Madam President, to verify an additional item, I believe it was placed on the Consent Calendar and Calendar Page 30, on Calendar Page 30, Calendar 592, Substitute for House Bill 5476.

THE CHAIR:

It is, sir.

SENATOR LOONEY:

It is on? Okay. Thank you. Thank you, Madam President. If the Clerk would now, finally, Agenda Number 4, Madam President, Agenda Number 4 one additional item ask for suspension to place up on Agenda Number 4 and that is, ask for suspension to place on the Consent Calendar an item from Agenda Number 4.

THE CHAIR:

Seeing no objection, so ordered, sir.

SENATOR LOONEY:

Thank you, Madam President, and that item is Substitute House Bill Number 5566 from Senate Agenda Number 4.

Thank you, Madam President. If the Clerk would now, if we might call for a vote on the Consent Calendar.

THE CHAIR:

Mr. Clerk. Will you please call for a Roll Call Vote on the Consent Calendar. The machine will be opened.

THE CLERK:

An immediate Roll Call has been ordered in the Senate.

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An immediate Roll Call on Consent Calendar Number 2 has been ordered in the Senate.

THE CHAIR:

If all members have voted, all members have voted, the machine will be closed. Mr. Clerk will you please call the tally.

THE CLERK:

Consent Calendar Number 2.

Total number voting	36
Necessary for adoption	19
Those voting Yea	36
Those voting Nay	0
Those absent and not voting	0

THE CHAIR:

The Consent Calendar passes. Senator Looney.

SENATOR LOONEY:

Thank you, Madam President. Two additional items to take up before the, our final vote on the implementer. If we might stand for just, for just a moment.

The first item to mark Go is, Calendar, to remove from the Consent Calendar, Calendar Page 22, Calendar 536, House Bill 5546. If that item might be marked Go.

And one additional item, Madam President, and that was from Calendar, or rather from Agenda Number 4, ask for suspension to take it up for purposes of marking it Go, that is House Bill, Substitute for House Bill 5417. Thank you, Madam President.

THE CHAIR:

Seeing no objection, so ordered, sir.

SENATOR LOONEY:

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HB 5260

COMMISSIONER WILLIAM RUBENSTEIN: Good afternoon, Senator Doyle, Representative Baram -- Baram, Senator Witkos, and members of the General Law Committee. It's really a pleasure to be here today and especially to be outside the legislative office building among -- among our constituents. It's -- it's particularly good to be here today.

Your agenda today includes seven bills that were proposed by the Department of Consumer Protection so I want to start by thanking you for raising those bills for a public hearing. I'm providing you with the opportunity to testify today.

So, let me begin. I'll run through these bills in -- in order and just (inaudible) and, hopefully, we'll be able to go from there. Let me begin with Senate Bill 205, which is AN ACT THAT REALLY IS MAKING MINOR AND TECHNICAL CORRECTIONS AND CHANGES RATHER TO THE REAL ESTATE APPRAISAL AND APPRAISAL MANAGEMENT COMPANY STATUTES.

The Department of Consumer Protection has the responsibility for licensing and -- and oversight of real estate appraisals and appraisal management companies. That -- those statutory provisions are in chapter 400g of the General Statutes. And the purpose of this bill before you is to make minor and technical changes to these statutes really solely as a result of a compliance review that was conducted by the appraisal subcommittee of the Federal Financial Institutions Examination Council.

This body is established and charged with auditing every state statutory and regulatory structure, be a federal law referred to as Title XI of the Financial Institutions Reform

may be issued to a non-commercial organizations, eight to charitable organizations, and one to non-profit corporations conducting wine -- wine auctions. We, you know, we -- we would like to offer the opportunity for all these organizations to conduct 12 of these events a year.

So the next bill I want to address, 6, it's AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS. Now this bill makes several substantive changes to the Pharmacy Practice Act and the Pure Food and Drug Statutes, which fall under our jurisdiction.

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First, we -- we propose to amend section 20-619 of the Pharmacy Practice Act after having discussions with our sister agency, the Department of Social Services. As currently drafted, this statute provides requirements for filling prescriptions by pharmacies, but it has essentially put into place two systems within the pharmacy; one for filling prescriptions based on reimbursement criteria under DSS programs, such as Medicaid and ConnPACE, and second for all others.

While separate statutory requirements may certainly make sense for DSS reimbursement issues, both agencies agree that this is more appropriate to place those requirements within the DSS statutory authority. The bill, therefore, removes the DSS specific requirements from DCP's Pharmacy Practice Act, while companion DSS agency bill has been submitted to the Legislature to provide statutory authority in its appropriate chapters.

This statutory change reflects our belief that the practice of pharmacy protocols should be uniformly applied regardless of whether a

prescription is subject to DSS reimbursement issues or not. DSS can impose its own requirements over the top of the standard pharmacy protocols if it desires.

Sections 2 through 7 of this bill are intended to improve the department's ability to provide oversight in the operation of sterile compounding pharmacies. In general, a pharmacy is permitted to compound pharmaceuticals based on a prescription signed by a doctor on behalf of a single, specific patient.

Public awareness of out-of-state pharmacies abusing this ability by mass-producing compounded pharmaceuticals has grown recently with news accounts of contaminated product reaching the marketplace across the country, including here in Connecticut.

We recognize the benefit of continuing to allow pharmacies to compound pharmaceuticals for patient-specific products, and propose statutory changes in this bill which will strengthen DCP's oversight to improve patient safety.

The changes proposed include establishing a new chapter within the Pharmacy Practice Act specifically to cover sterile compounding pharmacies. It adds new licensing and reporting requirements by pharmacies for those that choose to engage in sterile compounding. Among other things, it requires those pharmacies to ensure a sterile environment and to report any changes in the physical structure or relocation of the sterile room, to ensure that DCP's drug control division can inspect the facility. It requires those pharmacies to comply with federal code for pharmaceutical sterile compounding.

This provision of -- of this bill has particularly importance because the oversight of -- of these compounding pharmacies is largely left to state regulatory authorities as opposed to the federal regulatory authorities. So we're the frontline on these products.

The bill also places new mandates and reporting requirements on those non-resident pharmacists -- pharmacies, those compounding pharmacies from out of state that are registered with us, but engaged in sterile compounding elsewhere.

Specifically this section requires these non-resident pharmacies to provide DCP with the most recent inspection report on their facility conducted by their own licensing agency and to notify DCP if they have any disciplinary action or written warning served against them by any state or federal authority and to provide DCP the names and addresses of all Connecticut residents to whom such pharmaceutical drug has been delivered if a drug recall is initiated.

The department is confident that the changes proposed will lead to increased patient safety through improvements in inspection and regulatory oversight of both resident and non-resident sterile compounding pharmacies.

And finally, section 8 of the bills adds a new section with the Pure Food and Drug Act pertaining to counterfeit substances. It provides a definition for counterfeit substances that mirrors the language recognized by the FDA and it prohibits the sale, delivery, or offer to sell any of these items to the public. This new section

recognizes the growth of a tremendous problem with counterfeit drugs finding their way into the marketplace.

Recent examples of counterfeit substances in Connecticut include counterfeit prescription drugs sold in retail outlets, as well as over the internet. This section gives the Commissioner the authority to investigate and enforce any allegation of selling counterfeit substances, including penalties for those engaged in the practice that do not hold a DCP registration.

HB 5260 Finally, the final bill I'm going to testify on today is AN ACT CONCERNING HEATING FUEL DELIVERY FEES AND SURCHARGES AND PREPAID GUARANTEED HEATING FUEL CONTRACTS. So this proposal makes two separate changes within the operation of fuel supply statutes and the heating fuel sales chapters.

As you are aware, the -- the department has jurisdiction over home heating fuel dealers so, you know, we're the appropriate agency for consumers to register complaints. Now especially at times like these with fuel prices becoming extremely high, the number of complaints is similarly high. Now, certainly not all complaints against dealers are valid nor lead to enforcement actions, but they may be deeply troubling to consumers nonetheless.

The General Assembly has, over the years, evaluated practices in this industry and created rules to make sure that they are fair and transparent to consumers. Two of these rules require further -- further adjustment in our view.

First, under the present law, home heating dealers may only charge customers a surcharge

know, be harder for us to administer than having the -- the private oversight of the surety. But -- but I'm -- I'm willing to understand any -- any mechanism that actually has the money there when you need it and have that outside the control of -- of the promisor.

REP. BARAM: My last question is on 5262 and it's just to help me understand this whole concept of sterile compounding pharmacies. Are we talking about any drug or these special drugs?

COMMISSIONER WILLIAM RUBENSTEIN: So -- so as I understand it, there are certain drugs that are -- are mixed from other drugs. And so it could be IV packages that have certain components to it. It could be a -- a cough syrup that's mixed from different elements. I mean, there -- there's a whole range of things where, you know, compounds that are off the shelf are mixed together to create a -- a different configuration of that compound. That's typically done -- often done in -- in a local pharmacy which we call compounding pharmacy.

Some of that is done -- required to be done under sterile conditions and some less are -- are non-sterile compounding. We're talking about the sterile compounding and things where the sterility of the products makes a health difference to the patient. So I mean, you know, those are the kinds of things that -- that drug manufacturers aren't manufacturing in bulk. They're -- typically they're -- they're typically compounded for smaller uses.

Although there's been a blurring of the line between what these compound pharmacies do and -- and they've turned themselves into little manufacturers and wholesalers.

REP. BARAM: And -- and when a pharmacy does mix drugs together to come up with a new configuration, do they have to get prior approval from the FDA or the State of Connecticut to do that?

COMMISSIONER WILLIAM RUBENSTEIN: They do that on the order of physicians. Physicians prescribe the -- the compound to be made.

REP. BARAM: As I remember a couple of years ago, I think it passed, we allowed pharmacies to add flavoring or color to some of these drugs, particularly for children's medicines. So essentially this is the same thing except they're taking different drugs and --

COMMISSIONER WILLIAM RUBENSTEIN: Okay. So -- so what -- what I understand is that -- that is not what we call compounding because you're not adding an active ingredient together.

REP. BARAM: Thank you very much.

SENATOR DOYLE: Thank you.

Any further questions?

Commissioner, I just have a couple quick follow-ups.

COMMISSIONER WILLIAM RUBENSTEIN: Okay.

SENATOR DOYLE: Your bill about the surety for the oil distributors, it clearly has identified a problem that a lot of -- the committee's concerned with the Legislature in the whole and especially the City of Meriden delegation because that's where the recent distributor there went belly-up and, you know, hurt the consumer. So there's a lot of interest.

HB 5260

NICHOLAS SCATA: I don't think it can be assigned to the consumer. I think if Tower Energy went bankrupt and they -- and there was value in those contracts, it would be an asset that -- that the receiver can try to liquidate. Whether the contracts are in the money or out of the money, it all depends on what the current market value is of the heating oil.

So they, you know, they can move with the entity because they are an asset of the entity if they're in the money. If they're out of the money, they can be a liability.

REP. BARAM: Now I better understand why you have to be a CPA to do this.

SENATOR DOYLE: Thank you.

Any further questions?

Seeing none, thank you very much, Mr. Scata.

NICHOLAS SCATA: Thank you.

SENATOR DOYLE: Next speaker is Annik Chamberlin, Greg Stafstrom, and Steve Sack.

HB 5262
ANNIK CHAMBERLIN: Good afternoon, Senator Doyle, and Representative Baram, and the members of the General Law Committee.

My name is Annik Chamberlin. I'm a pharmacist; a little bit change of pace for you guys. Kudos to the energy industry. You guys are rocking it out today. I'm a pharmacist and co-owner of Beacon Prescriptions Compounding Pharmacy in Southington, Connecticut. We are a full retail pharmacy that also specializes in compounding custom medications including sterile preparations.

I'm also a member of the Connecticut Pharmacists Association and have been participating in a task force to evaluate the practice of compounding medications to ensure best practices and patient safety. I'm here today to speak on Raised Bill 5262, AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.

I'm going to focus on Section 2, which creates new legislation for compounded medication. This is a section I'll spend my few minutes on from a pharmacist's perspective that will help you focus more on this area.

For some of you who don't know, pharmacy compounding is a science of preparing personalized prescription medications for patients. Compounded medications are made from scratch. Individual ingredients are mixed together in an exact strength and dosage form required for the patient written through a prescription from a physician.

This method allows the compounding pharmacist to work with the patient and the prescriber to customize a medication to meet the patient's specific need. This art of compounding medications has been the genesis of our profession dating back to ancient times.

Sterile compounding is the preparation of custom medications for patients in a sterile environment to prevent contamination and maintain patient safety.

While we understand the basis of creating statutes in an attempt to prevent tragedies, such as the one that occurred in our neighboring state of Massachusetts, we appreciate the opportunity to have a dialogue

and talk about how pharmacists currently compound, because it's important to us that any additional legislation is meaningful and does not create burdens and costs that adversely impact the critical workflow that compounding medication depends on.

So the following is our comments with the proposed regulations. Section (b) language in the third line states that a facility that intends to compound sterile pharmaceuticals for use in Connecticut for the first time needs clarification.

The rationale behind this is that the language referring to for the first time should be clearer. For example, if a pharmacy provided sterile compounding for a period of time, then stopped for a few years and then resumed, according to the current wording, this pharmacy does not meet the first-time rule.

Section 2(d) needs to consider changing the last sentence to a two-week supply to a 30-day supply as -- as follows. A sterile compounding pharmacy may prepare and maintain on-site inventory of sterile pharmaceuticals no greater than a 30-day calculated from the completion of compounding, including the third party analytical testing per USP 797.

The rationale behind that is that testing turnaround for sterility testing is about 25 days to complete at this point. So to do -- to be able to keep just 14 days on hand would be very counterproductive.

You have my written testimony. There are many other points with my rationale. I thank you for your time in -- in reading and listening to my testimony. I invite any questions because I'm sure there are plenty.

I invite any of you and all of you to come to our facility to learn more about compounding, sterile, nonsterile, and all the practices that go along with it, so.

SENATOR DOYLE: Thank you.

Just before your questions, so pharmacists, I mean, doctors will call you -- I'm sorry, this is new to me.

ANNIK CHAMBERLIN: Sure.

SENATOR DOYLE: You (inaudible) you know, dispensing pills, they -- they have you actually create? So it's kind of like what you -- in what form is it like? A liquid or pills or (inaudible)?

ANNIK CHAMBERLIN: In our practice we do anything from liquid, capsules, injectables, suppositories, topical preparations, injections, eye drops, pretty much anything, ear drops, everything you could think of.

SENATOR DOYLE: But they don't know -- this is not done at the normal CVS or something like --

ANNIK CHAMBERLIN: This is not your typical where you'd find, you know, a regular retail establishment. This is -- this is custom, something that's not available in the marketplace or manufactured by a manufacturer.

SENATOR DOYLE: So it's a little niche, it's a small --

ANNIK CHAMBERLIN: It's a niche.

SENATOR DOYLE: -- a small need that's small in the market?

ANNIK CHAMBERLIN: I wouldn't say the need is small, but it is niche.

SENATOR DOYLE: Small, I mean small in the sense that to -- in terms of number of -- of clients or patients it's limited, because otherwise it would be made in a mass scale I would think, right?

ANNIK CHAMBERLIN: Exactly. Yes, yeah, yeah.

SENATOR DOYLE: Okay.

Any questions from the committee?

Senator Witkos.

SENATOR WITKOS: Just -- this is -- obviously, this is new to me, too. So how does the process work? You go to your MD and they say you need this medication. And depending on -- most people would say well who is your pharmacy? You go there, drop off your script, or it's called in and you pick it up.

ANNIK CHAMBERLIN: Yeah.

SENATOR WITKOS: Now in this scenario, how -- how do the doctors or the hospitals or whomever know that you're in existence where they would say, hey, we know this -- this pharmaceutical place -- I don't even know if it's a place where people can go, they will actually, in the laboratory, mix whatever and they -- and it comes in whatever form you want it. How does that --

ANNIK CHAMBERLIN: How do they know what's available --

SENATOR WITKOS: Well, just could -- well, you can talk about that, yeah.

ANNIK CHAMBERLIN: Yeah, sure. There's a lot of examples that compounding is used in. A lot in pediatrics where, for example, a child has cancer. The only thing that's manufactured is, you know, adult strength things that are needed for pediatric use.

So what we do is take that, we make it into a form that a child can take, liquid. Whether it be a liquid or a capsule that's in a smaller dosage that's appropriate for their size and weight.

Another example would be, you know, you rip your cornea and you need some fortified eye drop that's not available on the marketplace. You know, come to us and we can make that from scratch and have it available to help somebody.

SENATOR WITKOS: And because you're a niche, do you fall into the same regulations and requirements as other pharmacies, if you will, I'll use that as a generic thing. So under the FDA and our own DCP as far as --

ANNIK CHAMBERLIN: Sure. Yeah, so --

SENATOR WITKOS: -- reporting requirements and things like that?

ANNIK CHAMBERLIN: We're an independent pharmacy. We have a full retail establishment as well as part of our compounding. We just happen to specialize in compounding as well, but we do fall under all the -- the laws and regulations of DCP, FDA.

And, you know, there are currently some regulations written for -- talking -- speaking to sterile compounding, but I believe that the department is bringing these up to kind of sort of be proactive in their efforts with the tragedy that's happened.

I don't know if you guys remember the Massachusetts compounding pharmacy that maybe got a little ahead of themselves and mass produced things that ended up going all over the country and causing fatalities. So I think the department is just looking to be proactive and --

SENATOR WITKOS: And this is probably a question I've should have asked the Commissioner, but are you aware of how many compounding pharmacies we have?

ANNIK CHAMBERLIN: That are doing sterile?

SENATOR WITKOS: Yeah.

ANNIK CHAMBERLIN: Is it like 18?

A VOICE: At the most, yeah.

ANNIK CHAMBERLIN: Yeah, no more than 15, 18 I think that they've identified. You know, currently you don't have to sign up that you're a sterile compounding pharmacy. So I think part of these regulations will also identify, you know, who is doing it so that the department can sort of, you know, keep an eye.

SENATOR WITKOS: What's the basic educational requirements or work experience for somebody to work in this field in the laboratories there?

ANNIK CHAMBERLIN: Well, your pharmacists overview always --

SENATOR WITKOS: You have to be a licensed pharmacist?

ANNIK CHAMBERLIN: Of course, you have pharmacy technicians that are working under licensed pharmacists. And then there are many training programs, you know, externships, conferences, seminars, to stay on top of --

SENATOR WITKOS: Continuing, okay. Thank you.

Thank you, Mr. Chairman.

SENATOR DOYLE: Thank you.

Any other questions?

Representative Baram.

REP. BARAM: Thank you.

When you talk about sterile environments, the reverse of that, are there these compounding pharmacies that act in a nonsterile environment?

ANNIK CHAMBERLIN: So, yeah. There is this clear distinction between nonsterile compounding and sterile compounding. We actually do both; nonsterile and sterile compounding. Sterile compounding are the things that you, obviously, would want to remain sterile and contamination-free, things that being injected, things that are going in your eye, things that are going in your spine injected. Those are things that you would want to keep contamination-free.

Nonsterile compounding, we do a lot of, too, done at a different sort of room, but you're

not as concerned with the sterility and contamination issue, and so --

REP. BARAM: Can you give -- give me an example of what that might be?

ANNIK CHAMBERLIN: Oh, sure. Nonsterile, think of your furry friends. We do lots of compounding for animals. We do tons of compounding for, again, children who might need topical applications. Your hospice patient who can no longer take medications by mouth and needs other routes of administration. We do a lot of hormone replacement therapy. We do a lot of different capsules. That would be more the nonsterile component.

REP. BARAM: And are there out-of-state facilities that -- that sell, you know, to Connecticut residents or do they have to be --

ANNIK CHAMBERLIN: Oh, I'm sure --

REP. BARAM: -- a licensed Connecticut pharmacy?

ANNIK CHAMBERLIN: -- there are -- I'm sure there are pharmacies that are, you know, shipping across state lines, and I believe the proposed regulations are actually addressing that as well and -- and saying that those pharmacies also need to get a license in Connecticut and follow the rules that, you know, resident pharmacies have to follow, so.

REP. BARAM: And lastly, some of the chain pharmacies, let's say that are national in scope, if they have to compound a medication, do they do that internally or do they call someone like yourself?

ANNIK CHAMBERLIN: I think some of these bigger chains might have a central location that they

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do send some of their compounding, but, you know, if you have a good relationship in your community usually you know who the CVS pharmacist person is and they'll say, hey, Annik, I have this -- I can't do it here or I'm not capable or I don't have the tools, can you do it? And they just send us the stuff, so. You kind of get to be known for what you're doing and taking care of people, so.

REP. BARAM: Thank you very much.

ANNIK CHAMBERLIN: You're welcome.

SENATOR DOYLE: Thank you.

You educate -- you learned from the oil industry now. You're educating the home heating industry about --

ANNIK CHAMBERLIN: I know everything about --

SENATOR DOYLE: -- compounding.

ANNIK CHAMBERLIN: -- energy. It's wonderful.

SENATOR DOYLE: Lots -- they may go into the compounding industry.

ANNIK CHAMBERLIN: Love it.

SENATOR DOYLE: Any other questions?

Seeing none, thank you.

ANNIK CHAMBERLIN: Thank you.

SENATOR DOYLE: Next speaker is -- Representative Altobello want to speak or is he? Okay. Next speaker is Greg Stafstrom, Steve Sack, (inaudible).

Department of Consumer Protection



Testimony of William M. Rubenstein
Commissioner of Consumer Protection

HB 5258 HB 5261
SB 206 HB 5263
HB 5262 HB 5260

General Law Committee Public Hearing
February 25, 2014

Senator Doyle, Representative Baram, Senator Witkos, Representative Carter and distinguished members of the General Law Committee, I am William Rubenstein, Commissioner of Consumer Protection. Your agenda today includes seven bills that were introduced by my Department, so let me begin by thanking you for agreeing to raise these bills for the consideration of the committee and for providing me with the opportunity to testify in support of these important proposals.

S B No. 205 (RAISED) AN ACT MAKING MINOR AND TECHNICAL CHANGES TO REAL ESTATE APPRAISER AND APPRAISAL MANAGEMENT COMPANY STATUTORY DEFINITIONS.

The Department of Consumer Protection has responsibility for licensing and oversight of Real Estate Appraisers and Appraisal Management Companies with statutory authority provided in chapter 400g. The purpose of this bill before you is to make minor and technical changes to these statutes solely as a result of a compliance review conducted by the Appraisal Subcommittee of the Federal Financial Institutions Examination Council. This body is established and charged with auditing every state's statutory and regulatory structure, via a federal law referred to as Title XI of the "Financial Institutions Reform, Recovery and Enforcement Act of 1989." Following an audit of Connecticut's statutes in these areas, the Appraisal Subcommittee provided a detailed compliance review report to the Department. While the audit stated that Connecticut is "substantially" in compliance with federal requirements, it recommended that our statutes be

attempting to automatically renew a contract without the consumer receiving notice and given an opportunity to non-renew.

Section 4 makes a one word change within the New Home Guaranty Fund statute. If this change sounds familiar to the committee, that is because an identical change was made in the last legislative session within the Home Improvement Guaranty Fund. Specifically, we proposed a minor change to replace the term "real" property with "personal" property when attempting to satisfy a judgment against a contractor. This change clarifies the steps a consumer must undertake in order to have access to the Guaranty Fund when a judgment is rendered against a new home contractor.

Finally, sections 5 through 7 are offered to respond to frustration the Department often hears from charitable organizations in their desire to conduct numerous fundraising events throughout the year. Under present law, the number of times per year that an organization may obtain a liquor permit for fundraising events is specified in statute, and differs from organization to organization based on the way they are established. The Department proposes to increase the number of permits that all charitable organizations may obtain to twelve (12) per year. Presently, six permits may be issued to "noncommercial organizations," eight to "charitable organizations," and one to "nonprofit corporations conducting the sale of wine at an auction."

We are pleased to offer the changes contained in this bill to provide additional consumer protections, and to assist charitable organizations in their efforts

H.B. No. 5262 (RAISED) AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.

This bill makes several substantive changes to the Pharmacy Practice Act and the Pure Food and Drug statutes which fall under the jurisdiction of the Department of Consumer Protection. First, we propose amending Sec. 20-619 of the Pharmacy Practice Act after having had discussions with our sister agency, the Department of Social Services. As currently drafted, this statute, which provides requirements for filling prescriptions by pharmacies, has essentially put in place two systems within a pharmacy: one for filling prescriptions based on reimbursement criteria pertaining to DSS's programs such as Medicaid and ConnPACE, and second one for "all others." While separate statutory requirements may certainly make sense for DSS reimbursement issues, both agencies agree that it is more appropriate to place those requirements within DSS statutory authority. This bill therefore removes DSS-specific requirements from DCP's Pharmacy Practice Act, while a companion DSS agency bill has been submitted to the legislature to provide statutory authority in its appropriate chapters. This statutory change reflects our belief that the practice of pharmacy protocols should be uniformly applied, regardless of whether a prescription is subject to DSS reimbursement issues, or not. DSS can impose its own requirements "over-the-top" of the standard pharmacy protocols if it desires

Sections 2 through 7 of the bill are intended to improve the Department's ability to provide oversight in the operation of sterile compounding pharmacies. In general, a pharmacy is permitted to compound pharmaceuticals based on a prescription signed by a doctor on behalf of a single, specific patient. Public awareness of out-of state pharmacies abusing this ability by mass-producing compounded pharmaceuticals has grown recently with news accounts of contaminated products reaching the marketplace. We recognize the benefit of continuing to allow pharmacies to compound pharmaceuticals for patient-specific products, and propose statutory changes in this bill which will strengthen DCP's oversight to improve patient safety.

The changes proposed include establishing a new chapter within the Pharmacy Practice Act specifically to cover Sterile Compounding Pharmacies. It adds new licensing and reporting requirements by pharmacies for those that choose to engage in sterile compounding. Among other things, it requires those pharmacies to ensure a sterile environment and to report any changes in the physical structure or relocation of the sterile room, to ensure that DCP's Drug Control division staff can inspect the facility. And it requires those pharmacies to comply with the federal code for pharmaceutical sterile compounding.

The bill also places new mandates and reporting requirements on those "non-resident" pharmacies that are registered with DCP and engage in sterile compounding. Specifically, it requires them to provide DCP with the most recent inspection report on their facility as conducted by the licensing-authority of their state, to notify DCP if they have had any disciplinary action or written warning served against them by any state or federal authority, and to provide to DCP the names and addresses of all Connecticut residents to whom such pharmaceutical drug has been delivered if a drug recall has been initiated.

The Department is confident that the changes proposed will lead to increased patient-safety through improvements in inspection and regulatory oversight of both resident and non-resident sterile compounding pharmacies.

Section 8 of the bill adds a new section within the Pure Food and Drug chapter pertaining to "counterfeit substances." It provides a definition for counterfeit substances that mirrors language recognized by the FDA and prohibits the sale, delivery or offer to sell any of these items to the public. This new section recognizes the growth of a tremendous problem with counterfeit drugs finding their way into the marketplace. Recent examples of counterfeit substances in Connecticut include counterfeit prescription drugs sold in retail outlets, as well as over the internet. This section gives the Commissioner the authority to investigate and enforce any allegation of selling counterfeit substances including penalties for those engaged in the practice that do not hold a DCP registration

H.B. No. 5260 (RAISED) AN ACT CONCERNING HEATING FUEL DELIVERY FEES, CHARGES AND SURCHARGES AND PREPAID GUARANTEED HEATING FUEL PRICE PLAN CONTRACTS.

This proposal makes two separate changes within the "Operation of Fuel Supply Business" and "Heating Fuel Sales" chapters that seek to provide additional consumer protections



Statement Before
The General Law Committee
Tuesday, February 25, 2014

Re: Raised Bill 5262: An Act Concerning the Pharmacy Practice Act and Counterfeit Drugs

Good Afternoon Senator Doyle, Representative Baram and members of the General Law Committee. My name is Annik Chamberlin. I am a pharmacist and co-owner of Beacon Prescriptions Compounding Pharmacy in Southington, CT. We are a full retail pharmacy that also specializes in compounding custom medications including sterile preparations. I am also a member of the Connecticut Pharmacists Association and have been participating in a task force to evaluate the practice of compounding medications to ensure best practices and patient safety.

I am here today to speak on Raised Bill 5262 An Act Concerning the Pharmacy Practice Act and Counterfeit Drugs.

Section 1 clarifies the responsibility of the pharmacist when receiving prescriptions that state either "brand medically necessary" or "no substitution". We support those recommendations.

Section 2 creates new legislation for compounded medications. This is the section I would like to spend a few minutes sharing information from a pharmacist's perspective that will help you focus on this area.

Pharmacy compounding is the science of preparing personalized prescription medications for patients. Compounded medications are "made from scratch" – individual ingredients are mixed together in the exact strength and dosage form required for the patient. This method allows the compounding pharmacist to work with the patient and the prescriber to customize a medication to meet the patient's specific needs. The "art" of compounding medications has been the genesis of our profession dating back to ancient times. *Sterile* compounding is the preparation of custom medications for patients in a sterile environment to prevent contamination and maintain patient safety.

While we understand the basis of creating statutes in an attempt to prevent a tragedy such as the one that occurred in Massachusetts, we appreciate the opportunity to have a dialogue and talk about how pharmacists currently compound, and that any additional legislation is meaningful and does not create burdens and costs that adversely impact the critical work flow that compounding medication demands.

The United States Pharmacopelal (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. USP created the standard 797 as oversight and guidance to sterile compounding practice. The state currently requires sterile compounding pharmacies to comply with USP 797. After reviewing the draft of the proposed legislation we are providing comments for your consideration.

Section(b) Language in the third line states that a facility that intends to compound sterile pharmaceuticals for use in CT "for the first time..." needs clarification.

Rationale: the pharmacists think that language referring to "for the first time" should be clearer. For example; what if a pharmacy provided sterile compounding for a period of time, stopped for a few years, and then resumed. According to the current wording, this pharmacy does not meet the "first time rule." Suggestion was to say for the first time ever or within 2 years from the date of last inspection.

...please see reverse

Section (d)(2) Need to consider changing the last sentence to from a two-week supply to a 30 day supply as follows:

A sterile compounding pharmacy may prepare and maintain on site anticipatory inventory of sterile pharmaceuticals no greater than a 30 day supply calculated from the completion of compounding including the third party analytical testing per USP 797.

Rationale: Testing now takes approximately 25 days to complete. To do this for a 14-day supply becomes counter-productive and costly.

Section (e)(2) Remove the last two sentences of this paragraph.

Rationale: If the pharmacy remodels, relocates, upgrades or repairs something that requires sterile recertification....to be performed by an independent licensed environmental monitoring entity, the pharmacy should be required to "show evidence" of recertification but should not have to wait for "approval from the department" to resume sterile compounding. This could be laborious to the agents and could be problematic for the pharmacy when a simple notification or proof of recertification could suffice.

Section (g)(1)AND (2) requires notification of patients, care giver, practitioner and the department by the end of the next business day.

Rationale: There was some concern that if the product was provided to a large volume of patients that the next business day may not be enough time to. Perhaps some language could be added to state by the end of the next business day or a reasonable time period based on volume.

Section (j) First sentence should have language added to state....by the nonresident pharmacy's home state regulatory oversight agency every 2 years.

Rationale: They should be held to the same standards as resident pharmacies.

I also have some additional comments:

Suggestion: There should be language that exempts a pharmacy from this statute if they are an "outsourcing facility" and following GMP.

Suggestion: There was strong agreement that if an "outsourcing facility" is operating in our state that there should be a requirement to have a pharmacist in charge on site.

Suggestion: There should be an Advisory Board comprised of experts in both sterile and non-sterile compounding to augment the efforts of, and assist the pharmacy commission or the DCP Commissioner, in standards of practice for sterile and non-sterile compounding pharmacies.

Rationale: While USP 797 is an important guideline, interpretation is sometimes left up to individuals that may not have the experience in the standards of practice. An Advisory Board could enhance the knowledge and practical applications of the inspectors in a collaborative and productive fashion.

We support of the remaining sections of this legislation with one additional comment. Section 8(b) we would like it to read that "No person shall knowingly purchase for resale, sell, offer for sale or deliver in any manner a counterfeit substance".

Thank you for your time in listening to the comments regarding the proposed regulations. The Connecticut Pharmacists Association and the compounding pharmacists in the state stand ready and available to continue to provide information and expertise on this issue to your Committee as needed.



OPPOSE HB 5262

Joint Committee on GENERAL LAW
February 24, 2014

Respectfully submitted by Heather R. Cascone – Director, Government Affairs

Thank you for the opportunity to submit our testimony on HB 5262, an act concerning pharmacy practice. Express Scripts respectfully opposes the bill.

Express Scripts is pharmacy benefit manager, or "PBM," and it is our goal to make prescription drugs safer and more affordable. We believe HB 5262 would restrict our ability to implement important plan management programs – tools that plan sponsors use to help keep costs down – and ultimately drive up the cost of pharmacy care for the state and its employers.

Section 3(a) of the bill amends the definition of "nonresident pharmacy" to mean any pharmacy located outside the state that "provides any aspect of the practice of pharmacy to residents of this state." We believe this definition would create an overly burdensome regulatory landscape which would drastically increase the number of pharmacies over which the State Board of Pharmacy would be responsible for oversight.

Section 5(a)(4) would require the reporting of "any disciplinary action taken against the nonresident pharmacy by any state or federal agency" to the Board. We are concerned that this reporting could result in duplicative punishment from the State Board of Pharmacy for non-resident pharmacies.

It is for these reasons we respectfully oppose HB 5262. If you have any further questions or concerns, please do not hesitate to contact me at (201) 269-6401 or heather_cascone@express-scripts.com.



**TESTIMONY OF
CONNECTICUT HOSPITAL ASSOCIATION
SUBMITTED TO THE
GENERAL LAW COMMITTEE
Tuesday, February 25, 2014**

HB 5262, An Act Concerning The Pharmacy Practice Act And Counterfeit Drugs

The Connecticut Hospital Association (CHA) appreciates this opportunity to submit testimony concerning **HB 5262, An Act Concerning The Pharmacy Practice Act And Counterfeit Drugs**. CHA opposes the bill as written.

Before outlining our concerns, it's important to detail the critical role hospitals play in the health and quality of life of our communities. All of our lives have, in some way, been touched by a hospital: through the birth of a child, a life saved by prompt action in an emergency room, or the compassionate end-of-life care for someone we love. Or perhaps our son, daughter, husband, wife, or friend works for, or is a volunteer at, a Connecticut hospital.

Hospitals treat everyone who comes through their doors 24 hours a day, regardless of ability to pay. In 2012, Connecticut hospitals provided nearly \$225 million in free services for those who could not afford to pay.

Connecticut hospitals are committed to initiatives that improve access to safe, high-quality care. They are ensuring that safety is reinforced as the most important focus—the foundation on which all hospital work is done. Connecticut hospitals launched the first statewide initiative in the country to become high reliability organizations, creating cultures with a relentless focus on safety and a goal to eliminate all preventable harm. This program is saving lives.

Generations of Connecticut families have trusted Connecticut hospitals to provide care we can count on.

HB 5262 contains important changes to various pharmacy laws designed to protect patients. CHA supports these efforts to protect patients, but we wish to set forth some necessary clarifications to avoid unintended negative consequences for patient care.

Section 1 of HB 5262 seeks to clarify how a prescribing practitioner can require a pharmacist to fill a prescription with a brand-name-only drug; it prohibits a pharmacist from making a generic substitution. We have concerns about the implementation of this requirement. For this to function properly, electronic prescribing systems will need to be reprogrammed, and physicians and other prescribers will need to be retrained. We ask that more time be allowed for implementation by making the effective date January 1, 2015 instead of July 1, 2014.

Without the additional time, we are concerned that some patients may not have access to the drugs they need.

Sections 2 through 6 of HB 5262 are targeted at compounding and out-of-state pharmacies that may not have sufficient oversight or controls to ensure safe drug preparation and safe manufacturing. Over the last year, Connecticut patients and Connecticut hospitals were faced with alarming situations caused by out-of-state compounding pharmacies that delivered inferior and, in some cases, dangerous products. We fully support the Department of Consumer Protection moving forward with efforts to rein in pharmacies that do not meet basic levels of safe practice. But CHA believes that the bill as written would have the unintended consequence of applying similar controls to hospital pharmacies, which have not been the source of any such problems.

Specifically, we believe that hospital pharmacies should not be required to obtain a manufacturer's license, or be regulated in the same manner as compounding pharmacies, when preparing compounded preparations for their own use and their own patients. To avoid such over-inclusion, we respectfully ask that an exception be made for hospital pharmacy by making the following change to Section 2(a)(1):

(1) "Sterile compounding pharmacy" means a pharmacy, an institutional pharmacy within a facility licensed pursuant to section 19a-490 of the general statutes other than a hospital, or a nonresident pharmacy as defined in section 20-627 of the general statutes, as amended by this act, that dispenses or compounds sterile pharmaceuticals; and

We also request adding the following sentence to the end of Section 6(a):

For the purposes of this section, a pharmacy within a Connecticut licensed hospital shall not be considered a compounding pharmacy.

Additionally, HB 5262 seeks to increase oversight of companies that trade in counterfeit substances, including mislabeled or falsely identified drugs. CHA supports giving the Department of Consumer Protection the authority to investigate and, if necessary, take action against companies that intentionally falsify labels or pass along counterfeit substances, including drugs.

CHA believes, however, that such a law should not also apply to the innocent victims who may be duped by these malevolent actors. Under Section 8 of HB 5262, a pharmacy, physician, or hospital that dispenses or purchases a drug that is falsely labeled or otherwise counterfeit would be in violation of the law – despite the fact that the pharmacy, physician, or hospital was an innocent victim of the fraud. To remedy this, we suggest that Section 8 of the bill be changed.

Section 8 of HB 5262 is designed to expand on a law passed in the 2013 Legislative Session concerning General Statutes Section 21a-432, which included the “knowingly” element to be in violation of the prohibition against counterfeit substances. We believe that, without restoring the “knowingly” element, Section 8 of HB 5262 is particularly unfair to unsuspecting victims of fraud.

CHA respectfully requests that Section 8(b) of HB 5262 be amended as follows.

(b) No person shall **knowingly** purchase for resale, sell, offer for sale or deliver in any manner a counterfeit substance.

Thank you for your consideration of our position. For additional information, contact CHA Government Relations at (203) 294-7310.

AMEND**Raised Bill**
No. 5262

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TESTIMONY TO AMEND SECTION 1 SUBSECTION C OF RAISED BILL
NUMBER 5262 (TWO ATTACHMENTS – MEDWATCH FORM, ARTICLE 70
MILLION AMERICANS ON MIND ALTERING DRUGS)

***AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT
DRUGS***

Section 1. Subsection (c) of section 20-619 of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2014*):

insert: the practitioner shall provide in writing information regarding accessibility and availability of the federal MEDWATCH reporting system, which shall include email address, website, and 800 phone number of the MEDWATCH reporting system.

Ablechild appreciates the opportunity to submit testimony to the Committee of General Law about the need to ENSURE that consumers are made aware of the existence, and availability, of the federal Food and Drug Administration's MedWatch System as part of ***AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS***. This is to ensure that consumers are made aware of the availability of the MedWatch System.

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Amend 5262

What Ablechild is proposing does NOT require additional funding.

The FDA's MedWatch System was instituted in 1993 and is intended to provide important information to the federal agency from health care professionals and consumers. The reporting of drug adverse events to MedWatch can prompt the FDA to act on updating safety information, make labeling changes, influence how patients receiving drug products should be monitored, and issue warnings, safety messages and even prompt drug recalls.

The MedWatch system is completely voluntary, private and there are no costs associated with its use.

Due to the lack of knowledge about the MedWatch system, the FDA acknowledges that it receives less than one percent of all adverse reactions that actually occur.

The MedWatch system is the front-line defense against products that may pose safety hazards to consumers and, in short, saves lives.

The Sandy Hook investigation revealed how the MedWatch system could have benefited Nancy Lanza had the information been provided.

Despite advising the healthcare professional at the Yale Child Study Center that Adam Lanza had experienced an adverse reaction to the antidepressant he had been prescribed, no information about reporting this adverse event to MedWatch was provided to Nancy Lanza. Nor is there any record of the healthcare provider reporting the event to MedWatch.

It is precisely this type of information that the FDA wants to know. Yet, as is seen in the case of Nancy Lanza's concerns about the drug Adam was prescribed, no one made any effort to report the adverse reaction to MedWatch.

Ablechild is simply requesting that practitioners make available in writing (website address, email address, and 800#) to consumers information about accessibility of the MedWatch Drug Reporting System.

It is important to remind lawmakers that there currently are 70 million Americans prescribed mind-altering drugs.

There is no downside to implementing a MedWatch education program in the State.

MEDWATCH FORM

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf>

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<http://www.dailymail.co.uk/news/article-2555950/70-MILLION-Americans-mind-altering-drugs-shock-statistic-shows-extent-use-legal-legal-narcotics.html>

70 MILLION Americans are on mind-altering drugs

- **One in Five adults take prescription psychiatric drugs**
- **Prescription drugs are the second most common substances to be abused**

-
- **27,000 unintentional drug overdose deaths occurred in the United States**
 - **250million prescriptions for anti-depressants were written in 2010**
 - **10 per cent of high school pupils are prescribed drugs for ADHD**
 - **Anti-depressants have been linked to a series of school shootings**

By Tom Gardner

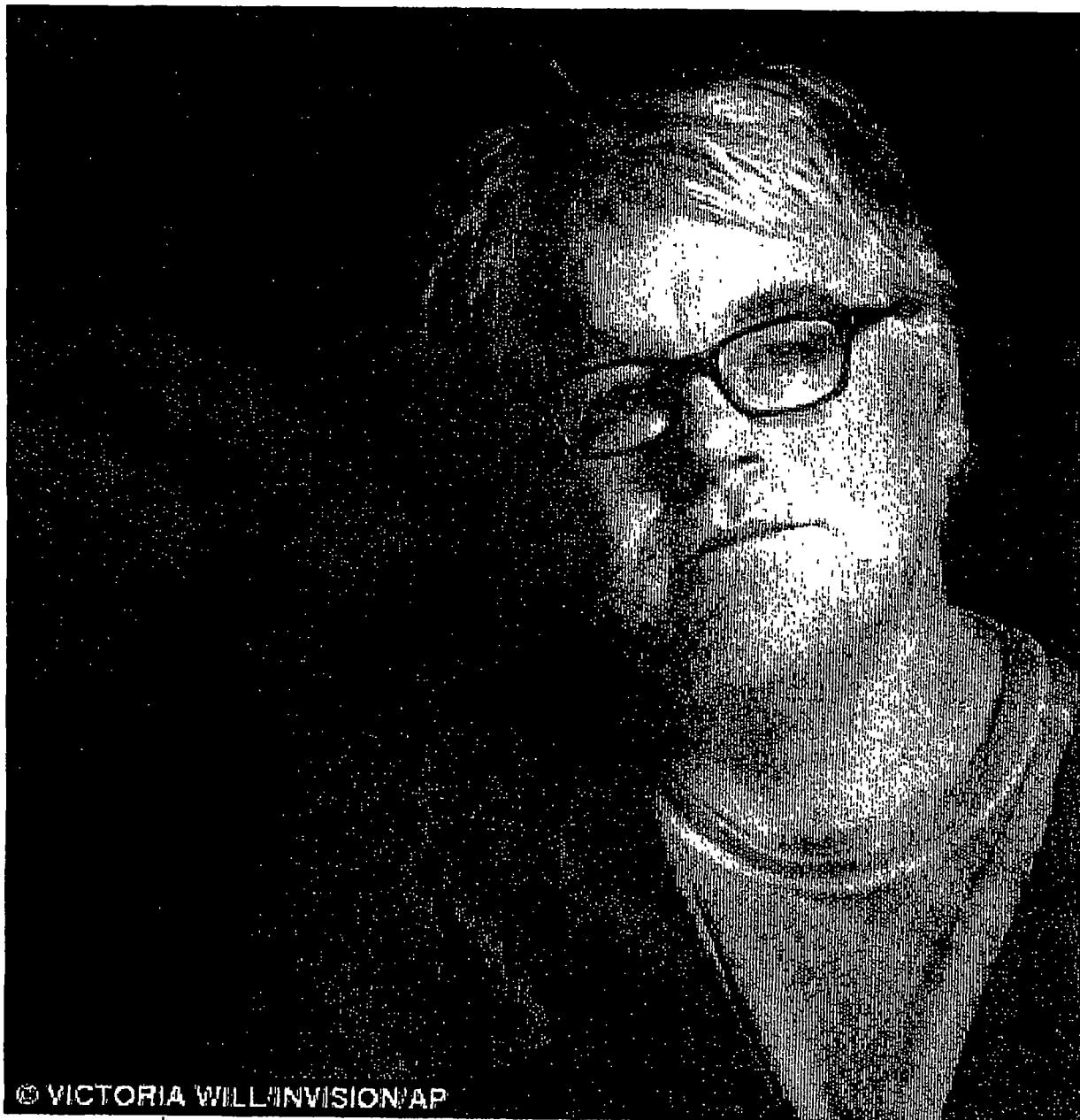
PUBLISHED: 12:21 EST, 10 February 2014 | **UPDATED:** 12:10 EST, 12 February 2014

More than 70million Americans - or one in five of the population - is on mind-altering drugs, a new study reported by WND.com has found.

The shocking survey revealed that prescription drug abuse as well as illegal narcotics use has reached epidemic proportions across the country.

Nearly 50 million people are thought to have been given high-strength substances by their doctors - leading to an alarming spike in drug-related deaths.

The death of movie star of Philip Seymour Hoffman from an apparent heroin overdose again promoted the spectre of illicit substances in the country's psyche.



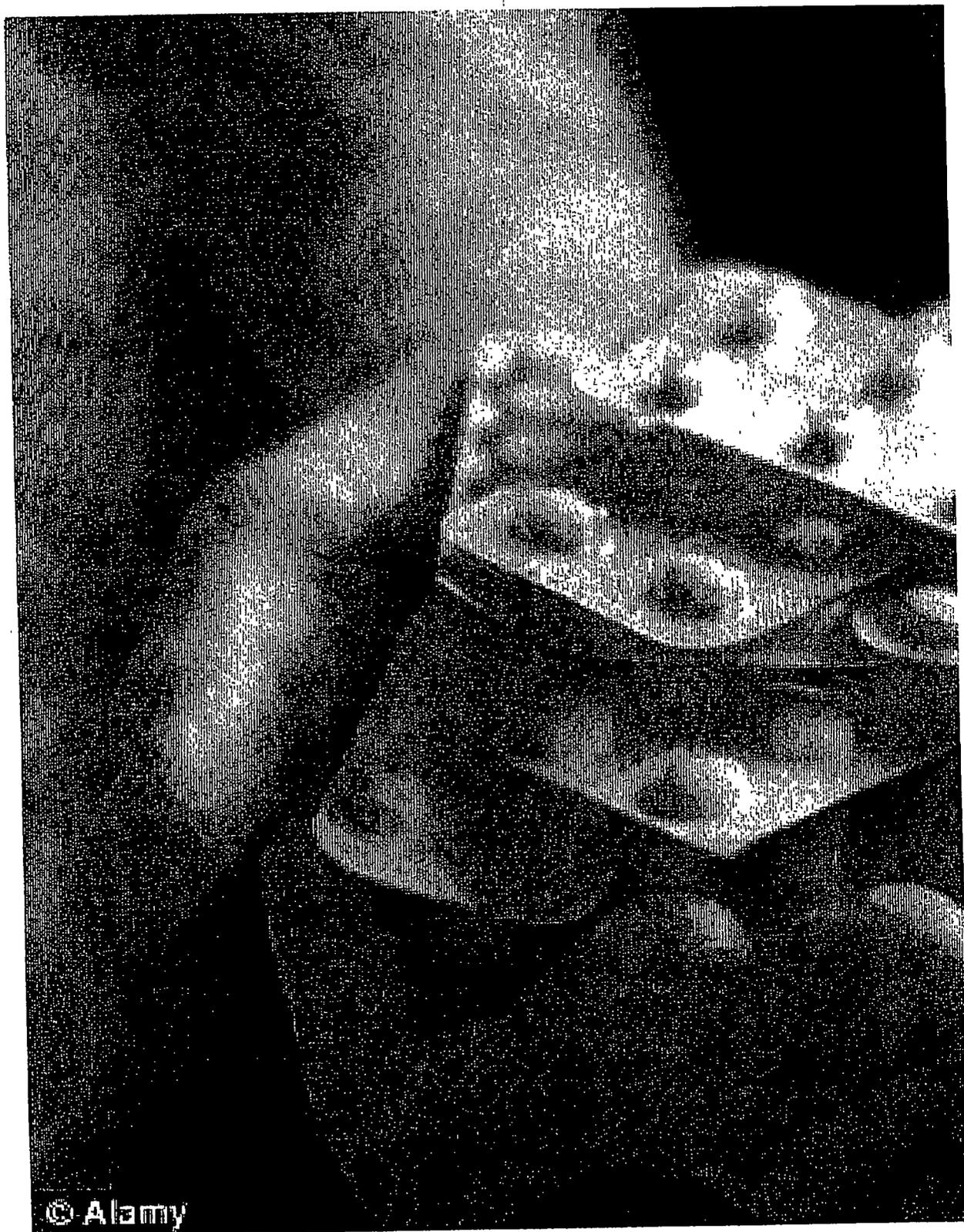
Overdose: Philip Seymour Hoffman was found dead in his New York apartment in a suspected heroin overdose

But new research by the Centres for Disease Control and Prevention has suggested the far greater hazard is posed by over the counter prescription drugs, such as anti-

depressants, sleeping pills and anxiety relief substances.

Experts have warned legal substances caused more overdose deaths than heroine and cocaine combined during the past decade, according to the U.S. report.

In 2010 more than 250 million prescriptions for antidepressants were written for Americans.



Shock: More than 27,000 people died in a single years as a result of an unintentional overdose on prescription drugs

A staggering 27,000 unintentional overdoses deaths were ascribed to prescription drugs in a single year, the Centres for Disease Control and Prevention found.



Experts have warned that prescription drug addiction has reached epidemic proportions

The organisation was so alarmed by the figures, its report noted, WND reports, that: 'Prescription drug abuse is the fastest growing drug problem in the United States.'

For the last decade, 'more overdose deaths have involved opioid analgesics than heroin and cocaine combined.'

It feared the rise in the rate of opioid analgesics prescriptions – drugs marketed under the brand names Norco, Vicodin, Dilaudid, Exalgo, OxyContin, Percocet, Astramorph, Avinza - was likely to drive the trend even higher in the coming years.

The dangerous implications of so many people being prescribed these powerful mind-altering substances are finally being understood.

Recent research is beginning to draw a link between a popular sleeping pill called Ambien and - called as a hypnotic drug - to a series of crimes and serious accidents.

The drug was famously thought to have been a factor in a car crash involving the Republican Patrick Kennedy.

Research into school shootings and violence among young people is finding links with the use of anti depressants.

Four and nine million by most estimates, mostly boys – to take Ritalin or similar dangerous psycho-stimulant drugs which can have similar side effects to cocaine or the amphetamines.

19 percent of high school-age boys in the U.S. are being diagnosed with ADHD and about 10 percent are currently being prescribed drugs for it, while 10 percent of high school-age girls are being likewise diagnosed.

Dr. William Gräf, a pediatric neurologist in New Haven and Yale medical professor told the New York Times: "Those are astronomical numbers. I'm floored."