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RPTS MCKENZIE

DCMN HOFSTAD

REFORMING THE DRUG COMPOUNDING REGULATORY FRAMEWORK

TUESDAY, JULY 16, 2013

House of Representatives,  
Subcommittee on Health,  
Committee on Energy and Commerce,  
Washington, D.C.

The subcommittee met, pursuant to call, at 3:05 p.m., in Room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Ellmers, Dingell, Schakowsky, Green, Barrow, Christensen, Castor, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Sean Bonyun, Communications Director; Noelle Clemente, Press Secretary;

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Paul Edattel, Professional Staff Member, Health; Julie Goon, Health Policy Advisor; Sydne Harwick, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Oversight; Alli Corr, Minority Policy Analyst; Eric Flamm, Minority FDA Detailee; Elizabeth Letter, Minority Assistant Press Secretary; Karen Lightfoot, Minority Communications Director and Senior Policy Advisor; Karen Nelson, Minority Deputy Committee Staff Director for Health; and Rachel Sher, Minority Senior Counsel.

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Mr. Pitts. The time of 3 o'clock having arrived, we will call the meeting of the subcommittee to order.

The chair will recognize himself for an opening statement.

As we all know, in the summer and fall of 2012, a Massachusetts company, the New England Compounding Center, NECC, shipped over 17,000 vials of an injectable steroid solution from three contaminated lots to healthcare facilities across the country. And after receiving injections of NECC's contaminated steroid, over 50 people died from complications associated with fungal meningitis and 700 others were stricken with meningitis and other persistent fungal infections. The outbreak ranks as one of the worst public health crises associated with contaminated drugs in the history of the United States.

Shortly after the contamination came to light, the committee began an investigation into the matter, requesting documents from the Food and Drug Administration and the Massachusetts Department of Public Health, examining whether the outbreak could have been prevented and reviewing existing Federal and State regulatory authority over compounding pharmacies acting as manufacturers.

Both this subcommittee and the Oversight and Investigations Subcommittee have held multiple hearings on the issues surrounding compounded drugs. Today's witnesses are here to discuss three legislative proposals released since the outbreak, including a discussion draft authored by my colleague, Morgan Griffith.

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[The information follows:]

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Mr. Pitts. The Griffith draft includes targeted provisions that both clarify FDA's authority as it relates to Section 503 of the Food, Drug, and Cosmetics Act, while ensuring that traditional compounding remains within the purview of State boards of pharmacy.

I would like to welcome our witnesses.

And I will yield the balance of my time to Representative Griffith.

[The prepared statement of Mr. Pitts follows:]

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Mr. Griffith. Thank you, Mr. Chairman. I appreciate that very much.

The fungal meningitis outbreak that was associated with the tainted sterile compounded drugs from the NECC is something that I have followed since the beginning. Obviously, you are always concerned when something affects anybody in the United States but particularly when it has the impact that it had in my district and in the areas immediately around my district, where we had 2 deaths, 50 confirmed cases, approximately 1,400 patients that were notified that they had gotten the tainted injects, creating great concern.

Now, I do acknowledge, and we have had hearings on it -- and, Dr. Woodcock, you have been very good about answering my questions, and I appreciate that -- where we looked into it and found that the split in the circuits was caused by the issue on the advertising portions of the original bill. And as we previously discussed, it is a shame that this issue wasn't taken up sometime ago, but it wasn't. And we are here now, and we are going to try to clarify the law to make sure that we don't have this problem again. And I appreciate the fact that you are going to help us work on that.

You know, we have been following this. And what we want to do is make sure that we do, as the chairman said, protect public health and ensure that small businesses, like the 130 legitimate community pharmacists that are located in my area, are not subject to unnecessary

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and burdensome Federal regulations. I also recognize the importance, as a former State legislator, that we continue to have the States be primary over the true local compounding pharmacies.

We have before us a draft. We are still working on it. We want to clarify the FDA's authority in this realm, particularly in regard to compounders who try to pretend that they are not manufacturers. And that is sometimes difficult, and I understand that, but we think that we have a bill that will help on that.

There are still questions that we are trying to get answered from stakeholders to complete the legislation. That is why in the draft you will see a couple of places where we have some blanks. I am proud to be trying to work out those differences with my colleagues across the aisle, Congressman Green and Congresswoman DeGette, to see if we can reach a bipartisan consensus and something that works to protect the health of Americans and protect the interests of small compounding pharmacies, which provide a great service to our public.

My goal has always been to draw a clear line on defining what a traditional compounding pharmacy is, and that should be regulated by the States, and what a manufacturer, a drug manufacturer is, which properly should be regulated by the FDA.

I look forward to today's hearing and from hearing from all of our witnesses as we continue this process to clarify FDA's authority when it comes to compounding pharmacies.

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And I thank you, Mr. Chairman, for this opportunity and yield back my time.

[The prepared statement of Mr. Griffith follows:]

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Mr. Pitts. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

Mr. Waxman. Thank you, Mr. Chairman.

It has been 10 months since we saw the tragic fungal meningitis outbreak caused by the New England Compounding Center in Massachusetts. More than 60 people have died, over 740 people were sickened, and more than 13,000 others in 20 States are still waiting to see whether they will get meningitis. This is the largest outbreak of healthcare-associated infections in U.S. history and one of the Nation's worst public health disasters in recent memory.

We have learned a lot through our investigation, especially that FDA's authorities over compounding pharmacies are broken and inadequate. And I am glad we have finally begun the process of repairing them.

FDA has repeatedly testified that the agency desperately needs new authority to protect the public from another contamination incident. The agency has described how circuit court decisions have forced FDA to cobble together a piecemeal approach to regulating compounding pharmacies that are different in some parts of the country that in others. This has created loopholes that companies, like the New England Compounding Center, have been able to exploit.

FDA has also described the fact that the pharmacy compounding

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industry has changed dramatically since 1997, when Congress last legislated. Hospitals have grown dependent on so-called outsourcers, which are very large compounding pharmacies that mix batches of customized drugs for a particular hospital.

FDA says it is not enough to simply fix the defect in the current statute. We need a new paradigm to handle this new state of affairs. The reason we need a new paradigm is that the new class of outsourcers does not fit neatly within the binary structure that exists in the current statute. They are neither traditional compounders nor drug manufacturers, so we need to tailor FDA's authorities to fit the reality that the agency faces.

But we also need to ensure that we properly circumscribe what these outsourcers can make so that they cannot become an avenue for undercutting FDA's gold-standard drug approval process. FDA needs strong records-inspection authority to be able to determine whether a compounding pharmacy is performing only a traditional compounding or has crossed the line into becoming an outsourcer or even a drug manufacturer.

In addition, these nontraditional compounders or outsourcers need to register with the FDA and tell FDA what drugs they are producing. They should be required to follow good manufacturing practices as set by the FDA and label their products as compounded so that healthcare providers and patients know that the products are not FDA-approved

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drugs.

As illustrated by the recent tragedy, these entities should also be required to promptly report adverse events to FDA so that FDA and the States can work together to identify dangerous compounded drugs and prevent them from reaching consumers.

In order for FDA to be successful at carrying out these new authorities, we need to ensure that FDA has a steady stream of resources. We will not have accomplished much if we enact a new statutory scheme but deny the FDA the dollars it needs to use its new authorities.

We have learned that there is a gaping hole in our drug safety laws. American families expect us to work together to develop an effective legislative response, and we need to do this as quickly as possible. We know that, otherwise, it will not be if another dangerous catastrophe occurs with compounded medicines, but when.

Thank you, Mr. Chairman. I yield back the balance of -- unless any of my colleagues on the Democratic side would like the minute?

Okay. I yield back the time.

[The prepared statement of Mr. Waxman follows:]

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Mr. Pitts. The chair thanks the gentleman and recognizes the vice chairman of the committee, Dr. Burgess, for 5 minutes for an opening statement.

Dr. Burgess. Thank you, Mr. Chairman.

You and the ranking member have said it very well. This is a continuation in this committee's examination of the meningitis outbreak that was caused by contaminated methylprednisolone acetate prepared in a preservative-free fashion that killed 53 Americans and harmed over 700, many of whom will suffer for the remainder of their lives with significant medical complications.

So 53 Americans are no longer here because the Food and Drug Administration refused to use their statutory authority to enforce existing regulations. I am willing to update the authority that the FDA already has. I don't know that I am willing to vest the FDA with new authority.

Besides refusing to use their existing statutory authority, the Food and Drug Administration is stalling the process to clarify existing regulations. We have been meeting for weeks now, both this subcommittee and the Oversight and Investigations Subcommittee, trying to determine how best to clarify existing regulations.

The Food and Drug Administration refuses to give an inch. They say they want clarity. Well, when we ask what kind of clarity, there is no answer. When we suggest a volume limitation by which to define

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a manufacturer, they say it is not workable. When we suggest a time period to determine whether an entity is a manufacturer, we get back, "It is not workable."

So my ask to the FDA is: Stop telling us it is not workable, and start helping us with a practical solution. If you are holding out for a power grab for a vast, new, unfunded authority, I am not going to help you get there.

So far, the only thing I have heard from the Food and Drug Administration are complaints about sequestration. I get it. They complain that user fees don't address their financial needs, especially under sequestration. I really get it. But to have the Food and Drug Administration come to Congress, seeking completely new user fees and authorizations to inspect facilities, when existing regulations clearly give the authority to inspect anyone who is a manufacturer, I have to tell you, I just don't get it.

The fact that the Food and Drug Administration has continued to inspect facilities -- they have closed facilities. How are they inspecting these facilities if they have no authority to do so?

Representative Griffith's bill represents the best effort to date to address some of the FDA concerns while adhering to the spirit of the law. And I am comfortable supporting that bill. But, honestly, all the laws in the world are not going to save a single patient if there is no one enforcing the law.

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We read the chain of emails from two administrations of the Food and Drug Administration. It was painful to read those emails. They would come right up to the edge, right up to the point where they might close someone down, and then say, well, we can't send another warning letter because we have already sent too many, so we don't know what to do. Well, I know what to do: Close the place down. It was the right answer, and it still is today.

Who at the Food and Drug Administration has been fired over this incident? Again, 53 Americans died, 700 are living with a disability. Who has been fired in this exercise?

So I would say enough is enough. Let's put pen to paper and make sure the bad actors are not able to hide from clear enforcement authority, but let's make sure the enforcement authority is actually going to be enforced.

Mr. Chairman, I thank you for the time, and I yield back to you.

[The prepared statement of Dr. Burgess follows:]

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Mr. Pitts. The chair thanks the gentleman.

I would like to thank all of our witnesses for coming.

On our first panel today, we have Dr. Janet Woodcock, director of the Center for Drug Evaluation Research of the U.S. Food and Drug Administration.

Thank you very much for coming, Dr. Woodcock. You will have 5 minutes to summarize your testimony. Your written testimony will be entered into the record. So, at this time, you are recognized for 5 minutes for your opening statement.

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**STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION  
AND RESEARCH, FOOD AND DRUG ADMINISTRATION**

Dr. Woodcock. Thank you.

Since the last hearing before this subcommittee, which was just 7 weeks ago, we have had another multi-State outbreak involving contaminated methylprednisolone acetate, preservative-free. Even with all the publicity and attention surrounding this problem, we are still seeing multiple contaminated compounded products on the market.

We really appreciate the committee's interest in exploring legislative options to try to help prevent future tragedies. And I would like to start with what I think are the common legislative goals I hope we all share.

Any legislation that is passed should provide clarity so that people know who is on first -- FDA, the States, compounders, and healthcare providers all know their roles and responsibilities and obligations under the law.

We feel that there should be a legal framework that is a better fit for the industry that has now evolved and is well beyond compounding by a corner pharmacy for a single patient, by prescription, in response to a practitioner from a medical need. It has gone well beyond that. We have outsourcers who supply large amounts of sterile products to

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hospitals across the country.

Enforceability: We need legislation that we can implement on the ground, that we can actually make work, and is resourced to be successful.

We need to preserve the benefits of traditional compounding. We have always recognized these benefits, where there is a medical need not met by the products that are FDA-approved. And we need to preserve the ability of pharmacists to compound and physicians and other prescribers to order compounded products to meet those medical needs.

And, most importantly, we need better protection of the public by bringing the highest-risk practices under Federal oversight. This includes really focusing on prevention rather than reaction when outbreaks are occurring.

We want to work with you to achieve those goals. We believe that for the highest-risk compounding pharmacies we do need legislation that requires Federal registration so we know who they are and where they are, that holds them to Federal quality standards, which we call the GMPs, for production, that also requires the compounders to tell us when serious adverse events related to their products are reported to them so that we can intervene before these problems get out of hand.

And we think for all pharmacy compounding, certain basic protections should be in place, including clear authority for us to inspect records so we can determine the cause of an outbreak or decide

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whether a compounder actually fits into the highest-risk category; restrictions on compounding complex products that even conventional drug manufacturers, who test their products, find difficult to produce safely; and a requirement to start with safe and high-quality ingredients when you are compounding.

And, finally, we feel that clear labels on compounded drugs to allow prescribers and patients to make informed choices are important.

We appreciate the leadership of Mr. Griffith, Mr. Markey, and the Senate HELP Committee in drafting legislation to try and tackle these issues. It is not easy. While the administration has not taken a position on any of these bills, I am happy to provide my views on the extent to which they address the goals that we have for any new compounding legislation.

The fungal meningitis outbreak has been a nightmare that continues for over 700 people sickened by these drugs and their families. And it is just the worst of a long series of outbreaks over the past 2 decades that include deaths, blindness, and hospitalizations.

And this continues. As we proceed with our inspections -- we have had 61 and counting -- of the industry, we continue to see a pattern of profoundly disturbing lapses in basic sterile practices that should be in place to assure the sterile drugs -- the drugs that are injected in the blood, the spine, the eye, and so forth -- are actually sterile.

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So I reiterate my statement from the hearing you held 7 weeks ago. It is a matter of when this is going to occur, not whether it is going to occur. We owe it to the public and the victims of this incident and the numerous other outbreaks over the years to enact legislation that provides better protection in the future.

I look forward to answering your questions.

[The prepared statement of Dr. Woodcock follows:]

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Mr. Pitts. The chair thanks the gentlelady.

And I will begin the questioning and recognize myself for 5 minutes for that purpose.

Dr. Woodcock, isn't it true that, assuming the circuit split ambiguity is resolved, FDA now has the authority to regulate nontraditional compounders as manufacturers?

Dr. Woodcock. Yes, that is true.

Mr. Pitts. Doesn't that mean that FDA could already require that such compounders pay user fees and submit applications to show that they can produce drugs under GMP conditions?

Dr. Woodcock. That is a possible outcome. We would have to find out who they are, because they don't register, and where they operate. And it is possible even if we close one entity down, another could quickly grow up.

There is no real preventive structure here; this is a reactive structure that would rely upon us finding these folks and taking action. And it isn't clear in the judiciary if we would prevail because of still-remaining ambiguities in the law.

Mr. Pitts. In your testimony, you note that there is need for appropriate and effective oversight of the pharmacy compounding industry. According to the FDA, this industry and the healthcare industry have evolved and outgrown the law.

How do you recommend we draft this legislation to ensure that this

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industry does not outgrow this legislation?

Dr. Woodcock. Well, I think one of the keys -- and I recognize it is very hard -- is making that distinction between traditional pharmacy compounding, which was for a single patient, medical need, prescription for that compounded product, and the kind of practices that are going on now. And those practices involve making large batches often, small to large batches, and of course shipping them many places, often without a prescription.

Mr. Pitts. Now, are large-scale compounders, compounding manufacturers we would call them, more similar to pharmacies or manufacturers? What qualities do they share with manufacturers?

Dr. Woodcock. They share with manufacturers the fact that they are manipulating drug products and making them in batches, large to small batches, and shipping them to various places.

They share with pharmacies that many of the practices that they are doing used to be done in the hospital pharmacy, and the hospital pharmacies have outsourced much of these operations because they don't have the appropriate facilities. But, frankly, no one is looking to see if these new outsourcers have the appropriate facilities and practices.

Mr. Pitts. Considering that they are more similar in function to manufacturers, should they be regulated within the manufacturing framework?

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Dr. Woodcock. They are similar but not identical. Most of them make large numbers of different products in much smaller amounts than a pharmaceutical manufacturer would make. Many of them are starting from FDA-approved products and putting them in syringes or little IV bags and all sorts of things for the particular doctor or practice or hospital and what their needs are, all right?

So if you wish to have NDAs and the entire panoply of the FDA review process, what we do for regular pharmaceutical manufacturers, this industry could probably not exist, all right? So that is a choice that you have to make. Do you create a new framework that encompasses this, or do you want to stick to the current binary structure that we have?

Mr. Pitts. Would it be better to regulate large-scale compounders under the manufacturing standards rather than establishing a new category?

Dr. Woodcock. We believe that the main issue with these large-scale, especially sterile, compounders is that they are not following what we call aseptic processing practices that are appropriate, which are part of our good manufacturing processes, okay, and practices.

And we feel that if that was required, to use appropriate sterile processing and certain other aspects of the good manufacturing practices, that they could make quality products that would be safe.

Mr. Pitts. Under the proposed Senate framework, FDA would be

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barred from requiring compounding manufacturers to submit NDAs and ANDAs pre-inspection and labeling requirements before these drugs reach patients.

Would any of these tools be available to FDA as it relates to compounding manufacturers, even if agency regulators identified high-risk compounding manufacturers where they, upon inspection, thought such tools were appropriate to utilize in order to protect public health?

Dr. Woodcock. Well, we need to have tools that prevent this industry in general from subverting the new drug review process and the generic drug review processes that were established by Congress a long time ago and have served us very well. So there have to be provisions that make a distinction between what constitutes manufacturing a new drug or a generic drug and these practices. And that is not easy or straightforward to do.

But we have proposed that for all compounding pharmacies that there be certain things that they would not be doing. They would not be making copies of FDA-approved drugs, for example. Why would you need a higher-risk product if there were approved drugs available?

We have also proposed that medical need might be a criterion. That is really the reason you use a compounded drug, is because there isn't an FDA-approved drug available for that medical need. And so that is the reason that compounding exists, to meet that need.

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Mr. Pitts. Thank you. My time has expired.

The chair recognizes, filling in for Ranking Member Pallone, Mr. Green of Texas, for 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Dr. Woodcock, thank you for continuing your willingness to advise the subcommittee on this subject. The question that has been at the forefront of our policymaking is how to establish a bright line between State and Federal jurisdiction between the traditional compounders and those operating closer to manufacturers. No approach is without its challenges, and certainly none are perfect.

I understand that a lot of the FDA answers are premised on the fact that you cannot know what you don't know before you know it. However, under the assumption that you get the records inspection authority necessary to look at the records of the suspect entities, that there are other factors that Congress gives you to establish risk, such as sterility, interstate commerce, and the existence or not of a prescription.

With that in mind, how can we go about setting a production volume level threshold as a proxy for assessing risk? Other than the options that are on the table from the Markey, Griffith, and Senate drafts, how else can we go about targeting our regulations toward the highest-risk entities?

Dr. Woodcock. Well, one thing we don't want to do, in talking

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about volume or those types of things, is create a large loophole so that manufacturers can actually circumvent the entire legislation.

The problem with volume is that the traditional compounding volume unit is one. It is one compounded product that is made in response to one patient's medical need --

Mr. Green. Which is currently regulated under State law.

Dr. Woodcock. Yes. And that is the way it should be, we feel. That is a traditional pharmacy practice.

The risk of that is limited by many things. If you make one sterile product, one transfer, you have less personnel, you have less manipulations. Obviously, the exposure, if you make a lot, 17,000 or 7,000, then the risk is spread across many people. But the actual risk as you go from 1 to 10 to 100 increases, and so it is hard to make a bright line on --

Mr. Green. Okay. There is other criteria other than volume. Length of time. I have seen 7 days, we have seen 10 days. Because if you are warehousing this product on a shelf, it can deteriorate and bacteria can grow, which is, I assume, what happened up in Massachusetts. So we are looking at, also, some kind of timeframe for the use of that drug; is that correct?

Dr. Woodcock. Timeframe could be a criterion that could be used. You know, we have put forth criteria --

Mr. Green. Well, we are looking at multiple criteria, I hope.

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Dr. Woodcock. Certainly, the longer any sterile drug product is stored, or any drug product for that matter, the riskier it becomes.

And one of the reasons the hospitals gave the IG, when they did their survey, of why they outsourced the products is they say that compounded products have a longer beyond-use date. They might have up to 6 months. But, in our inspections, what we found is they didn't establish that by testing. They just maybe looked in a compendium or something and said, well, 6 months looks like a good beyond-use date. They had no data to back it up.

Mr. Green. Okay.

Dr. Woodcock, the National Association of Boards of Pharmacy are testifying on our second panel, and they suggest a revision of the FDA's proposed statutory framework for traditional compounders. Their goal is to allow patients to access limited amounts of compounding products made by traditional compounders in advance of a prescription when they are in clinics, doctors' offices, or other healthcare settings. And I would use the example of a hospital, for example, made by from a compounder because of, you know, the volume.

Specifically, one of the limitations they suggest is to limit the total quantity provided to a healthcare provider to a 10-day patient supply. What are your views on that?

Dr. Woodcock. Well, my understanding is that 10 days would be the amount that that entity, healthcare entity or clinic, whatever,

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needed for 10 days. Right? And so, say they needed 50 vials; they used up 50 vials in 10 days. And then the clinic shifted to 100 providers. That would be 5,000, right?

So I don't know that that is a very good -- and then you would make a batch of 5,000 and that would be okay. So I am not sure that is okay.

Mr. Green. Well, the other concern from your earlier testimony is that we want to make sure that that longevity, the efficiency of that compounding substance is actually 10 days instead of whatever you guess it is. Other pharmaceuticals have to show that their shelf life --

Dr. Woodcock. Yes. Under the GMPs, if we had Federal regulation of a sector, we would require that stability be demonstrated.

Mr. Green. Well, again, I am out of time, but I appreciate you working with both Congressman Griffith Congresswoman DeGette and I and our ranking members to see how we can get this right.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman and now recognizes the vice chairman, Dr. Burgess, for 5 minutes for questions.

Dr. Burgess. I thank the chairman.

So, Dr. Woodcock, you know, we have these large outsourcers. And is that part of the problem, you don't know who they are?

Dr. Woodcock. We have large outsourcers; we don't know who they

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are. They are doing a variety of things, including making a lot of convenience dosage forms for hospitals and clinics. They are also compounding from bulk for shortages, making hyperalimentation and so forth --

Dr. Burgess. Let me ask you a question about that then. Are they not already required to register with the Food and Drug Administration under Section 510 of the act?

Dr. Woodcock. Not according to them.

Dr. Burgess. But according to you. I mean, you are the enforcer.

Dr. Woodcock. If we can find them and we can conclude that they are, you know, violating -- that they are required to register. But, according to them, they are registered pharmacies in their -- whatever State, doing pharmacy operations.

Dr. Burgess. Those small pharmacies that compound as a result of receipt of a prescription, I mean, they are exempt under the law.

Dr. Woodcock. Yes.

Dr. Burgess. And there is value in that. I mean, we all get it, that if a kid needs Tamiflu and there is no pediatric formulation available, someone needs to be able to crush up the tablet and mix it with the cherry favoring so that the kid gets it. We all want that.

But this is not that situation. These are companies that make a large volume, and they make it not on receipt of a prescription. They

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make it well in advance of anyone ordering it. So, for all the world, they look like a manufacturer to anyone else.

Dr. Woodcock. Well, I wish the distinction were that simple. However, as I just stated, if you have a pharmacy that is making office stock and they are going to give that clinic 50 vials a week, all right, in response to a usual need, which is a practice in many States that is allowed, all right, and they have 100 customers, then they are going to be making a batch every week or perhaps every 2 weeks of 5,000 to 10,000 vials.

Dr. Burgess. But --

Dr. Woodcock. And is that different? I mean, they are allowed under the State pharmacy laws to have anticipatory compounding.

Dr. Burgess. So they would be regulated by the State boards of pharmacy, would they not?

Dr. Woodcock. Yes. They have to have a pharmacy license, uh-huh.

Dr. Burgess. So they are licensed and regulated. Now, when they engage in interstate sales, that seems like it would come under your jurisdiction, would it not?

Dr. Woodcock. My understanding is there are reciprocal licensing agreements amongst the various boards of pharmacy in all the different States.

Dr. Burgess. I just have to tell you, it doesn't sound like a

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gap in the statute, it sounds like an enforcement issue. And from everything that we received on the events leading up to the New England Compounding Center disaster, I mean, there were people within your agency over and over again that said, "Well, we can't just send them another warning letter. We have to actually do something." And then they would get to the point of doing something, and no one would do it.

Let me just ask you again. I mean, I assume there has been some sort of internal look at the breakdowns in the system as they existed in the Food and Drug Administration; am I correct?

Dr. Woodcock. Yes.

Dr. Burgess. And have there been disciplinary actions taken against any individuals?

Dr. Woodcock. Well, this is more a collective failure than an individual failure. We are now using our authorities very aggressively --

Dr. Burgess. Okay, let me stop you for a second. A collective failure, and we want to give you new authority? I mean, honestly, do you see the problem with that logic?

Dr. Woodcock. I understand your problem. However, we are right now being very aggressive in using our existing authority.

Dr. Burgess. Correct. And you are using that existing authority, and you are using it to the end that you are inspecting

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people, and you have closed some people down, have you not? I mean, before Main Street Pharmacy, you had closed other entities down. When either you or Dr. Hamburg came here earlier this year, you probably told us about some people you had closed down.

Dr. Woodcock. We have taken actions. You know, basically, the State boards of pharmacy have closed a number of entities down. We have taken other judicial actions. It remains to be seen if these are contested.

Dr. Burgess. Right. But the Food and Drug Administration has -- I mean, they have shown up with their official FDA jackets and seized records and seized product and closed facilities down, did you not?

Dr. Woodcock. We have done 61 inspections, and we found many serious violations of sterile practices and many products that are posing risk to the public.

Dr. Burgess. So this is what I just don't get. You have the authority, since October of 2012 or whenever it was that we decided to do this, but you didn't have it the year before. And nothing has changed in statute over that time. So you had the authority in 2006, 2007, 2008, 2009, did you not?

Dr. Woodcock. We had the authority we have now. We feel --

Dr. Burgess. Yes.

Dr. Woodcock. -- our authority is limited. But we can do the

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things that you say, and we are doing those.

Dr. Burgess. It doesn't look limited to somebody looking from the outside. It looks like you are exercising your authority and it is working.

Dr. Woodcock. Well, for example, we have received reports of contaminated products and injuries of people from pharmacies we have never heard of. Now, it is hard for me to imagine -- you know, I am somebody who is an executive. Okay, manage things. How am I going to find these and anticipate that they are going to cause problems and shut them down if I have never even heard of them?

Dr. Burgess. Well, Mr. Chairman, I know my time has expired.

I may ask you this question in writing. I would just really like to know how you expect to do that under the new authority that the Senate bill is proposing or that Mr. Markey has proposed.

But I will yield back my time, Chairman.

Mr. Pitts. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for questions.

Mr. Waxman. Thank you, Mr. Chairman.

There was a provision, Dr. Woodcock, in the bill that Mr. Griffith introduced that I want to ask you about. It says that so long as a company holds a valid State pharmacy license and receives assurances from the healthcare providers to whom they are sending compounded drugs

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that the providers will send back prescriptions within 7 days after administering the compounded drug, that the company is considered to be doing traditional pharmacy compounding within the scope of State law.

In other words, regardless of the quantity of compounded medicines a company is making and whether the company is shipping those medicines all over the country, so long as that company receives prescriptions from their customers within 7 days after the medicines are actually given to the patient -- who knows when that will be -- there will be no Federal oversight of that company.

This seems like a particularly dangerous structure to me. It would allow a company like NECC, which caused the fungal meningitis outbreak, to operate freely without FDA oversight so long as it made a relatively minor change in its business practice: keeping copies of prescriptions sent to it after the fact.

Now, I am sure that wasn't the intent of the provision. And, actually, this provision is based on FDA's unreleased compliance policy guide, which was part of the documents that FDA provided in the context of the Oversight and Investigations Subcommittee investigation. FDA has indicated that this guidance was never released because the NECC meningitis outbreak made the agency rethink its approach.

Can you describe why FDA included this provision in the draft policy guidance? Do you still believe there is some merit in this

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provision, in the wake of the NECC outbreak?

Dr. Woodcock. Well, like the Members here and in the Senate, we are struggling to put some type of quantitative limits on what can be done. And we are working within the framework that existed at the time and still exists.

We have learned a lot since then. And one of the things we have learned is that this approach can be worked around, as you said. And you can do the math on that and see that you can get up to a very large volume of shipping if you are able to receive names back, similar to if you have a 10-day limit or whatever, you are able to get up to a very large volume if you have enough customers. And then that raises the risk up very high.

I don't think we have, you know, the magic answer about how to identify those highest-risk facilities and what characteristics they should have. And we want to work with the Congress on this because it is a difficult line to draw.

But I feel that the 7-day -- there is a loophole there that would allow a proliferation, a very large volume of shipping as long as there was receipt of those names. And that would be very difficult for us to enforce. So we go into a pharmacy, we look, there are lists of names. You know, what are we going to do then?

It really puts the onus, actually, the way I think the bill is drafted, on whoever receives the stuff to send it back, to kind of

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promise to send the names back in 7 days.

Mr. Waxman. It appears to me that you are operating within the confines of the current statutory framework and doing the best you could under that regime. Now, you have suggested that Congress should enact an updated statutory framework that would be better tailored to this new class of large compounding companies.

If we adopt a framework like the one you have described, do you think this 7-day reconciliation provision is still necessary or useful in some way?

Dr. Woodcock. It depends on probably how the definition of "traditional compounding" is taken forward. Because we feel that for the large-volume outsourcers, they are really not getting prescriptions. That is not the business they are in. As I said, much of their business is doing what the hospital pharmacies did in their pharmacy years ago. And that has been outsourced -- that is why we call them outsourcers -- to larger facilities.

Mr. Waxman. Are you worried, though, that this 7-day provision might become a loophole?

Dr. Woodcock. Well, it could be a loophole. It absolutely could be a loophole. And so I think, collectively, we have to think very clearly about how we draw those lines so that something like NECC does not happen again.

Mr. Waxman. Yeah. Okay. Thank you.

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Mr. Pitts. The chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes for questions.

Mr. Griffith. Thank you, Mr. Chairman. I appreciate that very much.

Let's talk about this 7-day issue and related to the volume. One of the frustrations that we have had with some other folks is that we have actually been asking -- and you will see some blanks in the bill, because we are trying to sort that out, which is why sometimes it is nice to have hearings and you can ask these questions in public.

We are trying to figure out at what volume do you all consider them to be large enough that they ought to be considered manufacturers, no matter what they call themselves, that they are, in fact, manufacturers.

And what I have heard from your testimony today is, you said that under the bill, you know, there could be 5,000 to 10,000 vials a week being sent out, and that is too much. So now we have a number at least of 250,000 a year. I multiplied it by 50 instead of 52, figuring there might be a little break in there somewhere. But we have that minimum of 250,000.

So the question is, we are not trying to just say the 7 days; we are looking for something else that we can identify?

Dr. Woodcock. Yes.

Mr. Griffith. Crossing States lines doesn't do it, because in

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my district, I have two cities that are shared, Bristol, Virginia/Tennessee, Bluefield, Virginia/West Virginia, and all kinds of places where the lines -- you know, you can get from West Virginia, Kentucky, Tennessee, and North Carolina all in the span of about an hour and a half if you drive the right routes. And so, you know, saying that just crossing the State line won't do it.

So we are looking for some help from you all as the experts. And you indicated that is a difficult line to draw. And I understand that, but we have to draw it. And I think it is our responsibility, with your help, to draw that line.

So I would say to you, do you have an answer to that question today? And if not today, can you give me one?

Because if the right number is, if you produce more than 20,000 vials, then I think we have something we can work with and we can discuss. And I understand you may not be able to give me an exact answer today, but I think that is part of what we need.

Because Congressman Waxman is absolutely right; I don't think 7 days, acting alone, works. With a volume or some other qualifier and the 7 days -- the 7 days is to make sure we don't put everybody out of business who is trying to do it right. But the volume number would really help us a lot.

Or if you have some other fix that works besides, you know, just crossing over State lines when you have small-town pharmacies that

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could be hit when they are in a split city. What do you say to that, and what can you help us on?

Dr. Woodcock. Well, we --

Mr. Griffith. We are just trying to get this thing worked out and do it right.

Dr. Woodcock. Yes. We would really like to work with you. Any number that we come up with, any set of limits, have challenges, right, as far as how they are defined. The existing --

Mr. Griffith. But here is the problem: We are not going to get it perfect. We --

Dr. Woodcock. Right.

Mr. Griffith. -- are never going to get it perfect. But, you know, in that football field analogy, let's get it 80, 90 yards down the field. Then we can start worrying about how we get the last 10 yards. Right now we don't have any yards on that.

And I am just trying to, you know, solve a problem. And let's not throw out the really good, trying to get to the perfect.

Dr. Woodcock. Well, the traditional definition of "compounding," the number is one. I would just like to make that very clear. It is a pharmacist compounding in response to a prescription for an individual patient need.

So, as we get above one, we start going into practices that are batch manufacturing, basically. And what your pharmacy community will

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probably say is, well, we like to do that because we have multiple --

Mr. Griffith. It is not just the pharmacies. It is the docs and some of the hospitals.

Dr. Woodcock. Uh-huh.

Mr. Griffith. Because, you know, if you are an ophthalmologist and you need those drugs, if you have an emergency eye surgery going on and you need something right away, you can't wait for it to be compounded up, so you do want to have a supply.

Now, in that regard, as well, you know, we are looking for some help on that number. If 120 days is just picked out of the air and it is the wrong number, help us find the right number for how long, you know, these drugs have a shelf life, or give us some guidelines on how we figure that out.

Because, again, we are not trying to make it hard on anybody. We want the ophthalmologist to be able to provide emergency services. We want the hospitals to be able to have what they need there. But we also want the safeguards that the American public expects and it has a right to expect when we are doing something this complicated.

Dr. Woodcock. Well, with regard to the stability numbers or the shelf-life numbers, all right, for pharmaceuticals, those are generated using the actual product and doing actual testing. So then we have a hard number; we know how long it is stable, whether it deteriorates with the stopper that is used and, you know, the degree

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of the bacterial contamination and so forth, which is not supposed to be in there anyway.

So, other than doing testing like that, you are going to need a very short shelf life to retain confidence that the products are still good.

Mr. Griffith. And I think that is something that we can work out, is a short shelf life. If you can give us some help on what that should be, whether it is 10 days or 20 days. As long as the hospitals and the people doing those emergency surgeries know, then they can adapt to that. But, you know, that is one of those issues that we are trying to figure out.

You know, I know this is difficult, and I really appreciate the work that you have done and the fact that you have given us what I believe to be very clear and honest answers. But sometimes we have to pull the trigger and figure out what the numbers are.

Dr. Woodcock. Yes, we do have to act.

Mr. Griffith. So if you could help us with that, I would greatly appreciate it.

This is not, as you know, a Republican or a Democrat issue. This is just trying to get it right.

But I do agree with Dr. Burgess that, you know, we can clarify but I don't think that there is new authority that is needed. But clarifying the authority that we believe exists will help you, will

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it not? And we only have time for a "yes" or "no."

Dr. Woodcock. Yes.

Mr. Griffith. All right. I appreciate that and yield back.

Thank you, Mr. Chairman.

Mr. Waxman. Mr. Chairman, may I ask unanimous consent --

Dr. Woodcock. Without objection, so ordered.

Mr. Waxman. -- to submit a statement?

[The information follows:]

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Mr. Griffith. And, Mr. Chairman, I did, likewise, forget to do a unanimous consent on a couple of documents, if I might.

Mr. Pitts. Without objection, so ordered.

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Mr. Waxman. And I have a document also. And I also wanted to thank Mr. Griffith for his willingness to talk this through and work it out.

Mr. Pitts. All right. At this time, the chair recognizes the ranking member emeritus, Mr. Dingell, for 5 minutes for questions.

Mr. Dingell. Mr. Chairman, thank you. I commend you for holding this hearing.

Dr. Woodcock, welcome. My questions will require "yes" or "no" answers.

Nearly 9 months after the initial outbreak of fungal meningitis from contaminated steroid injections at New England Compounding Center, it is clear to me that Food and Drug needs strong and clear authority over compounding pharmacies, which it now lacks.

My home State of Michigan has been especially hard-hit. To date, there have been 264 cases related to NECC and 17 deaths in Michigan alone, the most in the Nation.

I am confident we can come together in a bipartisan manner to clarify and strengthen the authority of FDA over compounding pharmacies.

Today we have three bills before us which take different responses and answers to solving the problem. Each has its strengths and weaknesses. I am going to focus my questions on important authorities that I believe should be included.

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Question one: Does FDA believe that classifying an entity according to the existing statutory scheme of either a traditional compounding pharmacy or a conventional drug manufacturer could cause disruptions in our healthcare system, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Does FDA have the authority to require all compounding pharmacies to register with the agency, yes or no?

Dr. Woodcock. No.

Mr. Dingell. No?

Dr. Woodcock. No.

Mr. Dingell. Would you submit for the record what authority you need?

Dr. Woodcock. Certainly.

[The information follows:]

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Mr. Dingell. Does FDA have authority to require all compounding pharmacies to report adverse events, yes or no?

Dr. Woodcock. No.

Mr. Dingell. Does it need that authority?

Dr. Woodcock. Yes.

Mr. Dingell. Submit to us, please, what you think you need, for the purposes of the record.

[The information follows:]

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Mr. Dingell. Does the FDA have the authority to require all compounding pharmacies to follow good manufacturing practices, yes or no?

Dr. Woodcock. No.

Mr. Dingell. Do you need it, yes or no?

Dr. Woodcock. "All" might be an overstatement. Yes, for some.

Mr. Dingell. All right. I would like to have you define what it is you happen to feel you have need of.

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Mr. Dingell. Does FDA believe nontraditional compounders should be subject to appropriate good manufacturing practices like manufacturers are, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Please elaborate for the record.

Dr. Woodcock. Certainly.

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Mr. Dingell. Does FDA believe a risk-based inspection schedule is appropriate for nontraditional compounders, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Tell us why for the record, if you please.

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Mr. Dingell. Next question: Does FDA have full authority to see all records when inspecting any compounding pharmacy, yes or no?

Dr. Woodcock. No.

Mr. Dingell. Does it need it?

Dr. Woodcock. Yes.

Mr. Dingell. Please define for the record what you think you have need of.

[The information follows:]

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Mr. Dingell. Has FDA faced litigation regarding its ability to inspect records in pharmacies, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Please describe for the record what you feel you have need of.

[The information follows:]

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Mr. Dingell. Now, do you need this authority to effectively regulate compounding pharmacies, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Please state why for the record.

[The information follows:]

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Mr. Dingell. I have long believed that we must provide agencies like FDA with the necessary authorities and researchers and resources to properly protect public health. FDA has a user-fee system for the approval of pharmaceuticals and medical devices, amongst others. If we give FDA increased authority in this area, which I believe we should, then I believe we should also have a stronger user-fee program.

Now, would the user-fee provisions contained in the Senate bill provide FDA with the necessary resources to carry out these authorities, yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Would you discuss for the record, please?

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Mr. Dingell. Now, the American people deserve a response to the NECC outbreak so that we can ensure that this never happens again. I am committed, like most of my colleagues here, to seeing to it that we work towards a proper bipartisan solution to the problem. And I plan on continuing my discussions with my friends on both sides of the aisle until we reach agreement on the best way forward.

I would like to have you discuss a little further some of the comments that you made in response to Mr. Griffith's rather excellent questions.

I have a curiosity. Is the number of shipments by the compounder as important as to whom they are shipped and what the compounding might happen to be and who the individual is that is making the shipments?

Dr. Woodcock. We feel that the highest risk relates to sterile products. So that is number one. Things are going to be injected into your body, right? And the contamination, that --

Mr. Dingell. So you need authority to define those things, don't they?

Dr. Woodcock. That is one.

We propose using interstate commerce as a proxy for risk, because if you are shipping all over the country, you are making more, it is taking longer, right? So the shelf life is going to be longer, and there is time for bacteria or fungi to grow and so forth. And your batches are probably larger, and that increases the risk of errors,

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and, also, it just simply increases the number of people who could be harmed.

Mr. Dingell. I am running out of time. And out of respect for my colleagues, would you please submit for the record a statement on this particular point?

Dr. Woodcock. Certainly.

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Mr. Dingell. Thank you.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentlelady from Tennessee, Ms. Blackburn, for 5 minutes for questions.

Mrs. Blackburn. Thank you, Mr. Chairman.

And thank you for being with us. We appreciate your time and coming back. I know that you probably and your staff probably feels like we have talked about this issue nonstop, but it is of tremendous concern to us. For those of us in Tennessee, it is especially concerning. We have 14 individuals that lost their lives and so many who are still suffering.

And I will just associate myself with Mr. Burgess's remarks in regard to it being a collective failure. We do realize that there were actions that you all should have and could have taken, and it is of concern to us.

A couple of things I just want to ask you about. Looking at drug shortages, are there any instances where FDA is permitting compounding pharmacies to make products on that drug-shortage list without having those facilities go through the inspections and qualifications?

And, then, are there people that are on the ANDA list that have submitted those applications where you have not gotten around to approving those applications?

Dr. Woodcock. Well, first of all, we prioritize any generic drug

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application that is related to a shortage and try to get it through the process as quickly as possible.

As far as compounding pharmacies, yes, they are making drugs to address shortage issues, but, no, we have no real oversight of that right now. That is not the scheme that is in place. That is regulated primarily by the State boards of pharmacy.

Mrs. Blackburn. Okay. On the ANDAs, you said you prioritize those applications. How long does it take to get one of those through the process?

Dr. Woodcock. Well, it varies tremendously, whether or not the application is in good shape. If there are multiple foreign facilities involved in production of the drug that we haven't inspected before, we may have to go to other countries and inspect those facilities. So that sometimes can be a rate limiting step.

Mrs. Blackburn. On average.

Dr. Woodcock. I could get back to you on that. I don't have it.

Mrs. Blackburn. Okay. I would love that. I think that it would be instructive to us.

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Mrs. Blackburn. Mr. Griffith mentioned something about limitations. I understand that many States have used some form of volume limitation for anticipatory compounding to determine whether an entity is acting within the scope of their license.

So do you think that a volume limitation in conjunction with other factors from 503(a) could help distinguish between entities that are engaged in large-scale compounding similar to manufacturing or in traditional compounding?

Dr. Woodcock. It is possible. The States have a patchwork of laws which are different. Some allow anticipatory compounding; some allow office stock. So there are a variety of interpretations or laws across the different States.

Clearly, volume is another proxy for risk. And the larger the volume of the batch or lot you are making, the higher the risk that is imposed if you are not using good manufacturing practices.

So that is possible, but we have struggled with this, and we have had a very difficult time coming up with a coherent scheme that would use volume. And then that would have to be usually enforced by the States, because it would apply to all the compounding pharmacies. It wouldn't be a uniform Federal standard, or it would be very difficult for us to enforce it even if it were, because, as the testimony shows, there may be 23,000 pharmacies or something that are doing compounding of different types.

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Mrs. Blackburn. Okay. Thank you for that. I would think that volume could be one of those indicators that may be a bit more illuminating as you try to work through this process. It would seem it would be a key indicator.

With that, I will yield back.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentlelady from the Virgin Islands, Dr. Christensen, for 5 minutes for her questions.

Dr. Christensen. Thank you, Mr. Chairman.

And welcome back, Dr. Woodcock.

Dr. Woodcock. Thank you.

Dr. Christensen. Some of these questions have been asked one way or another, but I want to just to be clear. And I would like to talk about one of the concerns we have been hearing a lot about, having to do with the proposed statutory framework.

As has been said, FDA has suggested that Congress should revise its statute to clearly delineate which compounding entities should be subject to Federal oversight and which ones should remain the purview of States. Specifically, you have recommended that facilities be subject to FDA oversight if they conduct sterile compounding, which you said is the highest risk; second, whether they compound medicines in advance of or without a prescription, which I don't understand; or if they ship compound medicines across State lines.

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One of the problems, according to some of the stakeholders, is that this construct would prevent doctors' offices from obtaining limited amounts of compounded medication without a prescription that would be kept as office stock. So they feel that these medicines need to be in their office so that they can be given to a patient who needs them right then.

It is my understanding from your answers that FDA doesn't support this. So could you explain the rationale for not allowing some limited amount of office stock to be exempt from the triad of requirements?

Dr. Woodcock. Certainly.

We are not -- we aren't wedded to anything. We need to find a workable scheme, right? Each doctor's office or clinic may say, as I said, they may say, we only use 25 of these vials a week. Okay? But if the compounding pharmacy has 1,000 customers, right, then that is 25,000 vials. And would you say that is too many?

So if you simply use that and allow a certain amount of anticipatory office stock, that is what you could end up with. And so you just have to kind of play out this scenario in your mind and what this would look like. And I don't know, maybe you think that them making 25,000 sterile vials is okay, is not manufacturing, right?

Dr. Christensen. I think that anything that goes beyond a specific compound for a specific patient is too much, trust me. And --

Dr. Woodcock. Could I say one more thing?

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Dr. Christensen. Sure.

Dr. Woodcock. We are not proposing that this be prohibited. We are saying that it should go into a category that involves good manufacturing practices so that there would be oversight of the aseptic processing so that we would be assured it would be done correctly and at least these products would not be contaminated.

Dr. Christensen. Got it. And are there certain types of compounded drugs for which some limited amount would not be subject to the limitation? Are there specific drugs that you could conceive of that could be compounded without -- for which some limited amount should not be subject to the extra oversight?

Dr. Woodcock. Well, we have proposed that the category of federally regulated would be, you know, interstate commerce without a prescription of sterile drugs, right? And that leaves a large variety of other things to the States, including intrastate sterile drugs, which still, arguably, can be of high risk, and all other compounded products, which would be the oral, the creams, the lotions, all those sorts of things.

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RPTS BINGHAM

DCMN ROSEN

[4:00 p.m.]

Dr. Woodcock. Now we have proposed that there be a floor that you should not be able to compound drugs, say, that FDA pulled off the market because they weren't safe, okay, and that you shouldn't compound drugs from a monograph, you know, from an appropriate source okay, and so forth. So we had certain criteria we think should apply to all pharmacies who compound. However that vast majority of nonsterile, non-injectables so we really are not proposing to have under this broad scheme, this new scheme that we were talking about.

Dr. Christensen. And are there any exemptions to the across State line borders for pharmacies that are close to State borders or that routinely operate across State borders today?

Dr. Woodcock. Right, well that is, I think, the question that we just heard that that creates some unfairness like any scheme we are going to apply there would be some disparities. We weren't proposing that there would be that exemption for States that were close by or four corners or whatever.

Dr. Christensen. The question has been raised that you all had a lot of authority that you hadn't exercised before so, and you said that FDA took some aggressive action and when you have taken that

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aggressive action, is it that FDA has gone over out on a limb in the interests of public health risking court challenges? Or did you find some authority that you didn't think you had before?

Dr. Woodcock. Well, as I said, we, I think we may get court challenges. I think in some cases, the States have taken action because we have brought this to their attention, and they are the holders of the, you know, they issue the pharmacy licenses. And so although we have even inspected 61 pharmacies, now if you think of the universe that we are talking about, it is a much larger universe, and new ones can grow up all the time.

So although we are taking aggressive action, the fact that we do have to think through the judicial consequences and so forth meaning each of these actions, as I would call them pretty lawyer intensive, all right, and we don't have unlimited legal resources.

Dr. Christensen. I have gone over my time, thank you.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentlelady from North Carolina, Mrs. Ellmers, for 5 minutes for questions.

Mrs. Ellmers. Thank you, Mr. Chairman, and thank you, Dr. Woodcock, for being with us again.

To the best of my knowledge this is about the fourth hearing that we have had in the subcommittee on this issue, especially in relation to the New England Compounding Center, and I think there are still some

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questions out there that many of us have about how that process is moving forward.

It seems to me, after looking at all the information that the FDA did have some authority at that point to shut down NECC, and of course, that is not the possess that went forward and we obviously need to clarify, of course, the FDA authority as been discussed many times here already today.

Dr. Woodcock, in your opinion, would you agree with my statement and might you have anything to add? What can we do to bridge this? Because as we are having this conversation, there are many times that you say that we did have authority, we did not have authority, but we have got to fix this problem. So what is your solution? What do you want to see done?

Dr. Woodcock. Well, what FDA has proposed is that we have different legislation, I won't say it is quote, that the large scale industry that has grown up especially that is making sterile products be subject to Federal regulation. It is basically a new type of industry, the scale, the fact that it is sterile and so forth, and it is not the traditional corner drugstore making --

Mrs. Ellmers. And that, I guess at that point is now where we have the question of the amount that is being compounded, meaning each individual vial, or, you know, sterile unit, I know I have heard shelf life be discussed, and of course, I think that does have more to do

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with the actual make-up of the compounded prescription, which leads me again to the question, I know when we have a traditional pharmacy, we have a prescription, and that is filled for the patient. Then we, as you pointed, out have this situation where we have hospitals and different, you know, maybe outpatient surgery clinics that use those compounded products as well.

Why can't -- I guess my question is rather than concentrating so much on the number, obviously there is a safety issue there, we want to make sure we are producing a sterile product, but when it comes to going to a hospital or an outpatient surgery center, why can it not stay under the same category that it is right now rather than moving into a larger manufacturing label or status?

Dr. Woodcock. Because they make -- the people who supply these outpatient clinics like NECC, okay, make large scale volume, which Dr. Burgess has said, well, that clearly is manufacturing, we know it when we see it, right, the question is how do you distinguish that.

Mrs. Ellmers. Well, and that leads me to my next thought, and I realize that we are talking about legislation that is already being proposed, but if we know that an outpatient clinic does a number, a particularly an average number of cases every month, and they were to receive that compounding product for that amount, would that not essentially be kind of a large-scale prescription when you think about it? Is there not another avenue we can take here rather than just add

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more regulation and more costs, but at the same time, continue to produce a very safe product?

Dr. Woodcock. Well, that is the issue, continuing to produce a safe product. As I said, we have had another outbreak since the last time this body had a hearing, all right.

Mrs. Ellmers. I am going to stop you there, thank you, I do have about 50 seconds which leads me to my next question. At the time of the outbreak, the NECC outbreak, there was a compliance policy guide that the FDA was preparing, but I think that had been put on hold.

Has that now been, has that policy been evaluated? And what is the FDA doing?

Dr. Woodcock. We have learned since then, and as I told Dr. Burgess we are aggressively applying our existing authorities under the law to these pharmacies. Existing authorities require prescriptions.

Mrs. Ellmers. So the question, again, is has the agency evaluated the compliance policy guide? Has that been --

Dr. Woodcock. Yes.

Mrs. Ellmers. Is that being implemented now as this authority?

Dr. Woodcock. No, we feel that parts of that are actually unfeasible based on what we have learned. We have learnt a lot since the NECC outbreak all right and we have revised our approach to be more practical.

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Mrs. Ellmers. Thank you and my time has run out thank you.

Mr. Pitts. The chair thanks the gentlelady. I recognize the gentlelady from Illinois, Ms. Schakowsky 5 minutes for questions.

Ms. Schakowsky. I am over here, Dr. Woodcock.

Dr. Woodcock. I am sorry.

Ms. Schakowsky. Did I hear you at some point say that there ought to be labels of dates certain and information for the consumer on compounded products?

Dr. Woodcock. Yes, after this NECC outbreak, many of the FDA staff who had to go in the hospital they said, well, we don't even know what products we are getting that are compounded when they are having a procedure or something. There is no label that is required now that identifies a product as a compounded product.

Ms. Schakowsky. Here is my question problem, that I began my activism decades ago to get expiration dates on products sold in the supermarket. I am for consumer information. But when it comes to prescription drug, particularly if you are in the hospital, are you suggesting that in some way, we leave this up to an informed consumer to be able to make decisions on whether or not they want that or that it be suitable for them?

Dr. Woodcock. Not really. We think that this simply raises awareness about the use of compounded drugs. The use of, there are beyond use dates on compounded products now. Our issue with them is

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that they aren't based on evidence, based on experiments that are done on that compounded product from what we have seen in our inspection.

Ms. Schakowsky. Well, let me ask you about all the prescriptions that we get. They all now have a date on them and I regularly go through my shelf and dispose of --

Dr. Woodcock. Excellent.

Ms. Schakowsky. Outdated drugs. Are all of those, do we know that those are accurate?

Dr. Woodcock. Absolutely. They have to perform experiments on stability and dating period and submit all that information to FDA and we have to agree with it.

Ms. Schakowsky. Okay, so that is not part of the requirement and something that you would need the authority to require that?

Dr. Woodcock. Performing stability testing, so forth, on products is part of good manufacturing practices.

Ms. Schakowsky. And so that would, under your new categories, would be required of these compounders?

Dr. Woodcock. We are proposing that for the highest risk facilities that make sterile drug products and ship them inter State.

Ms. Schakowsky. So if we are not doing it by quantity, what are we doing it by? What do you recommend we do it by?

Dr. Woodcock. We propose by risk and simply pulling off the highest risk class of products which is the sterile products that are

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shipped inter State so they are going, causing multi State outbreaks, and that are without a prescription and the prescription -- without a prescription is a proxy for mass production, okay, because it is not one pharmacy making one sterile product for a person, say, in another State. They are making large batches and then shipping them all around.

Ms. Schakowsky. So the FDA has talked a lot about medical need as a condition for compounding a product. So how should we incorporate this concept into legislation?

Dr. Woodcock. We feel that is a fundamental concept for compounding. It is the reason -- why else would you give people products that didn't go through the system that Congress has established for drugs, right, which is they are tested for safety and efficacy, and they have applications and everything, and the reason is there is a medical need that is not met by existing products. And so we feel to raise practitioners' awareness that they would indicate that there was a medical need for this product, and why are we doing this? Because when we talk to people who bought products from NECC, the practitioners, what they said, well, there was just the order form online, and we just ordered like any other order that you would make. And so there was no awareness, there was no practitioner awareness that this was a higher risk product.

Ms. Schakowsky. I see. In your testimony, you explain that

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certain products with limited exceptions are not appropriate for compounding under any circumstances. Would you include this situation that we are just talking about, that, you know, the practitioner just went online, found this to be available? Should those products not have been compounded under any circumstances?

Dr. Woodcock. No, we have very specific criteria for what we think shouldn't be compounded under any circumstances, and that would be, for example, the drugs that FDA has pulled off the market because they dangerous. We don't think they should be compounded. Very complex dosage forms, our, the pharmaceutical manufacturers have trouble making certain dosage forms right. For example, extended release may cause dose dumping and get all the dose in the body at once and could kill you, for example, and they have to do extensive testing on their products to make sure they have been manufactured correctly. So we don't think some of these very risky products should be compounded either.

Ms. Schakowsky. Thank you. I appreciate it. I yield back.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questioning.

Mr. Bilirakis. Thank you, Mr. Chairman I appreciate it very much. Thank you for your testimony. Dr. Woodcock, you mentioned that copies of FDA-approved drugs should never be compounded. What about the drug progesterone, which, for years, was compounded by pharmacists

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for pregnant women to prevent premature births? In 2011, FDA approved Makena, which is a manufactured form of progesterone. The manufacturer sent a cease and desist letter to compound pharmacies, and FDA weighed in and said pharmacies could continue to compound this drug even though a more expensive manufactured drug is available.

If we explicitly prevent compound pharmacies from making copies of FDA-approved drugs, what will happen to pregnant women's access to achieve drugs, affordable medication to prevent premature births?

Dr. Woodcock. You know, I can't comment specifically on that instance because of ongoing litigation issues. However, I think in general, Congress set up a system that required new drugs to go through the FDA review process, and that was because of the many abuses and many deaths and many problems there were long ago when there wasn't a system to make sure drugs are safe and effective. So there were many outbreaks in the past as well as like the thalidomide crisis and so forth, all of which led Congress to do this.

Now, if we feel, in general, if there is a safe and effective drug available to the public, people should not be exposed to drugs that are of lower quality unless there is a medical need for that other product.

Mr. Bilirakis. Next question, you mentioned needing the power to access pharmacy records. Are you looking for the authority over pharmacy records in general, or just the nontraditional compound

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pharmacies?

Dr. Woodcock. Well, we would like to, so to speak, be able to distinguish, more or less, the sheep from the goats. We need to know, people have said, well, why don't you act on this or that or other, haven't we acted if we can't demonstrate that a pharmacy is shipping large quantities of drugs that violate whatever scheme Congress comes up with, right, then we won't have the power to use our authorities. And the way we do that, you look at their shipping records and say if there is a requirement for names or prescriptions, we would need to be able to verify that, otherwise we -- there are bad actors out there and there are people who say oh get all that stuff or we don't do this, and if we can't verify that then it really ties our hands.

Mr. Bilirakis. How about, you mentioned using the administrative warrants to compel access to records.

Can you explain what this process is and how do you go about getting the records, the warrants?

Dr. Woodcock. Well, I am not a lawyer, all right. But my understanding, I have asked the lawyers and we have to go to a court and we have to ask the court. And sometimes it can be done rapidly, but often it averages about 2 weeks. And we are concerned, first of all, of course, if there is an outbreak, that is too long because lives are at stake.

Another thing, a problem we can have is that people can clean up

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and destroy their records in the time that it takes for us, and, of course, we don't have evidence that they have destroyed records because they may be destroyed, but when our investigators are in some of these firms, they have had a very strong smell of bleach which we think means that the mold has been bleached off of the counters and so forth, and that there was a lot of cleanup during the time we went and tried to get a warrant to get in.

Mr. Bilirakis. Thank you. We all, of course, want to ensure the safety and sterility of compounded drugs. We must also not lose the sight of the important role that compounded drugs play in patient care. Some physicians keep a supply of compounded drugs available for anticipatory office use because in waiting for the drug to get compounded for the patient, that waiting period could endanger the patient's health. I know we touched about upon this, but some of the bills we are reviewing today include patient specific prescription requirements for certain compounded drugs.

Do these prescription requirements really address and improve the safety and sterility of compounded drugs? Are there other measures that can be taken to improve the safety of these products that also ensure physician and patient access to compounded drugs for use in the office setting?

Dr. Woodcock. Well, our proposal doesn't preclude lack of prescriptions in the anticipatory compounding. What we are saying is

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when you do that for sterile products, you should make the products under good manufacturing practices, proper aseptic processing so you don't contaminate them. Now, that is one way to deal with this. That is what we are proposing is if you wish to ship products, sterile products around and not get prescriptions, then you should make them under good manufacturing practices because you are likely to be making batches of sterile products, and that really doesn't look like compounding, it looks more like manufacturing when you are making batches.

Mr. Bilirakis. Thank you, Mr. Chairman. I yield back.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. Castor. Thank you, Mr. Chairman, and thank you Dr. Woodcock for being here. The last time you were here you were kind of to allow me to change the subject and ask you about one of the serious drug shortages facing our country, and that involves the injectables, injectable nutrition that primarily affects premature infants and our children's hospitals continue to raise the issue and practitioners and scared parents across the country. I know at the end of May, FDA acted to allow some imports of those nutrition elements.

Can you give us an update on how it is going? Is the situation improving? Have you hit any roadblocks.

Dr. Woodcock. It took longer than we had hoped and when I talk

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to you last, I thought it was imminent and it took longer than what we hoped to get those products in. We believe we are alleviating these shortages, but we are not out of the woods yet. We do not have a U.S. manufacturer online to my knowledge that can give us a stable supply but we are working on that.

Ms. Castor. Are there prospects for U.S. manufacturers to come online?

Dr. Woodcock. That is what we believe, yes.

Ms. Castor. And what would that time frame would be?

Dr. Woodcock. Pardon me.

Ms. Castor. What do you think the time frame would be?

Dr. Woodcock. I don't know. We can get back to you with details if you would like.

Ms. Castor. Good. I look forward to that, thank you very much. And you really have clarified over the number of hearings that we have had back on this topic on reforming drug compounding, we have had a series of hearings, and your message is sinking in, I believe. We now have three bills that are out there, you have got a Senate bill by Senator Harkin, you have got one that is kind of on the other end of the spectrum by former Representative Markey, you have Mr. Griffith's bill now that he is working on.

When you look at the three bills that have been drafted, can you point to a section of any of those bills that you say boy, that is really

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the most important thing that could be accomplished here or that would be one of our priorities going forward for FDA and protection of the public health?

Dr. Woodcock. Well, we do feel the Senate bill has the right framework. There is still issues about, but you know it does provide registration so we can find out who the people are, it provides reporting of adverse events so that if any compounding pharmacy starts getting into trouble, we can react quickly. It does have a user fee program, it does carve out a section of a sterile manufacturers who would be subject to higher standards and it does provide some other Federal standards. So we feel that is a good start, but all -- this is a very difficult issue to draw these lines correctly and they are trade-offs that have to be made, and we recognize that everyone is struggling with this and we want to work with you all.

Ms. Castor. In that Senate bill, is it clear to you when you read it that the traditional neighborhood pharmacist that are not in the, not making thousands of batches or even hundreds of batches are clearly exempt.

Dr. Woodcock. Yeah, the Senate bill has State law prevail on the traditional pharmacy compounding, and we feel, unfortunately, there is a bit of a patchwork there because each State has a different set of laws, so your two pharmacies are 20 miles apart in different States may be operating under totally different frameworks, and we think that

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will be difficult for us to enforce, pending one might be regulated by us, and the other on the other State regulated by the State, and that is very difficult.

Ms. Castor. Well, thank you very much. I was thinking about this earlier today reading over the testimonies and I think if we just put ourselves in the shoes of the average American consumer, I think what they want most of all is to be assured that especially the highest-risk drugs, the ones that are being injected, like you said, are being manufactured in a way that is safe and that the government at least has the authority to know who they are, where they are, so that we can ensure that no one is harmed to the extent of what happened with NECC. So thank you very much. I yield back.

Dr. Woodcock. Thank you.

Mr. Pitts. The chair thanks the gentlelady and recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes for questions.

Mr. Lance. Thank you, Mr. Chairman.

Dr. Woodcock, your opinion should entities making nonsterile products in advance of prescription shipping interstate be regulated by the FDA as traditional manufacturers or by States as traditional compounders?

Dr. Woodcock. So should traditional, should manufacturers who are making nonsterile products and shipping them interstate.

Mr. Lance. Interstate?

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Dr. Woodcock. Interstate, perhaps in very large quantities be regulated as manufacturers or.

Mr. Lance. Or as traditional compounders.

Dr. Woodcock. I think that is a policy call. There are trade-offs there; there are is far more of that. These are lower risk products, and what we have proposed is other restrictions like not copying FDA-approved product and only working from certain bulk product, API's and so forth, that would put some boundaries on these practices but I think there is some danger of folks going into business as a kind of shadow generic company without FDA oversight, if they could ship broadly.

Mr. Lance. If they were regulated under the FDA what would the proposed framework be? As opposed to being regulated by the States.

Dr. Woodcock. Well, we haven't proposed anything for that group. Generally speaking, doing those practices, you would have to, right now under the current law, which we have been talking about, you have to file an application for every single form that you are shipping, and often, of course, these are customized to different doctors' preferences and so forth, and these groups make thousands of different dosage forms, they would have to file an application for each one with extensive documentation and pay user fees.

Mr. Lance. Thank you. I know that you have recently conducted a series of inspections compounding pharmacies and as I understand it,

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you have done that in conjunction with State officials; is that accurate, Dr. Woodcock?

Dr. Woodcock. Yes, in almost all cases, we have gone in with the State.

Mr. Lance. And you have stated that the agency needs full record inspections authority for every pharmacy in the country and in that, if you are conducting these inspections with State Pharmacy Board officials, do you believe as well that you need independent authority independent from the State boards?

Dr. Woodcock. We have had some cases where the State officials, due to resource constraints, have not been able to go in with us and we are concerned that might be even more happen more often in emergency where we feel that we really need the ability to get in there. We do always try to have the State officials come with us because they have we have joint authorities.

Mr. Lance. Are some States better at this than others traditionally, or does it just vary based upon State resources at the moment.

Dr. Woodcock. I don't think we have a large enough sample size to say which States, you know, we know some States as the Board of Pharmacy Association has testified, some States are better staffed and so forth than others for their board of pharmacy operations.

Mr. Lance. Thank you. I would be happy to yield to any other

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member who wishes to speak.

Mr. Green. If I could, we are looking, and I think I share it with my colleague, Congressman Griffith, we are looking at multiple things that gives the FDA the authority to do it, because we don't want this to happen again, and I have to admit having served there a good while, that first hearing we had neither the FDA nor the compounders nor the State agencies showed that they were actually do the doing the job, so we want to make sure you have the tools, so it will be multiple and I would be glad to my colleague from New Jersey to yield to my colleague, Mr. Griffith.

Mr. Griffith. If I could have a minute of that time I would appreciate it, and one of the things we are also working on in the bill that I think is helpful and I think you would agree is that we set up a facilitating process where there are complaints from the State where they can work a little more efficiently with the FDA, and likewise, if you hear something go on from State A that the FDA can then communicate that it to that to State B and C, that this particular group may be having a problem.

Dr. Woodcock. Yeah, we would like to have, perhaps, a message board or something but we don't want to turn into the telephone operator.

Mr. Griffith. I understand that, but anything we can do to facilitate, because one of the problems is those who were here for the

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hearings know is that we had a couple of States that were blowing the whistle, and no action was taken, so we want to try to make sure we facilitate in making sure that the next time when Colorado or Ohio or some other State is, in fact, raising red flags that that message is getting through, and I do appreciate and yield back to --

Mr. Lance. Thank you very much.

Mr. Pitts. The chair thanks the gentlemen. That concludes questions from the members. I am sure they will have written questions. We ask that you please respond promptly. Dr. Woodcock, as always, you have been a very excellent witness. Thank you for your testimony.

Dr. Woodcock. Thank you. I am pleased to respond.

Mr. Pitts. Thank you. I will call the second panel up at this time and introduce them as they come forward. In this order they will testify: Dr. Doug Hoey, chief executive officer, National Community Pharmacists Association; Dr. Kasey Thompson, vice president, American Society of Health-System Pharmacists; Mr. Jeffrey Francer, assistant general counsel, Pharmaceutical Research and Manufacturers of America; Dr. David Gaugh, Senior Vice President for Sciences and Regulatory Affairs, Generic Pharmaceutical Association; Mr. Allan Coukell, Senior Director Medical Programs, the Pew Charitable Trust; Dr. David Miller, Executive Vice President and CEO, International Academy of Compounding Pharmacists; and, finally, Dr. Carmen Catizone, Executive Director,

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National Association of Boards of Pharmacy.

Thank you all for coming.

You will each have 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Dr. Hoey, we will start with you for an opening statement.

STATEMENTS OF B. DOUGLAS HOEY, CHIEF EXECUTIVE OFFICER, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION; KASEY THOMPSON, VICE PRESIDENT, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS; JEFFREY FRANCER, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; DAVID GAUGH, SENIOR VICE PRESIDENT FOR SCIENCES AND REGULATORY AFFAIRS, GENERIC PHARMACEUTICAL ASSOCIATION; ALLAN COUKELL, SENIOR DIRECTOR, DRUG AND MEDICAL DEVICES, THE PEW CHARITABLE TRUSTS; DAVID G. MILLER, EXECUTIVE VICE PRESIDENT AND CEO, INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS; AND CARMEN CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

STATEMENT OF B. DOUGLAS HOEY

Mr. Hoey. Thank you and good afternoon, Chairman Pitts and Vice Chairman Burgess and Ranking Member Pallone, members of the subcommittee, the National Community Pharmacists Association greatly appreciates the opportunity to testify today and share the community

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pharmacy perspective on legislation addressing pharmacy compounding.

NCPA represents the interests of America's community pharmacists, including the small business owners of more than 23,000 independent community pharmacies.

Almost 86 percent of independent community pharmacies compound medications. Our members perform a wide variety of compounding services, including working with physicians to create medications to help patients needing hormone replacement medications, help pediatric patients, and those with severe nausea and vomiting where commercially available medications are unresponsive or unavailable to give just a few examples.

NCPA commends members of this committee for taking a closer look at what actions and inactions led to the tragic NECC event. We believe this committee has taken the proper steps by focusing on investigations into clarifying existing oversight to ensure that the appropriate regulatory bodies are exercising their full authority.

NCPA is also grateful to Congressman Griffith for the tireless efforts to prevent a tragedy like NECC from occurring again. NCPA supports the approach of Representative Griffith's discussion draft as it is not a broad expansion of FDA power over historically State regulated pharmaceutical compounding. To the contrary, the draft strikes the proper balance of making certain that future tragedies are avoided while also preserving patients' access to vital compounds.

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In addition, NCPA fully supports the discussion draft to preserve State Board of Pharmacy oversight of pharmacy compounding. NCPA has historically, and continues to advocate that pharmacy compounding is best regulated by the State Boards of Pharmacy. Conversely, manufacturing is overseen by the FDA. If the FDA has a concern about an appropriately licensed pharmacy, then the FDA currently has the authority to ask the State Board of Pharmacy to work with them to address the issue. NCPA also strongly supports efforts by Representative Griffith's discussion draft to preserve office use and anticipatory compounding where State laws allow such practices.

In order to preserve access to compounds, the discussion draft acknowledges that pharmacies should not be hindered in their ability to engage in anticipatory compounding as long as it is reasonable and based on a historical pattern of prescriptions, or for specific patients served by that pharmacy.

Furthermore, NCPA strongly supports the efforts of the discussion draft in recognizing that strengthening communication between FDA and State Boards of Pharmacy is essential.

NCPA believes one of the leading contributors to the NECC tragedy was the failure of the FDA to exert its existing authority to oversee entities going beyond pharmacy compounding. Communication and coordination between State Boards of Pharmacy and the FDA is imperative.

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While NCPA appreciates all efforts on this very important issue, we do have strong concerns with other legislative proposals, including granting FDA additional authority to create "do not compound" lists.

Contrary to the discussion draft, other legislative proposals grant the FDA unrestricted authority to designate drugs or specific categories of drugs to a "do not compound" list. This would be an unnecessary expansion of FDA authority over the practice of pharmaceutical compounding while doing nothing to prevent another tragedy like NECC.

A second concern is requiring community pharmacies to notify FDA when compounding short supply medications. While the discussion draft adequately addresses the concern that shortages of prescription drugs have tripled during the last 5 years, other legislative proposals place burdensome FDA notification requirements on compounding pharmacies.

Mandating all compounding pharmacies to bypass their State Board of Pharmacy does nothing to prevent another NECC.

And, third, exempting pharmacies within health systems from compounding standards, while the discussion draft holds all compounding pharmacies to the same compounding standards, other legislative proposals exempt all pharmacies within health systems from the proposed compounding requirements.

A recent OIG report found that almost half of hospitals stated that cost and space limitations would be major challenges to achieve

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USP 797 compliance. Thus, as Congress addresses this very important issue, the intent should be to ensure all patients receive safe and quality compounded medications.

In conclusion, NCPA is committed to working with Members of Congress in order to make certain that a tragedy such as the New England Compounding Center does not occur in the future, while also preserving patients' access to customized and safe compounded medications.

Thank you for inviting NCPA to testify and to share the view points of independent community pharmacy owners and operators across the country on compounding. I look forward to answering any questions you may have. Thank you.

Mr. Pitts. Thank you, Dr. Hoey.

[The prepared statement of Mr. Hoey follows:]

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Mr. Pitts. Dr. Thompson, you are recognized for 5 minutes for an opening statement.

#### STATEMENT OF KASEY THOMPSON

Mr. Thompson. Good afternoon, and thank you, Chairman Pitts and distinguished members of the committee for holding this hearing. I am here today to provide ASHP's perspective as a professional society that represents over 42,000 pharmacists who practice in hospitals, health systems and ambulatory clinics, and has been a recognized leader for over 20 years in the development of guidelines on sterile compounding, nonsterile compounding and guidelines on working with outsourcers. The event caused by the New England Compounding Center resulted in 61 unnecessary deaths and more than 700 meningitis cases.

ASHP strongly believes that the authority and accountability between the FDA and State Boards of Pharmacy needs to be clarified. We believe that compounding outsourcers that prepare customized sterile preparations that are not commercially available should be held to the highest standards for quality, including relevant current good manufacturing practices and should be required to be registered with and routinely inspected by the FDA.

Further, we believe that these entities should not copy commercially available products except in the cases of drug shortages

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or to make a medically necessary variation that meets patient specific needs. The drug approval process in the United States is the gold standard and should be maintained as such. However, it is important to recognize that there are many legitimate and medically necessary compounded sterile preparations that simply are not available from a brand or generic manufacturer in the strength or dosage forms that patients need.

U.S. hospitals prepare a vast array of compounded sterile preparations from FDA-approved products every day in order to meet patient-specific needs. The compounded medications that hospitalized patients need range from simple intravenous admixtures to complex customized medications that are not available off the shelf, such as multi-ingredient cardioplegia solutions for heart surgery, epidural pain medications for women in labor and delivery, concentrated pain medications for cancer patients, and adult medications prepared in concentrations that can be safely administered to babies and children.

Where necessary, hospitals enlist the services of qualified compounding outsourcers for some preparations for several reasons. For example, some hospitals may not have the necessary equipment or facilities to prepare some high risk sterile preparations, which is sometimes the case in small and rural hospitals. Or they may face medication shortages for commercial products that can only be replicated by outside suppliers that provide customized compounded

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sterile preparations. They may also enlist the help of outsourcers to prepare FDA-approved sterile products in ready-to-administer packages in the strength and dosage forms they need.

The evolution of the compounding outsourcing industry over the past decade has outpaced the ability of State and Federal laws to keep up, creating legal and regulatory gray areas between State and Federal Government.

Unfortunately, it just isn't as simple as calling these large scale anticipatory compounding entities a pharmacy, a repackager or a pharmaceutical manufacturer. They are something in between each of these but no one category fits them perfectly.

Recent bipartisan Senate legislation addresses the need for clarity and distinguishing between compounding by a pharmacy and the activities of a compounding outsourcer. It assigns responsibility and accountability to the FDA for regulating compounding manufacturers while preserving the accountability for pharmacy compounding to State Boards of Pharmacy. It also establishes a user fee program to help ensure that the FDA has the resources it needs to effectively regulate compounding manufacturers.

Because of the potential nationwide scale of these operations, we are concerned that State Boards of Pharmacy may not be able to provide adequate oversight of these facilities. Many State boards may not have the resources or expertise to evaluate whether a pharmacy has crossed

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the line and become a manufacturer.

With respect to the regulatory framework proposed in the draft legislation by Representative Griffith, ASHP is concerned that the regulatory environment that allowed the New England Compounding Center to operate as a pharmacy would remain intact. In other words, if authority between State Boards of Pharmacy and FDA is unclear due to lack of accountability, we would be concerned that neither FDA nor State boards could be held accountable if an entity were licensed as a pharmacy, but was also preparing sterile compounded preparations without a prescription and selling across State lines.

In addition, our understanding of the draft legislation is that FDA would only be permitted to inspect a pharmacy that may be operating as a large scale compounding entity if FDA has received a submission from the State Board of Pharmacy.

This ability for FDA to have the necessary access to records and inspect a compounding entity would be contingent upon State boards being properly equipped with trained personnel to determine if an activity appears to approach manufacturing. We are concerned that FDA may not be fully accountable if the State board does not notify the agency.

Further, this approach would imply that State boards would inspect all prescription records and sales transactions of each licensed pharmacy in their State to identify those entities that may

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be acting outside the scope of traditional pharmacy compounding. Therefore, it would be referred to the FDA. We do not see that as realistic for many State boards, and therefore believe that these types of compounding outsourcers would be more appropriately regulated by FDA.

In conclusion, ASHP remains completely committed to working with Congress, the FDA and other stakeholders in developing a reformed regulatory framework for pharmacy compounding. Thank you, Chairman Pitts, for holding this hearing on this very important public health topic.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Thompson follows:]

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Mr. Pitts. Mr. Francer, you are recognized 5 minutes for an opening statement.

**STATEMENT OF JEFFREY FRANCER**

Mr. Francer. Thank you, Mr. Chairman and members of the subcommittee. I am Jeff Francer, I serve as assistant general counsel of the Pharmaceutical Research and Manufacturers of America. Thank you for the opportunity to present our views this afternoon.

PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies. In 2012, PhRMA's members alone invested nearly \$50 billion in discovering and developing new medicines. PhRMA shares the committee's goal of advancing public health and protecting patient safety by ensuring that FDA's statutory authority and safety standards for pharmacy compounding are strong enough to protect patients against the risks demonstrated over the past year.

There is no higher priority for biopharmaceutical companies than patient safety. We commend the committee's diligence in investigating the causes of the recent tragedies and examining potential solutions.

PhRMA believes that medicines manufactured by our member companies as well as those manufactured by nontraditional pharmacies and manufacturers should be regulated by FDA using a consistent,

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risk-based approach. This approach best serves public health because products that present similar risks should be regulated in a similar manner.

In light of the incidents surrounding the New England Compounding Center, it is clearly appropriate for Congress to revisit the FDA's authority to regulate compounding of prescription drugs. And consistent with the goals of clarifying FDA's authority and protecting patient safety, PhRMA would support legislation that would include the following seven attributes:

First, clarify that FDA retains its strong existing authority to regulate as a new drug any medicine that is compounded outside of traditional compounding. Large-scale, commercial manufacturing of prescription medicine should be governed by the same high standards, whether the commercial producer is designated as a pharmacy or as a manufacturer.

Second, the legislation would provide express inspection and registration authority for nontraditional compounders as manufacturers, including to the extent that such authority is not clear the ability to inspect records to determine whether pharmacies are actually engaging in nontraditional compounding.

Third, provide user fee authority which we believe already exists, to ensure that FDA has adequate resources to regulate nontraditional compounders as manufacturers.

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Fourth, ensure that nontraditional compounders may not compound copies of marketed drugs and thus subvert FDA's generic and bio similar approval processes.

Fifth, prohibit the compounding of specific drugs or drug categories for safety reasons.

Sixth, appropriately limit the channels of distribution of compounded drugs, including through a prohibition on wholesale distribution.

And finally, any new legislation should resolve any ambiguity in FDA's current authority by deleting the section of the Federal Food, Drug, and Cosmetic Act at issue in the Western States case.

Within this framework, FDA could and should take a risk-based approach to the regulation of nontraditional compounding using the same approach that FDA now takes to pharmaceutical manufacturing. However, complex legislation that creates a whole new classification of compounder, so-called compounding manufacturers, is unnecessary. Such an approach could result in regulatory confusion and the application of different regulatory standards for similar types of manufacturing. In fact, such a third class would actually decrease FDA's current statutory standards for regulating nontraditional compounders.

Finally, PhRMA is concerned about risks to patient safety that could result from proposals to allow compounding of copies of marketed

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pharmaceuticals in the event of a drug shortage. This potential exception could expose patients to unsafe drugs because the compounding need not establish that the compounded version has a safety and efficacy profile equivalent to the FDA-approved product.

In conclusion, Mr. Chairman, PhRMA thanks the subcommittee for the opportunity to provide testimony this afternoon regarding how to clarify FDA's existing authority to regulate nontraditional compounding. Biopharmaceutical companies are committed to patient safety. The same safety standards that govern pharmaceutical manufacturing should also protect patients who are treated with medicines manufactured by large-scale compounders. And we look forward to continuing the work with the subcommittee as it continues this important task.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Francer follows:]

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Mr. Pitts. Dr. Gaugh, you are recognized for 5 minutes for opening statement.

#### STATEMENT OF DAVID GAUGH

Mr. Gaugh. Thank you, Chairman Pitts and members of the House Energy Subcommittee on Health, and thank you for inviting me to testify before the subcommittee on this very important topic of drug compounding.

My name is David Gaugh. I am senior vice president for Sciences and Regulatory Affairs at the Generic Pharmaceutical Association and a licensed pharmacist.

GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceuticals and suppliers of other goods and services to the generic industry.

The quality and affordability of generic medicines is vital to the public health and sustainability to the health care system. Prior to joining GPhA, I was general manager of a generic injectable manufacturing company. I also served a leadership role in a major group purchasing organization and was assistant director of pharmacy in a hospital system in the Midwest where one of my responsibilities was oversight of traditional compounding performed by my staff.

GPhA supports the goal of clarifying the FDA's authority over

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compounding in order to protect patient safety and prevent another health care crisis like the fungal meningitis outbreak that was caused by the substandard compounded drugs.

Traditional compounding plays a vital role for patients and any new regulation should maintain that role. GPhA firmly believes that pharmacy compounding should adhere to the standard of one patient, one prescription, one drug. Patient safety is the highest priority for approved pharmaceutical manufacturers who comply with quality and sterile manufacturing processes and procedures as defined by the current good manufacturing practices, or cGMP. These regulations and associated guidances apply to all prescription drugs approved by the FDA for sale in the U.S.

The FDA's regulations and guidance are based on the fundamental principles that quality cannot be inspected or tested into a finished product, but quality must be designed into the product and the manufacturing process.

The large-scale manufacturing of sterile medicines, no matter who performs the functions, must involve similar activities as they have similar potential risks. In order to ensure the safety of the American public, the large-scale manufacturer of these sterile medicines should be regulated by the FDA in a consistent risk-based manner at the same high standards, including submitting documentation to the FDA and submitting to both preapproval and routine risk-based cGMP

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inspections.

A sterile injectable drug should not be the object of compounding unless these aforementioned regulations and guidances are enforced by the FDA or if the product is compounded for an individual patient by an individual prescriber.

GPhA strongly supports established standards for the quality of bulk substances used in compounding. We believe it is critical that these standards should include a requirement to the bulk substance used in compounding be from FDA inspected cGMP-compliant facilities, and that should be done prior to the compounding. GPhA recognizes that many in Congress believe that there should be an exemption to these requirements for certain medically necessary sterile products and shortage. We believe that the requirements for any category of large-scale compounding of sterile products should be the same FDA standards that apply to pharmaceutical manufacturers.

To solve a drug shortage of sterile injectable marketed drugs by lowering oversight, safety and quality standards is not in the best interests of the American public.

GPhA believes any drug substance exemption should include explicit language clarifying that the large scale compounder that is compounding marketable products on the FDA drug shortage list must immediately stop both the compounding and the distribution once notified by the FDA through established processes that the shortage

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has ended.

GPhA strongly supports the requirement for large scale compounding pharmacies or compounding manufacturers that plan to compound a marketed drug on the official FDA drug shortage list notify the FDA prior to starting that compounding.

We do not believe it is appropriate for notification only after initial large scale compounding has started. Additionally, the FDA should be given the authority to deny the request for compounding of a drug on the drug shortage list.

GPhA strongly supports providing the FDA with the additional resources needed to conduct inspections and do effective oversight through the fees on large-scale compounders. These fees should be sufficient to ensure that resources are not diverted from other areas within the agency.

In the interest of providing health care professionals and patients with complete information, any product compounded outside of the institution in which it is administered should be appropriately labeled as determined by the FDA and identified as a compounded product.

GPhA believes large-scale compounding pharmacies should be held to same adverse events reporting requirements as pharmaceutical manufacturers to allow the FDA ability to earlier identify and prevent any future health crisis.

In conclusion, Mr. Chairman, GPhA and our member companies are

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committed to ensuring both the role of the traditional compounders for patients, that need these patients are used and are safe for the patients and we look forward to working with the committee on this very important factor. Thank you.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Gaugh follows:]

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Mr. Pitts. Mr. Coukell, you are recognized for 5 minutes for an opening statement.

#### STATEMENT OF ALLAN COUKELL

Mr. Coukell. Chairman Pitts and members of the subcommittee, thank you for the opportunity to testify on pharmacy compounding and the need for legislation to protect patients.

My name is Allan Coukell. I am a pharmacist and director of drug and medical device work at the Pew Charitable Trust, independent research and policy organization with a longstanding focus on drug quality issues.

This subcommittee has heard previously about the risks of substandard compounded medicines and I won't reiterate those today, except to say that the recent fungal meningitis outbreak was far from an isolated incident, and even now, FDA inspections reveal alarming ongoing quality problems.

Today, I would like to propose ways for Congress to reduce these risks, and at the same time, ensure that patients have access to the medicines they need. Current law is inadequate for this purpose both because the courts have created uncertainty about the status of section 503A of the FDCA and because 503A does not recognize the emergence of a large scale compounding industry that is far removed from traditional

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pharmacy practice.

So let me begin with two points that I think all stakeholders should endorse. First, patients, doctors and pharmacists should prefer FDA-approved drugs over compounded medicines whenever possible. Only FDA-approved drugs have demonstrated their safety, efficacy and bioequivalence and have preapproved manufacturing facilities and methods. New legislation must not encourage compounding at the expense of traditional manufacturing.

Second, the preparation of customized medicines in response to a prescription for an individual patient is an established part of State-regulated pharmacy practice. But now let me make a third point, which is that there is a large-scale compounding sector that fits neither of the above categories. Instead, it does batch production of products, often high risk sterile products and admixtures of FDA-approved drugs for use in hospitals and clinics.

And the Inspector General recently reported that 85 percent of hospitals, hospitals of all sizes, large and small, purchased some intravenous drugs from outside pharmacies, sometimes thousands of doses a day. Together with the American Hospital Association and ASHP, Pew recently convened a pharmacy sterile compounding summit that brought together hospitals, purchasing organizations, compounders, regulators and pharmacy associations.

It also included experts on pharmacy and manufacturing who

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emphasized the enormous differences between the standards developed for pharmacy practice and the good manufacturing practices that apply to manufacturing. These experts stressed that only GMPs are adequate to ensure the safety of large scale, standardized production.

Oversight of such standards is a role for the FDA and not for State boards of pharmacy. Section 503A already recognizes FDA's responsibility to oversee some compounding, but merely reinstating the section would leave a lack of clarity about which facilities were subject to FDA oversight, and it would not clearly give FDA the ability to ensure that large-scale compounders comply with applicable GMPs. And shutting down a facility or requiring the filing of an NDA may not always be in the public interest.

So which facilities should be subject to FDA oversight? There is no single ideal solution, but a potential framework could include some of the following: Volume of production. Clearly larger scale operations expose more patients to risks. Those risks are not mitigated by an after the fact prescription. Large-scale operations should be subject to GMP. The nature of the products, manipulating a sterile product is a high-risk activity. Sterile drugs made from nonsterile raw ingredients are especially high risk.

Expiration dates. The longer a product sits before use, the more likely it is to degrade or sustain bacterial or fungal growth. Longer beyond use dating calls for higher quality standards and may also serve

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as a mechanism to distinguish between traditional pharmacy and this new compounding sector.

My written testimony contains additional recommendations for a practical and enforceable framework. In particular, facilities under FDA oversight must be required to register and to avoid an unfunded mandate to pay a fee. Compounded drugs should be clearly labeled as such and wholesale distribution prohibited. Current law gives FDA the authority to create a list of drugs that may not be compounded and to inspect pharmacies as necessary, and these authorities must be maintained.

I thank you for your leadership on this important issue. It is time to update the FDCA to remove ambiguities and create a clear, workable framework for patient safety. And I welcome your questions.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Coukell follows:]

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Mr. Pitts. Dr. Miller, you are recognized for 5 minutes for your opening statement.

**STATEMENT OF DAVID G. MILLER**

Mr. Miller. Good afternoon, Chairman Pitts, ladies and gentlemen of the committee, it is a pleasure on behalf of the International Academy of Compounding Pharmacists to appear before you today to talk about a situation that started with one pharmacy in Framingham, Massachusetts, but fundamentally has uncovered a real gap in our laws.

Now, I have been listening this afternoon to testimony, and you have the written testimony of my colleagues and myself, but I have heard six different terms used to define this thing that we are attempting to address and regulate.

Members of the International Academy of Compounding Pharmacists are pharmacists. We work in small drug stores, we work in large chain drug stores, at CVS, at a Publix grocery store in Florida, in hospitals.

Compounding is an essential core component of the filling and care of prescription medications for patients throughout this country. One of the challenges that we have found ourselves in is that the core concept of filling a prescription ordered by a physician either for the treatment of that patient in his or her home, or the use of that

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medication in the doctor's office for administration and treatment of a patient on site has somehow been clouded by the evolution of this other thing.

Tonight, this afternoon, we have heard that thing referred to as repackagers, traditional compounders, nontraditional compounders, outsourcing pharmacies, outsourcing admixture pharmacies, manufacturers, compounding manufacturers, batch production.

Now, again, I am a pharmacist. I look at this relatively simple. I get a prescription from a physician to take care of an individual patient, or I get a prescription to send a medication to a doctor's office so he or she can take care of that patient. IACP believes that currently section 503A is very clear that the Food and Drug Administration does have authority over the distribution of drugs in the United States, either through manufacturing or wholesaler distribution, and that our States have authority over the practice of pharmacy.

We believe at IACP that a great deal of confusion over this other entity that appears to not want to be regulated either by the FDA or falls within the gap of the regulation of the States, that is a separate group from pharmacy. And one of the things that we have seen as we have looked and worked with the Senate HELP committee on S. 959 is the core concept of preserving the integrity of the drug distribution system under FDA oversight, and on that side of the body it has been

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deemed a compounding manufacturer, unfortunately has gotten into the day-to-day practice of pharmacy and practice of medicine.

For example, on the Senate side, we now know that one of the things that we must have to ensure the protection, the safety and access of medications for patients is quality assurance. There is no language in S. 959 requiring all pharmacies or these other things to adhere by the nationally published standards of the United States pharmacopeia. There is no quality assurance.

There are specific language that intrudes on the practice of medicine and the practice of pharmacy. Most recently, the version of S. 959 that was distributed now includes a requirement that a pharmacist who fills a medication that may be a medication that is in drug shortage must inform the Food and Drug Administration within 3 days of filling that prescription. And we believe that is a significantly troublesome precedent.

There are also questions about whether or not all pharmacies would be actually required to participate and be overseen under this process and indeed within Senate 959 as my colleague from NCPA said previously, all hospitals and health system pharmacists are actually exempted from the Senate's new approach to regulating this issue.

Fortunately, Congressman Griffith has introduced a draft piece of legislation that we believe is really the closest solution to solving the questions that arose because of NECC's activities. We look forward

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to continuing to work with him and with this body on helping craft legislation that does a few most critical things: One, preserve patient access to medication; two, assure the American public of the safety of the medicines that they receive, that there are swift and accountable actions by our regulators at both the State and the Federal level to carry those laws out.

Thank you very much.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Miller follows:]

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Mr. Pitts. Dr. Catizone, you are recognized for 5 minutes for your opening statement.

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RPTS MCKENZIE

DCMN HOFSTAD

[5:05 p.m.]

**STATEMENT OF CARMEN CATIZONE**

Mr. Catizone. Good afternoon, Chairman Pitts and members of the subcommittee. On behalf of the National Association of Boards of Pharmacy and the State boards across the country, thank you for the opportunity to be here today.

NABP believes that the three legislative proposals provide the regulatory framework for us to address the issue of compounding manufacturing and to protect the public health. We support the Senate HELP bill and support the provisions that clearly distinguish traditional compounding, which should be regulated by the States and remain the purview of the States, and manufacturing, which should be the purview and remain the purview of the FDA. And we support the new category of compounding manufacturer that should fall within the purview and under the regulation of the FDA.

We commend Mr. Griffith and the other authors of the House bills for their diligence and concern for patient safety. However, we must also caution that there are provisions in the House bills that may not

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be intended to but could take us in the wrong direction, in a direction different from the legislative intent and a direction that could lead us to another NECC tragedy.

In regard to a primary issue identified by the House bill, NABP agrees that there is a bona fide but narrow need for pharmacists to compound a limited amount of products for administration to patients. The creation of the previously referenced third category, compounding manufacturer, seems to address the needs of the majority of patients. However, we are also sensitive to the fact that some stakeholders do not believe this is an appropriate category for this activity and would like to place this activity under the domain of traditional compounding and the purview of the State boards of pharmacy.

To respond to these concerns, specifically those of patient need, limiting the amounts of compounded products for direct administration in order to avoid any masking of manufacturing for compounding, we would support such an allowance provided there are limitations and qualifiers to those activities.

Those qualifiers include: First, the State has to allow such activity. Once that is allowed, the other limitations follow. There must be a demonstrated medical need for the compounded product. A non-patient-specific order must be written by the practitioner who will be administering or is directly responsible for administering the compounded product.

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The total quantity provided at the clinic office or healthcare setting per patient cannot exceed a 10-day supply. The compounded medication cannot be resold. The compounded medication must be prepared in accordance with applicable USP standards or GMPs, depending upon the product, as determined by the FDA.

There must be a limitation on the total quantity of compounded products that the pharmacy can prepare. Such quantity cannot exceed a certain percentage of or some other measure of the pharmacy's total number of prescriptions dispensed, dosage units, patient supply, or some other measurable and comparable factor.

The pharmacy must notify the applicable State board or boards of pharmacy and FDA of their involvement in this area in accordance with an appropriate process and frame times to be determined. And the FDA must have full legal access to all records of the pharmacy engaged in this activity. And equally as important, there can be no prohibitions on the sharing of information between the States and the FDA on these activities, as presently exists.

We want to note that these limitations and qualifiers for this activity does not erode the distinction between compounding manufacturing and compounding manufacturers created by the Senate HELP bill. They simply allow for an exemption with additional oversight under the category of traditional compounder.

Generalizing to a large extent, if the Senate HELP bill is used

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as a framework and modification from the House bills are employed, we would have three broad categories for compounding and manufacturing.

Traditional compounding: Per patient, patient-specific, regulated by the States, and all requirements of the States and USP standards in place. The FDA's current enforcement authority and responsibilities would remain. And the FDA could act, as they have been able to act, in the recent past.

Manufacturing and compound manufacturing: regulated by the FDA, complete access to all of those records, all of the requirements of the FDA, including GMPs.

And then this exemption, under traditional compounding: for those activities for administration within a clinic, healthcare setting, or hospital, shared authority between the FDA and the States, access to those records, and communication between the FDA and the States.

In closing, we appreciate the opportunity to be here today. We respectfully request that action be taken to develop and pass Federal legislation. We think it is important. We don't want to lose the opportunity.

Thank you.

Mr. Pitts. The chair thanks the gentleman.

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[The prepared statement of Mr. Catizone follows:]

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Mr. Pitts. Thanks to all the witnesses for your opening statements.

We will now begin questioning. I will recognize myself for 5 minutes for that purpose.

Mr. Hoey, the meningitis outbreak was a clear example of a communication breakdown between the FDA and the boards of pharmacy. How does Mr. Griffith's draft address strong lines of communication between boards of pharmacy and the FDA?

Mr. Hoey. Thank you, Chairman Pitts.

I think one of the key things that it does is that it requires the FDA to respond within 60 days when the board of pharmacy has sent a complaint or sent some kind of a warning to the FDA.

Clearly, that did not happen in the NECC tragedy. Despite numerous heads-up, numerous warning signs sent to the FDA, there was not appropriate action taken. Representative Griffith's bill would require that action be taken within that 60-day period.

Mr. Pitts. Mr. Francer, the Senate bill establishes a third category: compounding manufacturers. Do you think establishing a new category would provide clarity or confusion?

Mr. Francer. Chairman Pitts, we believe that a new provision like that would provide confusion and that it is not necessary. We believe that traditional compounding as it is now should be regulated by the States. And when there is not a prescription and we have a

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large-scale-type facility, it is manufacturing. And the FDA is quite good at regulating manufacturers.

Mr. Pitts. Mr. Gaugh, supporters of creating a compounding manufacturing category argue that the growing market from hospitals for outsourcers necessitates a need to exempt them from the new drug requirements of the FDCA.

Wouldn't this change permanently preclude the FDA from requiring pre-inspection of some facilities engaged in large-scale manufacturing from bulk API?

Mr. Gaugh. It very well could. So it is not totally clear, but, to your point, yes, it could blur those lines.

And even if you do outsource the product from a hospital to another provider, you still have that capability in 21st-century electronics to provide that prescription for the patient to the compounding pharmacy to compound that product one by one, patient to prescription.

Mr. Pitts. Now, in your testimony, you write about the importance of the drug manufacturing control processes written into the ANDA applications. Can you outline why this process between FDA and an applicant is critical to ensure the safety and efficacy of the product that will be ultimately marketed to the public?

Mr. Gaugh. Yes. As I said earlier in my statement, the fundamental principles of quality can't be inspected and tested with the finished product. They need to be designed into that product and

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into the manufacturing process. And so the NDA and ANDA holders, as they develop these products, are designing that in for both the product and for the manufacturing process. That is not being done in compounding.

Additionally, the ANDAs and NDAs that are filed contain specific specifications around stability, around impurities, around container closure, other manufacturing processes that, again, are not addressed by the compounding pharmacies.

Mr. Pitts. Dr. Miller, a couple of questions for you. Can you explain the importance of traditional compounding in our Nation's healthcare system? And then would you explain your thoughts on the creation of an expanded do-not-compound authority list for the FDA?

Mr. Miller. Yes. Thank you, Mr. Chairman.

I think the easiest way to understand why we need compounded medications is just to look at all of us in the room. We are all different sizes, we are all different ages, we are all different sexes, and each one of us metabolizes and uses drugs in different ways. One of the advantages of having trained pharmacists and physicians who understand the use of having medications customized to each one of us, it helps us get the therapy that we need.

The U.S. drug system is phenomenal. The vast majority of the products manufactured by my colleagues at PhRMA and the Generic Pharmaceutical Association meet most of our needs. But some of us

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require tweaks. So compounding pharmacists use techniques, tools, skills, and training to prepare medicines that are unique to a particular individual. Or, in some instances, as we have heard repeatedly this afternoon and I know that you will hear over and over again, compounding pharmacists in the short term can step in to fulfill drug-shortage or backorder situations. That is first and foremost why we need compounds.

Your question was, the second one?

Mr. Pitts. Your thoughts on the creation of an expanded do-not-compound authority list for the FDA.

Mr. Miller. IACP's position on this has been fairly consistent, sir. The FDA has had the authority to create a do-not-compound list based on a concern of safety or efficacy, and that we would leave in and strongly support.

Unfortunately, the agency has not updated that list in more than 10 years, and the provision of expanded authority to say, well, we can add a drug based on that it is hard to compound, or, you know, we think that you shouldn't use this particular active pharmaceutical ingredient -- there are some other clauses on the Senate side -- IACP strongly disagrees with that.

Because the fundamental reason for having a do-not-compound list is the agency should simply say, this medication is not safe, should not be used, is ineffective, it goes on the list.

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Mr. Pitts. My time has expired.

The chair recognizes Mr. Green for 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Dr. Thompson, in your testimony, you note that none of the classifications of "repackage" or "pharmacy" or "manufacturer" fits neatly with the regulatory needs of the large-scale compound or outsourcer.

Do you believe that asking the FDA to regulate these operations as manufacturers but leaving these specifics on how they are regulated up to the enforcement discretion of the FDA is a good policy?

Mr. Thompson. Sir, you know, reflecting on the Senate bill and how they have defined a compounding manufacturer, they defined it as an entity that is not preparing product in response to a prescription, is engaged in interstate commerce, as a proxy for risk.

We think as this industry has evolved over the last decade to provide necessary service to hospitals and clinics and others that it has really created this gray area that there isn't Federal legislation or regulation for. So we do think it is necessary to help clarify what those entities do, which provide very helpful services to healthcare organizations and patients.

Mr. Green. Have you looked at the enforcement discretion that is in Congressman Griffith's bill?

Mr. Thompson. Well, we don't think enforcement discretion is a

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good policy. And that is the thing now, that there are these companies out there that are selling products for anticipatory use that, under the law, really isn't allowed. But they do fill a need. They are doing it under, you know, under good standards in many cases, but those need to be clarified.

What we think in the Griffith draft, that, you know, in some ways, it creates a third category without calling it that. It still allows entities to prepare large-scale products without Federal oversight. It leaves it to State boards of pharmacy -- really, the same environment that exists now, that caused NECC -- it leaves it to the State boards to call the FDA and identify something. The State boards are under-resourced, they don't have the expertise, and they are not manufacturing-level inspectors.

Mr. Green. And I agree, although I think the Griffith bill also has some enforcement at FDA to respond to those State boards when they just send a letter. Because we had a number of letters in this situation that was done.

Mr. Miller, do you believe that using interstate commerce of sterile compounds in advance of a prescription is an adequate proxy to assess the highest-risk products?

Mr. Miller. We have to be very careful with that, because as Congressman Griffith has pointed out in his own State and even here within the Washington, D.C., metro area, where I grew up in northern

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Maryland, the concept of interstate commerce as the end-all-be-all definition of when something goes over that line, we have to recognize that health care in the United States is not limited to within State borders. So I would challenge our thinking that just the movement of a medication across a State line should be the trigger for FDA oversight.

Mr. Green. Okay.

Mr. Miller. The other portion --

Mr. Green. I only have 2 minutes left. But I understand that, because, you know, people in Beaumont, Texas, people come from southeast Louisiana to buy from a pharmacy. But me, as an individual, I can do it. But if you are selling across, there may be an issue.

But let me go on to another question. Of your members, how many are unquestionably small operations that would be caught up in a regulatory net created by establishing a proxy of interstate sterile and anticipatory compounding?

Mr. Miller. Quite honestly, sir, we don't know. And we don't know because there is very little data on the amount of prescription compounding that occurs not only in compounding specialty pharmacies but hospitals, home infusion, long-term care, others. That data is unknown. This could have significant impact on practice.

Mr. Green. The goal of this legislation would be primarily to protect the health and safety of our people and to also respect the

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various State laws in providing regulatory certainty to those who are regulated and to those who are purchasing regulated products.

And I agree -- some of us, I know the chairman has experience in State legislature. And we dealt with ours in Texas just like they dealt with in Pennsylvania. To me, our boards of pharmacy are certainly best equipped to regulate State agencies and the State-level activities.

However, don't you agree that engaging in interstate commerce creates a regulatory gray area that justifies a Federal response?

Mr. Miller. Well, you have to look at the model that has already been created by my colleague at the National Association of Boards of Pharmacy for the transfer of licenses between pharmacists across State lines. There is certainly a public-private partnership that can exist that currently shares information back and forth as pharmacies, say, in Texas wish to be licensed in the State of Louisiana.

We don't necessarily believe that a Federal response is the only workable solution.

Mr. Green. Well, and I think you are right, that it has to be a combination of State and Federal. But, you know, the problem we had in Massachusetts wasn't going across into Connecticut, necessarily. It was actually going across the country. And, again, traditional compounding is something we want to protect.

I know I am out of time, Mr. Chairman. Thank you.

Mr. Pitts. The chair thanks the gentleman and now recognizes the

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gentleman from Virginia, Mr. Griffith, for 5 minutes for questions.

Mr. Griffith. Thank you very much, Mr. Chairman.

I would say up front that I don't believe that our bill would have allowed the NECC situation to have occurred. I think the increased communications and the aspects that this bill has in it would have prevented that.

I do think that there are some things that we left holes in there and we are trying to sort out, and I think that is important. I also want to make it clear that if there is any indication, we can always tweak the language. That is why it is a draft bill. We are not trying to take anything away from the current FDA authority. If there is something that they currently have, we are not trying to take anything away. But we are trying to clarify, without going too far, what their authority is and try to sort these things out.

Mr. Coukell, I think you have it; we just have to figure out the combination. You listed in your testimony drawing the line, and you said some of the things we could look at were volume of production, nature of the products, percentage of sales, expiration dates, and interstate commerce.

As you heard previously when I testified, I don't think that interstate commerce alone necessarily does it, because it creates problems in those border areas or where the States are very close together or smaller. But some combination thereof is probably the

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answer.

What I would ask each of you to think about -- and you can always get back to me later -- is, what combination or which number of those factors do you think might be most important in figuring out that trigger to make that distinction? Because I think we all recognize, that is one of the issues we are trying to resolve.

And if we could start with you, Mr. Catizone, if you have thoughts now, or just say, I will send them to you later.

Mr. Catizone. Sure. Distinctions we make are: patient-specific, whether it is interstate or intrastate, it is compounding. Non-patient-specific, inter- or intra-, quantity, volume doesn't matter, it is manufacturing.

Mr. Griffith. Manufacturing. Okay.

Mr. Miller. Congressman, our perspective is, you have to be so careful with the issue of volume. It is an easy checkbox, you know, very easy to define. But, unfortunately, in health care, you can't usually rely upon easy --

Mr. Griffith. Let me ask you this, though. If we had volume, plus maybe a percentage of the business crossing State lines, if you threw two or three of them together, do you think that gets us closer to where we need to be?

Mr. Miller. Yes. And I think you have some precedence already in the Prescription Drug Marketing Act of 1987. That actually sets

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limits on retail pharmacies of 5 percent of sales to physician offices, hospitals, and clinics before they must register as a wholesaler -- precedent.

Mr. Griffith. All right. Let me keep moving down the line so that we don't use up all the time.

Yes, sir?

Mr. Coukell. Congressman, first, thank you for your leadership on that bill. We were heartened to see the placeholder language and would like to work with you on that.

A couple of points just now. One is, you know, just to emphasize, I think everybody agrees that if somebody is filling a prescription for a patient, that is a traditional pharmacy practice, and nobody is talking about that. So the question is, how much product should people be able to make on spec ahead of time?

And, you know, I mentioned the summit we held with ASHP and AHA. One of the quality experts there said, if somebody is starting with a non-sterile bulk ingredient, they are buying a bottle of methylprednisolone over the Internet and making a sterile product, that ought to be under GMP, no matter what. So his threshold there was zero for that particular type of product. For something that starts with a sterile precursor, you would set a higher threshold.

So I think it would be -- I will finish.

Mr. Griffith. Yeah, I hate to -- we are running out of time.

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Mr. Coukell. I think it would be impossible to say, basically, from a public health point of view, what is the limit at which we would not want people putting product out there.

Mr. Griffith. Okay. And if we could, I hate to limit the folks at the other end of the table, but we are running out of time.

Mr. Gaugh. We would leave it at two categories: traditional compounding and --

Mr. Griffith. Manufacturing.

Mr. Gaugh. -- pharmaceutical manufacturing, yes. Pharmacists are trained to compound. They are not trained to manufacture. It doesn't mean they can't learn, but they are not trained to do that.

Mr. Griffith. Right.

Yes, sir?

Mr. Francer. Yeah, Congressman Griffith, the touchstone clearly is whether there is a prescription or not. However, the FDA's current guidance in terms of its compliance lists a number of criteria, including compounding finished drugs from bulk active ingredients, using commercial-scale equipment. And the FDA actually has a multiple-factor test that they use.

Mr. Griffith. All right.

Yes, sir?

Mr. Thompson. Sir, we appreciate that the bill is a working draft, and we look forward to working with you to clarify key aspects.

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You know, the notion of percent of business might be a way to look at it. You know, volume, as mentioned by others, is a moving target. Risk level is a really key one, too. You know, high-risk-level compounding, compounding from API, nonsterile to sterile, is a very important area to focus --

Mr. Griffith. Okay.

Mr. Thompson. -- on. And I will leave it at that, and we will provide more --

Mr. Griffith. I appreciate that. Thank you.

Mr. Hoey. Thank you, Congressman.

A valid prescription, individual valid prescription, is key. That is the starting point and possibly the ending point, as well.

As far as interstate and percentage of prescriptions, percentage of volumes, those are possible, but they can be a slippery slope. And it is hard to have a one-size-fits-all in those categories.

Mr. Griffith. Right.

Thank you all very much. And I look forward to working with all of you in trying to sort this out at some point. We are going to have to make the difficult decision and draw that line somewhere. And I do appreciate it.

I yield back, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman and now recognizes the ranking member emeritus, Mr. Dingell, for 5 minutes for questions.

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Mr. Dingell. Mr. Chairman, thank you for your courtesy.

One main reason for the NECC outbreak was much confusion regarding FDA's authorities and the proper role of the States. This question is for all of the witnesses, "yes" or "no." Do you believe that it is important to have clear lines of division between FDA and State boards of pharmacy when it comes to regulating compounding pharmacies, yes or no?

Starting with you, Dr. Hoey.

Mr. Hoey. Yes.

Mr. Dingell. Next witness?

Mr. Thompson. Yes, sir.

Mr. Francer. Absolutely, yes.

Mr. Gaugh. Yes.

Mr. Dingell. Next witness?

Mr. Coukell. Yes.

Mr. Miller. Yes.

Mr. Catizone. Yes.

Mr. Dingell. Gentlemen, thank you.

Would you each submit, if you please, to the record how that division of responsibility should be created in the legislation.

[The information follows:]

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Mr. Dingell. Now, Section 503(a) of FDA Modernization Act of 1997 has been subject to court challenges which have limited its effectiveness. Since that time, our medical system has changed drastically.

This question is for Kasey Thompson of the American Society of Health-System Pharmacists.

Do you believe that our healthcare system has come to rely on what you call compounding outsourcers, yes or no?

Mr. Thompson. To a greater extent, yes.

Mr. Dingell. Now, in your testimony, you mention that your members also use compounded sterile preparations which are not available in an appropriate form from a manufacturer. Is that correct, yes or no?

Mr. Thompson. Yes.

Mr. Dingell. Now, can you please submit to the committee for the record a list of examples of these kinds of products?

Mr. Thompson. Yes, sir.

[The information follows:]

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Mr. Dingell. Now, do you believe that these compounding outsourcers should be subject to current good manufacturing practices and risk-based inspections by FDA, yes or no?

Mr. Thompson. Yes.

Mr. Dingell. Do you believe that State boards of pharmacy could adequately regulate these compounding outsourcers, yes or no?

Mr. Thompson. No.

Mr. Dingell. Now, these new compounding outsourcers are now routinely used by hospitals across the country. Any legislation must ensure that there are no unintended consequences which could have a negative impact on patient care.

Now, these questions are for you, Mr. Coukell of Pew. How is it correct that a recent study by the Inspector General at HHS found that 85 percent of hospitals which administer IV drugs purchased some of the products from outside the pharmacies? Is that so, yes or no?

Mr. Coukell. Yes.

Mr. Dingell. Now, Mr. Coukell, does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsourcers and our reliance on them, yes or no?

Mr. Coukell. It does not, not as such.

Mr. Dingell. Would you submit to us your thoughts on how that matter should be addressed?

[The information follows:]

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Mr. Dingell. And if the other members of the panel would do the same thing, it would be appreciated.

[The information follows:]

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Mr. Dingell. Now, do you believe that simply reinstating Section 503(a) would result in sufficient clarity regarding FDA's authority over compounding pharmacies, yes or no?

Mr. Coukell. No.

Mr. Dingell. Would you give us some comments for the purpose of the record on that particular point, if you please?

[The information follows:]

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Mr. Dingell. Now, I want to thank you all.

It is clear that we need to update and to significantly enhance FDA's authority in this area. I know there is bipartisan support for this issue. And we need, I know, to clearly define roles for the States and FDA concerning compounding pharmacies.

This committee has done good bipartisan work on public health in the past, and I believe that we can do it again. And I am looking forward to continue working on this issue with my colleagues on both sides of the aisle.

I want to commend each member of the panel for your excellent testimony. Gentlemen, you have done a superb job, and I want you to know how much I appreciate it.

And to you, Mr. Chairman, I thank you and yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentlelady from North Carolina, Mrs. Ellmers, for 5 minutes for questions.

Mrs. Ellmers. Thank you, Mr. Chairman.

Dr. Thompson, a moment ago, one of my colleagues had asked you about whether or not you felt that State boards could actually continue to regulate any of the basically nontraditional compounders. What is your reason? I mean, keeping in mind, of course, safety and sterility and best practices. Do you not feel that they have the capacity to

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do so?

Mr. Thompson. I think it really comes down, ma'am, to resources and expertise. You know, just like pharmacists, we are not inspectors of pharmaceutical manufacturers, and --

Mrs. Ellmers. Right.

Mr. Thompson. -- I don't think State boards tend to have that capacity either.

Mrs. Ellmers. Right. I guess this gets to the -- there again, we seem to get hung up on volume, and, you know, it seems to get back to the same things.

And, you know, to Dr. Woodcock I had posed a question of, if the nontraditional compounder were to be providing to a hospital or an outpatient surgery clinic, where the drugs would be administered under the supervision, obviously, of a physician to a patient within a reasonable timeframe and even possibly with, you know, some certain guidelines, like on a monthly basis, is it that they would be providing that to multiple entities and the volume there would be too much to be enforced?

Mr. Thompson. Well, I think the reason we think that some version of CGMPs is important is because it would really get into the specifics of sterility and stability tests in this per FDA and compendial standards. And that would really determine whether it had a 30-, 60-, 90-day, or 12-month beyond-use date associated with it. And that would

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really determine the storage conditions and when it needs to be administered.

But I think without, you know, a clearer process, whether it is CGMPs or some other process, that you just don't have that assurance in the current environment.

Mrs. Ellmers. Dr. Gaugh, shouldn't large-scale compounders be required to prove that they can manufacture under GMP conditions before patients are put at risk?

Mr. Gaugh. Yes, they should be.

Mrs. Ellmers. Okay. In your testimony, you write about the importance of the drug manufacturing control process. Can you outline why this process between the FDA and applicant is critical to ensure the safety and efficacy of the product that will be ultimately marketed?

Mr. Gaugh. Again, it is all about the CGMP requirements that exist between the FDA and the manufacturer. And those requirements don't exist between the State boards of pharmacy and the compounders to the same degree and the same level. And, as Dr. Thompson stated, they are not typically trained to inspect to that, whereas the FDA is. So it needs to fall into that same category.

Mrs. Ellmers. So can you explain, the similar scope of risk between ANDA holders manufacturing drugs and large-scale compounders in relation to, you know, explaining and creating two regulatory regimes for large-scale compounders and manufacturers. So I am

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concerned I don't understand that process.

Mr. Gaugh. So if I understand the question correctly, when you look at what the ANDA and the NDA holders are required to do, they have specifications they must meet around the potency of the product, around potential impurities and impurity growth around microbe growth. That doesn't exist currently in the compounding structure, in the compounding review. It would under CGMP requirements, but it doesn't under current requirements.

Mrs. Ellmers. So it would under -- okay, again --

Mr. Gaugh. It could, I should say.

Mrs. Ellmers. It could.

Mr. Gaugh. Yes.

Mrs. Ellmers. But it does not at this time?

Mr. Gaugh. It does not.

Mrs. Ellmers. Okay. And so, again, expanding on that, do you see risk in creating two more regulatory regimes? I mean, essentially, would there be two separate regulatory processes here or --

Mr. Gaugh. In our opinion, that would be creating two different regulatory processes at the FDA, if they were the ones controlling this. They would be controlling a manufacturer process for CGMP --

Mrs. Ellmers. For compounding and manufacturing.

Mr. Gaugh. -- to be different. And we don't see the manufacturing processes being different, so, therefore, the structure

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of control should not be different.

Mrs. Elmers. Okay.

I only have about 40 seconds left.

To Dr. Miller, again, getting back to just the importance of the physician role in this, why is the anticipatory compounding important to physicians?

Mr. Miller. Having medicine available. When the patient comes to you, you don't want to send that patient -- give them a piece of paper, send them down to the compounding pharmacy, where it may take 2 to 14 days to prepare and test that, then come back to be treated.

Mrs. Elmers. Uh-huh.

Mr. Miller. Physicians want to treat you today. Pharmacists want to treat you today. We have to be able to prepare medicines in advance.

Mrs. Elmers. Very good.

And I see that my time has run out, so thank you, Mr. Chairman.

Thank you to the panel.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentlelady from the Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Dr. Christensen. Thank you, Mr. Chairman.

Mr. Catizone, in your testimony, one of the limitations you suggest on compounding in advance of a prescription for traditional

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compounders is that the total quantity provided to a healthcare provider not exceed a 10-day patient supply.

I am interested in NABP's views on an alternative or additional approach to a limitation on compounding in advance of or without a prescription, of something like a 10- or 14-day expiration date from time of manufacture.

As I understand it, one of the aspects of traditional pharmacy compounding that contributes to safety is that it ordinarily is performed for an individual patient at a time the patient needs and will use the drug. One of the problems with allowing traditional compounders to make drugs in advance or without a prescription is that the drugs can be made in unlimited quantities and allowed to sit on a shelf, either in the compounder's warehouse or in the healthcare provider's offices, for extended periods of time. During that time, any bacterial, fungal, or other biological contaminants have time to grow and make the product more dangerous.

A relatively short expiration date from the time of manufacture would presumably limit the amount of drug that would be compounded in advance of an order, limit the size of orders that healthcare providers would request, and limit the amount of time any contaminants could grow.

So what are your thoughts about such an approach?

Mr. Catizone. Under the limitations we propose, there were two factors: one, the patient supply, as well as the total quantity the

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pharmacy would provide.

The 10- to 14-day expiration date is another variable that we could support, provided that that expiration date coincides with what the beyond-use dates are with the product so that we didn't put a 10-day or a 14-day expiration when the product was only good for 2 or 3 days. So coinciding those two factors makes that another very viable factor to look at in this process.

Dr. Christensen. Does anyone else have an opinion or want to comment on it?

Mr. Hoey. The USP requirement for a USP 797 standards would also help to address some of the issues that you are talking about.

I would also mention an example of the importance of anticipatory compounding. There was a situation where there was a shortage of injectable atropine for crash carts, for emergency crash carts. And because that drug wasn't available, a compounding pharmacy was able to make that. Well, if a patient is crashing, you don't want to have to write a prescription at that moment while your patient is coding. When that patient has had the proper treatment from the nurses and the physicians and the pharmacists, then you can write the prescription. But not having that prescription available at the time could cause someone to die.

So that is a situation where there is a shortage of the drug, and because compounding pharmacists have made that drug, it is available

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when the patient needs it immediately.

Dr. Christensen. Yeah. I think in a situation like that, as I understood it from Dr. Woodcock's testimony, because it is an emergency drug not available, that that would be something that they would allow.

Mr. Hoey. And there would have to be a stock on those crash carts that are on --

Dr. Christensen. Absolutely.

Mr. Hoey. -- certain floors in the hospital.

Dr. Christensen. Absolutely.

Mr. Hoey. And it wouldn't be just that drug. There would be several drugs that are on those crash carts.

Dr. Christensen. If there are no other comments, Mr. Chairman, I don't have another question.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5 minutes for questions.

Mr. Murphy. Thank you, Mr. Chairman. Thank the panel.

By the way, Mr. Chairman, I have an opening statement I would like to submit for the record, too.

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[The prepared statement of Mr. Murphy follows:]

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Mr. Murphy. All right. I am also the chairman of Oversight and Investigations, and we had a number of hearings on this to try and get the FDA to give us a straight answer. We didn't get it from Dr. Hamburg. I am going to try and ask you folks.

If the FDA has reason to believe that a compounding pharmacist is acting like a manufacturer, do you believe the FDA should have the authority to inspect a facility to the extent necessary to determine if that is the case?

Let's go down the panel. Dr. Hoey?

Mr. Hoey. In cooperation with the State board of pharmacy, yes.

Mr. Murphy. Dr. Thompson?

Mr. Thompson. If they are truly acting as a manufacturer, yes.

Mr. Murphy. Mr. Francer?

Mr. Francer. Yes.

Mr. Gaugh. Yes.

Mr. Murphy. Mr. Coukell?

Mr. Coukell. Yes, but of course they have to know that that facility is out there.

Mr. Murphy. Okay.

Dr. Miller?

Mr. Miller. Yes. And it already has that authority under 704(a).

Mr. Murphy. Thank you.

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Mr. Catizone. Yes.

Mr. Murphy. Okay.

So when we had our hearing before, I could not get an answer from Dr. Hamburg on that, because what it appeared was that they had, like, a 1-year moratorium against doing inspections without cause, it was said, that had made the medication that infected so many with meningitis.

And I asked several times, six or seven times, about this, and her responses were -- I said, "For example, in terms of dealing with the definition of a compounding pharmacy, who is responsible for that?" She said, "Well, it is not the FDA, it is Congress." I said, "But who keeps that definition?" She said, "Our chief counsel." "So have you reviewed this definition with your chief counsel?" She said, "I think everyone agrees." And I said, "I didn't ask you if you agree." She said, "The law is clear." And I said, "I want to know, have you reviewed with someone the definition of 'compounding' versus 'drug manufacturing'? Have you reviewed that with someone? When did that take place?" She said, "You know, we have had a lot of discussions." I frustratingly said, "So has someone reviewed with you the definition of 'manufacturer' versus 'compounding'?" She says, "You know, that is unfortunate. It is not clear."

It went on. I said, "Well, wait a minute. If you are telling me you don't have the authority to inspect based upon whether or not

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someone is a compounder versus a manufacturer, someone must be advising the FDA on where you have jurisdiction and where you do not." At that point, she said it was too complex and we couldn't understand.

Now, all of you answered that question pretty straightforward. You thought that there was authority with regard to this. But this is a key part of this issue and one that I want to find out. I mean, clearly, if we need more jurisdiction, we need to review that, in terms of the safety of patients and make sure people understand what is to be done here. But the way you all responded to me, it sounds like it already is there.

So I am going to go into a little more detail with this. Do you all believe, yes or no, is there a clear definition of "manufacturing" that defines when the FDA can come in and not?

Dr. Hoey?

Mr. Hoey. Yes, there is a clear definition of "manufacturing." And the FDA, as my colleague from PhRMA mentioned, the FDA does a good job of monitoring CGMP, and they do a good job of regulating manufacturers.

Mr. Murphy. Dr. Thompson?

Mr. Thompson. I think there is, yes. But these large-scale entities aren't behaving like manufacturers that have an NDA or an ANDA.

Mr. Murphy. When you say a large-scale entity, meaning what?

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Mr. Thompson. Well, like the compounding-manufacturer-type entities. I mean, they are really big compounding pharmacies. They are registered as pharmacies in all 50 States. There are nonresident license agreements.

Mr. Murphy. Okay, so this is not a mom-and-pop. This is someone who makes a lot of --

Mr. Thompson. Yeah, but they are essentially compounding at a very --

Mr. Murphy. On a large scale.

Mr. Thompson. -- large scale. They are not, often, commercially available products, unless there is a shortage, that are customized dosage forms. They are just doing --

Mr. Murphy. I see. And the FDA has the authority to go into those?

Mr. Thompson. I think they fall under the jurisdiction of the State boards under the current construct. And I think that is concerning for us, because these look more like manufacturing entities, but they are not. And I don't think the State boards have the capability to regulate them.

Mr. Murphy. Mr. Francer?

Mr. Francer. Congressman, I believe the FDA knows manufacturing when the agency sees it and that, as a matter of patient safety, they should be using their authority to the maximum extent possible.

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Mr. Murphy. Dr. Gaugh?

Mr. Gaugh. Yes. Once identified, I think they have the authority to step in.

Mr. Murphy. Mr. Coukell?

Mr. Coukell. I think the authority to investigate after a problem has been identified is not the same as having the authority and the tools to proactively ensure quality. And that is what we are missing.

Mr. Murphy. Yeah, what we found in this case with NECC is that they complaints from everybody -- patients, doctors, whistleblowers -- who were all saying, there is a problem here, and the FDA didn't act. So that is a question, and I still think that is one of my concerns with this whole issue. Is it that we need a bill or do we need an FDA that takes action within that?

Dr. Miller?

Mr. Miller. I am going to answer backwards.

Mr. Murphy. Uh-huh.

Mr. Miller. Yes, we believe they have adequate authority and a definition.

However, the approach and the answers that you received from Commissioner Hamburg implies that any one of us could go into our garage, start an illegal drug company, put that medication out into the marketplace, and the FDA would not be able to shut me down? If

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that is indeed the case and that is the confusion, when we address this legislation, we have to make it very clear that illegal, inappropriate manufacturing falls under the jurisdictional authority of the FDA.

Mr. Murphy. Thank you.

Mr. Catizone. There is not a clear definition.

Mr. Murphy. I see my time is up, and I am still seeking an answer. Thank you very much.

Mr. Pitts. The chair thanks the gentleman.

That concludes the questions from the Members who are here. We will have follow-up questions. I am sure other Members will have questions. We ask that you please respond promptly when we submit them to you.

I will remind Members that they have 10 business days to submit questions for the record. And so Members should submit their questions by the close of business on Tuesday, July 30th.

[The information follows:]

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Mr. Pitts. Superb hearing. Excellent testimony. Thank you all so much for coming.

Without objection, the subcommittee is adjourned.

[Whereupon, at 5:45 p.m., the subcommittee was adjourned.]