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DCMN CRYSTAL

EXAMINING DRUG COMPOUNDING

THURSDAY, MAY 23, 2013

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:58 a.m., in Room 2322, Rayburn, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Shimkus, Murphy, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Barton, Pallone, Dingell, Engel, Capps, Matheson, Green, Butterfield, Barrow, Christensen, Castor, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Mike Bloomquist, General Counsel; Karen Christian, Chief Counsel,

Oversight; Paul Edattel, Professional Staff Member, Health; Brad Grantz, Policy Coordinator, O&I; Sydne Harwick, Legislative Clerk; Nick Magallanes, Policy Coordinator, CMT; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Krista Rosenthall, Counsel to Chairman Emeritus; Chris Sarley, Policy Coordinator, Environment & Economy; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Oversight; Brian Cohen, Minority Staff Director, Oversight & Investigations, Senior Policy Advisory; Alli Corr, Minority Policy Analyst; Eric Flamm, Minority FDA Detailee; Ruth Katz, Minority Chief Public Health Counsel; Elizabeth Letter, Minority Assistant Press Secretary; Karen Nelson, Minority Deputy Committee Staff Director for Health; Stephen Salsbury, Minority Special Assistant; Rachel Sher, Minority Senior Counsel; and Ryan Skukowski, Minority Staff Assistant.

Mr. Pitts. The subcommittee will come to order. The chair will recognize himself for an opening statement.

The purpose of today's hearing is to hear from FDA and healthcare experts regarding the history and importance of drug compounding to patients and the current regulation of compounding on the Federal and State levels. As we are all aware, in the summer and fall of 2012 a Massachusetts company, the New England Compounding Center, NECC, shipped over 17,000 vials of in injectable steroid solution from 3 contaminated lots to healthcare facilities across the country.

After receiving injections of NECC's contaminated steroid, over 50 people died from complications associated with fungal meningitis; further, almost 700 others were stricken with meningitis or 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.

This committee began an investigation into the matter, and on October 9th a bipartisan committee letter was send to FDA requesting details surrounding the outbreak and the prevention of future outbreaks. On October 17, the committee sent a letter to FDA asking for all documents related to the outbreak, including internal memoranda and communications with NECC. The Oversight and Investigations Subcommittee held a hearing on November 14, 2012, where Dr. Margaret

Hamburg testified examining whether the meningitis outbreak could have been prevented. Two days later, on November 16th, the committee sent yet another letter to FDA stating that the agency had not provided any of the internal communications or memoranda in response to the October 17th letter.

It was not until March 21st, 2013, over 5 months after the original request, and after being threatened with the possibility of a subpoena, that FDA fully complied with the committee's document request. It should be noted that the Massachusetts Department of Public Health had fully complied with the committee's document request, turning over thousands of pages of documents related to its interactions with NECC before the November hearing took place.

On April 16, 2013, the O&I Subcommittee held another hearing entitled, "A Continuing Investigation Into the Fungal Meningitis Outbreak: Could It Have Been Prevented?" and released a 43-page report on its investigation into the NECC tragedy. The report stated that FDA had been aware of potential problems at NECC since 2002. During her testimony at the November hearing, Dr. Hamburg repeatedly expressed uncertainty about FDA's authority over compounding pharmacies, partially due to conflicting opinions on the matter issued by two different circuit courts of appeals in 2009.

This uncertainty, however, has not stopped FDA from engaging in

multiple enforcement activities against compounding pharmacies engaged in practices similar to those of NECC since the outbreak took place. This year alone, FDA has announced recalls from compounding pharmacies in Augusta, Georgia, and Lake Mary, Florida, and St. Petersburg, Florida. In addition, the FDA in October of 2012 was prepared to issue new guidance related to compounding enforcement under its authority under Section 503.

Since the outbreak, however, the FDA has called for new authority that creates a new category of compounding manufacturers. From what I understand, there are concerns that creating this new category could undermine drug safety by lowering standards and also weaken intellectual property protection.

I would like to thank Dr. Woodcock for appearing before us today to explain her understanding of FDA's authority over compounding pharmacies and what actions the agency is taking to ensure that future outbreaks can be prevented. And I would also like to thank all of our other witnesses for sharing their expertise on compounding and its importance to patients.

Thank you. And I will yield the balance of my time to Congressman Barton.

[The prepared statement of Mr. Pitts follows:]

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Mr. Barton. Thank you, Mr. Chairman. I am glad to be here today. We are glad to have Dr. Woodcock. She is a longtime witness before the committee, and we have great respect for her. We look forward to hearing what you have to say.

I think it is pretty obvious to neutral observers that the facts do indicate that the FDA had authority that it refused or chose not to use in the situation that we are investigating. I am sure Dr. Woodcock will elaborate on that and may have a counter point of view.

Mr. Chairman, on the second panel I have a good friend and former constituent, Mr. Joe Harmison, who is in the audience. He is the past president of the Texas Pharmacy Association, the past president of the National Community Pharmacists Association. He is that rare breed, he still owns and operates his own pharmacy. The only thing I can find negative about him is that he graduated from the University of Oklahoma School of Pharmacy back in 1970. Other than that, he is a great guy and a good friend, and I am sure he will be very helpful in his testimony on the second panel.

I might also take personal privilege just to say that Mr. Shimkus, to my right, threw out a runner at third base today in our intersquad game, as we get ready to battle the Democrats who have beat us the last four years in the congressional baseball game. So Shimkus is getting

in game for. With that, I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Barton follows:]

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Mr. Pitts. Now recognize the ranking member of the subcommittee, Mr. Pallone, 5 minutes for an opening statement.

Mr. Pallone. Thank you, Chairman Pitts. I am pleased that the Health Subcommittee is finally having a hearing to examine drug compounding. But, unfortunately, we are months behind. While we are having our first hearing today to gather information on this topic, our colleagues in the Senate have already worked together to produce and mark up bipartisan legislation in the Health Committee. And so I think this delay is regrettable here.

Access to compounding drugs is crucial for patients who have unique medical needs. We know that the New England Compounding Center that distributed the contaminated compounded product last year, resulting in the meningitis outbreak that claimed over 50 lives and infected over 700 patients, was clearly a bad actor. However, NECC will not be the last bad actor. Similar tragedies will undoubtedly occur again unless we address the significant gaps that exist in the current regulation and oversight system of compounded products. If patients are to have confidence in the safety and quality of these drugs, we must ensure that compounders meet safety and quality standards.

While traditional compounders who mix medications to fill a prescription for a specific person are regulated at the State level,

and drug manufacturers are regulated by the Federal Government, there are a growing number of companies that do not fall into either of these categories. Many companies are compounding drugs without prescriptions and shipping large quantities of the products across State lines; in essence, acting more like manufacturers than the traditional compounders. In the absence of clear lines of authority, these companies experience very little State or Federal oversight.

So as we begin to examine drug compounding, I urge my colleagues to use this as an opportunity to move forward to determine what changes are needed rather than looking back and casting blame. We must stop questioning whether the FDA needs new authority. In fact, the past few months of examination by our Oversight Committee and the Senate Health Committee it has become abundantly clear that conflicting court opinions and ambiguous language in the law show that the FDA does not have adequate authority to oversee compounders. And that is why I support efforts to help identify a new category of companies to be subject to Federal regulation and oversight and provide FDA the tools and resources it needs to properly regulate them.

So, Mr. Chairman, I hope today can be the start to this committee coming together in a bipartisan manner to address this issue and create greater clarity in the law so the tragedies like the one involving NECC do not happen again. The American people should know that the drugs

that they receive are safe and effective.

So I thank all our witnesses. I know we have a second panel. I look forward to hearing about how Congress can best address the gaps in regulation and oversight that were unfortunately highlighted by the NECC meningitis outbreak and how all stakeholders can work together to protect the public health.

I don't know if anybody wants any of my 2 minutes on my side. You would, Mr. Dingell? I yield to Mr. Dingell.

[The prepared statement of Mr. Pallone follows:]

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Mr. Dingell. I thank the gentleman for yielding. I thank you for having this hearing. I welcome our first panel member today. Good to see her back before the committee.

This committee has a great opportunity. We can quibble all we want about whether we have the authority, whether it is needed or not. Simple fact of the matter is people are dying, people are being made sick. And many people in this compounding industry, if that is what you want to say it is, have been studying ways to get around food and drug regulation and to continue, for all intents and purposes, becoming manufacturers.

The question is, do we want to persist on that while we engage in a monstrous quibble, or do we want to get down and cut the corners that come from courts and judges trying to resolve a question that is probably well beyond their competency.

Having said these things, I would urge us to move forward on legislation, effective legislation. This committee has a remarkable history in this Congress, which is noteworthy for having done very little, to have in fact moved forward with a number of important pieces of legislation in a bipartisan fashion. I see no reason why we should not continue that kind of effort with all the blessings to the public that that obtains.

So I would urge us to move forward. Let's put these rascals in

the compounding industry into a place where they have law to obey, where everyone understands what it is, and where we can make our people safe. My State of Michigan suffered huge losses to people in sickness and death stemming from wrongdoers who were deliberately skating around the law. And unsafe pharmaceuticals well beyond the reach of Food and Drug were in fact poisoning and killing our people.

This is a wonderful opportunity. I commend you for making it possible. I look forward to working with you. I commend my colleague Mr. Pallone for his wise counsel and leadership. And I look forward to working on this matter in an effective way where we do go forward together to solve a major problem for our people. Thank you.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Dingell follows:]

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Mr. Pitts. Now recognize the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for an opening state.

Dr. Burgess. Thank the chairman for the recognition. And I do support the efforts to examine the role that traditional compounding pharmacists play in the healthcare system. I know the value that they provide, having used them in my practice for a number of years.

But we are also going to hear this morning how this incident necessitates broad new authorities. Recently the Food and Drug Administration has inspected over 50 compounding facilities. You have to ask yourself, by what authority did these 50 inspections occur? If the FDA has the authority today, they had it 6 months ago. The fact is one of the following statements must be true: The agency is acting without authority and risking litigation or they have the authority and have always had the authority and have simply failed to use it.

Documents obtained by the Oversight and Investigations Subcommittee are deeply troubling, and I believe show FDA negligence. New England Compounding Center was making upwards of 30,000 vials of product without prescriptions and yet the Food and Drug Administration questioned whether they had authority under the Food, Drug, and Cosmetic Act over manufacturing?

The Food and Drug Administration was aware that this compounding facility was making poor products for years. They never followed up

on warning letters. Frustrated FDA staff could not even warn the State of Massachusetts. Whistleblowers, doctors providing dozens of adverse event reports and law firms dealing with substandard conditions came forward and the FDA did nothing. They didn't even pick up the phone.

This is an example of circling the wagons after the crisis, and this member is having none of it. The bureaucracy held up the guidance for years. Testimony that is as provided through our Oversight and Investigations Subcommittee -- the testimony that has been provided to both the Oversight and Investigations Subcommittee and this subcommittee today has been carefully crafted to avoid asking who failed America and who allowed NECC to introduce contaminated product in its supply line.

I cannot in good conscience entertain discussion of legislation when not one person has been fired, reprimanded, or held culpable at the Food and Drug Administration. In fact, legislating transfers the blood of those dead and harmed from the agency responsible to us, the subcommittee and to Congress.

Massachusetts fired people because they should have known, and yet the Food and Drug Administration, who did know, now wants new authority. To what end is new authority going to provide protection to the public if the Food and Drug Administration, by its own admission

and track record, refuses to pick up and use the tools they had at their disposal. The Food and Drug Administration refused to go after those operating so far outside the bounds of legality in traditional compounding. Why in the world would we trust them to regulate a legitimate compounder?

Until the agency admits where it failed the American public, I for one am not going to be a party to letting them get away with this dereliction of responsibility. To do otherwise invites further incompetence from one of the most important agencies under our jurisdiction and sets a dangerous precedent for other agencies under our purview.

I would like to yield the balance of the time to the gentleman from Virginia, Mr. Griffith.

[The prepared statement of Dr. Burgess follows:]

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Mr. Griffith. Thank you, Dr. Burgess.

Last fall's fungal meningitis outbreak was a true public health crisis for our Nation. In Virginia's Ninth Congressional District, which I represent, there were two deaths and 50 confirmed cases of fungal meningitis associated with the sterile compounded injections from NECC. Approximately 1,400 patients in southwest Virginia were notified they could have been exposed to fungal meningitis because they received tainted steroid injections.

I clearly believe that FDA had the authority they needed to prevent the fungal meningitis outbreak. NECC was a manufacturer. The committee's thorough investigation has demonstrated the agency failed in their oversight and did not pursue regulatory action against NECC and Ameridose, who were acting illegally as manufacturers, not as compounding pharmacies, in violation of the Food, Drug, and Cosmetic Act.

With well over 130 community pharmacists provided invaluable access to health care in rural and remote communities in the mountains of southwest Virginia, I do not support giving FDA broad new authority over the practice of pharmacy, which is the jurisdiction of our States. The type of compounding that goes on in our local pharmacies involves making special medications subject to the needs of the individuals based on a patient-specific prescription from their physician.

The real problem is large-scale operations like NECC who are acting illegally as drug manufacturers by making large batches of drugs, some of which are just copies of FDA-approved drugs, and then selling and shipping them all over the country.

In her testimony, Dr. Woodcock acknowledges that FDA was in the final stages of publishing new guidance differentiating pharmacy compounding from drug manufacturing. Three years later, FDA finally had all of its ducks in a row and was ready to go forward, but they did not do so in their draft guidance document. I believe there are some areas that need clarification. So we have been doing our due diligence to understand this issue and develop legislation that will make it clear how we define what a compounding pharmacy is, which is and should be regulated by the States, and what a drug manufacturer is, which should be regulated by the FDA.

Yield back.

Mr. Pitts. Chair thanks the gentleman.

[The statement of Mr. Griffith follows:]

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Mr. Pitts. That concludes our opening statements. We have two panels today. Our first panel today we have Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration.

Thank you for coming, Dr. Woodcock. You will have 5 minutes to summarize your testimony. Your entire written testimony will be placed in the record. You are welcome and recognized for 5 minutes.

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

Dr. Woodcock. Thank you, Mr. Chairman, Vice Chairman, Ranking Member, and members of the committee. Thank you for the opportunity to testify.

This has really been an appalling tragedy of a kind not seen really since the early 1900s, where American citizens were harmed by grossly contaminated drug. But this is just the worst of a long series of outbreaks over the past 2 decades that have involved compounding pharmacies, and these have included multiple deaths, blindness, hospitalizations, and other types of harm. So this was just the worst of a continuing series of outbreaks.

As the Commissioner testified, we should have been more aggressive in applying our existing authorities to this industry, despite the ambiguities in the statute and despite challenges by industry. We are being more aggressive now, and we are inspecting the pharmacies that we know about that present the highest risk. And we are seeing really serious systemic quality issues, particularly around sterility practices.

In light of recent events, though, even with the tragedy that has

occurred, some of these firms challenge our authority when we try to go in and inspect them, and they delay or deny full access to our records. We have twice had to get administrative warrants from the court and have U.S. marshals accompany our inspectors. And we have had to threaten warrants in other cases to get cooperation to inspect these compounding pharmacies. And because we are inspecting and moving aggressively doesn't mean we are going to prevail in court.

Make no mistake, if the approach to this isn't changed, and I think legislation is probably the best approach, we will see more of these tragedies. We are already, since the outbreak, we have seen several episodes involving human harm from compounded products.

Lack of clarity in our statutory authorities really isn't the only concern. The industry has evolved tremendously since the time of the corner pharmacist and traditional compounding in response to a prescription. And this is still going on, and FDA has always said we felt this was appropriate. But another industry has grown up that is basically performing outsourcing for hospitals and making large amounts of dosage forms, often starting with FDA-approved products. And this industry was really never contemplated in the kind of authorities that we have.

So we feel that we need legislation to preserve the benefits of traditional compounding, which is in response to a prescription, and

which we are not proposing that we should have authority over, further authority over, while at the same time giving us the right tools to regulate high-risk practices and products. We feel we need legislation that requires compliance with Federal quality standards; requires Federal registration, because right now we don't know who they are, we don't know where they are, and we don't know what they are making; and requires reporting to FDA of adverse events so that we can act before the problems get out of hand. Right now there is no requirement to send us reports of death or other harm that might occur with these products.

And for all pharmacy compounding we feel basic protections should be in place, including the fact that FDA should have access to the records so that we can go in and see whether they are shipping large amounts of product, all right, and what they are doing; and also, should there be an outbreak, we are not delayed by having to go to a marshal and have access to the shipping records.

A prohibition on compounding the most complex and highest-risk products. Our drug manufacturers, as you know, have problems manufacturing certain products because they are very complex, and they put a tremendous amount of science and effort into that. We don't think they should be compounded. That is a small list, but we think that list should be maintained. And clear labeling of compounded drugs to

allow prescribers and patients to make more informed choices.

We look forward to working with you to explore funding mechanisms to support this oversight, should it be put in place. Remember, I think it really is a matter of when this is going to occur the next time, not if. That is the state that we are observing of the industry when we are inspecting them. We are all on notice, we owe it to the public and the victims of this incident and the numerous outbreaks over the years to provide better protection in the future. I look forward to answering your questions.

Mr. Pitts. Thank you, Dr. Woodcock.

[The prepared statement of Dr. Woodcock follows:]

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

Dr. Woodcock, since the outbreak, the FDA has executed dozens of inspections and at least 11 companies were ordered to stop producing some or all drugs. Have any of the companies you inspected challenged the FDA authority? If so, how many?

Dr. Woodcock. Certainly, as I said, we have had several challenge our authority to even go in the firm and look at their records. Others have challenged and then yielded when we got the lawyers talking to one another. Now, as far as whether there will be court challenges, that is something I really can't speak to. But that certainly has been the history in the past.

Mr. Pitts. Can you provide a list to the committee of the companies who you have inspected and who have challenged your authority?

Dr. Woodcock. We will be happy to do so.

[The information follows:]

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Mr. Pitts. According to the Senate HELP report, I quote, "As a result of increased oversight from both State and Federal regulators, at least 48 compounding companies have been found to be producing and selling drugs that are contaminated or were created in unsafe conditions or otherwise violate State licensing requirements. Ten companies have issued nationwide recalls of drugs compounded at their facilities. In at least four cases, the recall was issued in response to documentation of actual contamination. Further, 11 compounding pharmacies have been ordered to cease and desist operations, including two of those that had issued nationwide recalls."

Now, as you said, some of these companies challenged the FDA's authority. Can you explain how State and Federal regulators executed this increased oversight?

Dr. Woodcock. Well, we identified firms that we knew about basically from adverse event reports, from reports in the paper, from advertisements they had on a Web page and so forth, and we did a risk-based approach to inspecting what we felt were the highest-risk firms, based on what we knew. We don't know the whole universe of firms that are out there.

We also continue to do for-cause inspections. For example, if we get a report from a health department about a cluster of cases of an outbreak of one sort or another, we will immediately go into that

pharmacy and inspect them. In all of those for-cause cases, we have gone in with the State authority. So we have gone in together, all right. And in most of the other inspections that we did that we planned, the 31 inspections, we have gone in with the State authorities as well.

Mr. Pitts. What were the biggest challenges that you faced during that period?

Dr. Woodcock. Well, the challenges mainly were getting access in some cases to be allowed to inspect, all right, particularly some of their records. But the real thing that we have found is that the aseptic processing practices, which means how you try to make a drug to ensure that it is sterile, are not anywhere near the quality that is necessary to mass produce sterile drugs. There is a tremendous deficit of quality in their practices that almost assure that these drugs will at some point be contaminated.

Mr. Pitts. What are some of the lessons the agency has learned during the period of this outbreak?

Dr. Woodcock. Well, I think we have learned that there are pervasive practices that are unsafe that are going on across the portion of this industry that we have investigated. Primarily, we are targeting those sterile manufacturers because that is the highest risk when you are actually injecting drugs into the body. So that is one

thing we have learned, is the pervasive nature of unsafe practices across the section of industry that we have inspected.

Mr. Pitts. In your testimony you reference nine separate incidents where compounded products caused deaths and serious injuries. Explain briefly the actions the FDA took following each of these incidents.

Dr. Woodcock. Well, over the years, our actions have been primarily reactive. Okay. So when we have learned of an outbreak, as I said, we have gone in. Often we go in with the State. The State, because they hold the pharmacy license, they are able to shut down the firm right away. Like that is how those 11 firms you referred to were shut down. Okay.

We have to call for and we often do talk to the firm and say we are going to go to the press if you don't do a recall, because we don't have the authority -- they don't hold a license with us, so we can't just shut them down. We would have to then go court if they still refused to shut down their operations.

Mr. Pitts. My time has expired. Chair recognize the ranking member 5 minutes for questions.

Mr. Pallone. Thank you. Dr. Woodcock, your testimony mentions the various court challenges that the compounding industry has brought over the years regarding FDA's authority over compounding pharmacies.

But I would like to learn more about that litigation and the impact it has had on FDA's ability to oversee the industry.

Those cases center around Section 503A of the act, which was enacted as part of the 1997 FDA Modernization Act. And that law attempted to delineate when compounded drugs were new drugs and therefore subject to FDA regulation. Section 503A also restricted compounding pharmacies' right to advertise.

So I am going to put a map of the U.S. up on the monitors here. It is up there. This map was not prepared by me or my staff, it was actually prepared by the International Association of Compounding Pharmacies, the main compounding industry lobbying group. On this map, the red States and blue States do not represent States that voted Democrat or Republican. They represent the different rules under which compounding pharmacies operate.

[The information follows:]

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Mr. Pallone. So let's look at the red States. Those represent the Ninth Circuit Court, whose jurisdiction includes the Western States. And as IACP notes on this chart, in 2001, the Ninth Circuit Court ruled that the advertising component of Section 503A was unconstitutional and that the rest of 503A was void because it was inextricably tied to the advertising component, or that it was not severable, as we say. Is that correct?

Dr. Woodcock. Yes.

Mr. Pallone. Okay. Then in 2002, the Supreme Court agreed with the Ninth Circuit that the advertising ban was not constitutional, but the Court did not address the question of whether that ban could be severed from the rest of Section 503A. The result of that decision then was that the advertising ban was unconstitutional throughout the country, and the entirety of Section 503A remained invalid in those red States on the map. The Supreme Court decision also meant that whether the remaining parts of Section 503A was effective in the rest of the country was an open question. Is that your understanding?

Dr. Woodcock. That is my understanding.

Mr. Pallone. So let's look now at the blue States on the map, Texas, Louisiana, and Mississippi. Those States represent the Fifth Circuit. 2008, the Fifth Circuit Court of Appeals held that the unconstitutionality advertising restrictions did not affect the

standing of the rest of Section 503A. So that means that in Texas, Louisiana, and Mississippi, Section 503A is in effect. Am I correct on that?

Dr. Woodcock. That is my understanding.

Mr. Pallone. And am I correct that the gray States on the map then represent the rest of the country, where we just don't know how courts would rule on whether Section 503A, apart from the advertising restriction, is or is not in effect?

Can you tell us what the impact of this 503A patchwork has been on FDA's ability to oversee the compounding industry? Have compounding pharmacies been able to take advantage of this confusion over the law to block FDA's ability to aggressively enforce the court authority it does have over compounders?

Dr. Woodcock. Yes, I think that definitely contributed to the inability of FDA to have an effective regulatory program. All right. We have different circuits with different meanings of the statute that was passed by Congress in 1997. In some areas, the statute is thrown out; in other areas, it is partially operational; in other areas, we don't know if we went to court what type of decision we would get.

Mr. Pallone. So this seems to me to be all that we as Members of Congress need to see to understand the dire need for clarifying the FDA's authorities here. What I don't understand is I am hearing from

the GOP here on the committee that they don't seem to want to give the FDA additional authority even though the Senate passed a bill on a bipartisan basis that does. And yet I don't see any alternative.

In 1997, for better or worse, Congress spelled FDA's authorities over compounding pharmacies. I think that law is out of date and should be updated. But putting that aside, courts have invalidated that statute, our statute, in a major swathe of the country. I think it is irresponsible for us to stand by and expect FDA to cobble together a piecemeal approach to regulating the practice of compounding pharmacy, a practice that, as evidenced by the NECC, bears great risk for patients all over the country.

I don't quite understand why my colleagues on the other side, at least here in the House, not in the Senate, don't want to step in and clarify the rules of the road. I think we have to do that, otherwise we are going to continue to have these problems with compounding pharmacies. And I hate to say anything positive about the Senate, but they are moving in that direction and we need to do the same.

Thank you.

Mr. Pitts. We are presently voting on the floor. We have two votes. We will recess until the second vote is over and then reconvene. We will have another series of vote around noon. So if you can stay, Dr. Woodcock, we will recess at this time for floor votes and be back

as soon as the members finish their second vote.

[Recess.]

Mr. Pitts. Time of our recess having expired, we will reconvene and continue our Q&A session. Chair recognize the vice chair of the subcommittee, Dr. Burgess, 5 minutes for questions.

Dr. Burgess. I thank the chairman.

And thank you, Dr. Woodcock, again for being here.

So between 2002 and 2012, according to our investigation on Oversight and Investigations Subcommittee, the New England Compounding Center was the subject of at least 52 adverse event reports. Numerous offenses documented throughout the investigation that was undertaken by both FDA and State regulators.

So, you know, the big question is, why not do something? Why not take action? And to tell you the truth, it was a little hard to read through some of the emails that we finally got. Your folks were literally pulling their hair out about we can't just send another warning letter, we have already sent one to which it took us 2 years to respond and we will have to do something. And it was like they got right up to the point of having to do something and then no one wanted to do it. Is that an unfair assessment.

Dr. Woodcock. Well, I am unable to comment specifically on NECC because of the ongoing criminal investigation. However, generally,

I would say we should have been more aggressive overall in this industry. There was a pattern for many firms that we were looking at of adverse events. And, as I said, there were a series of outbreaks. Every year, practically, we would have an outbreak due to contaminated compounded product, and we should have been more aggressive in going after this industry.

Dr. Burgess. Well, again, I just don't understand some of your folks. They just had to be losing their minds over this stuff. Samia Nasr, a name kept coming up in the emails that were provided to us. Does she still work at the agency?

Dr. Woodcock. Yes.

Dr. Burgess. I know you can't comment on employment. But, I mean, I think she did the right thing to bring all these things to people's attention, but it must have driven her crazy that the people just above her wouldn't do something.

Dr. Woodcock. As I said, overall, we should have been more aggressive as this industry continued to be responsible for outbreaks. We investigated outbreaks, we investigated reports, and we did respond reactively to problems. But we did not proactively do everything we could.

Dr. Burgess. And as a consequence you had 50 deaths and 500 people who are living with long-term disability as a consequence of

the Exserohilum in the betamethasone.

Dr. Woodcock. Well, we have more people who have died than that. We have people blinded. We have people with disabilities as a result of these outbreaks over the last 12 years. And I would say, frankly, if you want my opinion, that we could have done more --

Dr. Burgess. I do.

Dr. Woodcock. -- the States should have done more, and Congress could have intervened when these statutes were struck down.

Dr. Burgess. You know, and the ranking member had a nice map up there. He made a nice little comment about red and blue States. But, honestly, the 503A limitation doesn't affect Massachusetts at all. I mean, we are talking about Texas and California, Fifth Circuit, Ninth Circuit, but Massachusetts is outside that. So what prevented you in Massachusetts?

Dr. Woodcock. As I said, I can't specifically discuss this particular case because of the ongoing investigation.

Dr. Burgess. Okay.

Let me ask you this: How difficult is it to get an injunction from a judge? You go a judge and say, we have got a problem here. How difficult is it to get an injunction?

Dr. Woodcock. We, as I understand it, I am not one of the agency lawyers, I am a physician, as you know, but we make a recommendation

to the Justice Department, who then proceeds to do the legal activities. And just because we initiate legal action doesn't necessarily mean we will prevail in court.

Dr. Burgess. How many times have you not prevailed?

Dr. Woodcock. I don't know. We can get back to you.

Dr. Burgess. Would you get us that information?

Dr. Woodcock. Absolutely.

Dr. Burgess. Out of all of the challenges that you have submitted to companies, how many have actually stood up to you and said, we don't want to do it?

Dr. Woodcock. Certainly.

[The information follows:]

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Dr. Woodcock. I think there are -- we do bring our cases that have the best facts, all right, as we sort through the cases we put forth those that have the best facts that we would be most likely to win.

Dr. Burgess. Well, again, it is just so frustrating to think that the guidance that supposedly was going to come out, that was going to solve this problem, just really seemed to be enmeshed in the bureaucracy for 3 years. Is that a fair time length?

Dr. Woodcock. I think that is fair. However, that was trying to make the best of a bad situation. We do not have the tools that fit this industry, right?

Dr. Burgess. You know what? I disagree. Because do you not have power under the Food, Drug, and Cosmetic Act to regulate manufacturers?

Dr. Woodcock. Yes.

Dr. Burgess. You define manufacturers. Someone is making 30,000 vials of stuff a month, is that a manufacturer?

Dr. Woodcock. Well, say, if I am Janet the pharmacist, all right, and I have a pharmacy that is licensed in a State, right, and I am compounding drugs, right, and then I decide, well, I want to broaden my activities, and my State allows the anticipatory compounding and my State allows office stock, right, so I can compound those in advance

of or without a prescription and send them. And there is no --

Dr. Burgess. 30,000 vials a month?

Dr. Woodcock. There is no -- what is the number? That is the thing we have been struggling with for 12 years. Is it 10 vials? Is it 1,000 vials?

Dr. Burgess. Well, let me ask you this question.

Dr. Woodcock. There is no volume limit in the statute. Excuse me for interrupting you.

Dr. Burgess. Well, Massachusetts Board of Pharmacy fired people. Is the Food and Drug Administration going to let anyone go?

Dr. Woodcock. No.

Dr. Burgess. No?

Dr. Woodcock. No.

Dr. Burgess. I yield back, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. Castor. Thank you very much.

I wanted to get just to that point. Where do we draw the line? Because I think as legislation is developed, and your testimony is that you do not want and it is not appropriate to capture the community pharmacists who are compounding --

Dr. Woodcock. That is correct.

Ms. Castor. -- and that is not the source of problems. So where do you recommend the dividing line should be? What is the criteria in law? Has the Senate addressed this in their bill? Where do they carve out so that the community pharmacists that are compounding are protected and others that have exceeded that and are really the large-scale manufacturers, how do we develop that criteria?

Dr. Woodcock. Well, the Senate is attempting to set forth a framework, and we feel they are going in the right direction. But those clear lines between who is a drug manufacturer, who is a traditional compounder, and who is the new category of compounding manufacturing, we still feel are not clear enough. So that we could have people masquerading -- and some of the other witnesses I think are going to talk about this, by my reading of their testimony, okay -- that we could have people masquerading as traditional compounders or as compounding manufacturers who really were competing with the generic drug industry or the innovator drug industry and actually should have sent us applications and paid a user fee and gone through the established process that we have had in the United States since 1962. And so that is really the issue, is how do you draw those boundaries.

Ms. Castor. And what are your recommendations then?

Dr. Woodcock. Well, what we had proposed is that we pick off the

highest risk category, which is those sterile products that are shipped interstate. All right. So they are shipped around the country. That is probably the highest risk, because the longer you store the sterile product the more likely, if they are contaminated, that there will growths that can grow up. And obviously sterile products are a high risk. And interstate is one sort of marker for volume.

And this industry that has grown up, the outsourcing industry is valuable to hospitals. We have heard from the hospitals. They feel they can't do without these folk. And they generally take FDA-approved products and they mix them or they put into convenience dosage forms. If you have gone to a clinic in an office building and you have had a procedure, you may have received products from one of these firms that put you to sleep or whatever. And they package them, say, in syringes and so forth and send them to these various clinics and also to hospitals.

We feel that type of industry, they produce in pretty high volume that is the highest risk. And they should have full aseptic processing controls, just like the regular drug industry does. So we agree with carving them out and having certain requirements for them, but not submitting a new drug application, having to pay a user fee, and going through that entire process.

Ms. Castor. So highest risk, crossing State lines.

Dr. Woodcock. State lines.

Ms. Castor. Sterile products.

Dr. Woodcock. Right.

Ms. Castor. You recommend. And then to clarify your last part regarding -- what if it is a compounding that is going to hospitals within a State.

Dr. Woodcock. Well, what we propose is that would be regulated by the States. The States could decide whether they have capacity to do that. I think you may hear from some of the other witnesses that in fact that type of compounding, especially at volume, because it is the mass production that really increases the risk, both the risk of contamination and the consequences of contamination once it occurs, because it goes to so many people, right, and the risk is there for intrastate, but the States we feel could decide whether they would regulate those type of activities or not permit them, right.

And then the traditional compounding is really where a doctor -- and I have done this too, all right -- a doctor writes a prescription to a pharmacy and asks them to, for an individual patient who has a specific need, to make a dosage form that isn't available commercially because they have a very specific medical need for that. We feel that should be preserved, but a box should be put around it and there shouldn't be competition with established generic products.

Because there is always more risk than for a regular product for any of these compounded products.

Ms. Castor. Thank you very much.

Mr. Pitts. Chair thanks the gentlelady.

Now recognize the chair emeritus of the full committee, Mr. Barton, for 5 minutes for questions.

Mr. Barton. Thank you, Chairman Pitts.

I have very troubled, Dr. Woodcock, by your opening statement. I do give you credit for integrity and honesty and forthrightness. But you ended up saying that it is not if this is going to happen again, it is when it is going to happen. That is pretty strong. You are talking about people dying.

And I have attended, not in their entirety, but I have attended every hearing that we have done on this issue with NECC. And it is not that Republicans are not willing to regulate, it is not that we are not concerned. It is that we do think there is a true State-Federal partnership, and we do think that State regulatory authority is as good as Federal if it is within the State. And we don't see a reason to preempt the States unless the States either can't do it or won't do it.

And what struck me in the answers to Dr. Burgess' questions was at some point in the process anybody at the FDA could have picked up

the phone and called the State regulatory authority and apparently never did.

Now, I don't understand that. If you really believe that what you said is true, that it is not if it is going to happen again, it is when it is going to happen again, if you have a list of compounders that you think are problematic or in danger of actually endangering human life, if you really think the FDA doesn't have the authority to shut those people down or make them clean up their act, you have an obligation, or somebody that is designated by you, to call the State regulatory authority to inform them of the problem and to take whatever steps are necessary to make sure that the State does.

Now, why haven't you done that? Or why haven't people at your agency done that? That is what I don't understand.

Dr. Woodcock. We have done that more recently. And we have, as I said, we have worked hand in glove with the State authorities. We have done joint inspections with them. They have taken the steps to close down many of these pharmacies after the inspection. And we are sending them our findings, we send them letters. We post our 483s, which are our findings of the inspection, so they that are available to the public. And we work very closely with the State authorities.

However, there are 23,000 compounding pharmacies in the United States, according to the industry. They don't have to tell us who they

are and they don't have to report to us if they have problems. So we are --

Mr. Barton. Well, but they can't operate if they don't tell you or don't tell the State. You are not telling me there are 23,000 compounding pharmacists that are operating out in the ether and that are not subject or not licensed by somebody.

Dr. Woodcock. They are licensed by States. They are licensed pharmacies. And I read a report by some of the members who looked at what amount of control and tracking the States have over the different pharmacies, and many States do not have a lot of understanding of what activities those pharmacies are engaged in, particularly whether they are shipping to other States and so forth. Different patterns in different States, but not all States really have close control over what those pharmacies are doing as far as compounding.

Mr. Barton. Well, the witness that is in my district, Mr. Harmison, I have been in his pharmacy. I mean, he is the true small independent businessman. He has got a compounding room, I think one or two rooms, and has two or three pharmacists, including himself.

Now, I have also been in other compounding pharmacist situations in Texas where they have 10 or 15. And it is much more of a mass production-type situation. So there is a difference. But the FDA, in conjunction with the States, should be able to determine who has

jurisdiction and what needs to be done.

I don't think Mr. Pitts or Mr. Upton or any of the Republicans are unwilling to sit down and help clarify, to use your term, what needs to be done. If there truly is a gap and it truly is best to regulate at the Federal level, I would say that the Republicans are open to it. But if it is simply a question of communication between the Federal Government and the State regulatory authority, I would encourage you to facilitate that communication, because I don't want "if" to become "when."

Dr. Woodcock. Right. Well, we had a 50-State meeting. We have been in close contact with the Association of National Boards of Pharmacy. So we are talking to them twice a week. We are talking to all the State boards in the States where we go in and have these inspections. And, as I said, we do the inspections with them.

We have heard from many States that they would prefer Federal regulation of these larger-scale facilities. But the real question here is and has always been the question is where to draw the line. All right. So you have the traditional pharmacist, they are compounding in response to a prescription. I, as a physician, I have written prescriptions for compounded products that were very valuable to my patients. That is one. All right. And you mentioned, okay, then there is somebody, if they have five rooms --

Mr. Barton. My time has expired, and the chairman has been very gracious. We can work on helping define and helping to clarify. I think there is a bipartisan trust on this committee and this subcommittee that can do that, if you and the stakeholders will begin to communicate with each other. I think this is a solvable problem. But it is not necessarily the answer it is going to be more Federal regulation. It may be, but it is not automatic that it will be.

With that, Mr. Chairman, thanks your time, and I yield back.

Mr. Pitts. Chair thanks the gentleman.

And now recognize the ranking member emeritus of the full committee, Mr. Dingell, 5 minutes for questions.

Mr. Dingell. You are most courteous. Thank you, Mr. Chairman. I ask unanimous consent to insert 2 letters which I wrote to FDA on this record in the record --

Mr. Pitts. Without objection, so ordered.

Mr. Dingell. -- as well as responses from FDA. And I thank you, Mr. Chairman.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Now, these questions will be mostly yes or no. Does FDA have the authority to require all compounding pharmacies to register with the agency?

Dr. Woodcock. No.

Mr. Dingell. Yes or no?

Dr. Woodcock. No.

Mr. Dingell. Please submit for the record the new authority that you need.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Next question: Does FDA have the authority to require all compounding pharmacies to report adverse events?

Dr. Woodcock. No.

Mr. Dingell. What authority is needed? Submit for the record, please.

[The information follows:]

******** COMMITTEE INSERT ********

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

Dr. Woodcock. No.

Mr. Dingell. What authority is needed? Submit it for the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Question four: Does FDA believe nontraditional compounders should be subject to appropriate good manufacturing practices the way manufacturers are? Yes or no?

Dr. Woodcock. Yes, as appropriate.

Mr. Dingell. What is the authority which is needed? Submit for the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Does FDA believe risk-based inspection schedules are appropriate for nontraditional compounders? Yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. What authorities do you need to achieve that end? Submit for the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Does FDA have full authority to see all records when inspecting a compounding pharmacy? Yes or no?

Dr. Woodcock. I think that is being contested, as you know.

Mr. Dingell. Yeah, you have that problem between the different circuits.

Dr. Woodcock. Yes.

Mr. Dingell. Plus submit to us what authority is needed.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Does FDA need additional authorities in these areas to ensure that outbreaks of the kind we have seen does not happen again? Yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Yesterday, my colleagues in the Senate advanced bipartisan legislation giving FDA more authority over compounding pharmacies. It is my hope we in the House will do the same thing. I have long believed that we must provide agencies like FDA with clear authorities and necessary responses to properly help and to carry forward their mission. U.S. FDA has a fee system for the approval of pharmaceuticals and medical devices, amongst others. Please inform us whether you need that kind of authority, for purposes of the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Now, if we gave FDA the authority in this area, and I believe we should, I believe we also should have a strong user fee program. Would you submit for the record some information justifying such thing if you believe that is appropriate, Doctor.

Dr. Woodcock. Yes.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Now, would the user fee contained in the Senate bill provide the FDA with the necessary resources to carry out these new authorities? Yes or no?

Dr. Woodcock. Partially, 50 percent.

Mr. Dingell. Okay. Now, I have got just a little bit of time left. I am reminded of the situation we have here. We have got people being killed because we have unclear authorities. We have a responsibility to see to it that we clarify that as a part of our oversight responsibilities.

There is a great joke that they tell about a fellow who got a letter from an undertaker saying that his mother, or his mother-in-law, had just had a stroke and passed on. And he asked for instructions. He said should we cremate, should we bury, or should we embalm. And the guy thought for only a second and he sent back a telegram saying, do all three, take no chances.

Now, I think here we have got a problem where people are being killed by a dichotomy in the industry. And, Doctor, I want you to tell me, you have roughly three classes of compounders. Right? You have got essentially the manufacturing compounders who ship all over the country, huge volumes. Right?

Dr. Woodcock. Correct.

Mr. Dingell. You don't have very clear authority over them, do

you?

Dr. Woodcock. No.

Mr. Dingell. And the States don't have the resources to do it, do they?

Dr. Woodcock. That has been documented.

Mr. Dingell. Okay. Now, having said that, you also have the ordinary pharmacies. We are not particularly after them. And they are supposed to be regulated by the States. They are licensed by the States. And they are identified by State regulations to the States. Right?

Dr. Woodcock. Yes. We believe the traditional practice of pharmacy compounding should be preserved and regulated by the States.

Mr. Dingell. Okay. Now, then we have the additional situation where you have the hospitals. And they have either in-house or they have people who contract with them to compound them to meet the specific needs of patients in the hospitals. Right?

Dr. Woodcock. Correct.

Mr. Dingell. What authorities do you need there?

Dr. Woodcock. Well, we believe that the hospitals could operate under the regular rules of pharmacy. These are hospital pharmacies that are licensed by the State and also regulated by other authorities. We believe that outsourced contractors should be regulated under the

compounding manufacturing.

Mr. Dingell. So here now you have a muddled situation where the courts are getting in and assisting us to confuse an already obfuscated situation, and we need to do something to clarify it. And since the great events in Michigan, where a bunch of my constituents and others were killed, we have seen that the compounders have continued their same merry practices of disregarding the law and proceeding to send noxious compounds around that are compounded in unsafe atmospheres and climates. Is that right?

Dr. Woodcock. We have seen since the outbreak --

Mr. Dingell. Yes or no?

Dr. Woodcock. Yes. Yes.

Mr. Dingell. Mr. Chairman, I have used 44 seconds too many. Thank you.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions. Mr. Griffith, you are recognized for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman.

Thank you, Dr. Woodcock.

I am looking at your draft, not for implementation report on pharmacy compounding that was done in August of this year, and I want

to clarify this court issue. Disagree with me and tell me yes or no, I will ask you at the end of each part of this. But it appears that in April of 2002, based on this report, and I believe it to be correct, that the U.S. Supreme Court affirmed the Ninth Court's decision related to advertising and solicitation, but did not take up the severability as to whether or not the rest of the act would be in place after that date. Is that correct?

Dr. Woodcock. My understanding, yes.

Mr. Griffith. And is it also correct that the Fifth Circuit found it was severable, and that decision came out in 2008?

Dr. Woodcock. Correct.

RPTS BINGHAM

DCMN BURRELL

[11:30 a.m.]

Mr. Griffith. The FDA took no action -- am I correct the FDA took no action to clarify the law between 2002 and 2008 when the Fifth Circuit came out with their opinion, isn't that correct? Yes or no.

Dr. Woodcock. Yes.

Mr. Griffith. And it would also be correct that from 2008 until the incident with the fungal meningitis, the FDA never came to Congress and said we need clarification, isn't that true? Yes or no.

Dr. Woodcock. Yes.

Mr. Griffith. And isn't it true that you were working on these draft guidelines because you believe there was a way to figure out around the court decision issue and regulate to the best of your ability with the Ninth Circuit being a little more difficult but that is why you worked on these guidelines for over 3 years; isn't that correct?

Dr. Woodcock. As I said, we were trying to make the best of a bad situation.

Mr. Griffith. Wouldn't the right thing to have done to have come for clarification on the severability and just reenact the old law and take the advertising section out, the only part that any court said

actually violated the Constitution and the whole issue was severability; wouldn't that have been the better thing to do from 2002 until 2012?

Dr. Woodcock. Yes, I think in retrospect that would have been better. I think there was a fear getting a worse --

Mr. Griffith. Was there a fear of coming to Congress and asking for help when you needed it?

Dr. Woodcock. Well, you know, the late Senator Kennedy did develop a bill and asked around about it with some other Senators and there was so much opposition that they never introduced that. And I think that was --

Mr. Griffith. Did the bill do anything other than clarify that the bill could be severed and that the only parts that weren't in place or should be in place were the advertising restrictions?

Dr. Woodcock. I am not familiar with what exactly it is.

Mr. Griffith. Because I don't know what was in that bill and I suspect there was something other than clarifying the law was in there.

Dr. Woodcock. Oh, yes.

Mr. Griffith. And I would have to say in the draft guidance that you all were about to propose the FDA defined a new framework for compounded drugs that would be administered in a health care setting and basically what you proposed was was that you could compound for

more than one patient in the hospital setting or in a medical practice setting as long as there was a prescription that followed if you knew you were going to use it in like in an ophthalmological setting or in a hospital setting as long as you could tie that later to a direct patient, isn't that correct?

Dr. Woodcock. That is my understanding.

Mr. Griffith. And so under that reading of that, other than clarifying that the advertising section is no longer the law, you really didn't need any new authority to do that, did you?

Dr. Woodcock. To make that interpretation?

Mr. Griffith. Yes or no? To make the interpretation.

Dr. Woodcock. I don't understand your question.

Mr. Griffith. It is in your guidance request so I assume that is correct. Is that correct?

Dr. Woodcock. That is correct.

Mr. Griffith. And I appreciate that. And I am looking up to see how much time I have left.

We also have this business about talking to the States. There is nothing that prohibited you in the law from talking to the States when you got complaints from say Colorado or Ohio, which actually happened in the NECC case, nothing prevented you from calling Massachusetts, did it?

Dr. Woodcock. No.

Mr. Griffith. And, in fact, in the guidelines you are setting up a new way to make that work so it is efficient, isn't that correct?

Dr. Woodcock. The guidelines --

Mr. Griffith. The guidelines of sharing information between the States and making sure that everybody is keeping an eye on these folks.

Dr. Woodcock. The guidance, hmm, yes.

Mr. Griffith. So you didn't need any new authority to do that, did you?

Dr. Woodcock. We don't need authority to talk to the States. We do that all the time in many different areas of regulation.

Mr. Griffith. But you failed to do that in the NECC matter, and I guess my concern is, is that while I too have learned to respect your veracity and think you are a great witness, much better than that other lady that came in here, we couldn't get anything straight out of her, so I do appreciate it -- but I would have to say that one of my concerns is that the FDA had all these tools available to it, if it had chosen to do so and I understand people make mistakes, things happen, I understand that, I am not being critical, but instead of asking for new authority shouldn't we just clarify the fact that the advertising restrictions aren't the law, and that if there are areas that need to be clarified, not giving new authority but just clarifying some things,

that we could follow your guidance proposal from August of last year and come up with a pretty good proposal, isn't that true? Yes or no.

Dr. Woodcock. No. I don't think so.

Mr. Griffith. So that was a bad proposal that you all were putting guidelines out on?

Dr. Woodcock. The guidance --

Mr. Griffith. Yes or no. Were those guidance proposals bad?

Dr. Woodcock. They were based on the 503, which is not really that workable for the current industry that we have. I am sorry I can't give you just a "no" answer. I don't think we have a good --

Mr. Griffith. All right. I am out of time so if you could submit your recommendations I would greatly appreciate it.

Mr. Chairman, I yield back.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentleman, and now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Dr. Woodcock, thank you for being here today, and I am concerned that the majority side has looked at this issue and said the FDA has the necessary authority to properly regulate. As Commissioner Hamburg explained at the last meeting, the current level of scrutiny being applied by the FDA is a result of the outbreak. The court case may be strengthened, but a favorable ruling on the authority over compounding manufacturers and non-traditional manufacturers is far from certain.

As a result, I think we must pass limited legislation that allows the FDA to regulate compounding manufacturers across State lines. The draft currently being debated in the Senate is a good first step, but I think there are some changes we could made to strengthen the bill.

In her testimony before the committee, and I won't judge on Commissioner Hamburg's testimony, asserted the agency needs greater authority over large compounding pharmacies that are essentially manufacturers. The Senate legislation would create a new category of compounding manufacturers that would be under FDA regulatory authority.

Commissioner Hamburg also told us that the FDA agrees that the

regulation of a traditional pharmacy compounding should be left to the State legislators and State boards of pharmacy. We have laws in my home State of Texas that allow when medically necessary and in very limited circumstances a compounding of medications before the receipt of a patient specific prescription for administration in the office of the prescribing physician. Those are called office use compounding. It is my understanding a majority of States have these similar laws.

Dr. Woodcock, what do you recommend that Congress craft or how do you recommend that Congress craft language to give the FDA the necessary authority to regulate large, interstate compounding manufacturers while still preserving the ability of States to regulate the traditional compounders?

Dr. Woodcock. It is a complicated question. We want to make sure that the traditional compounders can flourish because they provide a valuable service but not that they don't go to 20 rooms or 50 rooms, right, and start making large scale. So there have to be boundaries there.

Traditional manufacturers, obviously, have to submit applications to FDA, pay user fees and then undergo review and frequent inspections for GNPs. The hospitals have told us, the hospitals in your district and all around the country have told us that they rely

on this industry now for the compounding manufacturing industry, if you wish to call it that, for certain services that used to be done in the hospitals but are now outsourced. However, these operations are proceeding under the rubric compounding right now but they are doing something quite different and in a larger scale. And so if Congress would see fit, what we are saying is not we want more regulation, we want regulation that would fit this new activity, right, and would be appropriate for that and allow them to flourish.

Mr. Green. I only have a couple minutes. For example, if a hospital in Houston wants to contract with a company in Massachusetts, that still should be under FDA authority.

Dr. Woodcock. For sterile products is what we are proposing, so if they want to get injectables from a New Jersey firm, they want to buy injectables and use it in their hospital or in their clinic, we think that should be under FDA authority if those are sterile products.

Mr. Green. Okay. Do you agree that legislation should clarify the current law in the area and protect the ability of States and boards to decide what is the appropriate scope of practice for traditional pharmacies?

Dr. Woodcock. Absolutely.

Mr. Green. Including the areas of anticipatory and office use compounding?

Dr. Woodcock. Well, we have to make sure that it draws the line and doesn't allow them to produce, say, and how do you do that, is 17,000 vials, is that anticipatory compounding? You have to have some clarity on that.

Mr. Green. It seems like it would be. What is the FDA's position on office use compounding pursuant to State law where it occurs? Under the current Federal law, FDCA, and under the legislation being considered in the Senate?

Dr. Woodcock. Well, right now, under current Federal law it is blurry, all right, as far as how much you could make? You all are saying to me that you think you can tell what a manufacturer is but there is no bright line in the statute that says when you cross that line and become a manufacturer.

Mr. Green. And that is our job to define that.

Dr. Woodcock. That would be very useful.

Mr. Green. The other thing I am concerned about is traditional compounder in an area that is close to State boundaries. Again in Massachusetts with New England there is maybe a different problem whereas in Texas it is not that big a problem except along our border with other States.

How do we keep those traditional compounders from being classified if they work across State lines, geographically fairly

close, from being classified as a compounding manufacturer?

Dr. Woodcock. Well, we think there are some Federal standards that ought to be in place, okay, that distinguish even a traditional compounder so that there are certain things that they are held to do and then they remain traditional compounders.

Mr. Green. Thank you, Mr. Chairman. I appreciate it and look forward to working on the legislation.

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

Mr. Murphy. Thank you for being here, Dr. Woodcock, I have the highest respect for you and I appreciate your candid conversations.

I want to cut to the chase here because I don't want this to be a political discussion and I think it is being mislabeled as that.

I held hearings in my Subcommittee on Oversight and Investigation and it was my impression we weren't getting clear answers about missteps within the FDA. And I just want to make sure that I know that the FDA is saying we have learned from our problems and here is how we change.

So let me run through a series of questions with you and help get that on the record.

First of all, the FDA has repeatedly cited the fact that the Fifth and Ninth Circuit Courts of Appeals have issued conflicting decisions on whether section 503(a) of the Food, Drug and Cosmetic Act remains

valid, and in a written statement on November 14th of last year oversight committee hearing Commissioner Hamburg cited the Circuit Court's split as having "amplified the perceived gaps and ambiguity associated with FDA's authority over compounding pharmacies."

Now the Fifth Circuit Court decision was July 2008, is that correct?

Dr. Woodcock. Right.

Mr. Murphy. In May 2009, just prior to Commissioner Hamburg being confirmed, a briefing was provided to Acting Commissioner Joshua Sharfstein proposing several paths forward in light of the Fifth Circuit's decision upholding 503(a).

Do you recall participating in that briefing? Yes or no.

Dr. Woodcock. No.

Mr. Murphy. The FDA produced to the committee an email chain from the Office of the Chief Counsel from July 2009. A copy of this document I think is now in front of you. The top email is from Michael Landa, FDA's Acting Chief Counsel at the time, and notes the plan is to enforce section 503(a) nationwide except in the Ninth Circuit and that, quote, Josh is on board, unquote.

Mr. Landa then notes that Dr. Sharfstein, quote, would touch base with Peggy but did not think she would have any objection, unquote. Do you know whether or not Commissioner Hamburg was consulted in the

decision to proceed with enforcement of section 503(a)?

Dr. Woodcock. I do not know affirmatively, no.

Mr. Murphy. Do you suspect that she did or --

Dr. Woodcock. I would suspect that she was.

Mr. Murphy. Thank you. And if you turn to the second page of that email chain, the leader of the compounding team in FDA's drug center, your center, notes that Dr. Sharfstein and Deb Otter asked to chart the timeframe for each step we plan to do to implement the new plan.

Dr. Woodcock, this plan had yet to be implemented when the outbreak began in September, 2012, am I correct?

Dr. Woodcock. That is correct.

Mr. Murphy. And yes or no, prior to announcing the new plan FDA felt as though it needed to draft a new guidance document detailing the approach it would be taking as well as various regulations that 503 required? Yes or no.

Dr. Woodcock. That is my understanding.

Mr. Murphy. Thank you. And yes or no, during this time period inspections and enforcement actions came to a standstill.

Dr. Woodcock. My understanding is that it is not true, that we did certainly went for cause inspections.

Mr. Murphy. Certainly with NECC.

Dr. Woodcock. I can't comment specifically on NECC. I am sorry.

Mr. Murphy. Is that --

Dr. Woodcock. Due to the ongoing criminal investigation.

Mr. Murphy. I understand. By August 2012 your center signed off on another draft guidance document that was going through final clearance, yes or no.

Dr. Woodcock. Yes, my understanding.

Mr. Murphy. Thank and a briefing has been had, in fact been scheduled to discuss the new guidance documents with Commissioner Hamburg back in September 2012, is that correct.

Dr. Woodcock. That is correct.

Mr. Murphy. And yes or no, Commissioner Hamburg testified before O&I that she was really not that aware of issues related to drug compounding until after the meningitis outbreak; therefore, would any additional changes to this draft document guidance have been made based on Commissioner Hamburg's input.

Dr. Woodcock. I don't know. That would be speculation.

Mr. Murphy. Okay. The point is the agency had a solution here that would have allowed it to conduct inspections was my understanding. But so the FDA failed to even acknowledge the existence of this guidance document until it produced it to this committee in March of 2013, well after the FDA promoted an entirely new regulatory paradigm.

Here is where I want you to help clarify this for all of us. My question is what does FDA now know about the compounding industry that it did not incorporate in this guidance document and is provided as a learning experience to make some changes? You may respond.

Dr. Woodcock. What we have seen as we have done inspections of this industry, we have focused on the highest risk areas and we have seen violations of aseptic processing, that basically mean that there is no insurance of sterility of the products coming out of these compounding pharmacies.

And this means that this outbreak that we have seen will happen again. Since the outbreak, we have had an instance of fungal bodies being observed in an IV bag ready to be given to a cancer patient, all right, that came from a compounding pharmacy. We have also had other instances of patients having eye infections and other instances of non-sterility of products. So we have had harm as well as the nonsterile practices that lead to the harm.

Mr. Murphy. With regard to the way that FDA approaches these things and I understand you are looking for more authority to handle some things but what we really need to know is within the realm of the authority you already had -- and I am not asking you to hang anybody out right now, that is not the purpose of this hearing -- but are there internal lessons that the FDA has learned they could have handled some

things differently that could have possibly led to different results other than dealing with the lawyers' issues here.

Dr. Woodcock. Well, I think we should have been more aggressive. There was great concern about our, the limitations of our authority and that we would lose and then have even less ability to influence this industry. But in retrospect I think it would have been more important to simply go forward and see how it turned out in the courts, aggressively exert our current authority, which is primarily new drug authority.

Mr. Murphy. Thank you. That is why I like hearing from a physician instead of a lawyer. I will need to submit these e-mails for the record if that is all right, Mr. Chairman.

Mr. Pitts. Without objection, so ordered.

Mr. Murphy. Subject to redactions by staff.

[The emails follow:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentlelady from California, Mrs. Capps, for 5 minutes for questions.

Mrs. Capps. I believe -- am I before Mr. Engel?

Mr. Pitts. Yes.

Mrs. Capps. Oh.

Mr. Pitts. We are going in order of appearance.

Mrs. Capps. Okay, all right. I thank you. I just want to thank you for your testimony today, Dr. Woodcock, and I want to thank Mr. Pallone for holding this necessary hearing. This is an important issue and I believe needs to be revisited.

Under current statute, a great deal of uncertainty and variation exists between regulations. And this uncertainty creates gaps that can lead to compromised patient safety, as we have seen most recently with the meningitis outbreak. We cannot wait for another public health crisis to act, and what we have right now isn't working.

Dr. Woodcock. Right.

Mrs. Capps. I believe you would agree. Families don't have the peace of mind they are receiving effective drugs that they can trust and compounding pharmacies across the States are not on a level playing field. Many States are inadequately inspecting facilities. After a similar incident in my State of California almost a decade ago, regulations were enhanced and sterile compounding pharmacies now

require an inspection or accreditation through a national agency. You know, this isn't good enough because many hospitals and clinics in California buy drugs from out of state, compounding pharmacies in other States, including the Massachusetts pharmacy. So hospitals and States don't exist in isolation. Hospitals have a great need to be able to buy large quantities of compounded drugs.

Mr. Migliaccio suggests in his written testimony that there should be no special regulatory program for these large scale drug compounders. Instead he implies that they should be treated like conventional drug manufacturers and should have to go through the new drug application process to manufacture and distribute any drugs.

My question now, Dr. Woodcock, could you explain to us why you believe requiring new drug applications for all drugs would not be warranted and what the consequences would be particularly for hospitals if FDA were to take such an approach?

Dr. Woodcock. Well, that approach would be our current authorities. It is not that we don't have current authorities. Our current authorities require submission of applications, payment of a user fee, thanks to the user fee bill you all passed for generics recently, and we have had the new drug one for a while, and review of all the information, a large package submitted to the agency, and then we inspect those facilities frequently, including a preapproval

inspection to make sure everything is okay before the product gets out on the market. So that is our current authorities.

Now many of these outsourcers, what they are actually doing is taking FDA approved products and putting them into convenience forms or putting them into, combining them, say for hyper alimentation or something like that, and then shipping them around the country based on patient need.

The industry has basically told us that they can't make all these different very patient specific forms and convenience forms. And there are questions of efficacy that are related because these are already FDA approved products. The key is, and this used to be done by the hospital pharmacy, by the clinic they would do this. I did this when I was an intern, all right, when the interns were able, had to be kind of worker bees. So we made up the chemotherapy, we put things into bags and the nursing staff would do this as well or the hospital pharmacy.

Now, with the very large scale of medicine they want to buy these, and many of the clinics are in office buildings, they don't have a pharmacy or clean room there. So they need to order these products, right.

Mrs. Capps. I want to get to another question.

Dr. Woodcock. I am sorry. It is so complicated. Let me finish

then. So there isn't good regulatory fit right now. It isn't where we say we have to have all these broad new authorities, no, there is no fit for this industry that has grown up.

Mrs. Capps. All right. I want to make sure that I am able to enter a statement from the American Society of Health System Pharmacists which addresses this issue as well. Their statement details the many ways in which hospitals have come to rely on compounded medications from outside compounding pharmacies which you are alluding to.

And I want to ask that this statement that I am holding up be entered into the record.

Dr. Woodcock, if there is a time for you to address this, would a two-tiered regulation system that clarifies a uniform set of rules for compounding manufacturers while preserving the State's role in traditional pharmacy compounding be a practical thing?

I will just let you comment on that.

Dr. Woodcock. Yes. We have proposed something like that as something that would be practical but it would require a new regulatory scheme for this new industry that has evolved to make sure they are making the product safely. It is no good to have convenience products if they are contaminated or they are super potent or there are other things wrong with them. However, of course that is up to Congress

whether they want this industry to persist because our current regulatory authorities require submission of application.

Mrs. Capps. I see. Okay, thank you I yield back.

Mr. Pitts. And did you want to submit that for the record?

Mrs. Capps. Yes, I would like to.

Mr. Pitts. Without objection so ordered.

[The letter follows:]

******** COMMITTEE INSERT ********

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

Mrs. Ellmers. Thank you, Mr. Chairman, and thank you, Dr. Woodcock, for being here today. I just want to clarify just a few terms because I think we are putting terms out and I want to make sure I am understanding. When we are talking about traditional compounders, who are we talking about?

Dr. Woodcock. We are talking about pharmacies, licensed pharmacies who react to a prescription for a specific individual patient and make a specialized dosage.

Mrs. Ellmers. And right now that is under the authority of the State, not under FDA, correct?

Dr. Woodcock. Correct.

Mrs. Ellmers. And when we are talking about the compounding manufacturers, how is that different -- is that different from the term, the compounding manufacturers -- I mean the compounding manufacturers and the drug manufacturers.

Dr. Woodcock. Compounding manufacturers is a new term that is contained in the Senate bill, okay --

Mrs. Ellmers. Right, so this is Senate language.

Dr. Woodcock. -- to reflect this large scale industry. They are not usually reacting to a prescription. They are making things that

hospitals need and order frequently so they make them at large scale like a drug manufacturer. But often they are not -- a drug manufacturer starts from scratch. They start from what we call the active pharmaceutical ingredient, which often someone will buy from India or China, bring it in, test it and then make the product.

Mrs. Ellmers. So sometimes it may be in a different form but is it not the same product, and you are saying that because products might be coming from somewhere else that that is the essential difference?

Dr. Woodcock. No, there are two different activities that are lumped under this compounding manufacturing. One is what we call the outsourcers, okay, they get generally outsource from a hospital or clinic, something the clinic or hospital pharmacy used to do, all right, and that is putting things in syringes, little IV bags, diluting chemotherapy, getting everything all right so they can just hang it on the patient rather than having to do that --

Mrs. Ellmers. Rather than having to actually do it in house. Now --

Dr. Woodcock. That is one. And then the other is people who are doing larger scale compounding.

Mrs. Ellmers. Larger scale. And that would currently fall under the jurisdiction of the FDA.

Dr. Woodcock. That is what kind of is under dispute.

Mrs. Ellmers. And that is what we are trying to get to is when do we make that distinction between compounding pharmacy and compounding manufacturer.

Dr. Woodcock. And also a manufacturer who is already a pharmaceutical company has to submit an application to FDA and be under that regime.

Mrs. Ellmers. Now, currently, so basically the compounders have the same regulations and requirements as the drug manufacturers? Yes or no?

Dr. Woodcock. No.

Mrs. Ellmers. And I am not just talking about numbers but I am just talking about regulations again, is this State versus Federal, is that the main difference that we are talking about?

Dr. Woodcock. The States regulate pharmacies. They license pharmacies and these activities right now occur all in licensed pharmacies.

Mrs. Ellmers. Okay. What are the changes to compounding you propose making in order to prevent the meningitis outbreak last year to ensure compounded products are safe? If you can just quickly give us an idea of what you would like to see.

Dr. Woodcock. Well, limit the traditional compounding to more or less reaction to a prescription, okay, and compounding something

for a specific patient, that is traditional compounding. And don't allow compounding of really complicated dosage forms that even the traditional manufacturers have trouble making. Then we are saying establish a new group, the compounding manufacturers is what the Senate called them. They don't get prescriptions, but they have to register and list with FDA. Tell us who they are, what they are making and where they are located, right, and then they have to submit adverse events to us. And they would be subject to proper GMP requirements to make sure they make safe products, okay, but they wouldn't have to submit applications to us.

Mrs. Ellmers. But you did mention application process a moment ago. Can you re --

Dr. Woodcock. Sure. Some of the members are talking we have current authorities, yes, we do have authorities. Our authorities are you are a new drug manufacturer or a generic drug manufacturer, you must submit an application to us. You must a pay user fee or you should not be producing drugs in the United States.

Mrs. Ellmers. So once that application process is fulfilled, that, it is just so that you know that that particular facility exists and what their plan of action is?

Dr. Woodcock. I am sorry, it is really hard to do this. That is our current authorities. That is how we regulate generic drugs and

new drugs in the United States, all right, through that process. That is not what compounding is.

Mrs. Ellmers. Okay. Now let me ask this question because I know the number and how much we are making is it seems to be the issue of where it falls, what jurisdiction. In your own words, where do you, where would you see that line of action? What do you see, how much product can a compounder make without being designated a manufacturer?

Dr. Woodcock. That is what we have been struggling with since the 503 was passed, okay, there is no line in there in the statute. And so what is an inordinate quantity? We don't know. Is it 10 units? Is it 1,000 units? Is it 17,000 units? So we have endeavored to use other criteria to say, okay, when you would be subject to Federal jurisdiction.

Mrs. Ellmers. Well, my time is expired but obviously that is the main question here. So thank you.

Dr. Woodcock. We would be happy to work with you.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentleman from New York, Mr. Engel, 5 minutes for questions.

Mr. Engel. Thank you, Mr. Chairman.

Dr. Woodcock, thank you for the good work that you do. We appreciate it very much.

Dr. Woodcock. Thank you.

Mr. Engel. I want to first ask a New York question. New York, it is my understanding that New York has no licensing requirements specific to compounding pharmacies and according to the National Conference of State Legislatures there is no requirement that New York pharmacies comply with the U.S. Pharmacopeia chapter 795 or 797 compounding standards and according to the Pharmacy Compounding Accreditation Board, which accreditation is entirely voluntary, they say there are only 10 pharmacies in all of New York accredited for pharmacy compounding.

So that being said, I am pleased that no New York pharmacies were included as part of the FDA's most recent risk-based priority inspections of 31 sterile compounding pharmacies. So what I want to ask New York specific is, does the FDA know which pharmacies in New York are compounding medications?

Dr. Woodcock. We have no way of nothing in any State, okay, we have been told by the industry that there are 23,000 pharmacies that may engage in some form of compounding across the country, but we don't know who they are, where they are or what they are making, because they don't have to tell us.

Mr. Engel. So I assume then that the answer would be "no" to this, does the FDA currently have the authority to collect and test samples or examine the records of a compounding pharmacy in New York? And can

you elaborate on why this information is critical for public health and safety?

Dr. Woodcock. Well, we do believe we have the authority to go in and get samples and look at records but it has been contested.

Mr. Engel. Okay. Thank you. I am intrigued by the part of your written testimony which lays out a proposed risk-based framework for a new legislative approach to compounding to ensure patient safety and health.

First, you proposed dividing the world of compounding into non-traditional compounders which would be subject to FDA's jurisdiction and traditional compounders who would remain under State oversight.

Is there a concern that non-traditional compounders may create a category of pseudo drug manufacturers? And if so, how do you protect against that?

Dr. Woodcock. Well, there is a concern that traditional manufacturers could actually be drug manufacturers in disguise and that non-traditional manufacturers could be. And for traditional we really feel that prescription requirement and the statement of medical need for the patient is important, for non-traditional we have proposed a series of things, including that they would register and list with us so we would not who they are and also not make copies of commercially

available drugs.

Mr. Engel. You mentioned the need for sort of do not compound list as part of this framework. Can you explain why this is necessary and why you cannot do this using your current authority?

Dr. Woodcock. Yes. Well, we feel that products say we have withdrawn from the market for reasons of safety should not be allowed to be then compounded and U.S. citizens would then be exposed to them again. And we are seeing this now as you know in dietary supplements, we have to go after them because they sneak in drugs that have been pulled off the market, all right. So that is one category.

Another category might be very difficult to manufacture dosage forms where the pharmaceutical industry that has a lot of science available to them and a lot of engineers and scientists still have trouble making them reliably, some of the patches, some of the inhalers and so forth.

Mr. Engel. You sort of touched on this, but can you elaborate further on what steps the FDA is taking now utilizing the authority that you believe the that FDA has to conduct improved oversight over compounding pharmacies?

Dr. Woodcock. Well, it is more oversight on whether it has improved because we are having to go to the ones we read about or we know about or we have had prior actions and we are doing a risk-based

approach and going to those pharmacies as well as going to pharmacies where you have had reports of problems recently, all right, and for cause type of inspections.

And as I said, we are going in with the States, the State board of pharmacy, their investigators, we often do an inspection together and we are taking very aggressive action. But we do not, for example, have recall authority, we cannot, we don't have the authority, we don't have recall authority for any drugs, right, and we do not have the authority to shut these pharmacies down, they are licensed by the State, but we have shared full information with the States, and they have shut 11 pharmacies down as a result of the findings in these inspections.

So that is improved oversight, but we will see about if we go to court like what kind of response we get from the courts as far as our authority.

Mr. Engel. Well, again thank you for the good work that you do. And I especially appreciate your testimony here this morning. It is concise, it is to the point. When we ask a question you respond very pointedly and it is very much appreciated. Thank you.

Dr. Woodcock. Thank you.

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

Mr. Lance. Thank you, Mr. Chairman. And good morning to you, Doctor. You stated to Dr. Murphy that if you had it to do over, you might move more aggressively regarding the situation that, unfortunately, occurred, is that accurate?

Dr. Woodcock. Well, I think we would have moved aggressively as we are now against all pharmacies. There was no way to predict at any time which of these pharmacies will cause this problem. And as I said, it will happen again because the conditions under which these sterile products are manufactured are not acceptable and the products are contaminated.

I have learned, what I have learned from this is the resilience of the human body to microbial invasion because we have cultured many samples from these pharmacies and we have grown organisms. And we haven't had outbreaks and that is because both the human body can repel them and because some of them aren't human pathogens.

Mr. Lance. Thank you. This is a very complicated subject and certainly I think answers require more than "yes" or "no."

Dr. Woodcock. I am sorry.

Mr. Lance. And you don't have to be sorry at all, I think that this is extremely complicated.

One of the difficulties as I read the background information is the split in the circuits.

Are you advised by attorneys at the Department of Justice on these matters or do you have attorneys at your own agency regarding the significant split between the Fifth and the Ninth Circuit and the Supreme Court decision?

Dr. Woodcock. We have our staff attorneys that belong to the Office of General Counsel at HHS and they are the FDA branch of that, and then they work with the Justice Department as well.

Mr. Lance. Perhaps you are not the appropriate person to ask, but it seems to me, speaking as an attorney, that there needs to be much greater clarification so that there can be one standard across the Nation and not a split between the circuits, with the Supreme Court decision that did not answer the question fully.

Would that be your understanding?

Dr. Woodcock. That is my understanding. I am not a lawyer, but I appreciate clarity when I try to perform regulations.

Mr. Lance. And I would hope moving forward in our responsibilities to protect the health of the Nation in conjunction with your responsibilities that we could work together to clarify the situation.

I have 2-1/2 minutes, and I defer to Dr. Burgess.

Dr. Burgess. I thank the gentleman for that. Well, Dr. Woodcock, what is it about the Exserohilum fungus that rendered

it such a bad actor? You said sometimes the human body actually can resist these things, sometimes they don't even register. But Exserohilum was a bad one.

Dr. Woodcock. Let me talk in general so I am not talking about NECC, but clearly it is the amount of bioburden of the contamination and that is why shipping these -- bioburden means how many organisms are in there, okay, for the nonclinicians in the room -- and so shipping something around unrefrigerated, which is happening a lot, okay, if you happen to get something in there, it gets a long chance to grow, all right. If you put it in a part of the body that is sort of protected from the immune system a little bit or is particularly vulnerable, if you inject with a steroid, we have had multiple outbreaks where there is an injection with a steroid and of course steroids suppress the immune system so then that weakens that part of the body and even systematically weakens the body's ability to respond to infectious attack because of the actual medicine that has been given. But we have had sepsis from IV products. Nine people died in 2011.

Dr. Burgess. Let me just stop you there because we could obviously could go on. But that is significant because you have a steroid which inhibits fighting infection, you have a space in the epidural space that is relatively protected from white blood cells and things that normally fight infection, it is preservative-free because

it is going into the epidural space if you had preservatives that would be bad for nerves so.

Dr. Woodcock. High risk.

Dr. Burgess. So it is the confluence of bad events. So you know this stuff is high risk.

On the issue of manufacturing, I just have to tell you looking at the notes compiled by the other subcommittee, Oversight and Investigations, going back to May 10, 2012, when the Colorado Board of Pharmacy issued to NECC a cease and desist order and the same day FDA's Denver office informed New England the cease and desist order, New England compliance officer responsible for NECC spoke to an optometrist with the U.S. Department of Veterans Affairs inquiring about whether or not they could use NECC to repackage Avastin. This communication is significant because once again it confirms that FDA understood that NECC was acting like a manufacturer not a traditional compounding pharmacy. An email response "I did not think they could use firms if profiles were unacceptable. NECC Framingham is profiled as a manufacturer because we determined that they are a manufacturer and not a compounding pharmacy," an email from the compliance officer for the New England district to FDA May 11, 2011.

Dr. Woodcock. Well, I am not going to argue with you about this particular case because I can't talk about the case. But clearly the

decision about whether a firm is making, is making product legally under 503(a) would be for the courts ultimately, all right, that is just how it was set up.

Dr. Burgess. But under the Food, Drug and Cosmetic Act, if I may, you have the regulatory authority over manufacturers and your own compliance officers identified NECC is a manufacturer, acts like a manufacturer, walks like a manufacturer, they are a manufacturer.

Mr. Chairman, I will yield back.

Mr. Pitts. The chair thanks the gentleman and I now recognize the gentleman, Mr. Butterfield, for 5 minutes for questions.

Mr. Butterfield. Thank you, Mr. Chairman. And thank you, Dr. Woodcock, for your testimony today.

I will be brief. The hour is certainly getting late. But in studying this issue, Mr. Chairman, it seems that the FDA likes clear direction and clear authority over what can be done once a compounding pharmacy is found to have failed to meet the standards.

And so, Dr. Woodcock, after the meningitis outbreak at the New England Compounding Center about a year ago, FDA increased its inspection of compounding pharmacies. I think that is true. The findings by Federal investigators have been alarming. And hopefully there would be more aggressive investigations.

I want to take you to the subject of sequestration. FDA is

understaffed, underfunded and stretched very thin, at least that is what we have been told. How are the cuts from sequestration hindering the FDA and your inspectors from conducting the thorough oversight that is critical to patient health?

Dr. Woodcock. Well, don't forget, the Energy and Commerce Committee overall have been very concerned that we haven't been to manufacturers overseas, traditional drug manufacturers, and that has been partly due to our resource limitations. Now we do have the user fee, the Generic Drug User Fee Act, and that will allow us to increase our inspectors who go overseas but my point is even the traditional industry we have difficulty covering that adequately. Now there are over 20,000 compounding pharmacies, and we don't know who is who. And so --

Mr. Butterfield. Can some of your lack of resources be attributable to sequestration?

Dr. Woodcock. Oh, yes, absolutely. Well, sequestration took another bite out of what was already a stressed agency, particularly as far as inspectional coverage and now, to give you perspective the whole drug industry has about 5,600 establishments, all right, and so we try to inspect those on a regular basis. To say now that there are 20,000, 26,000, 28,000 compounding pharmacies the question how do we get there, and then sequestration has reduced our funding, our user

fee funding as well as our base appropriation funding.

Mr. Butterfield. And is that really having a negative impact on your work?

Dr. Woodcock. Absolutely.

Mr. Butterfield. Now does your agency fully understand that sequestration is not a 1 year process, it is a 10-year process so unless it is repealed or modified it is going to continue for some years to come.

Dr. Woodcock. We have grave concerns about our continued ability to operate our programs under the various financial stresses that we have and these new activities that we need to take on.

Mr. Butterfield. What is an FDA Form 483?

Dr. Woodcock. That is a form with the investigators' observations that is left with the firm at the end of the inspection.

Mr. Butterfield. Are these posted on the Web site?

Dr. Woodcock. Yes. They are public.

Mr. Butterfield. Okay. And from what we can gather, some 48 form 483s that have been conducted are posted on the Web site?

Dr. Woodcock. Yes. We are posting them publicly to make sure that people understand what our findings are.

Mr. Butterfield. What are some of the worst conditions that have been observed by some of your inspectors?

Dr. Woodcock. Well, primarily, it relates to not keeping, not having practices that would assure the product would be sterile. Don't forget, these are going to be injected in people's bodies, into their eyes, around their spinal cord into their veins and the practices would allow fungal spores, mold, contamination from the body of a person so that would be bacteria, to actually get into the products and then multiply.

Mr. Butterfield. Finally, are there any tools other than money, of course, that Congress can provide to the FDA so the American people can feel more assured that the compounded drug they are taking is prepared in a safe and secure way?

Dr. Woodcock. We need clear lines of authority. We need to know what the States regulate, what the Feds regulate and what our authorities are. If we regulate part of the industry, I would like to know who they are, where they are located and what they are making so that then we can then prioritize where to go because we are not going to get to thousands and thousands of sites in the next several months.

Mr. Butterfield. Thank you. You have been very kind. I yield back.

Mr. Pitts. The chair thanks the gentleman. I now recognize the gentleman from Utah, Mr. Matheson, 5 minutes for questioning.

Mr. Matheson. Thank you, Mr. Chairman. Dr. Woodcock, it is

always good to have you before the committee. I have always appreciated my conversations with you and I appreciate your trying to highlight an issue where I think it is all important we take a hard look at this and figure out a better way to go forward. If I want to oversimplify this hearing, that is kind of where we are.

I fear my questions may be a bit repetitive for what you may have already covered that is the reality of being the last people asking questions.

But I was interested as I understand it when you were discussing, when the FDA discussed some informant actions back in 2006, after -- can you tell me at that point what actions -- can you elaborate what actions were discussed by the agency 7 years ago? Are you familiar with that discussion that took place? That is before your time. Maybe you can't answer that.

Dr. Woodcock. No. No. I wasn't. I wasn't head of Center for Drugs at that time either.

Mr. Matheson. You present several policy options in your testimony, and it is going to provide FDA some different authorities for certain compounders. Can you describe how those options, how they might have played out, allowed the 2012 outbreak to play out differently than it did if you had those options at that time?

Dr. Woodcock. If we have clear Federal authority and a clear idea

of what is traditional compounding and what is not traditional compounding because don't forget this industry maintained they are working within the scope of State pharmacy practice. That is what they have maintained all along, all right, and so we need a clear understanding of what is the scope of traditional pharmacy compounding practice which FDA has already supported as appropriate in providing individualized therapy for people, and what is beyond that and requires Federal oversight, and to make sure that is delineated. And I think you will hear from the other witnesses, that is delineated from people masquerading as one of these buckets who are actually drug manufacturers. So we need clarity in whatever.

And if Congress decides not to allow compounding manufacturing at all, all right, then we have heard from the hospitals and the clinics that that would be a tremendous burden on them because they would have to take back all this that they had outsourced.

Mr. Matheson. Mr. Chairman, that is all I am going to ask now. I will yield back.

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

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

Dr. Woodcock, your testimony states that the current legal

framework does not provide FDA with the tools it needs to appropriately regulate the compounding industry in its current state. You explained that you are referring both to section 503(a) and other parts of the Federal Food, Drug, and Cosmetic Act.

I would like to start with section 503(a), obviously as you explained to Mr. Pallone, there are major questions about whether it would even remain in effect if challenged in most of the country apart from the Fifth Circuit. With regard to the circuit split, Representatives Barton and Griffith have asked why you could not fix this with guidance.

Can you explain what a guidance could or could not do to address the circuit split?

Dr. Woodcock. Certainly. A guidance says on every page that it is not binding either on FDA or the industry. That is what it says on every page. It is more or less an explanation of our thinking. It doesn't add new requirements or cannot solve differences in court opinions.

Mr. Waxman. But putting that aside you say that section 503(a) actually contains provisions that have impeded FDA's ability to effectively regulate pharmacy compounding.

Can you elaborate on what those provisions are and how they have impacted FDA's oversight of compounding pharmacies?

Dr. Woodcock. Yes, well, I think there are provisions in there that are vague, and so we need clarity about what is the line. So, for example, it says you shouldn't compound in you know without a prescription an inordinate amounts. What is "inordinate?" That is in the eye of the beholder. The industry has maintained that all of their activities, regardless of their scale, are within the scope of traditional pharmacy compounding.

Mr. Waxman. The Oversight and Investigations Subcommittee of Energy and Commerce conducted a detailed investigation involving thousands of pages of FDA documents.

One thing we found in that investigation is that for years, going back to the Bush administration, key FDA decision makers have in numerous internal meetings and memoranda indicated that section 503(a) is inadequate and that new legislation is necessary.

Are you familiar with any of these documents or any of these internal discussions?

Dr. Woodcock. Well, I was present in the early 2000s when the court cases came down, all right. We had been preparing to try and implement 503(a) and making the preparations for that when these Circuit Court and then the Supreme Court ruled. So I am familiar with that set of discussions.

Mr. Waxman. Well, is it fair to say that the agency leaders going

back to the Bush administration understood that they needed new legislation because of fundamental weaknesses in section 503(a)?

Dr. Woodcock. Yes, it was very difficult to implement in any reasonable manner.

Mr. Waxman. Mr. Chairman, the notion that FDA is asking for legislation simply to cover for past mistakes or in some sort of power grab is not correct. For years through two different administrations agency leaders have known that there were problems with the underlying law.

Let's turn to the other provisions in the act apart from section 503(a).

Dr. Woodcock, your testimony indicated that you are encountering difficulty when you attempt to inspect compounding pharmacies now using your current authorities. You mentioned that you actually had to seek a warrant in two cases after the pharmacies delayed or refused your access to records.

Can you describe in more detail exactly what has happened during those inspections and describe which current statutory provisions are contributing to the difficulties you have faced when attempting to conduct inspections?

Dr. Woodcock. Well, I probably can't speak to statutory provisions. I am sorry. But what has happened is we have gone in there

and, as I said, the industry has long maintained that we do not have authority over these licensed pharmacies that are in States, right, and so we go in and we ask to either inspect or to inspect records. And they say under some of the court cases that have occurred we don't have to turn over records to you.

Mr. Waxman. So some might argue that there is no problem here since you were eventually able to conduct the inspections and obtain the records you were seeking. But can you --

Dr. Woodcock. Certainly.

Mr. Waxman. -- speak to that assertion?

Dr. Woodcock. The real problem is what is clarity? What is a compounding pharmacy? What is a traditional compounding pharmacy? What about the status of these large scale and how do you define a large scale operation? You might say, well, I know it when I see it. Okay, but how do you --

Mr. Waxman. Well, I was amazed to hear during your responses to earlier questions that in order for FDA to begin conducting the more recent inspections, you had to actually look in the newspapers and at the television ads and Web sites to even know where the compounding pharmacies were.

Obviously, we don't ask you to search the Internet or watch TV to figure out where drug manufacturers are.

What is the difference here and do you need new authority to remedy the situation?

And before you answer that, not only are we uncertain as to the continued validity of FDA's authorizing statutes with respect to compounding pharmacies, but that statute itself is plagued by problems. And so I think we need to clarify the situation.

But why should you have to go on TV and the Internet to be able to do inspections?

Dr. Woodcock. Because they don't have to tell us who they are, where they are operating, and what they are making. They don't have to submit anything to us. They are operating under State law. And they don't have to send us adverse events if they occur, even deaths, and we would read about them in the paper, hear about them from the CDC or State health department that is how we hear, or a consumer or doctor will call us.

And that is how we learn about this. And we don't know of all this universe of 28,000 firms. We don't know what they are doing. And so you might say, well, you should know about this but when it happens most of our actions have been reactive to things that we have heard about.

Mr. Waxman. Thank you very much. Thank you for your indulgence, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

We are voting now on the floor so we will again recess until the floor votes are concluded, and then we will come back and reconvene with the second panel.

I think all of the members have asked their questions. There may be some follow-up questions and we will ask you to please respond when we send you those.

Dr. Woodcock. Certainly.

Mr. Pitts. So at this point we will recess until conclusion of floor votes.

[Recess.]

RPTS JANSEN

DCMN CRYSTAL

[12:52 p.m.]

Mr. Pitts. The time of our recess having expired, we will reconvene our hearing. At this time, I would like to request unanimous consent to enter a statement from the National Association of Chain Drug Stores into the record. Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. At this point, I will introduce our second panel. Today on our second panel we have Dr. Scott Gottlieb, resident fellow, American Enterprise Institute. Mr. Joseph Harmison, owner, Harmison Pharmacies, on behalf of the National Community Pharmacist Association. Ms. Elizabeth Scott Russell, government affairs manager of the National Association of Boards of Pharmacy. Ms. Gabrielle Cosel, manager, Drug Safety Project, Pew Health Group at the Pew Charitable Trust. And Mr. Gerry Migliaccio, quality systems consultant, Migliaccio Consulting.

Thank you all for coming. You each will have 5 minutes to summarize your testimony. Your entire written statements will be entered into the record.

So, Dr. Gottlieb, we will begin with you. You are recognized for 5 minutes for an opening statement.

STATEMENTS OF SCOTT GOTTLIEB, M.D., RESIDENT FELLOW, AMERICAN ENTERPRISE INSTITUTE; JOSEPH H. HARMISON, OWNER, HARMISON PHARMACIES, ON BEHALF OF NATIONAL COMMUNITY PHARMACIST ASSOCIATION; GERRY MIGLIACCIO, QUALITY SYSTEMS CONSULTANT, MAGLIACCIO CONSULTING; ELIZABETH SCOTT (SCOTTI) RUSSELL, GOVERNMENT AFFAIRS MANAGER, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; GABRIELLE COSEL, MANAGER, DRUG SAFETY, THE PEW CHARITABLE TRUSTS

STATEMENT OF SCOTT GOTTLIEB

Dr. Gottlieb. Thanks a lot, Mr. Chairman Pitts, Mr. Ranking Member Pallone, and members of the committee. Thanks for the opportunity to testify today. I have a longer statement for the record. I would like to summarize a few key points for you this morning.

The tragic deaths of 55 Americans and the sickening of more than 740 resulting from contaminated steroid injections that were shipped by a disreputable firm have rightly focused public attention on a largely unfamiliar but prominent part of the drug supply chain, the practice of pharmacy compounding.

Before this Congress are proposals to tighten Federal regulatory

oversight of these compounding pharmacies and the practice of pharmacy more generally. Observers are calling on Congress to give the FDA more oversight of these firms. New laws merit consideration. We should articulate clear and bright lines between a legitimate practice of pharmacy compounding and those firms operating illegally as large-scale manufacturers under the guise of a pharmacy license. Some key considerations should, in my opinion, guide this work.

First, there exists a practice of pharmacy. It was never intended that all compounding would create a new drug and be subject to FDA regulation but for the enforcement discretion or for the willingness of Congress to provide explicit exemption to certain pharmacists and certain activities that pharmacists undertake.

Second, FDA has authority to target compounders that cross the line between the practice of pharmacy and engage in drug manufacturing under the guise of a pharmacy license. What FDA largely lacks is ease of administering this authority. FDA is generally not able to force firms to submit advance information to the agency before the firm is suspected of any wrongdoing, and so that the agency is more efficiently able to identify firms engaged in wrongdoing and target its oversight.

Third, FDA generally lacks tools and resources to regulate a new class of firms that the agency has dubbed nontraditional compounders. I would argue that the firms in question here are not compounders, and

calling them such confuses different issues. Rather, they are engaging in the bulk, large-scale repacking and manufacturing of sterile preparations of FDA-approved drugs, typically in advance of and often not in response to prescriptions for individual patients.

To the degree that these large-scale operations prepare sterile volumes of drugs in a bulk form and ship these units widely, they present some novel risks and they have the potential for what I would call distributed risks. The public health could benefit from applying additional oversight to these firms, especially requirements that they adhere to good manufacturing practices.

Fourth, as we address issues of supply, we must also address the policy decisions that have increased demand for products from some disreputable firms, from large-scale compounders who are breaking existing law and violating existing regulations. For example, the recent crackdown on manufacturing of generic drugs have shifted a lot of the demand for generic preparations to compounders. Likewise, decisions by FDA to suspend enforcement against compounders in certain select situations where the agency and policymakers had concerns about the high cost of FDA-approved drugs relative to the low costs of compounded versions has also given greater license to certain compounders to bend, if not break existing law.

Consistent enforcement is going to be especially important if we

create a new class of compounders that FDA has dubbed the nontraditional compounding. If FDA doesn't exercise its enforcement evenly and consistently, which means not allowing firms to compound identical versions of FDA-approved products, then the agency will give more incentive for drug makers to remask themselves as nontraditional compounders to skirt FDA's new drug requirements.

Finally, the market for compounding drugs is evolving very quickly. It is consolidating as other entities like distributors could well start buying out the large compounders. As this process unfolds, it will leave behind a much different compounding industry. This should serve as a cautionary tale to all of us. We should be mindful that the rules that we might write today would no longer be applicable to the market that we see tomorrow.

Thank you for the opportunity to testify this morning. I look forward to your questions.

Mr. Pitts. Thank you, Dr. Gottlieb.

[The prepared statement of Dr. Gottlieb follows:]

******* INSERT 3-1 ********

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

STATEMENT OF JOSEPH H. HARMISON

Mr. Harmison. Thank you, Mr. Chairman. I wish I could speak as quickly --

Mr. Pitts. Poke the button on that. If you will push the button, speak into the mike, please. Thank you.

Mr. Harmison. Okay. Excuse me.

Chairman Pitts, Ranking Member Pallone, Vice Chairman Burgess, thank you for the opportunity to be here today. As stated, I am Joe Harmison. I am a practicing pharmacist, pharmacy owner, and past president of the Texas Pharmacy Association and the National Community Pharmacists Association. NCPA appreciates the opportunity to share the community pharmacist's perspective regarding issues relating to drug compounding. NCPA represents the views of community pharmacists, including 23,000 independently owned community pharmacies. According to an NCPA member survey, 86 percent of our members do some kind of compounding. This can range from flavoring pediatric liquids to changing dosage forms to pay for patients that can't take oral solids to topicals to injections. In my practice, we mainly emphasize pain

medications. And we are U.S. Pharmacopeial 797 standard compliant.

Our hearts go out to the families who have suffered from the tragic events surrounding New England Compounding Center, and NCPA is committed to working with Congress on the issues of practice that exceed State-regulated compounding. NCPA commends the committee for taking a closer look at those actions and inactions that led to the tragic NECC event. We believe the committee is taking the proper steps to address this tragedy by focusing its investigations on what steps should have been taken and oversight that ensures that the proper regulatory bodies are exercising their full authority.

Compounding is the backbone of pharmacy. It goes back to the time of the alchemist. For centuries, pharmacy only did compounding, until World War II, then commercially prepared medicines became more prevalent, which is still the thing today. But it did start dawning on people a couple of decades ago that there are people that need something that just isn't commercially available. So compounding came back into being an important part of the pharmacy practice.

Another thing, compounding serves to bridge a gap which we are experiencing more and more when commercial products are not available. Patients must be assured that they are not forced to go without medicines or their treatment because medications are unavailable and compounding for that medication is prohibited or tied up in a

bureaucracy. It is important to reiterate that pharmacist compounding is an integral part of pharmacy profession and meets patients' needs in hospitals, long-term care, home infusion, hospice, every community setting I can think of.

NCPA has always and will continue to advocate that pharmacy compounding is best regulated by the State boards of pharmacy while manufacturing oversight is the purview of the FDA. Pharmacy compounding medication is an important part of the medical care and allows dispensing custom-made medications and should continue to be related by State boards of pharmacy, as all other medical profession licenses are.

State boards of pharmacies currently oversee all aspects of pharmacy and in most cases their records are public. So it is not hard to obtain who is doing what. If the FDA has concerns about appropriate licensed pharmacy, then the FDA currently has the authority to ask the State board of pharmacy to work with them to address the issues. If it is found that they have an entity that is acting under the guise of a pharmacy and is exceeding its State-regulated authority, then the States board of pharmacy should suspend the license of that pharmacy until it complies with the State regulations or meets the FDA regulations to be a manufacturer.

All parties involved must make certain that the State boards of

pharmacy are adequately staffed, trained, and funded to effectively regulate compounding. NCPA encourages the State boards of pharmacy to acquire uniform compliance with USP 797 standards in order to provide more uniform product standards. As such, every State will be assured that resident and nonresident pharmacies alike are all in compliance with the USP standards.

In most cases, compound medication must originate from a prescription for a specific patient. There are times that we may do things in advance, but we have to be able to prove that we use historically a certain amount in a very short period of time.

I see I am out of time. Compounding should not be defined by nuance, such as types of product, whether it is sterile or nonsterile, as risk of complexity of compounding is not solely dependent on the product type. Neither is quantity of the product made in a pharmacy of bearing because we can make many different things and they are all safe. And interstate commerce should not be -- because we, was stated earlier, we are a border State to 5 different States, and, being rural, there are places that just have to go across State lines. But if it is the issuance of a prescription for a specific patient for a specific malady, this should be allowed and under the purview of the States.

Thank you for the opportunity to be here. NCPA pledges to work with Congress to put this to rest.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Harmison follows:]

******** INSERT 3-2 ********

Mr. Pitts. Ms. Russell, you are recognized for 5 minutes for opening statement.

STATEMENT OF ELIZABETH SCOTT (SCOTTI) RUSSELL

Ms. Russell. Thank you. Good afternoon, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. The National Association of Boards of Pharmacy appreciates the opportunity to appear before you today and provide information related to pharmacy compounding. I am Elizabeth Scott Russell, government affairs manager for the association.

As part of a comprehensive action plan that assists States following the meningitis outbreak, NABP partnered with the Iowa Board of Pharmacy to begin conducting inspections of all of its approximately 609 resident pharmacies, focusing first on those delivering compounded drugs into Iowa. Our inspections confirmed that the activities that occurred with NECC were also occurring in other facilities in other States.

To date, NABP has inspected approximately 165 pharmacies and is in discussions about similar inspection programs with other States. We are building a system of proactive information exchange for all pharmacies that will include verifications of licensure, disciplinary

checks, and assurances of a timely and robust inspection that meets uniform standards at no cost to boards to assist them in making licensure and registration determinations for nonresident pharmacies.

NABP does believe that Federal legislation is needed to provide the needed distinction between compounding and manufacturing to address critical concerns and provide a safe and equitable environment for both to occur in the best interest of the patient. NABP supports the major concepts of the legislation proposed by the Senate HELP Committee and welcomes the proposed clarifications to the regulatory uncertainties that currently exist, uncertainties that were a primary factor leading to the recent meningitis tragedy.

In particular, NABP affirms that the regulation of the practice of pharmacy remains the responsibility of the State boards of pharmacy and agrees with the language in the proposed Senate legislation that defines traditional pharmacy compounding as part of the practice of pharmacy to be regulated by State boards of pharmacy. NABP also supports the establishment in legislation of a new category for the preparation of nonpatient-specific sterile products that would be registered and regulated by FDA and a clear distinction between this new category and traditional pharmacy compounding.

Although we understand that some terminology must be employed to describe this new category, we would prefer that the term "compounding"

not be included in the name because of potential confusion with traditional pharmacy compounding.

NABP supports Federal legislation prohibiting entities that fall into this new category also being licensed as a pharmacy by the State, as this separation is essential to addressing the ambiguous authority that currently exists between the States and FDA; that is, who is responsible. Our experience affirms the importance of a clear separation between manufacturing and compounding and clarifying what activities fall under Federal jurisdiction and what fall under State jurisdiction. Not having a clear separation could also provide a veil for unscrupulous entities to hide their activities.

NABP does not believe that the interstate distribution of nonpatient-specific sterile products should be a required criteria for meeting this definition, this new category, as is in the Senate proposal. We understand the need to establish a delineation point, but such differentiation between intrastate and interstate distribution could create patient safety concerns by allowing large-scale intrastate entities to avoid Federal regulation. NABP could still support proposed legislation that exempts intrastate distributions from the definition for this new category provided the situation is monitored for any additional future action that may be necessary.

In conclusion, NABP believes there is a need for Federal legislation that addresses the safe preparation of compounded medications for patients, that distinguishes between compounding and manufacturing, defines a new category of manufacturers under FDA regulation, balances effective regulation with reality, and carefully constructs the scope and activities of this new category to meet patient needs while maintaining necessary protections. We appreciate this opportunity for input and are available to discuss our comments and any legislative solution in greater detail. Thank you.

Mr. Pitts. Chair thanks the gentlelady.

[The prepared statement of Ms. Russell follows:]

******** INSERT 3-3 ********

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

STATEMENT OF GABRIELLE COSEL

Ms. Cosel. Thank you. Chairman Pitts, Ranking Member Pallone, Vice Chairman Burgess, and members of the subcommittee, thank you for the opportunity to testify on the need for Federal legislation to improve the safety of compounded medicines. My name is Gabrielle Cosel. I work on pharmaceutical quality and safety at the Pew Charitable Trusts, which is an independent research and public policy organization.

Pharmacists have always compounded medicines. But many of the activities we refer to as compounding today are far removed from traditional pharmacy practice. In recent months, this committee has stressed the responsibility of FDA to ensure the safety of activities that depart from traditional compounding and are more akin to manufacturing. Today I will focus on a regulatory framework that clarifies the agency's role, ensures that limited resources are used wisely, and sets clear expectations for the industry.

First, though, it is important to look over the risks. The fungal meningitis epidemic illustrates how patients can be harmed by

substandard compounded drugs. But it is far from an isolated incident. My written testimony describes 19 additional pharmacy compounding errors from the past decade that have caused serious injuries and deaths in at least 29 different States. The list includes meningitis, blood stream infections, and at least 38 patients who suffered partial or complete vision loss.

Recent history raises further concern. Two months ago, a New Jersey compounder recalled all of its products because of mold contamination. When a drug is produced in mass quantities, the potential harms from a quality failure also multiply. There are companies today that compound thousands of packages of vials of medicines and ship them to buyers all over the country. These activities have outgrown the State regulatory structures established to oversee them. Federal law already regulates some aspects of compounding, and today we urge you to make changes to ensure clarity and effective oversight.

First, large-scale compounding should be subject to higher quality standards, specifically applicable good manufacturing practices. Second, the FDA is the appropriate agency to oversee GMPs, and States should not exercise redundant oversight. And finally, patients must be protected by ensuring that compounders do not undermine gold standard FDA-approved drugs.

Compounding quality standards are currently set by the States, and they are variable. Pew recently joined with the American Hospital Association and the American Society for Health System Pharmacists to host a summit on sterile compounding, and experts at that meeting emphasized that pharmacy compounding standards were never intended and are not suitable for large-scale production. Compounding high volumes or repeat batches of medicines involves standardized processes and should be subject to applicable GMPs. The FDA is best placed to enforce these standards, but resources should be focused on activities that pose the highest public health risk. Facilities that produce large volumes of sterile products that may reach many patients or that carry out particularly high-risk compounding, such as creating sterile products from a nonsterile bulk ingredient, should be required to register with the FDA.

FDA should issue regulation clarifying the criteria for registration. As with pharmaceutical manufacturing, FDA should inspect compounding facilities on an ongoing basis with a frequency based on risk. And facilities should pay fees to ensure FDA is adequately resourced to provide this oversight.

Under this framework, States may continue to require FDA-registered compounding facilities to hold pharmacy licenses, but State enforcement of quality standards should be preempted for these

facilities. To exercise effective oversight, the FDA must have access to the records of facilities it regulates or that it believes fall under its jurisdiction. This requires a fix to current law. Even today, compounders continue to challenge FDA's access to records. Key safety requirements should also be set at the Federal level, such as a "do not compound list," and this should apply to all compounding facilities.

It is important to state that large-scale compounding cannot be addressed simply by requiring these facilities to submit new drug applications. Some large compounders fill a niche in our health system, such as for hospitals that don't have sufficient capacity to mix drugs in-house. However, any new regulatory scheme must not undermine the approvals process and encourage compounding at the expense of traditional manufacturing. While the goal is to ensure the quality of compounded medicines, patients, doctors, and pharmacists should prefer FDA-approved products whenever possible. Only the latter go through pre-market review to establish safety, efficacy, and bioequivalence, along with pre-approval of manufacturing methods and facilities. Legislation should be clear that a compounder may not make a copy or a variation of a marketed drug except when that drug is in shortage or to address a specific medical need of a specific patient.

In conclusion, I thank you for your leadership, and I urge you

to create a clear, workable framework to protect patients. I welcome your questions.

Mr. Pitts. Chair thanks the gentlelady.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Ms. Cosel follows:]

******** INSERT 3-4 ********

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

STATEMENT OF GERRY MIGLIACCIO

Mr. Migliaccio. Thank you, Chairman Pitts and Ranking Member Pallone, for inviting me here to speak today. My name is Gerry Migliaccio. I am a consultant in the area of pharmaceutical quality systems. In 2012, I retired from Pfizer, Incorporated, after a 33-year career in pharmaceutical manufacturing and quality operations. For 11 of those years, I served as the head of the Global Quality Organization at Pfizer. So this experience has provided me with quite an intimate knowledge of the quality requirements and regulatory framework applicable to manufacturing medicines for the United States public.

Patient safety is the highest priority for pharmaceutical manufacturers. Companies comply with the gold standard of quality manufacturing as defined by FDA's current Good Manufacturing Practice regulations and the associated guidance documents. These regulations apply to all prescription drugs approved for sale in the United States, wherever they are made, and extend to all components of a finished drug product, including the active pharmaceutical ingredients.

FDA's regulations are based on the fundamental principle that you cannot inspect or test quality into a finished product. Quality must be designed into the manufacturing process and designed into the product. The regulations also drive manufacturers to establish a quality systems approach to assure consistent quality.

In pharmaceutical manufacturing, quality systems and GMP requirements begin at the investigational stage. FDA requires that a new drug application describe the quality safeguards for the proposed manufacturer of a new medicine in the Chemistry, Manufacturing, Control section of the application. Part of the evidence required by FDA to demonstrate safety and efficacy is the requirement that a manufacturer provide, and I quote, "a full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of a new drug."

The manufacture of medicines, whether by NDA holders or large-scale compounders, involves similar activities and similar potential for risk. Large-scale compounding can involve mixing of active and inactive ingredients, as well as other manufacturing steps. Therefore, in order to assure the safety of the American public, the manufacture of medicines, whether by manufacturers or by pharmacies, should be regulated in a consistent risk-based manner. Large-scale commercial manufacturing of prescription medicines, whether the

producer is designated as a pharmacy or as a manufacturer, should be governed by the same high standards currently in effect for pharmaceutical manufacturing and subject to the same inspection and enforcement actions by FDA.

Moreover, large-scale compounders should be required to prove that they can manufacture medicines consistently and safely by submitting an application to FDA containing a Chemistry, Manufacturing, and Control section, and submitting to both pre-approval and routine GMP inspections.

Let me give you a personal perspective on the importance of GMP regulations. During my career, I considered the regulatory framework in the United States as the blueprint for assuring safety and efficacy. Whether you are a small startup company or a large multinational manufacturer, the regulations and guidance documents provided a template for success. From designing quality into a manufacturing process to the selection of material suppliers to construction of facilities, the selection of equipment, the training of employees, all the way to the final approval to distribute the product, the regulations and guidance documents provide for a consistent risk-based approach to assure quality. The regulations have also evolved to encourage innovation and continuous improvement and to help support the justification of new technology to further enhance quality assurance.

Therefore, it is just very logical to me that any large-scale manufacturer of medicines, including compounders, should comply with these same regulations. A manufacturer in full compliance will have a high degree of assurance that the medicines they produce will be of consistently high quality. A large-scale company making thousands of doses of medicine with the name "Pharmacy" on the door and another with the name "Pharmaceutical Company" on the door should be regulated in a similar manner when they perform similar manufacturing steps and present similar risks to patients.

Thank you for your attention.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Migliaccio follows:]

******** INSERT 3-5 ********

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

Dr. Gottlieb, the FDA has proposed creating a new category of, quote, "nontraditional compounders," end quote. Do you believe this has the potential to add confusion rather than clarity to regulated industry?

Dr. Gottlieb. I do believe there is this category of companies, large companies, that have grown up that basically do the outsourced work of the hospitals. And it is not really traditional compounding in the sense that we understand that word. What they are really doing is sterile preparations of drugs, breaking down FDA-approved products into different formulations that make it easier to administer to patients, and it is a completely different thing than what traditional compounding is.

I do think it creates the potential that traditional manufacturers might have a temptation to recast themselves into this new category if we don't have very equal enforcement and very aggressive enforcement of the existing law because there will be an incentive to go into this pathway because it will be sort of a regulatory light pathway.

The reason why Teva Pharmaceuticals doesn't, you know, manufacture all the formulations of Propofol that doctors might want

is because if they went about doing that they would have to file an ANDA for each one and pay a user fee for each one. So if we create this category, it could be an incentive for traditional manufacturers to try to move back into this new category, and that wouldn't serve the public interest.

Mr. Pitts. To follow up, impact on intellectual property rights. How would this new category potentially impact intellectual property rights?

Dr. Gottlieb. Well, again, I think it could create an avenue for people to try to game around the new drug regulations to create products that would fit into this category. And it is not an argument for not trying to think about how we could apply GMP regulations to this emerging, this new category of manufacturers. But it is an argument for trying to make sure that we enforce existing law against compounders who, for example, compound versions of FDA-approved products.

In recent years, the FDA has backed off enforcement that was put into place to crack down on people who are engaging in the compounding of drugs that exist in FDA-approved formulations. And so that creates an incentive to try to obviate existing intellectual property.

Mr. Pitts. Mr. Migliaccio, Director Woodcock mentioned on the previous panel that the agency could not require compounders to register with the FDA. However, the FDA has the full authority to

require manufacturers operating under the guise of compounders to register with the FDA, like NECC. Isn't that correct?

Mr. Migliaccio. Yes. Well, every manufacturing establishment within a pharmaceutical company has to have an establishment registration with the FDA.

Mr. Pitts. Hasn't the FDA recently used its manufacturing inspection authority to inspect manufacturers acting under the guise of compounding recently?

Mr. Migliaccio. I believe they have used their inspection authority to attempt to inspect compounding manufacturers. And I understand that they have been turned away in certain cases.

Mr. Pitts. Please explain the similar scope of risk between NDA holders manufacturing drugs and large-scale compounders.

Mr. Migliaccio. Well, pharmaceutical manufacturers make pharmaceutical products at very different scales. I mean, we make small volume, we make large volume. Compounders are doing the same thing. We are following similar manufacturing steps. We are taking active ingredients and inactive ingredients, combining them, trying to yield a product that has the potency and purity required by the patient.

Compounding the problem with sterile products is the risk around sterility. Sterility is not something that you can test into a

product. Yes, you do a sterility test, but it is not a reliable measure of sterility. You have to have a very robust system to assure sterility. And the GMPs require that we actually prove that to the FDA before we can market the product. We have to prove that we can assure sterility to a very high degree before we can put a product on the market. That is not the case, the risks are the same for compounding pharmacies, but they don't have to provide that same evidence.

Mr. Pitts. Could legislation that applies different standards adversely affect the quality of drugs made available to patients?

Mr. Migliaccio. Oh, I believe that compounding pharmacies making product at large volume are manufacturers and should be regulated according to the manufacturing regulations, the GMPs, which have proven to be very successful in protecting the American public.

Mr. Pitts. Let me squeeze one more question in here, Mr. Harmison. What safety precautions are you required to comply with?

Mr. Harmison. I comply with USP 797 and State laws and rules and regulations of the State of Texas.

Mr. Pitts. And can you briefly describe the importance of traditional compounding that occurs in independent pharmacies across the country?

Mr. Harmison. Mr. Chairman, that is a very broad subject. If we are talking about somebody making a cream, there is one thing. If I am making a sterile injection, that is quite another thing. I am making a capsule for somebody. We still strive, basically, we are not going to make anything we wouldn't give to our children or grandchildren.

Mr. Pitts. Thank you.

My time has expired. Recognize the ranking member 5 minutes for questions.

Mr. Pallone. I wanted to start with Ms. Russell. In your testimony, you cite the need for FDA to be given new and better authority over drug compounding. Obviously, your organization is made up of State agencies that regulate the practice of pharmacy, so you are in a unique position to have insight into whether FDA needed new authority in this area.

So, Ms. Russell, your testimony describes the fact that there were regulatory uncertainties that were a major factor leading to the NECC meningitis tragedy. Can you elaborate on what those -- I always hate to say elaborate -- but can you tell us what those uncertainties were and how they contributed to the meningitis outbreak?

Ms. Russell. Sure. I think that there are a number of entities in the United States, across the United States, that would tell boards

of pharmacy that they were distributing nonpatient-specific sterile products as an FDA manufacturer. And they may have actually gone on FDA's Web site and registered as a manufacturer and State boards of pharmacy didn't think they had jurisdiction over those particular activities. FDA didn't necessarily recognize them as an approved manufacturer because they hadn't filed an NDA. So there were uncertainties and ambiguities in who had responsibility over these particular firms.

Mr. Pallone. So you also indicate that NABP is supportive of the Senate legislation clarifying the distinction between compounding manufacturers and traditional compounders. And you further indicate that your recent inspections of compounding pharmacies has underscored the importance of getting this clarity through Federal legislation. So can you explain more about what you have done in your inspection's undertaking? I am curious about why, if any BP in the States have been able to conduct such widespread inspections recently, that isn't enough. In other words, what would be achieved by FDA through new Federal legislation that can't be accomplished by the State boards of pharmacy?

Ms. Russell. Maybe I wasn't clear. We do think traditional pharmacy compounding should remain the purview of State boards of pharmacy. But we do think that there are these entities that are

engaged in large-scale activities that more resemble manufacturing and that FDA should have jurisdiction to inspect and investigate those.

Our initial inspections that we have been involved in for the State of Iowa, part of it has been trying to determine which of these large-scale entities are engaged in these more resembling manufacturing-type processes, and those are not condoned by the Iowa Board of Pharmacy, nor most other States. And we don't think that State boards of pharmacy have the resources to be able to adequately inspect basically manufacturing operators that are operating under the guise of legitimate pharmacy practice.

Mr. Pallone. Thank you.

Let me ask Ms. Cosel. I would like to ask you a question that we heard a little about during the first panel. That has to do with hospital use of compounding medications. As we heard, hospitals have increasingly come to rely on compounded medicines that they obtain from large-scale pharmacies, and Dr. Woodcock talked some about how FDA's authorities to oversees these large-scale facilities are not appropriately tailored to the task. So I wanted to ask you, do you agree that hospitals do have a legitimate need for drugs from these large-scale pharmacies? Can you explain more about why they have come to rely on them? And what are your views on whether the FDA has the right authorities to handle regulation of that type of entity.

Ms. Cosel. Yes. And I think the question is very astute, because it hits on just what is at hand today. There is a question about bad actors and if they cross a certain line whether they should be shut down. Yes. But there is also a question of entities that do fill a niche in our healthcare system, such as the outsources you reference, sir. And it has become clear over the years that hospitals have increasingly looked to outsourced operations to provide them sterile mixed products, mixed variations of finished FDA drugs.

And the simple answer can't just be calling these entities manufacturers and requiring them to submit a new drug approval. We need to make absolutely clear that when you are compounding on a large scale and filling this niche for the health system you should be held to high quality standards, GMPs, as my colleague Mr. Migliaccio testified on as well.

Mr. Pallone. Mr. Harmison, I have got a little time. Your testimony can be summarized as follows: States always have and always should regulate compounders with no role for the FDA. But we know that numerous failure by Massachusetts regulators led to the NECC tragedy. In light of this tragedy, is it still your view -- and I don't mean -- you tell me if I am wrong -- is it still your view that States are capable of regulating large-scale compounders?

Mr. Harmison. Yes, Mr. Pallone. I think if they have the

willpower to do it, they have the ability.

Mr. Pallone. So you don't think there is a role for FDA in the regulation of large-scale compounders like NECC.

Mr. Harmison. I think the rule of the FDA is oversight. If they think that there is a problem, they should go talk to the State boards of pharmacy, say, come, go with me, let's inspect this. If it is in violation of the State law, then the State should take action on them. If they say, we don't have this, somebody decide if they are a manufacturer. If they are a manufacturer, certainly they are under the purview of the FDA.

Mr. Pallone. I don't know. It just seems to me that what you are proposing sounds nice in theory, but I think much of the testimony seems to indicate it doesn't work out practically. But whatever, I don't want to put words in your mouth. Thanks a lot.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the vice chair of the committee, Dr. Burgess, for 5 minutes for questions.

Dr. Burgess. Mr. Harmison, let's continue on that line for a moment, because when another subcommittee of the Energy and Commerce Committee, the Oversight and Investigations Subcommittee first started this investigation, we were joined by the brand new head of the Massachusetts Board of Pharmacy. And the reason she was the brand new

head was because the old head had been recently dismissed because of the problems that occurred.

We have heard from the FDA this morning that, no, we are not going to replace anyone in our organization. And looks to me like the Massachusetts Board of Pharmacy acted. Although there may have been problems leading up to the crisis, their response to the crisis and after seems much more reasonable than what I have seen under the Federal regulatory agency. Is that a fair assessment that I am making?

Mr. Harmison. As an employer, if I were in that position, somebody wouldn't be in my employ anymore.

Dr. Burgess. Well, that is, you know, this was so baffling about all of this. I mean, again, the poor individual who was the head, the brand new head of the Massachusetts Board of Pharmacy had to come here and answer some pretty tough questions and some for which she no answer, and simply said those people are no longer working for us. And you have to wonder if whether or not there are civil or even criminal activities are going to follow them for a while. I wouldn't be surprised to learn that.

But, again, you have a large Federal regulatory agency, and they are immobile. And not only are they immobile, after they find out that there is a problem, but the months and years leading up to this. Well, we are going to have to have guidance, and, well, it is bound up in

some stuff.

And I read you the email chain. From 18 months before this crisis hit, they recognized that it was manufacturing, that they were required to list these compounds, they were required to submit to GMP. The people in the FDA understood that. And for whatever reason it didn't translate to the street level to get it done. In fact, I don't think the people that were working in the agency, again, I just -- the mental image, they must be tearing their hair because they keep coming up to this point waiting for someone to say "go" and no one ever said "go."

And that is the problem I see if we divested away from the State agencies. Bad news at Massachusetts Board of Pharmacy. You know, bad news at what happened. But at least they have reacted in what I would consider a sensible way. I can't say the same to the FDA. That is painful for me to say that.

Mr. Harmison. Well, if I can go back to an old Paul Newman movie, it appears what we have is a failure to communicate between regulatory agencies and enforcement agencies.

Dr. Burgess. Dr. Gottlieb, let me just ask you because you have some experience working within the agency. Is that not correct?

Dr. Gottlieb. Look, I think NECC was breaking existing law. They were acting as a large-scale manufacturer under the guise of a pharmacy license. They were compounding identical versions of

FDA-approved products, they were doing it in bulk, they weren't doing it in response to prescriptions. They had had previous GMP violations. So they were known bad actor.

I think the issue isn't necessarily what is FDA's authority. FDA has extensive authority. I think that the challenge is that they don't have ease of administrating authority because they don't have the ability to compel the submission of certain information. And it is not the posture by which they typically regulate.

In the case of compounding, in many cases FDA is forced to have to make an affirmative case before it could go in and start to do its work. Typically, the FDA doesn't regulate that way. Typically, the FDA regulates from a posture where they compel submission of information to the agency and then they are able to target their activities based on that information. You know, under existing law they have extensive authority, in my view, but it is authority that makes it administratively more burdensome for them in this area than others.

Dr. Burgess. But, you know, the concept of an affirmative case, and for heaven sakes, the system was blinking red for years. For years. You had whistleblowers, you had people bringing brochures in, you had people showing up saying, this is what we heard at a conference. These guys were clearly skating way beyond the edge, way beyond the fringe.

And, okay, well, it may not be the normal FDA posture to take an affirmative case, when the evidence is laid in front of you, it shouldn't take --

Dr. Gottlieb. Well, this one was obvious.

Dr. Burgess. -- it shouldn't take years to come to the conclusion of filing the action that eventually closed the NECC. Is that correct?

Dr. Gottlieb. This was a known bad actor over a long period of time -- including, frankly, the time in which I was at FDA, we sent out a warning letter to this firm in 2006.

Dr. Burgess. Okay.

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

Mr. Pitts. Chair thanks the gentleman.

And now recognize the ranking member emeritus, Mr. Dingell, for 5 minutes for questions.

Mr. Dingell. Mr. Chairman, I thank you.

First question is for Ms. Russell of the National Association of Boards of Pharmacy and also Ms. Cosel of the Pew Charitable Trusts.

Ladies, do you believe that there is regulatory uncertainty regarding the FDA's role in overseeing compounding pharmacies? Yes or no?

Ms. Russell. Yes.

Ms. Cosel. Yes.

Mr. Dingell. Now, these next two questions are for Ms. Russell. In your testimony, you mentioned that NABP partnered with the Iowa Board of Pharmacy to inspect pharmacies which deliver compounded drugs into Iowa. Is that correct?

Ms. Russell. Yes.

Mr. Dingell. Now, in your testimony also, you also mention that your inspections found that what occurred at NECC was happening elsewhere. Is that correct?

Ms. Russell. Yes.

Mr. Dingell. Could you briefly describe what you found at some of the facilities where you found a repeat of this kind of situation?

Ms. Russell. We found large-scale operations similar to what NECC was doing where they were allegedly compounding or producing bulk quantities of sterile injectable products, some that were essentially copies of commercial products. We found issues with compliance with standards for sterility compounding and basically that they were shipping nonpatient-specific drugs into the State of Iowa in violation of Iowa State law.

Mr. Dingell. What did the Iowa agency do about this?

Ms. Russell. Iowa is in the process of -- they have got three attorneys now working on the inspections that we provided. And they have issued notices of regulatory hearing for 5 of the first 6

pharmacies that we went in, which were some of the larger-scale operations. Those hearings I believe will be held in June this year, next month.

Mr. Dingell. They seem to be in great haste. Am I correct?

Ms. Russell. Pardon?

Mr. Dingell. They seem to be in great haste to get around to processing this matter. Yes or no?

Ms. Russell. Yes.

Mr. Dingell. I don't see it that way.

Would you submit also for the record other details of the events that you found, if you please?

[The information follows:]

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Mr. Dingell. Now, in your testimony you mentioned there has been 19 significant compounding errors since 2001. Is that correct?

Ms. Cosel. Yes, 20, including NECC.

Mr. Dingell. Okay. Would you for the record submit the details of those events, please, to us?

Ms. Cosel. Yes, sir.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Now, how many people died as a result of these incidents?

Ms. Cosel. Not including NECC, there were 22 deaths associated with these incidents, and including NECC there were 77.

Mr. Dingell. Could you submit for the record the details on these things, if you please?

Ms. Cosel. Yes, sir.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Now, as far as you know, have there been further problems with compounding pharmacies after the NECC outbreak? Yes or no?

Ms. Cosel. Yes. We have seen a number of recalls related to quality problems with compounded drugs this year.

Mr. Dingell. Could you submit again for the record what you found in those matters?

Ms. Cosel. Certainly.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Dingell. Could you give us a brief perhaps picture of what you found done in these instances and whether this was the responsibility of the State agencies or the Feds?

Ms. Cosel. Well, I can give one example. There was a recall by a Georgia compounder this year, I believe in March, of all sterile products, because there were serious eye infections in at least 5 patients associated with a contaminated eye injection. In this case, this was a nationwide recall. So if we are -- if Congress is considering a new regulatory system that is clear that large-scale compounding of high-risk sterile products would be explicitly under FDA oversight, I think we would have had a much better chance of ensuring the safety of those processes.

Mr. Dingell. Particularly since they are shipping all across the United States and this is touching many agencies, many States, and people in many States and agencies. Is that right?

Ms. Cosel. Yes.

Mr. Dingell. And, by the way, thank you for your patience. It lets me get a lot more questions in.

Would you for the record please submit the information that you have on these instances?

Ms. Cosel. Yes.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The information follows:]

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Mr. Dingell. Now, in your opinion, is the outbreak at NECC an exception to the rule or do you believe that it is but one example of a larger problem?

Ms. Cosel. It is certainly an extremely horrific example, but it is just one of the larger issues we face. We acutely need greater clarity on oversight structures for large-scale compounding.

Mr. Dingell. And one of the things we have do is to clarify it so that everybody knows who is supposed to and who can do what. Is that right?

Ms. Cosel. Yes.

Mr. Dingell. Because we have the court cases that have screwed up the interpretation by both State and Federal agencies on this matter. Is that right?

Ms. Cosel. Legal uncertainty is one problem, as is changes with the industry and the emergence of the large-scale sector.

Mr. Dingell. I have used more than my time. Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. Griffith. Thank you, Mr. Chairman.

I have to tell you all, and I appreciate all of you being here,

that I think part of the problem is, is that we have a clash of two worlds, the legal world and the medical world. Because when I look at the authority granted to the FDA under the code, with the exception of the advertising overreach, which was stricken down, there is plenty of authority already there to get to every problem that you all have raised today. And that is my concern.

And I asked the doctor earlier, and she was very kind, you know, this happened, the Supreme Court case came down that dealt with the Ninth Circuit in 2002. Where was the request to Congress to clarify? Because the only clarification is that the rest of the authority granted, with the exception of the advertising provision, should have been reenacted by Congress.

Now, can we tweak it a little bit and make it a little bit better? I am sure we can. And I am certain that we will work on that, because none of us want to see this problem happen again. But I heard one of the witnesses, and I don't remember which one now, say that they understood that there had been problems, you know, getting the records and getting into things. And, in fact, I think because the medical world -- and I was a courtroom attorney, and so maybe it is a little different, not attorneys, but courtroom attorneys, they see things differently.

So I asked legal counsel who was here at a previous hearing, for

the FDA, do you have any trouble getting warrants? And I expressed that my opinion always was as a defense attorney, criminal defense attorney, that the government didn't have too much trouble getting warrants. He said, that wasn't my experience. And I asked him to get me information. Yesterday, we received that information.

[The information follows:]

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Mr. Griffith. And, sure enough, FDA cannot point to a single example of where they requested a warrant where they were denied that warrant. So while the common belief is they have a hard time getting this information, the data would indicate otherwise.

I also asked, how long does it take you to get the warrant? And they said, in the most recent administrative warrant we sought for a pharmacy, 10 days passed between when the refusal was encountered and when the warrant was signed by the magistrate judge.

I have got to believe that if, as somebody said earlier, the blinking light, the red light warning, warning had been going off for years, that if instead of being timid and being afraid of the law, the medical folks had burst in, as often police officers have to do -- if they think somebody has a DUI, they may not win the case in the end, but they get that person off the road, at least temporarily, to see what is going on -- that is what should have happened in this situation.

Would you agree with that, Mr. Harmison, that that is probably what should have happened, instead of coming in, trying to rewrite the law.

Mr. Harmison. Yes, sir. If there is public safety at risk, the State board of pharmacy absolutely has the power to come in and say, wait a minute, you are shut down.

Mr. Griffith. Yeah. And I think that the guidelines that were

worked on, never fully finalized, but that were worked on in the draft guidelines of August of last year that we didn't learn about until March of this year, make that clear as well. Because it goes through and when it talks about distinguishing between, as you all have called them different names, large-scale producers or production of compounded drugs, large-scale manufacturers, I think they are manufacturers. And I said in one of the earlier hearings, you know, I can call myself the Duke of Earl if I want to, but that doesn't mean I am getting diplomatic immunity.

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[1:46 p.m.]

Mr. Griffith. And that is where I think we run into this problem. But when they did that draft, they said, when you are looking at whether or not somebody is doing a compounded drug product that qualifies for the exemptions, they came up with 10 guidelines. And they are all significant and important, but I noted with interest two of those. Number 8 says the licensed pharmacist or licensed physician does not compound regularly or in inordinate amounts any drug products. Number 10 says that you should have a memorandum of understanding with the States so that you can work out these areas that aren't clarified or in a State where they have not entered into a memorandum of understanding the pharmacists shouldn't be sending to another State more than 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

These seem to me to be reasonable restrictions, and it makes the definition that I think each one of the witnesses here today is looking for, distinguishing between the traditional pharmacy that is doing some things for their patients and their customers and these large-scale manufacturers who are, in fact, in my opinion, they are not compounders

in the traditional pharmacy sense, but they are, in fact, manufacturers.

I look forward to trying to make sure that we clarify some of that because I do think that part of the problem is, is not having some street lawyers at the FDA who know that sometimes you have got to go in and kick the courthouse door down and say here is what we are doing. And when the judge sees the risk to the public he will say, okay, I will sign the warrant, okay, we will shut them down at least until we can find out whether or not they are a risk to the public. I think the authority already exists for that. I just think there has been some timidity in the legal department at the FDA.

And when you talk about registration, when you look at the rules in section 510 of the act, I think it is pretty clear that unless you are a small town pharmacist you are supposed to be registering anyway. Does anybody disagree with that?

Dr. Gottlieb, do you disagree with that?

Dr. Gottlieb. No, 510 has a requirement for registration. And I think 503A actually lays out some criteria to try to distinguish, you know, these illegitimate compounders from the legitimate ones. So the language does exist and this could -- even 503A could be better interpreted in regulation. But I think the compliance policy guide which you just quoted is a very good start for that.

Mr. Griffith. I think they did a nice job in that guidance. I am not going to say I would agree with every word of it, but most of it is pretty good stuff and it indicates the FDA had the authority to move forward even under the rules that they now say they don't have the authority to do.

With that, I see my time is up and I yield back. But I do appreciate all of you all staying through two vote series on a long day. Thank you.

Mr. Pitts. The chair thanks the gentleman.

And with that, we again thank the witnesses for your patience.

That concludes the questions of the members who are present. There are other questions I am sure that other members who are not here will also like to submit to you and we will ask that you please respond promptly once you receive those questions.

And I will remind members that they have 10 business days to submit questions for the record, and Members should submit those questions by the close of business on Thursday, June the 6th.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Very informative and important hearing. Thank you very much for your attendance.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:50 p.m., the subcommittee was adjourned.]