UNITED STATES OF AMERICA
DRUG ENFORCEMENT ADMINISTRATION

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PUBLIC MEETING

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PROCEDURES FOR THE SURRENDER OF UNWANTED CONTROLLED SUBSTANCES BY ULTIMATE USERS

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WEDNESDAY
JANUARY 19, 2011

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The Public Meeting was held in the Grand Ballroom of the Renaissance Mayflower Hotel, 1127 Connecticut Avenue N.W., Washington, D.C., 20036 at 9:00 a.m., Mark Caverly, Moderator, presiding.

T A B L E O F C O N T E N T S

P-R-O-C-E-E-D-I-N-G-S

8:59 a.m.

MR. RANNAZZISI: Good morning. Thank you for coming out on this dreary Washington morning.

A bit of a housekeeping note. If everyone would please silence all their communication devices, any computers, whatever the device you carry that's going to make noise and interrupt the speakers or the audience. I appreciate you all doing that now.

My name is Joe Rannazzisi. I'm the Deputy Assistant Administrator for the DEA Office of Diversion Control. On behalf of Administrator Michelle Leonhart and the more than 9600 men and women of the Drug Enforcement Administration, welcome to the DEA public meeting to discuss the development of procedures for the surrender of unwanted controlled substances by ultimate users and long-term care facilities for disposal.

Specifically, this meeting is intended to allow all interested persons, the general public, ultimate users, health care professionals, pharmaceutical industry groups, retail pharmacies, regulators, law enforcement, reverse distributors, and all others to express their ideas and views on the most safe and effective method for the transfer and disposal of pharmaceutical controlled substances in compliance with the Controlled Substances Act and with the new public law, 111-273, the Secure and Responsible Drug Disposal Act of 2010.

And I want to take this opportunity today to thank Representatives Jay Inslee, Lamar Smith, Bart Stupak, and James Moran, and Senators Amy Klobuchar, John Cornyn, Chuck Grassley, and Sherrod Brown for their leadership in passing this legislation.

This is the first opportunity for public comment since the passage of this act. The public will get a second opportunity to

provide written comments after a Notice of Proposed Rulemaking is published in the near future.

All statements that are made today will be transcribed and incorporated into a formal record of this meeting that will be posted on the DEA website.

We're interested in hearing your views, and we look forward to all of your presentations.

To get a view of why pharmaceutical controlled substance disposal is of great concern, let's look at some statistics.

The 2009 National Survey on Drug Use and Health data related to prescription drug abuse is alarming. Seven million Americans age 12 and older abuse psychotherapeutic drugs for non-medical purposes. That was up 13 percent in just one year.

5.3 million abuse narcotic pain

relievers for non-medical reasons. 2.6 million age 12 and older initiated for the first time with psychotherapeutic drugs last year. This averages to more than 7,000 per day.

There was an increase in 98.4 percent of ER visits attributed to pharmaceuticals alone, yet there was no significant increase in ER visits related to cocaine, heroin, marijuana, or methamphetamine.

The number of people seeking treatment for pain reliever abuse is up more than six fold in the age category 18 to 34. Every day, 2500 teens on average use prescription drugs to get high for the first time, and 16 percent of the teens who abuse pain relievers did so before the age of 15.

62 percent of those surveyed believe that teens got their prescription medications from where? Their family's own medicine cabinet for free.

Every leading indicator reflects a common theme. America has a serious drug problem, prescription drug problem, and the problem is getting worse.

As the statistics reveal, one contributing factor to this problem is the household medicine cabinet. Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, DEA did not have the authority to promulgate regulations to allow an ultimate user to deliver controlled substances to an authorized entity for disposal.

There was confusion among the public concerning the proper method to dispose of pharmaceuticals.

Most U.S. communities did not routinely offer opportunities to properly dispose of unused, unwanted, or expired pharmaceuticals or pharmaceutical controlled substances.

As a result, many people kept the

drugs in their households because they didn't know how to dispose of them. The household medicine cabinet has become a free source of supply for non-medical users.

Now, local and state law enforcement agencies, regulators, and community groups have been addressing this problem for years. Law enforcement and their community partners conducted local, county, and statewide take-back programs that collected unused pharmaceuticals. These take-back programs involved duly authorized law enforcement officials collecting unused pharmaceuticals from the public.

Unfortunately, these events were not available in every community, and were not, in many cases, regularly scheduled programs.

Most recently, DEA, in partnership with state and local law enforcement agencies, regulators, community leaders, and local governments, conducted a nation-wide

prescription pharmaceutical controlled substance collection and disposal initiative in September of 2010.

The collaborative effort with the International Association of the Chiefs of Police, National Association of Attorneys General, National District Attorneys Association, the Federation of State Medical Boards, National Association of Boards of Pharmacy, and the Partnership for a Drug-Free America resulted in the collection of approximately 244,000 pounds of pharmaceuticals from the public by approximately 3,000 agencies out of 4,000 collection locations.

We'll be conducting another nationwide initiative on April 30, 2011, and every six months thereafter, until we have disposal regulations in place.

Although serving a public need, these initiatives are temporary measures and do not take the place of a uniform, widely

available disposal program.

However, the passage of the Secure and Responsible Drug Disposal Act has provided DEA with the authority to promulgate regulations to create a system for the safe and secure transfer of pharmaceutical controlled substances for disposal.

This hearing is the first step, or this meeting is the first step towards the creation of these regulations.

I know that some of you have traveled great distances to be here and to be heard, and I thank you. I thank all of you for taking the time out to participate in this event.

And to my left is Mark Caverly. He's the Section Chief for the DEA Office of Diversion Control, Liaison and Policy Section, and he will act as a moderator and emcee for this event.

This is Mark's last official event as the Section Chief. He'll be retiring next

month, and he will be missed.

Thank you all very much.

(Applause.)

MR. CAVERLY: Gosh, how do I top that? As Mr. Rannazzisi said, my name is Mark Caverly. I'm the Chief of the Liaison and Policy Section for DEA. Can you hear me? Okay.

I wanted to introduce my DEA colleagues. Watch out for that microphone.

Cathy Gallagher is the Associate Section Chief, seated to my left, of the Liaison and Policy Section. And Colin Clark is a Policy Analyst for the Regulatory Drafting Unit within the Liaison and Policy Section.

Let me add my welcome to you folks. Kind of a historic location, the Mayflower Hotel, we're within three miles of the U.S. Capitol and about four blocks from the White House.

So it seems kind of appropriate

that we should be discussing a piece of legislation that was enacted just this past October, as Joe mentioned, the Secure and Responsible Drug Disposal Act of 2010.

We've been waiting for it for a long time, and I don't want to take any thunder away from Colin. We've actually been officially looking at this issue for about a couple of years.

We published an Advanced Notice of Proposed Rulemaking in January of 2009. And actually, as an issue, we've been looking at this for far longer.

This is something that we've been considering, we've been thinking about, we've been dealing with for probably close to four or five years, I would guess.

So, boy, let me move this up a little bit. Here we go.

Just to kind of set some expectations, I guess, for this process, DEA is the agency that's been charged with

implementing this piece of legislation, so we're in the process of writing regulations. We don't typically hold a public meeting in our rulemaking process, but we thought this issue was important enough that we would take that extra step.

So, what you should expect in terms of this meeting for the next couple of days is to hear folks, different stakeholders, different perspectives, basically telling DEA what's important.

And we're here to listen. We're here to take your comments, to roll them up, basically, with the comments we received during the Advanced Notice of Proposed Rulemaking.

And ultimately, we'll publish a Notice of Proposed Rulemaking, which will give you another bite at the apple, so to speak, another shot.

So we're here to listen. We don't expect to come out of here in a couple of days

with necessarily the solution. We're here to take your ideas, your suggestions, and your comments, and use them to ultimately publish our Notice of Proposed Rulemaking.

So, just to give you some idea as to what you can expect, it is a complex issue. As I looked through the agenda items, and I looked through the folks who preregistered with us, I was very surprised -- maybe not surprised so much as just impressed by the vast array of stakeholders in this room.

We have folks with environmental interests. We have Boards of Pharmacy. We have regulated entities, DEA registrants. I mean, there's just a whole wide variety of folks that you'll get to hear from during these next couple of days.

I think Mr. Rannazzisi mentioned that we are making a transcript of this meeting. We will ultimately post that transcript on DEA's website. And of course, we'll take the comments that we receive,

again, during this public meeting, to heart during our rulemaking process.

To just turn it over to Colin here shortly, we've asked Colin to establish sort of a baseline for us, to let folks know where we're coming from in terms of the statute, the Controlled Substances Act in terms of the regulations, to talk a little bit about the legislation that was passed, to again, give us a baseline -- to give you a baseline as we move through this rulemaking process.

So Colin's presentation is really intended to be an informational presentation, one, again, just to give you some information to let you see sort of where DEA starts in this whole process.

So Colin, if you're ready, I'm going to turn it over to you.

MR. CLARK: Thank you, Mark.

Good morning. My name is Colin Clark. I'm a Program Analyst at the Drug Enforcement Administration Office of Diversion

Control in the Regulatory Drafting Unit.

I'd like to also thank all of you for attending. DEA understands that this is a very important issue. We're thankful that you guys could attend and offer your opinions and your perspectives.

And DEA, as Mr. Caverly said, has been engaged in this disposal issue for years now, and we felt that we needed statutory change before we could move forward on this issue.

We have it now. DEA is excited that the Secure and Responsible Drug Disposal Act of 2010 has been enacted, and that we can finally move forward on this issue.

The purpose of my presentation is to discuss the Controlled Substances Act and its implementing regulations, and explain the framework from which DEA must work when we are drafting regulations for the disposal of controlled substances for ultimate users and long term care facilities.

I'd like to first start with the mission of the Office of Diversion Control, which is to prevent, detect, and investigate the diversion of controlled substances from legitimate sources, while ensuring an adequate and uninterrupted supply to meet the legitimate medical and scientific purposes.

One of our goals in anticipation of writing regulations for the disposal of controlled substances is to make sure that we don't add additional avenues for people to divert controlled substances.

And I'm hoping during the next few days we'll be able to find solutions to that concern that we have.

While discussing the statutory and regulatory background -- could you go to the next slide, please?

While discussing the statutory and regulatory background relating to the disposal of controlled substances, we will be referencing the following.

Oh, you can keep it on that slide.

Together, the law and regulations, the structure by which DEA registrants must operate regarding the disposal of controlled substances, the substances by ultimate users and long term care facilities, two notable statutory and regulatory actions have recently taken place. And they've been mentioned before, but I'm going to go over them again.

The Advanced Notice of Proposed Rulemaking was published by DEA in February of 2009, and on October 12, 2010, the Secure and Responsible Drug Disposal Act was enacted.

Both of these are keys for the discussions over the next few days. There are several key terms found in the Controlled Substances Act that are relevant to the discussion of the disposal of controlled substances.

Who is an ultimate user? Well, the Controlled Substances Act defines an ultimate user as a person who has lawfully

obtained and who possesses a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

So who is an ultimate user? It's all of us. It's our neighbors. It's our parents. It's anyone that fills or has filled a controlled substance prescription.

And the definition provides for the possession of controlled substances without being registered with DEA.

Another key entity that must be discussed when we're talking about the disposal of controlled substances are long term care facilities.

And long term care facilities are defined as a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.

Long term care facilities themselves do not possess controlled

substances, unless they are registered with DEA. They serve more as a custodian for controlled substances for residents that reside in these long term care facilities.

They have unique concerns when we are discussing the disposal of controlled substances because of the issues that arise as residents' medication issues change. They are often in possession of controlled substances when their residents either pass away or leave that facility.

Another key term that we need to discuss from the Controlled Substances Act is "distribute." This is defined as to deliver, other than by administering or dispensing, a controlled substances or a listed chemical.

As we can see from this definition, an ultimate user that returns a controlled substance to another person or entity, this action would be considered distribution, and any entity or person that distributes a controlled substance must be

registered with DEA.

You can go to the next slide.

And this slide is just clarifying that every person that distributes a controlled substance must be registered.

The next slide, please?

The closed system of distribution is established in the Controlled Substances Act. This accounts for all controlled substances. All entities found within this closed system of distribution must be registered, and these entities can transfer controlled substances from one to another.

The manufacturer can transfer controlled substances to the distributor. The distributor's going to stock the pharmacy, and so forth.

All of these entities must be registered. And with this closed system of distribution, all of the controlled substances are accounted for, up until the ultimate user receives this controlled substance.

Once this controlled substance is given to the ultimate user, the controlled substance is out of this closed system of distribution.

One of our challenges with the disposal of controlled substances is how we are going to account for an ultimate user returning this controlled substance back into this closed system of distribution.

DEA understands that having controlled substances in medicine cabinets across America is a diversion issue, but we also need to realize that when collecting these controlled substances for disposal, this is also a diversion issue that we need to account for.

This is one of the things that I hope that we as a group can find solutions for.

There are two exceptions to requirement of registration that need to be discussed. One of them is for ultimate users.

They may possess a controlled substance without being registered with DEA.

When the Controlled Substances Act was enacted in 1970, it did not contemplate a situation where an ultimate user would return a controlled substance to another person or entity for disposal.

This exception was amended by the Secure and Responsible Drug Disposal Act of 2010 to provide for ultimate user being able to distribute these controlled substances for the purpose of disposal.

When we were contemplating this return of controlled substances, as we've talked about and discussed, security and safety concerns arise.

DEA understands that ultimate users do not have a process or manner of ridding themselves of these unwanted controlled substances currently, nor do long term care facilities have an avenue to dispose of these controlled substances.

Prior to the Secure and Responsible Drug Disposal Act of 2010, they were not able to dispose of these things. And as we've talked about, we are very excited that this bill has been passed, and that we are able to start drafting regulations concerning the disposal of controlled substances.

The second exemption from DEA registration is given to law enforcement officials. Currently, they can collect controlled substances from ultimate users.

The disposal of controlled substances by ultimate users and long term care facilities is a very important issue to DEA. We published an Advance Notice of Proposed Rulemaking, and we collected a lot of ideas and perspectives. And we are going to be using those ideas and concerns when we are drafting the Notice of Proposed Rulemaking in the near future.

We requested comments regarding

how various entities would provide for the disposal of controlled substances. DEA posed several questions to the public, and these questions were separated into, as you can see from the side, several groups with different areas of interest.

It is clear from the list of interested parties that it touches a wide spectrum of people, and the challenge that DEA has is to reach or draft a rule that would speak to each and every one of these interested parties.

For example, the ultimate user is going to have a different set of issues than a long term care facility would have when trying to dispose of controlled substances.

Over the next few days, we expect to hear from a lot of you, and to formulate and come up with new ideas that would help us address these issues.

The Secure and Responsible Drug Disposal Act of 2010 provided DEA with the

statutory authority that we needed to address this issue with regulations.

The Secure and Responsible Drug Disposal Act amends the Controlled Substances Act to provide for the disposal of controlled substances by certain persons.

These persons include ultimate users, long term care facilities on behalf of residents, and survivors of decedents.

The Secure and Responsible Drug Disposal Act of 2010 requires the following considerations when promulgating regulations: public health and safety, ease and cost of program implementation, and this regulation may not require any entity to establish or operate a delivery or disposal system.

The Secure and Responsible Drug Disposal Act requires that the Attorney General promulgate regulations. This authority has been delegated by the Attorney General to the Administrator of the Drug Enforcement Administration. Therefore, it is

incumbent upon us to promulgate regulations to implement the Secure and Responsible Drug Disposal Act of 2010.

DEA would like to create a regulation that would implement a safe and easy to use drug disposal plan. While formulating this plan, safeguarding against the diversion of controlled substances is a key component to this disposal plan, and also in writing this regulation.

The closed system of distribution requires recordkeeping and accountability from all of its registrants.

We would like to -- this disposal rule must integrate these already existing recordkeeping and accountability requirements upon persons that engage in this process of disposal.

When collected, the controlled substances must be disposed in a safe manner dictated by federal, state, and local laws.

Again, we look forward to all of

your input in drafting a regulation that would serve all of the interested parties that are present and those that aren't present.

Thank you.

(Applause.)

MR. CAVERLY: Thank you, Colin.

As Colin pointed out, there are a number of voices to be heard in this particular issue, and it's going to be DEA's job to kind of juggle those voices as we work through our rulemaking.

I would be misleading you if I told you that there's not a draft of a rule already circulating.

I mentioned before that we've been looking at this issue for a number of years. We had an Advanced Notice of Proposed Rulemaking two years ago, and we'll come out with a Notice of Proposed Rulemaking, but it's still important for us to hear what you have to say.

So I encourage you to be frank

with us during these next couple of days, and I also encourage you to submit comments to our Notice of Proposed Rulemaking when it's published.

If you know the rulemaking process, it's kind of like watching paint dry or grass grow. It's very slow, or at least it's slow in my estimation, and very painstaking.

So, we still have some internal agency reviews, further drafting, internal agency review, it has to be reviewed at DOJ. The Office of Management and Budget has a 90 day bite at the apple. There will be an inter-agency review during those 90 days.

So, I know one of the questions we'll be asked during this public meeting is when, DEA, when?

As soon as we can is my best response to you, knowing that the rulemaking process is not done, that we're still drafting, and it likely will be several

months, even with an OMB 90 day review period.

So, none of you are as anxious, probably, as we are, to get this rule out. So -- but we encourage you again to participate during these next couple of days, to submit comments to us once the Notice of Proposed Rulemaking gets published.

And I'll make an admission. At least we DEA folk have a tendency to talk in acronyms and initialisms, so if any of us begin to talk fed speak too badly, throw something at us. You know, I won't think less of you because you do that.

So, as we start tripping with NPRMs and ANPRMs, and all of these other things, stop us, or stop the speakers, politely, and ask them to explain what the heck it is they're actually saying.

So I did want to acknowledge during the next couple of days, we have some dignitaries that will be addressing us as well, and it further underlines the importance

of this issue.

The Attorney General from the State of Maryland will be addressing us here shortly this morning, and we also have Representative Jay Inslee from the State of Washington that will be here tomorrow morning. So I look forward, personally, to hearing what they have to say.

As we move on towards our speakers, I want to invite Tim Condon, Senior Policy Advisor from the Office of National Drug Control Policy. And see, I said, Office of National Drug Control Policy, I didn't say ONDCP, even though I really wanted to, so. Okay.

Tim, if you're ready?

DR. CONDON: Well, good morning, everyone. I want to thank actually Administrator Leonhart and Joe and Mark and her colleagues in DEA for their leadership on this issue. This is very important.

I bring greetings on behalf of

Director Gil Kerlikowske, the Director of the Office of National Drug Control Policy.

As you heard, I'm Tim Condon, the Director of Science Policy Advisor. I've only been there since July. It's after a long career in addiction research at the National Institute on Drug Abuse, and so I come at this from a perspective of ensuring the public health as well as understanding how to ensure the public safety.

And so we've been working quite a bit on prescription drug abuse. And in May of last year, the President released the 2010 National Drug Control Strategy, and one of the hallmarks and one of the specific, as we call, signature initiatives within the National Drug Control Strategy is in fact the prevention of prescription drug abuse.

And as we start to elaborate on the actions called for in that 2010 -- last year's strategy related to this, this becomes a very interesting and complex problem to

solve, because this isn't just about interdicting drugs coming over the borders and illegal seizure of illegal drugs.

This is about medications that are life-saving, and are very important to the public health, at the same time, obviously, in the wrong hands, can be very destructive and addictive.

And we see really the solution to preventing prescription drug abuse as having four key legs to the table: education for parents, prescribers, patients, the public in general; monitoring, very important, we hope to beef up prescription drug monitoring programs and expand them across all states, and have them -- to operate across state lines; and disposal is what we're here today to talk about, a very important part of the solution to the problem; as well as enforcement, to interdict pill mills, prevent diversion.

And so I'm going to focus today in

talking about the disposal aspect. I want to give you a little bit of overview as Joe did, a very good job, of the prescription drug problem, the consequences, some of the risks, access and supply, take-back programs, ideals from our perspectives, some of the things that we at ONDCP -- I said ONDCP -- we at the Office of National Drug Control Policy have been thinking about and discussing about possible solutions, some examples of some take-back programs and some conclusions.

So we know that in 2009 there were 3.9 billion prescriptions dispensed in the United States. It wasn't just for controlled substances, it was for pharmaceuticals.

Seven million Americans reported non-medical use of prescription drugs in 2009, and that comes from the National Survey of Drug Use and Health.

And the definition, of course, of non-medical use is, was it prescribed for you? No. Did you take it for an indication other

than what it was supposed to be used for?

And so these are very large numbers. One in three people using drugs for the first time in 2009 began by using prescription drugs non-medically, and six of the ten top abused substances among high school seniors from the Monitoring the Future Survey are prescription drugs.

And these are actually frightening numbers. They're frightening because we see prescription drug abuse as the fastest growing problem of drug abuse in this country. It's not the most prevalent at this point, but it is, we believe, the fastest growing.

And what this shows you, is new users or new initiates in the past year for specific illicit drugs among persons age 12 or older. This is for 2009 and again, from the National Household Survey.

And as you can see, psychotherapeutics, which is combining pain relievers, tranquilizers, stimulants, and

sedatives, are the largest number of new initiates.

And for the second year in a row, there are more initiates for psychotherapeutics -- that means they took it for the first time -- than actually took marijuana for the first time. This is the second year in a row.

So this is one of the reasons we say this the fastest growing problem of drug abuse in the country, and we need to come up with some complex solutions to do something about it.

Prescription drug abuse consequences: emergency room visits, unintentional deaths, treatment admissions, and the economic costs.

Well, the emergency room visits that you might imagine as more people are abusing and initiating non-medical use have started to go up. And we see this for fentanyl -- for a few substances here, for

hydrocodone, hydromorphone, methadone, morphine, and oxycodone. And again, these are for specific pain relievers for the years 2004 to 2008.

This is probably the most important figure that I've come across in my six months or so at Office of National Drug Control Policy. This figure really says it all about the problem we're facing.

These are drug-induced deaths versus other injury deaths from 1999 to 2007, data from the Center for Disease Control. And as you can see, injury for firearms, homicides is in orange. And motor vehicles, of course, are the highest in the country, and that's the blue line.

But the red line are drug-induced unintentional deaths, and as you can see, that that number is increasing, has surpassed gun violence in the United States, as well as homicides. And in 16 states, we now have more drug-induced deaths than we do motor vehicle

accident deaths, in 16 states. And that was as of 2007.

So again, the seriousness of the problem is growing. We need to take some action. We need to do something about preventing the diversion and misuse of prescription drugs at the same time as ensuring the availability of these life-saving and very important medications.

I always say, as you get more mature, you realize how important you want it to be that these ensure the availability of these medications in your autumnal years.

The economic costs for this have been estimated in a couple of places. Economic costs of $180 billion for drug abuse in the United States since 2002, and of course, if one puts -- extrapolates, the number is much larger at this point.

There's also been a couple of studies looking specifically at the estimated cost of non-medical use of prescription

opiates, and one study estimated it to be $53 billion in 2006.

And opiate abusers generate, on average, annual direct health care costs 8.7 times higher than non-drug abusers. So, this is a population who are abusing these prescription medications.

These are individuals who are maybe addicted to these, and, in fact, they're consuming large amounts of our health care dollars as a result of it.

Perceived risk. Because prescription drugs are manufactured by pharmaceuticals companies, prescribed and dispensed by health care providers, they are often perceived as safer than street drugs. And of course they go through a very rigorous process of review for safety and medical utility by the Food and Drug Administration as well.

So there is a perception that these are safer than something that you may

get on the street as an illicit drug.

Studies show that teens perceive prescription drug medication as safer, less addictive, less risky than using illegal or illicit drugs, and that drugs obtained from a medicine cabinet or pharmacy were not the same as drugs obtained from a drug dealer.

And this is a number of the surveys that have actually asked young people this, and these are the perceptions that young people have.

So it's not a surprise that we're seeing an increase in the number of prescription medication misuse.

Accessibility and supply. Abused prescriptions like painkillers and anxiety medications are often taken on an as-needed basis. They're prescribed that way, so they're dispensed in quantities that are usually larger than are actually necessary.

They are kept in a medicine cabinet long after oftentimes the therapy has

been completed, and are easily available for others to abuse them.

In 2009, the National Survey of Drug Use and Health found that 70 percent of people who abuse prescription drug pain medications got them from a friend or a relative. And prescriptions for controlled substances and opiate pain relievers in particular have increased in the last decade.

And so the chart shows you that 55 percent -- and again, this is from the National Survey of Drug Use and Health, 55 percent report that they got them free from a friend or relative. Ten percent say they bought them from a friend or a relative. And five percent say they took them from a friend or a relative, with about 70 percent having gotten them from a friend or a relative.

So, we obviously have an abundant supply -- or our friends and our relatives have an abundant supply of medications that are available for diversion.

Pain reliever prescriptions from 2000 to 2009. This is from the SDI Vector 1 national database, and from the FDA Advisory Committee on the REMS last year.

And as you can see, the number of prescriptions, this is in the millions, for extended release opiates and for immediate release, IR opiates, has continued to increase over the last decade, such that we have 234 million prescriptions for immediate release opiates in 2009. That's a lot of medications.

As a consequence -- I believe as a consequence, always cause and effect, can't always prove it, but as a consequence and a correlation, along with those increases in prescriptions and the increase in diversion and misuse of prescription medication, persons classified with substance abuse and/or dependent on psychotherapeutics has also paralleled that increase in use of prescription drugs -- of misuse of prescription drugs. And this is again, these

are individuals classified with DSM IV substance abuse dependence symptomology.

Prescription drugs dispensed for selected opiates in the U.S. outpatient retail pharmacies, again, very much mimics what I showed before, the number of medications with of course, hydrocodone being the largest number of prescriptions.

And that leads us to, in fact, how do we get, how do we approach this very complex problem of trying to ensure that these medications get into the right hands of the people who need them, and yet, don't have them laying around in medicine cabinets, and don't have them available for diversion by our children, our house guests, people who come into our homes during a house tour if you have your property on the market. These are all real stories. These are real things that happened.

And so, this is a complex issue. And we're delighted to be working in

partnership with our good colleagues at DEA and FDA, working on all of these prescription drug problems.

What we think, at Office of National Drug Control Policy, is that take-back programs are a great idea, but we need to make them more readily accessible to consumers.

They need to be environmentally responsible. It's very important for them to be a public-private partnership, and what I mean by that, they need to be cost-effective.

One thing that we're very concerned about is that the cost of take-back programs not be passed on to the consumers who are already paying a hefty price for their medications, so that in fact, we need to find a way to really develop these public-private partnerships to actually pay for cost-effective take-back programs that effectively reduce the supply of medications available for diversion.

Now, our colleagues and our neighbors to the north, of course, have been doing take-back programs for a while, and they do it at a provincial level.

This is, not all provinces have these programs in place, but a number of them do at the provincial level, municipality level, and community programs.

The programs are initiated, as I said, by the provincial governments, pharmaceutical industry and our pharmacy associations. Major use community pharmacists -- the majority use community pharmacists as take-back agents.

And pharmacy participation in the provinces and the communities that this particular study has looked at were as high as 90 or 100 percent, which is a pretty good percentage.

The participation is voluntary. In British Columbia, they enacted regulation requiring pharmaceutical industry to fund

disposal activity. Ontario and Manitoba are developing similar regulations.

In other provinces, funding is provided by the pharmaceutical industry and/or government on a voluntary basis, again, a public-private partnership.

Post-consumer pharmaceutical stewardship associations support this in many provinces as well. And so, it just gives us some ideas about our colleagues to the north, our neighbors to the north, and how they're approaching this problem.

Our European colleagues have also approached this from a number of different manners. In France -- and again, I don't have an in-depth knowledge of what's going on in each one of these countries on the ground, but what we've been able to surmise from the literature and from speaking with people is that in France, there's 80 to 90 percent participation. It's funded by industry, pharmacy, and wholesalers.

In Portugal, it's pharmacy-based, with close to 100 percent participation, and again, funded by pharmaceutical stakeholder groups, so that's more of a larger catchment area.

Spain, pharmacy-based also, with 100 percent participation and funded by the pharmaceutical industry.

And in Sweden, pharmacy-based, but in fact is funded by the federal government, the national pharmacy system in Sweden.

So, in the United States there is an experiment that I wanted to mention to you that my colleague Chris Jones, who is here today, brought to my attention.

This was in Washington State, kind of a beta testing that they did, where they instituted a take-back program with one of the drug storage chains, Bartell's, in Washington state, initiated this test, and they had 14 Bartell retail stores and 25 group health clinic pharmacies participated.

They received a grant to do this for two years. And this is not for controlled substances. This was for other, non-controlled pharmaceutical take-back.

And they felt that they were very, very successful, and in fact, after the grant ran out, they continued the program. Bartell's did itself.

So, what they found from their survey was that 99 percent spent less than one hour a week on the program, in terms of the pharmacies. Ninety-eight percent think the program is somewhat, very, or extremely effective.

Seventy-six percent of the patients say that they're extremely likely or very likely to return the medicines. And overall comments from pharmacists and patients were positive and programs were viewed as beneficial.

So again, a snapshot in one state, not controlled substances, but nevertheless,

starting to give us some on-the-ground ideas about what may and may not work in various places.

Let's see. So, again, in our thinking, we suspect that a pharmacy-based program may in fact be one of the keys to take-back program. And our thinking relies on these points.

It completes the drug distribution loop that you already saw a picture of. Patient/pharmacist relationship already has been established and is developed.

One of the key factors in our thinking is that this actually also has the potential for a clinical intervention. That is, pharmacists are health-care professionals.

As take-back agents, the pharmacist might actually be able to do a clinical intervention with the patient. They may bring back opiate analgesics, talk to the pharmacist, and ask, if the pharmacist says, well, why didn't you take all of these, well,

because I became nauseous, I had a counter-indication for these.

So obviously, that's a clinical intervention that could be helpful to that patient in the future, as well as ensuring that in fact, the medications are disposed of properly, stronger patient/pharmacist/prescriber relationship, and I think improved health care outcome.

So again, this is a very nice model for intertwining both the public health and the public safety aspects of the prescription medication take-back programs.

Pharmacies already have a reverse distribution and disposal mechanism already in place. They already have security and diversion safeguards in place because of controlled substances. And pharmacy-based programs, as I said, as I showed you, have been effectively operated in other countries.

So, our conclusion, as an easily accessible, environmentally friendly method of

drug disposal is a key tool in reducing prescription drug abuse. We see this as critical.

The programs need to be cost-effective. The cost burden should not be placed specifically on the consumer. Utilization of public-private partnership is essential in the current economic environment, and from our perspective, pharmacy-based programs appear to be a logical approach.

User friendly strategies for communities for safe, responsible, and ecologically sound disposal, combined with robust patient, public and prescriber education, we think this equals a perfect formula for take-backs becoming what I call the new norm.

We need to educate the public, prescribers, pharmacists and physicians that, in fact, this should be the new norm, just as we're trying to educate -- young people don't think twice about recycling bottles and

things.

My generation had to be taught it. We really do need to start to approach this as take-backs to become just like recycling, to become the new norm.

Thank you very much for your attention, and I look forward to working with all of our colleagues at DEA in the future. Thank you.

(Applause.)

MR. CAVERLY: Thank you, Tim.

You know, it strikes me, as I listen to your presentation, that we are likely to hear some common themes throughout, and I don't want you to be dismayed. I don't want you to be bored or to think that there's some duplication going on.

Yes, there is some duplication, but what you're hearing are common concerns. You're hearing common interests from different stakeholders.

So, while it may dismay the

speakers more than it dismays the audience, I think it's important for us to understand that we didn't attempt to organize this intentionally.

There was no thoughtful mechanism by DEA -- for good or bad, you may think so, bad, at the end of the day, but no mechanism by DEA to screen our speakers' presentations or to coordinate the message.

So don't be dismayed if you hear some common themes throughout.

You know, you mentioned an issue in regards to societal, I guess, societal views or attitudes. And I don't know that that's something that we're going to be able to address with this rulemaking, frankly.

How do you convince our society that's an instant gratification society that if you suffer an ill, you take a pill, and you get well, how do you convince our society that maybe you don't need that pill, you don't need the amount of pills that the doctor's going to

automatically prescribe to you?

How many of us go to the doctor and we feel we haven't received adequate medical treatment if we didn't walk out without a prescription? "What do you mean, you won't give me an antibiotic? I have a cold. I need to feel better, you need to give me a prescription."

So these are some societal views that, unfortunately, we won't be able to address in our rulemaking.

And the other issue that I would be interested to hear some of the other speakers possibly address is motivation and cost.

We can put the best humdinger take-back program or programs in the world in place, but if people won't use them, if people won't pay the 2.99 or 3.99 for the mailer, or the cost to put it in the box to send it back to the reverse distributor, where are we?

And you know, this legislation

didn't enable DEA -- and maybe some of you will sigh a big sigh of relief, but didn't enable DEA to levy a fee on any particular sector, either the registrant population or the general public.

So that's going to remain an unanswered question, I think, as we go through this rulemaking. And I'll be interested to hear some of the speakers, and maybe I've placed too much of a burden on you, but some of the speakers to comment on those issues as we work through the next couple of days.

So I hope that Attorney General Gansler is here. He is?

We are privileged to have the Maryland Attorney General, Doug Gansler with us this morning. He has graciously asked to be included on our agenda, and we have graciously conceded, because we're excited to hear what you have to say.

Thank you.

MR. GANSLER: Thank you for

allowing me to be part of this, and thank you for your role in getting this bill passed, because this is something that we've been working on for about a year in our office through the Maryland Attorney General's Office.

But also, I'm the National Co-Chair for NAG, the National Association of Attorneys General, Environmental and Energy Committee, and this is an area that we've been looking at in terms of trying to get prescription drugs and other pharmaceuticals out of the water.

And so, we approach it differently. Some of the AGs are interested because of the public safety issue, of pharm, as you know, p-h-a-r-m parties, and other people going into medicine cabinets, and what we're supposed to do with these drugs.

So what we would like to do, we've given our comments to the Department of Justice, and we're going to work with DEA, we

hope to be able to work with DEA, in terms of formulating the regulations that would make this possible to have Maryland serve as a pilot state to actually take the Act and put it into practice and make it real, make it work, and make it acceptable for everybody.

We do find that around the country, the United States, there are a number of these take-back programs.

We've looked at a lot of them, the ones in the Dakotas, the mail program, Maine, and you know, there's different, they're all obviously well-intended. But we believe that the system that we want to put together will work and will serve as a pilot for the country.

We've talked to the pharmaceutical industry, PhRMA, they'll help fund us in the end of this. And we have worked with the pharmacies as well in terms of doing the program there.

And what we want to do is a little

bit -- and you just mentioned the overlap. You kind of put it exactly how we want to do it.

We want it to be pharmacy-based. We want to do consumer friendly, pharmacy-based program, where people can take over the counter drugs, prescription drugs, controlled substances, back to the pharmacy where they got them, and put them in a secure, five gallon receptacle. And then those will be taken off whenever they fill up or every month or so to be incinerated in an environmentally friendly way.

We think this is the best for the consumers, because they'll actually do it, kind of like if you drove down my street this morning, every single house had the big blue bin in Bethesda for the recycling.

And I think people will get a culture, an understanding that this is where they can bring their unused, expired drugs back to.

Obviously, the pharmacies like it, because it gives them another reason to go from the front door to the pharmacy section and they'll buy toothpaste and deodorant or what have you on the way. PhRMA likes it because people will stop beating up on them because of putting the drugs -- flushing the drugs down the toilet into the water.

And it's great for the environment. We have a problem in Maryland, and throughout the country, obviously, with fish not knowing if they're boys or girls anymore in some measure because of this issue.

So, what we would ask -- we submitted regulation to DEA. We need three things. And you know what we need, because you were supportive of the legislation in the first place.

We need the ability to have people be able to bring -- particularly controlled substances, actually, only controlled substances, from their home back to the

pharmacy.

In the real world, if somebody was doing that right now, would they be stopped by a DEA agent or a local law enforcement officer and be charged criminally? Of course not. If they had a box of controlled, dangerous substances in the back of their car, of course they would.

So, but we need to codify that in order to get everybody on board to say that if you are taking it from your home to the pharmacy, you will not be violating the law, and we have the language in there that says how you can do that.

The reality, by the way, right now, is that people will go to the pharmacy all the time and pick up drugs for their parents or their siblings or their children, and nobody questions them, but it's actually probably technically illegal, but no one sort of has a problem with it.

The second thing we need to be

able to do is people need to be able to deposit their prescription drugs or controlled substances into the receptacle, and there doesn't need to be recordkeeping of that, in other words, of what is being put into those receptacles. So we have to be able to waive that particular piece of it.

And finally, we need to be able to allow them to have the receptacle on premises, either behind the counter or next to the counter in a secured fashion while it fills up, and then it's taken away.

People say, well, of course that shouldn't be a problem, because they're keeping -- that's where you get oxycontin and everything else right there. That's where it's being kept anyway.

But right now, the way, technically, it's not -- it wouldn't be seemingly legal to do that. So we need the regulations to reflect the intent and principle underlying the legislation.

And if we can get those three things done, all of which seem pretty simple, but we have to make sure it's codified in the right way and the language is the right way, that everybody's comfortable with it.

And having been a prosecutor now for about -- almost twenty years, I understand that change is difficult, but we do need to codify that to make this a reality.

And then what we'd like to do is have every pharmacy in Maryland be a partner in this. And we need to advertise it. And there's basically, what we're trying to do is replicate our system in Maryland on what is already being done and has been done for almost 10 years in British Columbia, Canada.

This is the exact system that they do. It works. They've had no problems in terms of diversion issues or really any other issues at all in British Columbia. And that's sort of the model that we're using and want to use here in Maryland.

But we do look forward to working with the DEA to make this happen. We're excited about it.

I think it's a great thing for so many reasons. The Drug Enforcement Administration's role is to get drugs -- bad drugs off the streets. This will do that. This will encourage people to take them from their medicine cabinets or wherever they are and bring them back to the pharmacy, put them in the receptacles, and incinerate it in an environmentally friendly way.

So, as somebody who came out of the Department of Justice, I'm excited to be working with the Department of Justice on this effort, and hopefully we'll be able to get it done in the near future.

Thank you very much.

(Applause.)

MR. CAVERLY: Thank you, Attorney General Gansler.

We're running a little ahead of

schedule, but let's go ahead and take a break, and maybe come back at -- let's say 20 minutes after. Maybe we'll get a little extra time for lunch.

So go ahead and take a break.

One administrative note is that the restrooms are across the hall and downstairs. There's a stairwell that will lead you downstairs. So 20 minutes after, please.

(Whereupon, the above-entitled matter went off the record at 10:01 a.m. and resumed at 10:19 a.m.)

MR. CAVERLY: If folks could begin to come back in and take your seats, please, we'll resume our agenda.

Porch lag. Porch lag. I have a friend from New Orleans who refers to something called porch lag.

If you invite some people over to your house, maybe another couple, and you have a pleasant evening, dinner, and it's getting

late, and they say, well, thank you for inviting us. We're going to be on our way home.

And you move about three feet, and you have another conversation for about another ten minutes. And they say, well, we really ought to get home.

And maybe 30 minutes or 40 minutes later, they wind up on the porch, and there's this lag of time, you know, from the point of time where they say, well, it's time to go home until when they actually get in the car and they drive away.

So that's what we experience at meetings is conference lag, not porch lag, as folks begin to come back in.

We had a couple questions during the break that I'll attempt to start addressing now.

The first question was in regards to the presentations. We've had some requests, whether we would make these

presentations available to folks.

In the past, at conferences, we have done so with the permission of the presenters. So our intention at this point is to ask each of the individuals who have a PowerPoint presentation if it's okay with them if we get a copy of it, and we'll post it on the DEA diversion website as part of a record of this particular conference.

So far, we've had a yes. So we'll ask our next presenters as they come up whether we can include those as part of the record of this meeting.

The other question we're still kind of tossing around a little bit. We've had a question whether we would make the list of attendees available as part of this public record. And we're still debating that a little bit.

I don't know if there's some expectation of privacy that folks have. When they registered, we required folks to register

by email, so we have some email addresses.

And once we pass this information out, we kind of lose control over it. So I would hate for you to become on a spam list somewhere and get advertisements for online pharmacies or something like that, so.

Oh, I went to the DEA meeting, and now they want me to buy Viagra, and they keep sending me emails. We just don't want that to happen.

So, we're going to think about it a little bit over the next day or two, and we'll try to come to some reasoned conclusion.

Okay. As I grab my agenda, we have some folks from the National Sheriffs' Association. Richard Stanek, who is the Hennepin County Sheriff, will be addressing us.

And we have Ed Hutchinson and Stephanie Garlock, who are with the National Sheriffs' Association here locally in DC. So I'm going to turn it over to you folks.

MS. GARLOCK: Good morning. Since there are three of us, we're going to kind of do this in tag team. I'm going to speak, my colleague Ed is going to speak, and then we're going to call up Sheriff Stanek to speak and take up the remainder of our time. But we thought it would be easier if the Sheriff sat and came up afterwards so that not all three of us are standing here.

Thank you to the DEA for allowing us to have this opportunity to speak.

Unwanted, unused, and expired medications sit in medicine cabinets in almost every home, presenting a health and safety threat to people, pets, and the environment.

By languishing in homes, these medications increase the possibilities of accidental poisonings, drug overdoses, and criminal drug diversion.

Drug take-back programs are one of the most effective ways to collect and dispose of unwanted, unused, and expired prescription

medications in communities throughout the United States.

However, it is important to mention a few issues to consider, to ensure such programs are successful.

First, the cost associated to local law enforcement for participation in such programs. It is expensive for local law enforcement to participate in the disposal of unused prescription medication.

For example, in Cook County, Illinois, the cost for properly disposing the medication was $20,000. While Cook County may have the resources necessary to incur the cost, and while it may seem like a relatively minor cost, such a cost is substantial to smaller jurisdictions and may not be feasible as resources are tight in local law enforcement agencies nationwide.

In jurisdictions where they are unable to shoulder the costs associated with disposing medication, it could potentially

make local law enforcement hesitant to participate in drug disposal programs if they are solely responsible for incurring the cost involved in disposal and destruction.

Therefore, it is critical that all partners collaborate with drug disposal collections to alleviate the costs associated with destroying the medication.

Additionally, a sustainable program is necessary. In 2010, the DEA held its first national drug take-back program, and it was highly successful. And due to that, the DEA will be holding a second national drug take-back program in April.

It is our belief that in order to have continued success in disposing unwanted prescription medication and keeping it out of the hands of others, particularly the nation's youth, it is critical that these take-back programs are held on a continual basis, particularly at a state and or local level.

As such, all partners, local law

enforcement, DEA, local hospitals and senior living, local public health agencies, and local pharmacies need to have a seat at the table to discuss how to go about holding drug take-back programs to ensure their success and enable their discussions on how to hold such programs on a more consistent basis.

Decisions cannot be made without all necessary partners at the table, particularly local law enforcement, as local law enforcement are responsible for the possession of controlled substances from a consumer.

And now I'm going to turn it over to my colleague Ed to talk about two other points.

MR. HUTCHINSON: Good morning. Ed Hutchinson, I'm the staff liaison to the National Sheriffs' Association's drug enforcement committee. And I am the director of an older adult safety program called Triad, again with the National Sheriffs' Association.

This is more of a boots on the ground, a couple of points in that a critical element of a drug take-back program is the marketing and education of the issue or the event.

As well as needing sustainability to insure the success of drug take-back programs, sufficient and effective marketing is needed to ensure the same success in such a manner as an implementation handbook or tool kit.

The public needs to be aware of drug take-back programs that are being held in their communities and how to participate in the event and the procedures for moving forward.

Furthermore, program information also needs to be specifically targeted to certain subsets of the community, i.e., older adults, as they are likely to have an abundance of prescription medication, and rarely report crimes that are committed

against them by family members, caregivers, and their community, fearing repercussions.

Additionally, a strong educational component, speaking to the hazards, potential criminality, and potential dangers of non-disposal of prescription medication is needed.

There is a need to ensure that not only are the drug take-back programs marketed, but the rationale behind the collection and disposal of prescription medication is communicated to participants in the community.

As prescription drug abuse becomes more prevalent throughout the United States, particularly among youths, it is important that these programs are also used as a tool to educate communities on the prescription medication addiction and how they are obtained.

These events serve multiple purposes in communities: awareness, education, and prevention. And these purposes need to be emphasized in events moving forward.

An additional concern is the environmental impact. Drug take-back days are critical for environmental reasons.

Although it was previously acceptable to flush prescription medications down the toilet, research has indicated that this contributes to water pollution.

And furthermore, throwing away medication can have an adverse effect as well. Groundwater contamination can occur from medications leaching out of landfills and wildlife harmed by ingestion of these drugs, as well as lending opportunity to access these prescription drugs by others. Specifically, throwing away prescription medications can enable others who dumpster dive to obtain the medication.

Drug take-back programs enable the community to safely and effectively collect the unwanted medication and dispose of it in the safest manner possible.

We recommend a safe, effective,

cost-effective, and sustainable program accessible by all strata of law enforcement communities, containing an educational component, and implementation tool kit for the events.

And now, we'd like to bring up Sheriff Stanek from Hennepin County, Minnesota to talk about his experiences in actually implementing one of these take-back programs.

SHERIFF STANEK: Well, good morning. My name is Rich Stanek, and I serve as Sheriff in Hennepin County, Minnesota. It's the largest county in the state, with about 1.2 million residents, or about one quarter of the state's population.

We're almost one quarter of the state's population, about 22 percent. Hennepin County experiences almost half of the state's crime in Minnesota.

Hennepin County Sheriff's Office partners directly with 37 other local law enforcement agencies that operate in Hennepin

County, not including our state patrol, and of course our federal law enforcement partners.

Now, Hennepin's the sixteenth largest county in the country, so we're very active participants in both the major County Sheriffs' Association, as well as the National Sheriffs' Association.

I serve on the Board of Directors for both organizations, so my comments today reflect the sentiments of the members of both organizations, but specifically address your questions from the experiences of my own agency with the take-back event.

Now, why am I here? Real simple, as the Sheriff of a large, urban, metropolitan county, we book about 40,000 people a year through the front doors of our jail. Seventy percent of the folks who come through the front door of our jail are under the influence of an illegal drug. And then secondly, I am the concerned parent of two teenagers in high school.

On Saturday, September 25, 2010, the National DEA Take-back Day, the Hennepin County and five other metro area countries in Minnesota conducted a drug take-back event. The Hennepin County event was held in cooperation with the City of St. Louis Park at a county location.

The Assistant Special Agent in Charge, Dan Moran from the Minneapolis office of the DEA, assisted us in coordinating the metro area events.

Now, we had two primary goals when we set out that morning. One was to develop resident awareness of the gravity of the prescription drug abuse epidemic, as so keenly spoken here today, and remind residents to carefully monitor the drugs in their own medicine cabinets, and then secondly, to allow residents to safely dispose of unwanted prescription medications and over the counter medications.

A secondary goal for my county

Board of Commissioners and the Department of Environmental Services was to find an environmentally friendly alternative to most residents' current method of disposal, in the garbage or down the sink or toilet, which started out as a straightforward plan to provide a simple solution, it turned out to be anything but simple or straightforward. It became more complicated and convoluted as we worked to answer the most obvious questions.

First and foremost was how to identify the Schedule I controlled substances and separate them out.

And secondly, who takes possession of the drugs? Must these folks be licensed peace officers?

And third, who's going to take custody of the drugs once we get them, and what documentation do we need?

And fourth, how will the drugs be disposed of, since there's no legal venue for drug disposal in Minnesota? And what happens

if residents bring illegal drugs like marijuana or heroin in for disposal, and what do we do with toxic substances?

Our residents in 700 vehicles drove through our parking lot over four hours that Saturday morning. We had licensed peace officers overseeing contract workers who provided window service.

Essentially, you drive up to one location, they give you a plastic bag in the window, you drive another 15 feet, and in between that time, you put your prescription drugs into the plastic bag, and then 15 feet later, you hand them back out the window to a licensed peace officer who turned them over to a pharmacist, and the pharmacist sorted them out from what was controlled substances to something other than.

Our officers ensured the delivery of each package to a licensed pharmacist on site, like I said, who separated them out, measured and repackaged the Schedule I

controlled substances.

Now, we had licensed deputies take and maintain custody of the Schedule I packages, and then take them back to our local evidence storage facility.

A private company then took possession and assumed the responsibility for disposing of all the other medications and substances.

Tens and thousands of pills were dropped off, some with street values of $70, $75, $80 per pill in our local high schools.

The most common were Vicodin and other forms of hydrocodone, oxycodone, codeine, and fentanyl.

We also collected over-the-counter meds, pet medicines, vitamins and supplements. And we're scheduling three more similar events in 2011.

Our local law enforcement agencies across the country are working now to come up with reasonable ways for our residents to

safely dispose of their prescription drugs.

Many of our sheriffs from across the country have conducted drug take-back events, with great success, I might add. Sheriff Doug Gillespie of the Las Vegas Metro Police Department held three take-back events in 2010 called Operation Medicine Cabinet. They collected over 2300 pounds of controlled substances over the course of the three events.

They recently received $120,000 from their water reclamation department to install and promote 20 pill drop boxes in the metro region.

And other sheriffs in California and Washington have also taken drug take-back one step further by setting up permanent drug drop-off boxes.

As you know, the Controlled Substances Act established a closed system of distribution designed to prevent the diversion of controlled substances. And although

patients can legally possess prescribed controlled substances, they cannot lawfully transfer a controlled substance to another person or entity for any purpose, including disposal.

Now clearly, the safest manner to dispose of unwanted controlled substances is under the supervision of law enforcement, because of the risk of diversion. And to fully understand this risk, you really need to consider specific examples of abuse, especially amongst teens. The Attorney General this morning spoke of it, as did this gentleman.

Now, Minnesota kids have an underground drug culture. They trade and sell drugs via text messages and send invites on Facebook for pharm parties. And even though I'm from Minnesota, I don't mean farm in the traditional sense you might think, but pharm, P-H-A-R-M, as in short for pharmaceuticals.

The entry fee to a pharm party is

a contribution of drugs of any sort. The kids throw whatever they can find into a bowl or a baggie and call the contents skittles or trail mix. They take the mixed drugs by the handfuls, often weekend binging, and have no idea what substances they've ingested.

The Hazelden Center in Minnesota now reports that the kids are developing recipes for getting high, while emergency rooms in Minnesota reporting kids overdosing on bizarre combinations of drugs.

And where do they get their contribution for the party? Well, they farm their parents' or grandma's medicine cabinet. They farm them from other kids who either don't use or don't want to take their own prescription meds. Kids sell them to each other, and they trade.

A 2005 survey by the Partnership for a Drug-Free America found that 19 percent of U.S. teens have taken prescription drugs to get high, including Vicodin and OxyContin, but

also Ritalin and Adderall.

According to the National Center on Alcohol and Substance Abuse at Columbia University, more than one-third of the children ages 11 to 18 in Wisconsin and Minnesota who had been prescribed Adderall or other ADHD medications reported being approached to sell or trade their drugs.

As we know, dealers are simply ordering drugs off the internet, and they arrive in innocent looking postal boxes and Federal Express packages.

In my view, our federal drug take-back initiative sponsored not solely by federal law enforcement but in partnership with the pharmaceutical industry may be the best alternative for disposal, and is worthy of exploration.

We should be developing a mandatory take-back program for unwanted controlled substances so that consumers can easily return unwanted drugs to their

pharmacy.

Pharmacies are currently set up to dispense controlled substances, so they already have safe and secure facilities, and the licenses needed to possess and safeguard controlled substances.

Pharmacies are a convenient place for the public to dispose of controlled substances, and generally have the security, including cameras, in place to operate as both a crime deterrent and a mechanism to identify potential suspects of theft or robbery.

Our pharmacies work with pharmaceutical manufacturers and distributors every day, and for the most part, have processes in place for the safe disposal of controlled substances.

By comparison, for our event, disposal was the biggest challenge we had, and let me explain.

Under the Controlled Substances Act, controlled substances may be destroyed

only by incineration. The closest incinerator to Hennepin County is located in Sauget, Illinois, and for us, this would have meant an eight hour drive through three states.

Because controlled substances were involved in the shipment, an escort by licensed peace officers to maintain the chain of custody from the time of collection until the time of disposal or incineration is required. We would have incurred significant labor costs in addition to the logistical obstacles and liability issues.

In the end, the DEA took possession of the controlled substances and managed their disposal. They used an incinerator in Fargo, North Dakota, over the objections of the Minnesota Pollution Control Agency and the Hennepin County Environmental Services.

The private contractor couriered all other substances we collected to an incinerator located in Utah. And by the way,

the Las Vegas metro take-back drugs were also sent to an incinerator in Utah.

And given the complexities of the Controlled Substances Act and other federal law, and the limited disposal options available to local law enforcement in Minnesota, federal agencies simply are better equipped to manage the disposal and transfer of controlled substances across state boundaries.

The direct cost of our four-hour event was approximately $15,000, mostly labor, and the cost was approximately $23 per vehicle.

In addition, the indirect cost of planning for and managing the event was significant, but well worth the investment from a public safety point of view.

I believe this is one of the advantages to a mandatory pharmacy return program, as an alternative. It makes considerably more fiscal sense to have the

industries that benefit from the sales of these drugs pay for the programs to minimize the safety risks presented to the general public.

Prescription drug abuse is the fastest growing type of illicit drug use in the United States, and we are seeing the same trend in Minnesota, where, among kids, seven of the top ten abused substances are pharmaceuticals.

The availability of prescription drugs is an immediate threat to the safety of our kids. We need to work together to create safe and reasonable solutions for our residents so that they can return and dispose of their unwanted medicines.

They're looking to us for leadership on these issues, folks.

Now, I appreciate very much the assistance we received from the DEA in our drug take-back event, and your efforts in conducting these hearings, and I look forward

to your findings and recommendations.

I'll leave you three copies of my comments this morning. And I very much appreciate the time you've given me to tell you a little bit about my experiences in Minnesota in the position of major county sheriffs and the National Sheriffs' Association.

Thank you.

(Applause.)

MR. CAVERLY: Thank you, Sheriff Stanek, Mr. Hutchinson, and Ms. Garlock for your comments to us this morning.

I'll make a couple of observations, and then we'll go on to Lonnie Grabowska, who's Chief Agent with the North Dakota Bureau of Criminal Investigations. And I'll tell a North Dakota story, okay, but won't get myself in trouble, so just wait a minute. Wait a minute.

In regards to the rule-making and the Secure and Responsible Drug Disposal Act,

DEA really doesn't anticipate that this law enforcement exemption is going to be affected in any way, shape, or form, so I wanted to kind of throw that out there, that this is going to be an option that will remain available.

Congress didn't direct us to look at that particular aspect of the Controlled Substances Act, so we're not, so we anticipate that the law enforcement exemption will remain in place, and that these law enforcement take-backs can also continue to go forward.

But you've hit on the operative issue, and that's money. These things take money. And one of the biggest challenges for DEA in regards to its national take-back was your number two point, or one of your other points, was the disposal.

Where in the world do we take these pharmaceuticals, controlled substances and otherwise, to be lawfully incinerated?

It's not just the federal

environmental restrictions. There are also 50 individual states with 50 different restriction. Some view pharmaceuticals as hazardous waste.

We had some instances, in the national take-back, we had one state that wanted to have each of the individual police departments that were participating obtain a license as a waste generator, so we had some challenges in DEA's national take-back.

And just another disclaimer, we don't anticipate that this national take-back that DEA's sponsored is going to go on forever. We'll continue to do this. Mr. Rannazzisi has pledged that DEA will continue to do this until there are some regulations in place that afford for some other mechanism, some other way to lawfully collect and destroy pharmaceuticals, involved controlled substances.

So now I'll tell my North Dakota story. Everybody sees the drugs logo here.

We've kind of had that up throughout the whole thing. That actually was our second choice, or at least our second choice.

We had a little poster contest. The one we wanted to have used -- and that's going to be the official logo, so I'm a sore loser. The one that we wanted to have used was actually a wanted poster. You know, it said like, wanted, the old west, dead or alive, you know, wanted, we want your old drugs. Well, guess what? We lost.

But as we did the got drugs program, as we did this national take-back program, we wanted to be able to say that all 50 states were participating.

And we started mapping this out, and we put the little dots on the map and turned different states different colors. As we looked across the map of the United States, there was one state that had no collection sites, North Dakota.

Now, it's not because North Dakota

doesn't -- in fact, I'll put it this way. North Dakota has a very robust pharmaceutical collection program. In fact, they were so robust, they really didn't need us. Okay, they didn't need DEA.

But DEA wanted to say, we have all 50 states participating. So if you ever get to see the national map for the take-back program, North Dakota's included, because North Dakota took pity on us, and we had one collection site participate in the national take-back program.

So North Dakota was actually doing the right thing, and had been doing it for a number of years. We were just the Johnny-come-lately. So that's my North Dakota story.

So if I haven't embarrassed myself too much, Lonnie Grabowska? Are you here?

Here he is.

I'm going to sit down very quickly before he gets to the podium.

(Pause.)

MR. GRABOWSKA: Good morning, everybody. If I'm not speaking loud enough, please let me know, and when I start to roam because my ADHD away from the microphone, point me back, so someone can hear me.

North Dakota, what he said is probably very true. We have that small dot there most likely on the map.

North Dakota is fairly lucky for a couple of reasons. With our population base, the amount of law enforcement we have, we're able to work fairly close, and we're able to have a program that's been running for us for about a year and a half or so.

So what I'll do today is this. I'll talk about what our program is, how we do it, how it's affected us.

Now, you're going to have to take it with a grain of salt, understanding that what we do in North Dakota might be a little simpler than what it seems for some other states, so please keep that in mind.

North Dakota law does allow our law enforcement to incinerate our prescriptions at the local collection agencies, such as the city dump, if they have an incinerator, we can go there and do that. So there's a couple of things.

I'll tell the story about the Attorney General as long as nobody tells him that I told you. Does that sound like a deal?

All right, here it is. The Bureau of Criminal Investigation does two things. We do reactive drug work, just like most criminal investigative agencies, and we do proactive drug work, reactive criminal, proactive drug work.

Well, I used to do a lot of drug talks because I was running a drug task force for seven or eight years, so we were buying a lot of dope off and on.

And I went to a presentation. And the AG wasn't there, of course, or I wouldn't have said this, but I point to the picture and

I said, yeah, this is the guy I buy most of my dope from. Right, and it was funny, everyone laughed.

Well, I got back to the shop, and my boss calls me and says, did you do a talk today?

Yes, sure do.

Was the AG there?

No.

Was his mother-in-law there?

(Laughter.)

I don't know.

He goes, she was.

I said, oh, well, I've always liked him. So, you know, so I don't think I ever told him that story, and I don't think I ever will. I could get in trouble.

All right. Here we go, folks. I'll walk through what we do in North Dakota for our prescription drug take-back program.

In December of `09, the North Dakota AG, Wayne Stenehjem, he created the

prescription drug take-back pilot program to manage the disposal of our unwanted meds.

He did not get legislative funding for it, he did not do anything special. He just, as his goal to take care of scrip drug problem, because as the Bureau, we'd gone to many meetings and said, boss, marijuana's fine, meth is fine, we've got the coke, we've got the LSD, we've got all the goods, but the prescription drug is what's taking up the most time for us. We're out there buying it left and right.

We're buying it from Workforce Safety, we're buying it from the VA, we're buying it from the docs, everything.

So, we had to go back. And he said: "You know what? We have to do something about this." So we started targeting those efforts, and this was a spinoff because of that.

Here's what we wanted to do. We wanted to take care of disposing the unwanted

scrip drugs, and stop people from doing the big three we talked about today, throwing them in the trash, dumping them in a drain, or holding on to them.

Ninety percent, as already indicated, of the dope that we were buying, all the prescription drugs were coming from the kids usually who were getting them from the medicine cabinet.

We had a few who were making a very lucrative business off of VA and Workforce Safety. I would go every month and buy from the same guy all of his Vicodin that came in. He wouldn't even take it out of the bag for me, just hand me the postal envelope it came in.

So that stuff is out there. But most of it was still from the kids, and people taking it from the elderly who had it in their cabinets.

So I went and looked at my folks. My dad is 62. My dad has a CVS in his house,

so he and I had to talk about the prescription drug take-back program. Mom didn't care much, but Dad had to take care of it.

This is an article that we had from Minnesota just as we were starting our program, which of course talks about the pharmaceuticals in the lakes and the water supply, and then also that it's starting to show up in some drinking water in certain areas. So of course the problem is there.

We went on the 2009 Youth Risk Behavior Survey. This is what the AG used to decide he was going to do this program. And we just concentrated on three easy steps.

We said, 15 percent of high school students have been abusing scrip drugs. 6.3 in middle school, 5.6 of high school students have abused scrip drugs ten or more times.

Now, I've got a daughter who is 12, soon to be 13. She's just starting middle school right now. I don't want her to buy prescription drugs at school. I don't want

her friends doing it. I don't want anybody in my community doing it.

So, we had to start somewhere with this process, other than searching her backpack every day she comes home. This is what we had to deal with off the bat.

We sat down and looked at what we had at the time as far as DEA went, so, we had to look at the -- request assistance from DEA Special Agent.

We had two ways. If you were a registrant, DEA Form 41. If you weren't, you had to give name, address, date of birth, social security number, first born, and all of those things.

So we got through that part.

Then we had to look at the transfer to a person registered under the Act who's authorized to actually possess it, or you had to drop it off to the closest DEA office, or you had to destroy it in the presence of a DEA official, or according to

what the Special Agent in Charge could do, and that's who we worked with locally to start our project.

DEA did require for disposal of controlled substances shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures and laws and regulations adopted by the state.

So these are the main areas that we, as the Attorney General's Office, looked at to say, are we meeting all of these, and if we are, how do we make our program work?

So this is what we did. The AG did not have the authority to deputize pharmacists, because they all wanted to carry guns, and we said no.

Allowing them to fall under the DEA law enforcement exemption, the second, the HIPAA privacy rule does not prohibit or impose burdens on citizens returning unused controlled substances.

Here were some options for us. Could we take participating sheriffs and could they deputize pharmacists for a limited purpose of collecting substances?

Could we secure collection containers for law enforcement facilities?

Could we establish a voluntary pilot drug take-back?

And do we need to look at legislation that would allow for the flexibility of the program itself?

So this is what we did. In 2008, right at the end there, we rolled out with our first, just like DEA did back in September. We did it in Bismarck, North Dakota. Then we went over to Fargo and did it the next day.

AG Stenehjem came out and talked to the NAAG conference on March 2, 2010. Then we did a couple expos up in the Grand Forks area in April of 2010, and then we rolled out full and complete, November 1, 2010, where we currently have 22 collection locations

scattered across the state.

Our take-back program provides a very simple feature. It gives a disposal unit for people to dispose of their unwanted medications.

Disposal units are similar to the Sharps containers in hospitals. This is what they look like for us, the large exterior container on the side there with the key, and then the insert on the opposite side.

I did work with the company. Our inserts are blue in color, because I didn't want folks putting Sharps into the item that looked like a Sharps container, and we put "for prescription use only" on the blue container, the insert, and also on the outside of the cage that you see there also.

So that is what we purchased and installed in the 22 locations for law enforcement to supply to the public.

Then we bought this monster, and I bought five of these to start with, just to

get it rolling. What I had was our larger agencies were filling up that three gallon container fairly quickly.

We then put this into the evidence room at the law enforcement center, where the key only goes to the evidence custodian.

That person then allows law enforcement to take the three gallon, dump it into the 96 gallon, and that's what actually gets emptied, vice the three gallon, because it was just too time consuming for our agents to keep up with.

So currently, what we have is the containers that you've seen are now mounted in law enforcement agencies. Most of them are sheriffs, some of them are chiefs. That's how we're doing it right now.

Currently, we're in 22 locations as of the first. A little overview of North Dakota, those are the sites that we currently have with the items.

We went to the Chiefs and Sheriffs

Association. We went to multiple meetings with them, and we said, folks, this is what the program is. Do you want a container? And we had these agencies sign up for them.

We then, meaning the Attorney General's Office, would deliver to them their outer container, and two inserts. And for the larger agencies, the container, the two inserts, and the big container in order to dump into.

So what we did is this. Our process is: law enforcement agencies provide the disposal units. The general public can come in and turn in their controlled substances to us.

Municipal county, state, and federal agencies can oversee the collection of disposal units for emptying. The pills are turned in, recorded on our log sheets. Law enforcement agencies properly dispose of the prescription drugs in their incinerator.

So this is kind of how that works

for us.

What does it do, or who does it help? It benefits the community because they have somewhere to put their prescription drugs. Where? It's in the lobby of law enforcement agencies. We did that because it's controlled. Law enforcement has that exemption, and we have to keep a tight chain on what happens to these items once they're turned in to us.

When? We started on February 1, 2009. We're still currently doing this.

Why? Of course, to get commonly abused scrip drugs, such as pain and anti-anxiety meds, off the streets and out of the schools. Examples are Oxycontin, fentanyl, Valium, and codeine. Those are the big ones for us up north.

How? We place unused and unwanted medicines and controlled substances in the secured container located at the law enforcement center, no questions asked, no

cost to the community.

The only problem we had at the Bismarck and Fargo take-back was that we had a few rocket scientists bring their marijuana and turn that in, so we were happy to help them to the nearest correctional facility. That was free to the public also. We were happy to help.

What else do we do? We take our program and we run it in conjunction with what the pharmacies are doing in North Dakota for the take-away program. So, what we have is our take-back is not just for the prescription meds. We get people dropping off other things.

Most folks do not know what's truly controlled in their cabinet and what is not. If you were to ask them, is that a controlled substance? Aspirin, to some people, is a controlled substance.

So do we get Pepto-Bismol tablets? Sure. Do we get fentanyl patches? Yes. So

we get the gamut of the whole way across.

We had a real problem trying to break the habit of saying, okay, only your controlled substances come to us. Everything else has to go over here.

The problem is folks don't know, and they're not willing to pick up the phone and ask. It's just not an easy thing to do, calling the medicine shop and asking them if this is controlled, you're going to get the pharmaceutical answer, not the answer that they're probably going to understand and be able to interpret.

So, the pharmacies also work on a take-away program that I'll talk about in a little bit there.

Here's a sample log sheet that we use. We collect, we weigh the quantity only. So what happens is when law enforcement's container is full, the Attorney General and BCI, our agents are the ones that go and empty these.

Now, it's not a perfect scenario, but it's the best that we can do with the money and the resources we have. So that's what happens.

Our agents go out to the law enforcement agencies, grab onto the bags, weigh them, and then our guys are the ones that are actually incinerating them right now.

So, there's our collecting agent, and there's the disposal date on there also.

Here's what it cost us in gear. We did our -- first, we had to order two gallon containers because it's all I could find. Then, he was able to make me three gallon containers, so we got those done. We did our wall cabinets. We did 96 gallon containers, a few of those, and our freight charges.

So for right about $1300, the AG in North Dakota has been able to buy the gear to make this program go to the 22 locations it currently has. So it was fairly cost-

effective for us to be able to get it done.

It's basic. There's nothing fancy. There's no big truck that pulls up and grabs this stuff. It is labor intensive for us, absolutely. But it's what the AG wanted to get done, so that's what we had to work with.

Totals right now: 1306 pounds, that's what we have as far as from our 22 sites, so that is, again, taken by our agents. And that's incinerated at the local dumps or the city dumps under the supervision of our agents.

To run with our program, we worked with the pharmacies in the North Dakota Board of Pharmacy to come up with a program where the pharmacies would also have a container for drugs to go into, non-controlled substances. That's the caveat for these folks.

So, North Dakota Attorney General Prescription Drug Take-back Program is designed for the disposal of narcotic drugs.

The North Dakota Board of Pharmacy and the North Dakota Pharmacists Association co-developed the sister program and the takeaway program.

This program was developed as North Dakota's Patient Medication Disposal Program, utilizing community pharmacies. Non-narcotics, and the default is still the take-away program, so they can still always drop it at law enforcement if they have any question, but if they're at the pharmacy, they can drop their non-controlled there also.

That was grant funded through the Board of Pharmacy, $38,000 is what they had. These funds allowed them to put 232 pharmacies in North Dakota with a starter pack. That starter pack was a 20 gallon takeaway system, 15 mail-in envelopes, counter display, front window wall hangers, and a business plan.

The continued packets and the upkeep for that are the responsibility of the individual pharmacies. They did a one-time

buy for them.

There's kind of a nice little snapshot of what their takeaway boxes look like. They're cardboard; they have a liner inside of them. They dump the contents in.

They're then mailed to the incinerator in New Jersey somewhere, same with the envelopes. People can take the envelopes home if they would like to put their prescriptions in them at home, seal them, and mail them that way. Non-controlled, of course. That's what the pharmacies are doing right now.

We do tell them also to have what's acceptable and not acceptable, so people know that when they come if there's any questions as part of their marketing process for them.

Here's our version that we'll put up once in a while so people know the take-back is on the left and the take-away is on the right there.

Over-the-counter medicines, who can take what, we explain what the cost of the program was paid by. We talk about where they can go. We talk about the main difference between the two programs, and the recordkeeping for them. That's available to the general public.

And this is our main flyer that goes out to the Sheriffs and to the general public if they have questions between which program is which. We have the drug take-back program and the take-away on the other.

We've had good luck with the program so far. Perfect scenario, no, but for what we were able to accomplish with the funds that we had and the means that we still have available, it worked well for us to partner with the pharmacies to make sure that we were both doing something to let people do this.

We do have folks come in with hundreds, literally hundreds of pounds of things, and they'll come with a huge bag of

stuff, and they can drop it off. That's what our people will do. We'll collect it and we'll dispose of it for them.

We would rather take that step than have it end up on the diversion side of the house, where we're buying it back later.

So, any question on either program that I can field for a minute or two?

Sir?

AUDIENCE MEMBER: Could you explain on the volume numbers, whether you're including the bottle itself, or is it just the pills?

MR. GRABOWSKA: Correct, okay, yes. The question is, the actual volume by weight.

That is just the pills itself. We do recommend to most of the people if they come in with their container, because most will come in, we'll get some folks come in with five or six with all their vitals on it, have the name and the doctor.

We'll say, folks, take those with you. They'll uncap them. They'll dump them into the top of the container, and they'll be able to get them back.

Could you bring up where we have both those pictures of the container and the other one? Could you bring that up for me?

So, yes, the answer to that is, only the pills are weighed, and only the pills are collected. The containers, if you look -- that's okay. There you go, thanks.

Up on the top there, folks, you can actually see, that has just a small enough opening where you can take the container and dump it in without getting anyone's hand in there.

Now, we did have a couple young gentlemen ask us, or try one time, they were going to run and grab the whole prescription container and rip it off the wall. It didn't work, but we were able to escort them to the correctional center also, which was nice of

us. Public service again.

AUDIENCE MEMBER: With your pharmacy take-away program, those that show up with controlled substances, are they turned back, or what happens there?

MR. GRABOWSKA: Yes, sir. The question was, if anyone shows up with controlled substances at take-away, what's done?

The pharmacies are telling them to go to the law enforcement center and use that receptacle for controlled substances. Correct.

Now, are they still getting some? I would say yes, especially if the folks bring in a paper bag just full of random pills, which we are getting sometimes, too.

It would be a perfect scenario if we could break down each of the pills coming in and find out which is which, and which is controlled, which is not. There's just no time for it. There's not enough money or

time.

Ma'am?

AUDIENCE MEMBER: I thought I heard you say that you logged everything, but if they're just dumped in there, how do you log --

MR. GRABOWSKA: Sure, the question is, how are things logged if everything is just dumped into the containers?

The log is just the actual weight of the collected prescription drugs or capsules or whatever it is. Nothing is done as far as a break-down between, this is Oxycontin, this is Lorsaid, this is aspirin.

Ma'am?

AUDIENCE MEMBER: So then are you treating all of the prescription drugs, over-the-counter or prescription, as controlled substances?

MR. GRABOWSKA: Are we?

AUDIENCE MEMBER: Yes.

MR. GRABOWSKA: We are collecting

all of them. Yes.

AUDIENCE MEMBER: But I thought their treatment had to be -- their disposal, and how they're logged in and how they're treated, I thought that controlled substances were treated differently from non-controlled substances, or at least the responsibility for documenting them.

MR. GRABOWSKA: Right, as far as the documentation goes, we're just documenting the actual weight of them, and that they're disposed, not the actual breakdowns.

AUDIENCE MEMBER: Thank you.

MR. GRABOWSKA: Yes.

Sir?

AUDIENCE MEMBER: The costs that you've incurred on the program, does that include the incineration cost, or how is that dealt with?

MR. GRABOWSKA: The incineration cost is actually free to us, except for the man hours to go out. It's, like I said, in

North Dakota, things are done a little more simple once in a while, and we are very fortunate because of it.

But we do literally have our Agents call the city and say, I want to incinerate evidence, which is something that we do quite often.

If it's marijuana, methamphetamine, whatever it is, we will take those pills to the incinerator, put them in, and they'll actually burn them for us at no cost.

And that's more of a political connection between the Bureau and the Chief of Police or the Sheriff in that county that allows us to have that.

Yes, ma'am?

AUDIENCE MEMBER: So with the -- you're looking at two things. You're looking at the take-backs. You've got two take-back programs going, and now -- and then you're looking at the diversion side.

You're looking at an expenditure on your take-back side, and you're looking at the costs on your diversion.

Are you seeing a balance, or are you seeing a change in diversion, so you're not spending as much trying to buy back all of those drugs again, or is that coming down the pipe, do you hope?

MR. GRABOWSKA: Right. We are not seeing any correlation with that right now. We've only been doing this for a year, and we are just now up in the 22 different spots. I would hope that's something we would be able to find.

The diversion side is a monster. You know, as the Sheriff had talked earlier, when he got up, it's -- I think this is a great safety factor. I think this is going to have a great impact, but the diversion side is still something that we're going to have to keep continually addressing. But we have not seen that correlation yet.

AUDIENCE MEMBER: But you're hoping?

MR. GRABOWSKA: Absolutely. I would hope we can fix it tomorrow, I would. Love to.

Ma'am?

AUDIENCE MEMBER: Are you doing this on a continual basis for the controlled substances, or are you just doing certain days of the week or month?

MR. GRABOWSKA: This is continuous, so at any time, they can come in and drop off those scrip drugs.

What we were finding is that we only held it on certain days, we were getting the influx of people, but if you couldn't make it at your convenience, most folks just aren't able to alter a schedule to attend. So we have kind of 24 hour access to it.

AUDIENCE MEMBER: I've spoken to a pharmacist from a military base in North Dakota to help get some ideas for a program.

I'm just wondering, did you guys go to the military folks or the VA folks, or did they come to you, or --

MR. GRABOWSKA: We're actually working with them now on this. When we initially put this out, they were involved in the communication, but I think they had some permissions maybe that they had to get through on their end that were a little bit more complicated than the pharmacies were able to work with us.

But yes, we are working with the Air Force bases that we have in North Dakota.

Yes?

AUDIENCE MEMBER: A bit of an extension. What about nursing homes and long term assisted care facilities as sources? Any success looking at them?

MR. GRABOWSKA: We have started communicating with them for that. They right now in North Dakota kind of have their own system of gathering those together and sending

them off is what they're currently doing, and they're incurring those costs.

So we are mainly seeing only the general public right now turning in, but we're not working directly with the long term care facilities.

AUDIENCE MEMBER: Have you run into any environmental issues using regular draft incinerators to dispose of products that are controlled?

MR. GRABOWSKA: We haven't.

Ma'am?

AUDIENCE MEMBER: Actually that was my question.

MR. GRABOWSKA: Just by the state regulation that the AG had worked through was able to allow that.

Yes, sir?

AUDIENCE MEMBER: You're using that exemption, the law enforcement exemption -- you're not, you don't have to follow those rules?

MR. GRABOWSKA: I don't quite understand your question, sir, I'm sorry.

AUDIENCE MEMBER: When you burn it like in a regular city dump or something, you're burning a list of chemicals that's pre-listed waste, it should be incinerated at a fully proper use facility, you're burning it at a city dump, and I take it from your slide that you're using the law enforcement exemption for what you're trying --

MR. GRABOWSKA: Correct.

MR. CAVERLY: You know, when we did the national take-back, we became aware of all of these environmental restrictions that we don't necessarily deal with on a daily basis.

When we talked to local law enforcement and we issued that SAC authorization letter or SAC endorsement letter, we tell the local PDs that they should destroy controlled substances in accordance with federal, state, and local laws.

But we don't follow around behind them to make sure that the incinerators have the proper permits, and so on and so forth. So, while we're making, I think, a good faith effort to ensure that, you have to recognize, for law enforcement folks, you're speaking a different language, so it's not something that we're accustomed to hearing.

It's something that we've become -- we at DEA have become certainly much more aware of, and will work even harder for our second take-back April 30 to ensure, but that's something that we in law enforcement aren't used to dealing with and aren't used to hearing.

That doesn't mean we shouldn't hear it or we shouldn't be aware of it, but we leave it up to the local agencies to appropriately destroy it.

In North Dakota, they're using the means that they have available to them, and Lonnie, I guess you're not aware, and I

certainly wasn't of some of these restrictions.

One more question and then we'll move on to our next speaker.

MR. GRABOWSKA: Yes, sir.

AUDIENCE MEMBER: I'd like to just start by saying, I think programs like this are a wonderful idea. And I realize that the answer to my question probably isn't known or can't be known, but as programs like this move forward and more and more take hold, I would imagine at some point, we'd have to ask the question, what percent of what's out there are we getting off the streets?

And not to be cavalier, but if despite all of our efforts, we're taking a half percent or one percent off the streets, is it worth it? Has anybody looked at this?

MR. GRABOWSKA: You know, as far as numbers, no. And that's what our goal is going to be as our program rolls, also, is to find out, is this actually making the proper

effect that it's supposed to?

AUDIENCE MEMBER: It's a problem of measurable, but I guess you would just have to look at maybe emergency room visits, that kind of stuff as the markers.

MR. GRABOWSKA: And how much you're able to buy out there, how much can we illegally get our hands on is going to be a big measurement tool. When it's not available anymore, then we kind of know that we did something. Yes.

Thank you, folks. You bet.

(Applause.)

MR. CAVERLY: One of the huge challenges when we talk about prescription drug abuse is the issue you raised.

You know, what's the universe of prescription drug abuse? How many drugs are being abused, what percentage of controlled substances that are manufactured for legitimate uses ultimately get diverted and misused?

We had a former Administrator within DEA that would consonantly ask us that question, very frustrated. You want to know -- we can tell you how many abusers there may be based on drug abuse surveys, but we really don't know what the universe of drugs are that are being used illicitly.

We do find a correlation between volume and abuse. It seems like the more drugs that are produced, presumably for legitimate uses, the more drugs we also see in the illicit market.

We've seen that with specific drugs that have been manufactured for specific uses. As they become more commonly prescribed, they become more commonly found in the illicit market.

But it's very difficult to get that outcome percentage, and it's very frustrating to us, frankly, because how do you measure your success?

The other issue with take-backs,

and I don't want to address things that other folks will talk about, we're sort of talking about the end of the pipeline as we discuss it.

We're talking about controlled substances that are dispensed to ultimate users. They've left that closed system of distribution that Colin talked about this morning, and have sort of left the recordkeeping and security. So they're out there. They're at the end of the pipeline.

What we don't talk about often are what goes into the pipeline, and that involves things like education to prescribers. There are some third-party insurance issues that we don't talk about either. You know, the insurance companies pay the pharmacy a dispensing fee for each prescription that that pharmacy dispenses, so it's cheaper for them if you get a 90 day supply and only use 10 days than if you get a 10 day supply and have to go back for a refill, because the pharmacy

gets a second dispensing fee.

So there's all kinds of dynamics and issues that affect what's being prescribed, what's being dispensed from the pharmacy that we're really not addressing here, and I don't know that we can in this particular meeting.

So, complex issue, isn't it? When we first started looking at it, people would come to us and say, oh, this is simple, this is easy. DEA, you guys can hash this out. Sleep on it and tell us tomorrow what you're going to do.

It's very complex. It's extremely complex, and I think you'll hear a little bit more as we go through the speakers, some of the layers of the onion, so to speak.

And the other issue, Lonnie, that you mentioned, is that the general public doesn't know the difference between what a controlled substance is and isn't. So, we've been challenged over the past few years with

people who wanted to initiate controlled substance take-back programs, but didn't have an effective means to keep controlled substances out, so that's a huge challenge for us as well.

The general public just doesn't know that the antibiotic they have is not controlled. They may know the pain medication they have is controlled, but they probably don't know what that whole universe of prescription drugs is.

Depending on who you talk to, between 10 and 13 percent of the universe of pharmaceutical drugs are controlled substances, and the general public doesn't know the difference. Most of the people -- most individuals in the general public just don't know.

So let's go on to Roy McKinney, who's next on our agenda.

Roy is with the Maine Drug Enforcement Agency. Now, if you really want

to insult someone from DEA, call it the Drug Enforcement Agency. You know, we're the Drug Enforcement Administration, you know, not the Drug Enforcement Agency.

So Roy does not work for the Drug Enforcement Administration. I'm just trying to make that clarification. Roy works for the Drug Enforcement Agency, the Maine DEA, a Maine law enforcement agency.

So now that I've laid out all of DEA's dirty laundry, I'll ask Roy up here.

MR. MCKINNEY: Thank you, Mark. And trust me, I try to instruct the media and correct them often in Maine when they're writing an article and they reference the US DEA that it is Administration and not Agency.

My name is Roy McKinney, and I am the Director of the Maine Drug Enforcement Agency for the Maine Department of Public Safety. It's a pleasure to be here today before you.

To give you a little background on

MDEA, it's a statewide drug task force with personnel assigned to one of its eight regional district task forces from state, county, municipal, and tribal law enforcement agencies.

And our primary mission is to address the threat to the health and safety of Maine citizens that is posed by the distribution of controlled substances.

Over the past decade, controlled prescription drugs have become a major public health and safety problem in Maine. The misuse of these drugs is evidenced in the exponential increase in overdose fatalities.

Substantial increases have been evidenced in treatment admissions, crime rates, and drug prosecutions, emergency service ambulance runs, as well as admissions and hepatitis C rates among users.

In 1998, MDEA's controlled prescription drug-related arrests were at seven percent of all its arrests statewide.

That number rose to 39 percent of the total number of arrests in 2008 and for the last year, 2010, it sits at 43 percent.

Maine's unintentional poisoning deaths, most of which are all related to prescription drugs, rose 210 percent from 1999 to 2004.

In 2009, the last year for which figures are available, 179 Mainers perished from drug poisoning, 92 percent of them from controlled prescription drugs. In that same year, 155 people died in highway crashes.

Controlled prescription drugs in medicine cabinets are oftentimes providing easy access to non-medical users, accidental ingestion, or to sell for profit, as you've heard here today from many other presenters.

They also lead to home burglaries, home invasions. Last year, the then Maine Attorney General Janet Mills called the misuse of prescription drugs the number one cause of crime in Maine, up to and including homicide.

The National Drug Intelligence Center's National Drug Threat Survey 2009 revealed that Maine law enforcement agencies ranked first in the nation in terms of the perceived relationship of controlled prescription drugs to violent and property crime, and second in the availability of pharmaceuticals for abuse.

Forty percent of all reporting Maine law enforcement agencies perceived prescription drug misuse as the state's most serious drug threat.

Maine has used several models in the effort to reduce the amount of unwanted controlled and non-controlled prescription drugs, to include one-day collection events, ongoing collection events via drop-off and pickup by law enforcement agencies, and a mail-back program.

Each has their strengths and their weaknesses. Each has involved the participation of law enforcement to overcome

the limitations that were imposed by the Controlled Substances Act in how the ultimate user may dispose of those drugs.

Each is not embraced by every law enforcement agency in Maine. The collection and safe disposal of unwanted medications from households is one method of preventing these drugs from getting into the hands of non-medical users.

It removes a potential avenue of diversion, limits the availability of medications to drug seekers and abusers, and decreases the potential for accidental ingestion and poisoning.

So law enforcement stepped up to the plate, partnering with many stakeholders so as to provide a means by which to remove those excess substances from the house.

Collection events rely on voluntary action by individuals, local municipalities, community service organizations, and law enforcement agencies

for success.

The longest running one-day collection event has been taking place in the greater Brunswick, Maine area for the last several years in coordination with three law enforcement agencies, Sagadahoc County Sheriff, Bath PD and Brunswick PD, and numerous groups including the Mid Coast Hospital. A four hour collection event is conducted every six months.

Each event pulls in more unwanted medications than the previous ones. They always think they're going to reach the end, where it's going to be a plateau, but every single event, every six months, there's more than there was the previous six months.

Police department drop-off and pick-up are methods that have been deployed through local community policing efforts. Both are not yet widely available, but continue to grow in popularity in local communities in Maine.

Chief Mike Gahagan of the Caribou Police Department began collecting unwanted medications about five years ago. Rather than using a drop box located in the police station's lobby, an officer is dispatched to meet with a citizen to collect their unwanted medications.

All law enforcement agencies in Aroostook County in which Caribou is located now participate in drug take-backs. And the Caribou PD and the Prescow PD, the two largest law enforcement agencies in that county secure those unwanted medications until such time that they can be properly disposed of.

Penobscot County, Glenn Ross utilizes a lobby drop box. And last year, Kennebec County Sheriff Randy Liberty began dispatching deputies to collect unwanted medications, and now has a policy in place where the deputy inquiries of every complainant, whether they're responding to a burglary, a theft, a criminal mischief,

inquires of that resident if they have any unwanted medications they desire to get rid of, and the deputy will take those with him or her.

Sheriff Liberty recently secured funding for the purchase of 12 secure drop boxes to be located in 12 police departments across two counties, and which will be maintained by his deputies.

More specifically, I want to speak to Maine's mail-back program. In 2002, the Maine Benzodiazepine Study Group and the MDEA began to consider drug return programs.

Stakeholders from child advocacy, substance abuse treatment, law enforcement, environmental organizations including the state department of environmental protection, medical associations, university research programs, as well as legislators and other policy makers began meeting to discuss the issues surrounding an effort to provide the public with an effective means to dispose of

unused pharmaceuticals based on two main concerns, protecting the safety and welfare of Maine's citizens by preventing the diversion, and two, developing drug disposal methods that help prevent contamination of the environment and its water supplies. Maine takes its environment very seriously.

These efforts led to the passage of Public Law 2003, Chapter 679. The law, referred to as Maine's Unused Pharmaceutical Disposal Program, charged the Maine Drug Enforcement Agency as a central agency with creating a system for the return of unused pharmaceuticals, and that that system would employ pre-paid mailing envelopes into which the unused pharmaceuticals were to be placed, and that they'd be returned to a single collection location, beginning as soon as in July of 2006.

The law also enabled the MDEA to randomly assess the materials or substances that were received under the program, as long

as that assessment results do not identify the patient, the person who mailed the material, the prescriber, or pharmacy.

In addition, the law mandated that the MDEA ensure that only agency officers handle the unused pharmaceuticals received and that the unused pharmaceuticals must be disposed of in a manner that is designed to be effective, secure, and in compliance with local, state, and federal environmental requirements, and further, that included the Federal Resource Conservation and Recovery Act of 1976.

The legislation also directed the formation of a drug return implementation group to work on those implementation issues for this program. That group met four times in 2005, and among the recommendations of that group was the encouragement of local turn-in events for people to drop off unwanted medications for disposal, that the legislature consider product stewardship in which

pharmaceuticals manufacturers would fund or provide funding for all aspects of local turn-in events, and that the MDEA send a letter to the U.S. Drug Enforcement Administration supporting an amendment to the federal regulations to provide for safe and effective means of disposal for controlled substances.

The implementation of Maine's disposal program began in earnest with a grant awarded to the University of Maine Center on Aging from the U.S. Environmental Protection Agency in their area-aging initiative program.

The Safe Medicine Disposal Program for Maine is a state wide model for the disposal of unused household medications, using a mail-back and return system. With the involvement of law enforcement, the MDEA, the program was in a position to handle both controlled and non-controlled medications.

Our first step was to have many meetings, whether it be with the U.S. DEA, the U.S. Postal Service, with state, the

environmental agency.

And our first step was securing an operational test agreement, as it's called, with the United States Postal Service, that outlined MDEA's obligations regarding requirements for the mailing of unwanted or unused pharmaceuticals, including controlled substances, for disposal.

Many of those obligations -- of the many obligations, some included that the mailing envelopes used by the ultimate users had to be in compliance with USPS regulations, that the use of a merchandise return service with first class mail or priority mail for all mailings, and that there be a return label on those, and that each of the mailers had to have a step-by-step instruction sheet with each mailing container or envelope that clearly stated a number of factors or steps for instruction to the ultimate user in the mailing of that package.

On an annual basis, the MDEA seeks

authorization from DEA's New England Field Division Special Agent in Charge to conduct its drug collection program. In commencing with controlled substances are first collected, they remain within MDEA's control until their ultimate disposal.

With this combination of vast rural areas and urban centers, the mail-back program is an appealing option, having the advantage of being continuously available, whereas drop-offs are not as convenient, and may contribute to the accumulation of medicines between take-back events, the very situation that we're seeking to prevent.

Maine's pilot program began with eleven participating pharmacies and has since expanded to over 150 locations where the envelopes are available. These do include pharmacies, health and human service agencies, and law enforcement agencies in all 16 counties of Maine.

The program currently maintains a

waiting list of interested distribution sites.

Maine's unused pharmaceutical disposal program statute provided for the random assessment of what was returned, as I mentioned earlier.

This proved most valuable and should be considered in the drafting regulations. Cataloguing of returned drugs was done under law enforcement supervision by volunteer project pharmacists and pharmacy students.

Using a 20 percent sampling method was found to be the most cost-effective, and yielded a data sample that was statistically representative of the full inventory data set.

From this approach, knowledge about the amount of excess drugs collected in Maine has been informative in refining Maine Medicaid policy, for example, limiting or leading to limits for some drugs on how much can be prescribed, which thereby reduces costs and waste.

With Maine's stringent environmental regulations, controlled substances may be incinerated at any one of the licensed solid waste incinerators located in Maine.

However, non-controlled medications must be treated as hazardous waste, necessitating a hazardous waste contractor and transport of those substances to an out-of-state license facility for ultimate destruction.

Whereas the Controlled Substances Act did not permit transfer of controlled substances to a hazardous waste contractor, medications collected by whatever method in Maine required -- necessitated segregating controlled medications so that they may be incinerated in Maine and the non-controlled in compliance with the strict environmental regulations would be transported out of state for ultimate destruction.

This obviously creates more of a

burden in the segregation. Certainly it's valuable in the research part that has been done through the University of Maine. There is a report online available as to their data collection and their findings from the first two pilot phase.

Initially, the program focused just on senior citizens, but has been expanded to all age brackets throughout Maine.

To date, through last September, through the mail-back program, which commenced in May of 2008 with the first mailers being received, we have collected and disposed of in excess of 4,000 pounds of controlled and non-controlled. What the data set has found is somewhere in the neighborhood of 17 percent of that which is returned is controlled substances.

I want to thank you for the opportunity to be here before you today, and I have a few moments to answer any questions that you may have.

AUDIENCE MEMBER: Do you have some information about the cost differential about having to do all that segregation and sending them to multiple locations?

MR. MCKINNEY: We call those cataloguing events, and what happens is, the MDEA officer who maintains -- is our evidence officer picks up the medications, or I should say, the mailers from the local post office. They're secured until such time as there is a cataloguing.

The University of Maine, the Center on Aging, their research part, coordinates volunteer pharmacists and pharmacy students on the identification of what's controlled and non-controlled within those packets.

So, to answer the dollar question, no, I don't, because a lot of it is the volunteer part of identifying what is in those envelopes.

AUDIENCE MEMBER: What are your

plans how does this get funding going forward?

MR. MCKINNEY: The question is funding. The EPA grant did expire. I don't recall when it expired, about a year ago; I suspect now, a year and a half, eighteen months ago.

The Maine State Legislature appropriated money from this Healthy Fund for Maine, which is tobacco settlement money. They made an allotment available to the MDEA to continue that program.

The MDEA has also put money in from drug forfeiture equitable sharing awards that it's received towards that program. So right now, the funding is in place through the end of this year, 2011.

There have been efforts at product stewardship in the last legislature that died. Whether or not there will be another bill introduced in the current legislature, I don't know as yet.

Yes, sir?

AUDIENCE MEMBER: How are the mailers packed to prevent diversion?

MR. MCKINNEY: That was a concern at the development of the program, as regards to the theft of these mailers as they make their way through the system.

We had extensive discussions with the U.S. Postal Service and the Inspector's Office in regards to that.

Currently, right now, there is a number on each of these mailers, there is an 800 line that is maintained, and in the instructions on the insert for the envelope, the consumer is encouraged to call that number when they drop that envelope in the mail and provide that four or five digit number.

That is done, I think, roughly about 80 percent of the time the caller does provide that number.

Over the course of the time since May of 2008, we've not come across any incident where the consumer has notified us of

the number and that we've not received that package, and we still continue to have ongoing discussions with the Postal Service in regards to the tracking of those packages or those envelopes, and how to beef up that security side of it.

Thank you very much.

(Applause.)

MR. CAVERLY: Thank you, Roy.

We're running a little ahead of schedule. Let me make a couple of comments, and we'll go to lunch a little bit early.

In regards to the agenda for this afternoon, as you look at your agenda, in terms of format, when folks registered or pre-registered to this public meeting, we afforded them the opportunity, if they desired, to make comments.

So, starting at 1:00, we'll take comments from those presenters who indicated that they wished to do so.

We've tried to do it a little

alphabetically, at least within each grouping, and so if you are a presenter -- presenter number one will be Marcie Bough, Steve Brachman number two, Ron Buzzeo number three, and so on and so forth.

We will afford you the opportunity, obviously, to have a microphone. There's limited time. There's about a ten minute slot, I think, we've afforded to each presenter.

We did want to make a comment that those presenters who use Power Point slides may also include those slides as part of the record as well, so if you choose to not necessarily make those available to the general public in terms of our website, those presenters that use PowerPoint slides can also attach them to the record as part of their comments.

So, and then after that, we'll have a break. And then we have another block of time for presentations from the registered

public.

And then we'll have a little bit of time in the afternoon for an open microphone.

We are genuinely interested in getting comments from folks on this rulemaking, and are trying to be as absolutely transparent and as inclusive as we possibly can be. So, we'll have some open microphone time later on this afternoon, actually, on both days.

So I have about 20 minutes to 12. If we can be back here at 1:00, we'll go ahead and start the rest of our program, so, thanks very much.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 11:40 a.m. and resumed at 1:00 p.m.)

A F T E R N O O N S E S S I O N

1:00 p.m.

MR. CAVERLY: I've got 1:00 by my watch. As we have a little conference lag here, if folks could begin to take your seats, come on in, and sit down, and we'll begin the afternoon portion of our public meeting.

(Pause.)

We'll be taking presentations from the registered public as we pick up here, and in an attempt to keep things flowing between presenters, so we don't eat into someone else's presenting time, we've got some chairs set up here. This is not a firing squad. We will not take your picture.

But if you are slotted one through five in the afternoon 1:00 to 3:00 session, if you could come on up front and take your appropriate numbered seat. We're not playing musical chairs. You don't have to march around.

And then if six through ten, and I know we've had a substitution, Phil Burgess is now number six as opposed to Sierra Fletcher. She's going to take his slot in the 3:15 and on.

If six through ten could just find their way up to this front row and get seated up there. We're just trying to save time in shuffling folks around.

So I see five bodies and five chairs. That's good. And I see some movement towards the front row, so that's great.

Well, I hope that everyone had a good lunch. This is kind of the Bermuda Triangle of conference times. You know, it's the time right after lunch. Everybody's stomach is kind of full, and you're comfortable, and the room was a little chilly this morning.

It seems like it's warmed up a little bit, or maybe I've just warmed up. And you know, Joy just put her hand up, yes,

thumbs up, it's a little warmer.

So we'll -- I don't know, if we could throw dry erasers at people if you begin to nod off, or if we'll just point and laugh or something. I don't know. But hopefully the presenters will hold your attention during these next few minutes.

So, if Marcie Bough? Marcie, if you're ready?

Let me -- I'll let you have that microphone.

John Purcell who is known as John "Crazy Man" Purcell, Sergeant in Arms -- I'm trying to scare the presenters here.

Since we've given you ten minutes to present, we'll hold up number times -- number five, five minutes, two on the back and zero.

Since we're trying to preserve paper, we actually printed the number two on the back of the number five sign, so we get some points for recycling at least, anyway.

So, okay. Official timekeeper. All right.

MS. BOUGH: All right. Well, thank you.

My name is Marcie Bough. I'm a pharmacist and Director of Federal Regulatory Affairs for the American Pharmacists Association here in DC.

APhA is the oldest and largest professional association for pharmacists, and we represent over 62,000 members practicing in all different practice settings.

My goal is to build on some of the successful discussions you heard this morning, integrating pharmacists in a proactive perspective, as we look at implementing new and improved disposal programs.

APhA supports DEA's and the administration's efforts to better facilitate the safe and secure disposal of controlled substances in any medications.

Such efforts will help to remove

unused medications from potential unsecured public access, and will help to reduce unintended use of those.

We also appreciate that these efforts are aimed to further help prevent unintended or even intentional use, abuse, misuse, or diversion of medications by reducing the potential diversion route.

Maintaining the integrity of the drug supply is one of the biggest and highest priorities for pharmacists, and is assured by the existing chain of custody and FDA requirements followed by licensed manufacturers, wholesalers, reverse distributors, pharmacies and pharmacists.

The need and desire for take-back programs and other methods for disposing of controlled substances needs to be balanced and not compromise the safety and the security of the existing drug supply, whether it's on the front end or the back end of receiving the prescriptions.

Related to existing disposal programs, APhA has been a leader in the area of pharmaceutical waste disposal through implementation of the Smart Rx program in 2008.

The program is a public/private partnership with APhA, the Fish and Wildlife Service, and PhRMA to provide consumers with better options for medication disposal, raise awareness, and provide additional options that are environmentally friendly for disposing of medications with crushing and mixing with other ingredients prior to throwing in the trash.

We encourage DEA to consider how it can utilize existing information and existing programs and outreach from those programs as it evolves with the disposal programs, similar to some of the existing programs we heard this morning.

In November of 2010, as we heard this morning, there was a very successful DEA-

sanctioned national take-back initiative that resulted in a great amount of drug disposal that hadn't been in place before.

The demonstration of this success and these local programs suggests the need and the desire for such measures, regardless of it being a controlled substance or not. We received much interest from pharmacist members about participation in the initiative and for future efforts.

Therefore, APhA encourages DEA to continue with such programs and outreach, and we recommend DEA partnering with pharmacy communities, both at the national, state, and local levels, to further increase the awareness and participation of these future initiatives.

Related to pharmacy issues and options for disposing of controlled substances, one of the most common approaches of disposal of medication dispensed to the public has been through voluntary programs at

the community or through pharmacy take-back programs.

Other types of programs that we're aware that pharmacies and pharmacists are participating in include community-sponsored, company-sponsored partnerships with local hospitals, and partnerships with city and county or with state pharmacy associations, much of which we heard this morning.

It's encouraging to hear reference to wanting to loop pharmacists into the implementation of these programs, and we certainly welcome their proactive outreach and support for that from DEA, ONDCP, the state programs, and other stakeholders.

There's a side benefit for having the pharmacists in the loop on all of this is that it may trigger a nice dialogue with the patient about why they have so much medication that may need to be disposed, adherence issues, right medications, those types of dialogues that are helpful for the patient to

have regarding the safe use of their medications.

As discussed in comments that APhA submitted to DEA in 2009 related to disposal, medication disposal by patients can be problematic for pharmacies, pharmacists, staff, and that patients, because of lack of awareness of requirements and options, compliance challenges, restrictions on the controlled substance issues, which we're aware of, and then confusion with overlapping regulations in place, both at the local, state, and federal level.

While each state may have different requirements, there can be even more confusion when you start overlapping the different federal requirements, when you start looking at DEA, EPA, Department of Transportation, OSHA, ONDCP, and then some potential CMS activities.

While we surveyed some of our members in 2009 for developing those comments,

we did find some helpful information on take-back programs, that the programs are typically pharmacy-based, and that the pharmacies are voluntarily choosing to pay those increased additional costs to implement those programs.

There were successes noted, and coordinating activities with other pharmacies and hospitals increased utilization of existing state programs were some of those successes.

We did also hear back that 85 percent of survey respondents indicated that at least once a month, patients were asking them about receiving medications at the pharmacy as take-back, but about 88 percent of the respondents were saying that they were not participating in those programs.

My remaining recommendations will focus on the safe and secure disposal of controlled substances that we encourage DEA to consider as they move forward with disposal programs.

Therefore, APhA recommends that one, DEA work with ONDCP to secure successful increased coordination between the various federal agencies with these overall activities and requirements. This includes ensuring that somewhere we've got information about what might trigger take-back program activities into a different set of regulations, depending on the amount of disposal material gathered.

Number two, ensuring that various options for implementing disposal programs are in place for states, local communities, and individual locations interested in implementing voluntary programs.

Three, allowing designated or credentialed-type agent registration for pharmacists and pharmacies, or other appropriately certified community locations to receive controlled substances for the purposes of patient disposal.

Number four, allowing for non-registered DEA long term care facilities to

facilitate reverse dispensing to reverse distributors for safe and proper disposal of controlled substances.

Number five, we encourage DEA to ensure consistency and standardization of general program implementation and requirements.

Number six, ensure education and outreach materials are provided to stakeholders to increase awareness for program logistics and implementations.

Number seven, ensure that program materials and regulations clearly state that disposal programs did not constitute refunds or redistribution of unused medications processed through the disposal programs. I think that will be a very important point to make as this evolves.

We also encourage DEA to work with other agencies, such as CMS and other stakeholders, on efforts to address medication at the beginning of the prescribing process

and potentially limiting amounts that patients are dispensed, or short-cycle dispensing.

We further recommend that DEA allow the public to have access to mail-back or postage paid envelopes for controlled substances at the pharmacies to process and/or mail to reverse distributors or law enforcement facilities.

We also recommend that the public have access to secure drop-box or other appropriate receptor options for controlled substances at pharmacies or their community locations.

Towards the bottom of my list, I've got a few more remaining, focused on limiting the burden on paperwork and the logistics or cataloguing, what is being provided back to the pharmacy or community setting for a take-back program, so that we don't add on administrative burden and paperwork that undoes the efficiencies that we might have with some of the programs right

now.

The weight based discussion was interesting this morning with North Dakota on efficiencies that may be gained with that, but ensuring that we have the right information we need to meet requirements.

Then number twelve on my list is considering developing a government-funded pilot mail-back program for controlled substances that builds on the successes of the DEA organized take-back day to see if there's a way to utilize the success of that program, but in a mail-back format, but continuing with the initiative forthcoming.

We also recommend utilizing information from existing government and stakeholder partner disposal programs, much of which we've heard at this meeting, and we'll hear again more this afternoon and tomorrow.

And then finally, my last recommendation from APhA is to make sure we address costs associated with disposal

programs. It's come up several times, the need to explore various external funding, grant, fee, or manufacturer support or other payment options yet to be discussed to cover costs to implement these programs and help manage the pharmaceutical take-back programs and services.

In closing, pharmacists are often considered logistical repositories as an option for collections of unwanted medications in communities, but shouldn't be the only option.

We need to make sure that we can customize take-back programs to what the community and locations need to make their needs.

While some pharmacies are well equipped to voluntarily undertake these programs, we know that some are not, and it would prevent them from participating in these programs.

We do anticipate that a

streamlined regulations and increased awareness of various programs and funding options, new DEA registration or credential options, and increased utilization of existing programs would help to provide additional options and flexibility for implementing more programs.

We support improvements to the current federal, state regulatory processes and infrastructures in streamlining existing systems so that we can have new options for safe and secure disposal of controlled substances.

And all of these activities will help ensure that we're increasing patient awareness about the safe use of their medication, appropriate taking, adherence, and monitoring of their medications, and ensuring that they know that they can talk to their health care provider about their medications.

So finally, APhA offers our support and interest to DEA and the

Administration and the other agencies and stakeholders on future efforts with distributing information to pharmacists about where we're at with activities for disposal and ensuring that we can all work together to improve the programs for disposal.

Thanks for considering the APhA's views.

(Applause.)

MR. CAVERLY: Thank you, Marcie.

Steve Brachman?

MR. BRACHMAN: Good afternoon. I'm Steve Brachman. I'm the Waste Reduction Specialist with the University of Wisconsin Extension. And one of my roles is also to serve as the Co-Chair of the Wisconsin Pharmaceutical Waste Working Group, which is a coalition of over 40 people representing pharmacies, local and state government agencies, long term care facilities, consumer organizations, and a variety of others that have been trying to address this issue for

nearly five years now.

What I'd like to do is provide you with a brief overview of what Wisconsin's efforts have been over this period, and also share with you some of our findings as we've gone through this process, some broad recommendations in terms of the surrender of unwanted controlled substances and other pharmaceutical waste, and obviously, to provide support for whatever we can do to get old medicines out of household medicine cabinets, which is the primary place of diversion.

Just a brief history. As I mentioned, Wisconsin began back in 2006 looking at this issue. We launched the first series of one-day collection programs in about a half a dozen communities.

That quickly grew by 2007 to over 30 collections around the state. And for the first time that year, we established an ongoing collection at one of our county

household hazardous waste collection points.

We also initiated, as I mentioned before, with the Wisconsin Department of Natural Resources, this working group to help come up with a variety of solutions to address this program, not only in terms of collection and disposal, but long term solutions in terms of prevention.

By 2008, the one-day collection programs had doubled again within the state, and we were also asked by this working group to develop a pilot mail-back program.

And we conducted that in two counties in Wisconsin in conjunction with Wisconsin's reverse distributor capital returns, where they operated slightly different from Maine, an 800 number instructing people what to mail back, and then people received a container and shipped it back to capital returns for safe disposal.

This eight-month pilot served over a half a million people, and was very

successful.

Surveys were conducted at that same time to try to figure out what consumers really needed in terms of a successful drop program or collection program.

But we also surveyed law enforcement to see what their attitudes and practices were as well.

By 2010, we began, over a network of some time, the development of a law enforcement permanent drop boxes in sheriff's and local police departments.

And by last count, I believe we have 35 in the state, but nobody really has the accurate number on that, because they seem to be popping up all the time.

And of course you heard about the successful one-day collection in September. The DEA, I believe they collected 2.4 tons out of Wisconsin alone, and this is despite all the collection efforts that have been going on over that initial time period.

And 2011 will bring us some further opportunities. We're going to be launching a five-state product stewardship initiative in the Great Lakes area, and we hope to expand our mail-back program to the 36 counties that abut the Great Lakes in Wisconsin and serve over two million people with that program.

So what have we learned? A number of things. One is that consumers really like a wide variety of disposal options. One size unfortunately doesn't fit all, because people have different perceptions on what the proper way is to dispose of materials, and different levels of comfort with ways in which they participate.

We've learned also that mail-back participants in particular, once they participate in the program, turn out to be the most knowledgeable about both the risks to the environment of these materials as well as the health and safety issues.

We found also, from our surveys, that the biggest obstacle to success in these programs really is participation. People who indicated why they didn't participate in a program said they simply didn't know about them.

So one of the major tasks of any successful program going forward is going to be raising the public's awareness of what the options are and how to pursue them.

One of our broad findings is also that to collect controlled substances separated from non-controlled medicines is very difficult, and we liked the process where we can combine them in the collection process.

We found that having, for example, with the exception of the mail-back program, an on-site pharmacist at every collection event is extremely impractical. It's time consuming and costly, and the separation of materials is often challenging as well.

And lastly, and this has been said

before, consumers just don't know the difference between controlled and non-controlled substances. So instructing them, even when you're saying we're just going to collect non-controlled materials, is not terribly successful.

We've also learned that any program has simply got to be convenient. And I think this gets at the issue that Mark raised earlier, which is, how do we motivate people?

Well, we've got a lot to learn from a lot of different programs. But recycling, in particular, has found that if you make a program easy, they're going to participate. We ask to separate it 15 different ways, it's difficult to get folks to comply, but putting it all in one container typically is quite successful.

So whether it's mail-back, secure pharmacy drop point, at law enforcement or other registrants, even one-day collection

events, which I don't think are terribly efficient, but certainly raise awareness, I think are good disposal options.

It's equally important, and one of the key findings and recommendations from our task force, that any solution be cost effective. Disposal and staffing costs are high for these programs, so whatever we do to reduce it is important.

If we can aggregate materials, for example, prior to safe disposal by high temperature incineration, we're going to save a lot of money.

And in Wisconsin, we've done that on numerous occasions, so that it only takes one law enforcement officer on a hazardous waste disposal company's truck to go to the incinerator and witness the burn.

Anything we can do to reduce the need for law enforcement on site is really important, and you've heard this from others as well. Their time is valuable, and as

budgets have tightened for law enforcement, it's become increasingly difficult to expect them to participate in these programs.

And then lastly, whatever could be done to establish a network of high temperature incinerators would be very helpful for the development of these programs.

Many states have quite a cost burden because they don't have licensed hazardous waste incinerators in their state, so the transfer of materials to those can be quite challenging.

And we have, in Wisconsin, experimented under a special exemption from the Wisconsin Department of Natural Resources, allowing a power company to handle a small quantity of material from one county, just to overcome that issue.

So in conclusion, I'd like to applaud the DEA in their efforts. I think it's really great, moving forward on this issue, finally.

We're going to be able to raise awareness, I think considerably, as we get a consistent, ongoing program development. And we're hopefully going to address the challenges to make sure that any program that's developed is convenient and continues with ongoing disposal.

I look forward to development of the rules that both reduce cost and improve upon collection and disposal systems in our state in particular, and certainly around the country.

Thank you very much.

(Applause.)

MR. CAVERLY: Thank you, Steve.

Ron Buzzeo.

MR. BUZZEO: Thank you, Mark. Good afternoon. My name is Ron Buzzeo. I'm a former Deputy Director of the Drug Enforcement Administration's Office of Diversion Control, and I'm currently Chief Compliance Officer of Cegedim Relationship Management.

One of our business units provides federal, state, and international operational regulatory services to the domestic and international pharmaceutical industry.

Cegedim, our parent company, is a worldwide company with more than 8,500 employees in 80 plus countries.

We assist pharmaceutical and other science companies to strengthen their customer relationships, enhance sales effectiveness, optimize data quality and improve marketing performance, and mitigate regulatory compliance risks.

Today, my comments are based upon our operational regulatory experience working with all categories of registrants.

Based upon this experience, I'll address proposed processes for the disposal of unwanted controlled substances to reduce current diversion methods, prevent the creation of new and unwanted avenues for diversion, and provide the safest manner to

dispose of unwanted controlled substances while preventing diversion.

My remarks will not address the federal and state environmental issues, the impact of being a waste generation location, patient medication exemptions, or etcetera, as I'm sure others will.

A number of states have implemented or are initiating activity to address home generated waste disposal, take-home, take-back programs, no flush campaigns, and water studies.

I would also say from the onset that over the years, health care providers have had limited availability to approved processes and have turned to us to assist the ultimate user with disposal of unwanted controlled substances.

This issue, combined with the increase in diversion and abuse, has provided and allowed for the development of potential avenues for diversion.

From a federal perspective, the option of which seemed to work best for the ultimate user in long term care facilities is to return the unwanted controlled drug product to the provider pharmacy or directly to a DEA registered reverse distributor.

However, two issues must be addressed. First, how would the pharmacist, the pharmacy technician, or employee handle the return? And two, what kind of controls could be implemented for this option, this collection, to prevent diversion?

We strongly recommend that the safest return and disposal method would be for the return process to be through the use of existing DEA-regulated registrants or through law enforcement and regulatory agencies.

Considerations would be for tear and tamper resistant disposal bags with signature lines, substantially constructed limited access security enclosures, and utilization receipts for tracking.

The ultimate user who receives their controlled medication from a retail pharmacy would return their unused prescription to the pharmacy.

The medication would be presented only to the pharmacist in charge, an attending pharmacist, or pharmacy technician. Deterrent, the return would be within a tear and tamper resistant disposal bag provided by the pharmacy at the time of the dispensing that included a signature line on the bags for patient and/or long term care management, pharmacist, and/or technician.

A DEA required intake record must be completed and signed by both the pharmacist in charge or an attending pharmacist or pharmacy technician, and the ultimate user or the management of a long term care facility, much like a receiving document, and include the name of the drug, quantity and date of return, with a copy maintained by the pharmacy and/or the long term care facility.

Providing a disposal bag at the time of dispensing would assist in educating the ultimate user of the process available for disposal, and would reduce the time involved by the pharmacy for handling the return processing.

The return would be maintained within a substantially constructed, limited and controlled access container.

The pharmacy would forward the container with an inventory of contents, based upon the receipt record, to a DEA registered reverse distributor, or the reverse distributor would pick up the containers utilizing secure handling methods.

This option closely follows DEA receipt, distribution, and destruction requirements.

If the ultimate user or LTCF returns regularly to a DEA registered reverse distributor, the user would use some of the processes outlined above, such as a tear and

tamper resistant disposal bag provided by the pharmacy at the time of the dispensing, a receiving document that includes the name of the drug, quantity, and date of return, with a copy maintained by the reverse distributor and appropriate security.

This option also closely follows the DEA receipt, distribution, destruction requirements.

A return option for those receiving their controlled substance prescription via mail order is to enclose a tear and tamper resistant bag in with the order.

This bag is for the ultimate user to return any unused portion of their controlled substance prescription to a DEA registered reverse distributor or to an original mail order pharmacy, who would then forward the medication to a DEA registered reverse distributor.

They would have to include the

name, address, and probably postage for the ultimate user to even consider this method.

Another option would be a smaller version of the National Take-Back Day conducted last year across the U.S. Delivery would be to a state, county, federal sanctioned collection site. Currently there are collection sites on given times of year whereby citizens can bring environmentally hazardous items for disposal.

Would it be viable to have such a collection on a quarterly or periodic basis that has the approval of state and local law enforcement and local DEA, where the unused portion of the controlled substance prescription be dropped into one-way containers that include a solvent for instant dilution and/or destruction of the controlled substance without maintaining a record of what's being received?

Or, could the controlled substance, without solvent, be collected and

delivered to an incineration site with the destruction witnessed by a law enforcement or regulatory agency?

There has to be a reason for ultimate user to use this, to not just flush the controlled substances, dump the drugs into the trash, or leave the drugs in the house. There is no incentive, unless the patients realize the safety issues and diversion potential.

Public education is important for them to realize the dangers of leaving an unused controlled substance in the house, and environmental issues with flushing. Isn't it easier for me to just flush or throw the controlled substance in the trash? Who is going to let me know that this is a bad idea?

But how do we make the process easy so that people will use it?

In addition to addressing diversion prevention methods, major issues that require solutions are as follows.

Who pays for the handling by the patient, the pharmacy, the LTCF, and the return to the reverse distributor and the destruction?

What are the additional costs to the state and county agencies? What are the additional costs to DEA? What about the security for the collection sites, the cost for advertising to the population to make them aware of the issues?

The above must be addressed with minimal cost to our patients, registrants, institutions, and/or insurance, private and government and regulatory enforcement agencies.

How do we balance the course? In my opinion, we all have to share in that course.

Even though individual patient returns through sanctioned take-back may not sufficiently address the entire waste problem, they should be encouraged.

The large quantity from long term care facilities and hospital witness wasting should and must be addressed to decrease diversion and make it easier to return or dispose of unused medication in a safe and controlled environment, especially in institutions where large quantities or on previously unused delivery systems that could be a health hazard to our professionals if not handled properly.

In closing, based upon my experience as a former regulator and currently Chief Compliance Officer, I believe this is an important initiative, and we fully support that the regulations be changed.

Hopefully this initiative will decrease diversion. There are, of course, regulatory and security hurdles to overcome.

For example, there is a need for increased training, public education, unannounced auditing, truck security and surveillance, secure receiving and the ability

to secure materials at storage locations, and discrepancy reporting.

So these and other requirements outlined in the CFR and new proposed rules result in a very positive initiative that will allow for the development of a positive plan of action.

Thank you.

(Applause.)

MR. CAVERLY: Thank you, Ron. David Case?

MR. CASE: Well, on a baseball team, the fourth batter up is referred to as the cleanup hitter, and that's appropriate for me, because I represent hazardous waste cleanup companies.

My name is David Case, and I'm the Executive Director of a trade association called the Environmental Technology Council, and we represent the commercial hazardous waste management industry in the United States.

Our companies know disposal. That's what we do, and we do it very, very, very well.

We operate the high-temperature hazardous waste incinerators that people have referred to already today, and we operate a variety of other transportation, storage, and disposal facilities specifically designed and operated for very hazardous and dangerous materials.

Certainly, the issue of unwanted controlled substances are very challenging, but no more challenging than the hazardous chemical wastes we manage, the radiological waste, the medical waste, the explosive waste that is our business.

DEA has asked: "what is the safest manner of disposal for unwanted controlled substances, and what manner will prevent or minimize diversion?"

And I'm here to say, I think the answer is: disposal by a commercial hazardous

waste company that is a reverse distributor.

This is a melding of the two programs, and it has been working very well. We think that hazardous waste companies should register as reverse distributors so they are known by the DEA, they are inspected, they provide all the paperwork that a reverse distributor has to provide, they are subject to all the recordkeeping and reporting requirements of a reverse distributor.

We've been doing this now for the last three or four years for these types of materials, and it's worked quite well.

I'll get, a little later in my presentation, into some refinements or streamlining of the reverse distributor program that would enhance the disposal practices, but let me get there in due time.

Hazardous waste disposal companies that are reverse distributors are particularly well-suited, because -- for managing these materials, because we have -- we spend a lot

of time and money training employees on the proper management of these materials, having secure facilities for their storage, and having, obviously, very secure and effective disposal facilities.

We often provide contractors support to local communities for drug take-back programs, both household hazardous waste and household drug take-back programs.

In fact, one of the advantages, I think, of using commercial hazardous waste companies is, we specialize in turn key operations. We'll do it all.

We'll show up at the take-back site. We will have trained personnel with the right equipment, respirators, moon suits, whatever is necessary to take back the material. We'll inventory it. We'll keep very detailed records, both highly computerized recordkeeping.

We have reverse distributor agents who are authorized to witness destruction

burns, so that law enforcement officials are not necessary to witness the burn.

We can literally take it from the pickup -- from the take-back program site or from the pharmacy all the way to final destruction.

We are used to tracking every single drum, container, box that we pick up that is hazardous waste. We have electronic tracking systems for everything we pick up. We have records of destruction for everything we destroy.

We have a very high level of security at our facilities. Under the Homeland Security Act, we are one of the facilities that has to have sufficient security to deter terrorists.

If a terrorist can't get into our facility, I don't think a teenager can. So I'm pretty confident that we have the types of facilities that are appropriate.

Now, you've heard several people

refer to environmentally friendly incineration, or high-temperature incineration. It's worth just a few minutes of your time for me to explain a little bit what that means.

All incineration is not incineration. There are great differences between a municipal trash incinerator and a high-temperature, permitted hazardous waste incineration.

Probably the most important one is, to get a permit as a hazardous waste incinerator, you have to demonstrate at least 99.99 percent destruction of the contaminants that you're burning. We call that the four nine standard, and in fact, many incinerators achieve five and six nines destruction.

So if you're worried about the controlled substance actually being destroyed, only a hazardous waste incinerator can demonstrate that kind of destruction rate.

Secondly, we operate the facility

in a way where there is a required residence time for the material, there's a mixing process to ensure that the material is fully incinerated, there are emission controls for a very full suite of hazardous contaminants, and we have to obviously operate the incinerator below the emission standards for all of those contaminants.

I would contrast that, for example, with a municipal trash incinerator, which, if it monitors anything, may monitor only particulate matter or something very simple.

So, when you hear someone say, well, we can send it to the trash incinerator, we've never had a problem, they've never looked for a problem. They don't monitor for the types of hazardous chemicals that would result from incinerating uncontrolled substances.

And along those lines, not to get too technical, but the other issue that arises

is not only the emission of the chemicals in the controlled substance, but they tend to interact and create what are called products of incomplete combustion or PICs.

Dioxin is the most prominent PIC, and we monitor for all products of incomplete combustion as well, to ensure that we don't emit those.

I have to -- this is a little bit awkward, but I noticed in the DEA collection event in September that the DEA operated open burning equipment for the destruction of the controlled substances that they collected.

You know, a big roll off with a fire is not going to do it. You can get in there and poke in among the ashes and find bottles that have not been destroyed with usable substances in it.

In addition, you're going to have emissions that aren't monitored. The chemicals will vaporize, be emitted out the stack or in the open air in the case of open

burning, condense, and deposit on the land or waterways.

It makes no sense to try to keep these chemicals out of the sewer and out of surface water and ground water but then just burn them in an uncontrolled fashion and have them deposited on the land and in the water anyway.

So that's why we think hazardous waste incineration is by far the best method, and if the current DEA regs simply provide -- follow federal, state, and local requirements, I don't think that's enough. I think the DEA should seriously consider requiring destruction in a hazardous waste facility.

Now, I've mentioned that some of the current DEA procedures for reverse distributors are onerous and burdensome. They work pretty well, I think, in your closed loop system that was described this morning.

But when it comes to accepting controlled substances from ultimate users and

health care facilities, counting every pill and having a pharmacist present to do that and having law enforcement all the time, including all the way through to the destruction is going to be costly and burdensome and unnecessary.

We hope that the current regs can be revised somewhat in this rulemaking process to provide somewhat simpler notification, somewhat simpler recordkeeping. We think, for example, keeping records of the weight of the material destroyed is adequate without having to have a pill count.

We agree with kind of with the general principle that there should be standards for record-keeping and tracking every shipment, for identifying the number of packages and weight of each package that is picked up, transported, and disposed, that each package be sealed in the manner that the previous speaker described; that's what we do.

We provide all that kind of secure

transport and disposal, so we're more than happy to follow those kinds of procedures.

Finally, you've heard several speakers mention the mail-back program, and I want to speak in favor of that. One of the things you've heard today is, the more options available to consumers, the better, provided they're secure and prevent diversion.

We've had a lot of success with mail-back programs for other hazardous household materials, such as fluorescent lamps that have mercury and PCB containing ballast, or mercury thermometers, mercury containing thermostats.

We provide mail-back programs for all of those types of household hazardous waste, and we do it through pharmacies and chain stores like Wal-mart.

Wal-mart is one of our customers, and we handle a lot of their hazardous materials that are returned, products, hair spray, paint, whatever.

So we're there. We're at the Wal-mart store, we're at the pharmacy, we can work with them to have packages for mail-back, and we can keep track of those packages, monitor, and track them.

We think this program works very well. It's very cost effective. Depending on whether you want to use the U.S. mail or someone like Federal Express or UPS, the cost can be anywhere from $10 to $15 per package.

If you can't get homeowners with controlled substances to spend $10 to send all of their stuff back, then we've got a serious education problem. I think that's reasonable, and I think they will do that.

So, in conclusion, I just urge you to work closely with the hazardous waste industry. I know its foreign territory to most of you. I had to spend a lot of time learning about reverse distributors, which was foreign territory to me, but we've been at this for 20 years.

We pulled the United States out of the era where there was the Valley of the Drums, and Love Canal, and improper disposal of hazardous waste.

We now dispose of our hazardous waste very safely and securely in this country, and it would be very appropriate to include controlled substances and other unwanted medicines as part of our disposal program.

Thank you.

(Applause.)

MR. CAVERLY: Thank you, David.

Cynthia Finley.

MS. FINLEY: My name is Cynthia Finley, and I'm from NACWA, the National Association of Clean Water Agencies.

NACWA represents the interest of nearly 300 publicly owned treatment works, or POTWs, throughout the nation.

Our members range in size from serving populations of less than 2,000 to

serving populations of 7.5 million, and our members serve the majority of the sewered population in the United States.

NACWA members are increasingly concerned about pharmaceutical and other pollutants from consumers that enter the sewer system, make their way to the wastewater treatment facility, and into the environment.

Studies have shown that pharmaceuticals are widespread in the aquatic environment and may be affecting aquatic species.

The Environmental Protection Agency is scrutinizing pharmaceuticals and other emerging pollutants more closely, potentially leading to water-quality based target levels for these substances that could result in permit limits for waste water facilities.

Waste water utilities are the last line of defense for keeping substances that enter the sewer system out of the environment.

However, waste water treatment plants were not designed to remove pharmaceuticals. They were designed to remove solids and disease causing organisms from municipal sewage, not to remove the huge variety of compounds found in pharmaceuticals.

Any pharmaceuticals that are removed from the waste water in the treatment process may end up in the bio-solids, which are then often applied to soils as fertilizer.

The Clean Water Act allows utilities to control the discharge of pollutants that might interfere with or pass through the treatment process, but this only applies to commercial and industrial sources of pollutants.

Waste water treatment plants have no authority to regulate the flushing of pharmaceuticals in homes and other facilities, nor is it practical to do so.

While protection of water quality and the environment is the primary concern of

NACWA and its members, we also understand the need to prevent diversion and illicit use of pharmaceuticals. We believe it's possible to meet both of these objectives.

Various government agencies currently recommend that consumers dispose of drugs in the garbage disguised by undesirable substances such as coffee grounds or kitty litter. Disposing of pharmaceuticals in garbage that's then taken to municipal solid waste landfills is not protective of the environment, though.

Pharmaceuticals have been found in leachate from landfills, and this leachate is often conveyed into waste water treatment plants for treatment. The end result is the same as if the pharmaceuticals were flushed. They are released into the environment after going through the treatment plant.

Incineration is therefore the best method for preventing environmental harm from unused pharmaceuticals.

Waste water treatment utilities have taken the lead in many communities to establish take-back programs where the pharmaceuticals are collected and then incinerated.

You'll hear shortly from Dave Galvin of King County, Washington, one of our members, and their role as a partner in take-back programs at pharmacies, which was actually shown this morning in the Bartell Drugs description.

Other NACWA members have posted take-back days, but these are limited by the constraints of the Controlled Substances Act. As you know, the requirement for a law enforcement officer to collect controlled substances and the transport restrictions of these substances makes these take-back days very difficult and expensive.

The need to separate controlled and non-controlled substances also adds difficulty to these programs.

NACWA has communicated in the past with EPA, FDA, and the Office of National Drug Control Policy, about consistent messages from all government agencies on the best disposal methods for unused pharmaceuticals.

Currently, recommendations still exist that some drugs be flushed. We recommend that a consistent message be developed for all government agencies, and that DEA work on this as part of their work on this issue.

NACWA has supported the work of the Product Stewardship Institute to study the issue of pharmaceutical disposal, and we support the recommendations that PSI has developed for the safe collection, transport, and disposal of controlled substances. And you will hear more about this later from PSI.

NACWA and its agency members look forward to the development of regulations that will enable take-back programs that are efficient and convenient for consumers and

that also protect the water environment.

Thank you for considering our comments, and we look forward to providing more input on the proposed rulemaking. Thank you.

(Applause.)

MR. CAVERLY: Thank you, Cynthia.

If we could dismiss our five speakers. David, we're going to have ten speakers in this. Have we exceeded the baseball rule? You know, nine speakers -- or we can go with the designated hitter rule. So, okay.

If our speakers six through ten could please join us.

And I think our substitute hitting for Sierra Fletcher is Phil Burgess, so come on up, Phil. Pinch-hitting.

MR. BURGESS: And thanks to Sierra for letting me switch with her to be able to talk with you today.

My name is Phil Burgess. I'm a

pharmacist, and so I'm going to be talking to you from a pharmacist's perspective.

I'm President of the Community Pharmacy Foundation. I'm Executive Director of the Illinois Board of Pharmacy. I've been Chair of the Board of Pharmacy for the last three years, served on the board for eight years.

So I understand the role that pharmacists can play in helping patients better understand their therapy. And I also understand DEA's concern with regard to diversion, and have sat through many disciplinary hearings with pharmacists with regard to various and sundry acts, more than I would like to count.

That being said, the pharmacists can play a key role in helping control the proper disposal of controlled medications. They are the most readily available health care professional.

You saw the ads during the

political campaign where they talked about, if you had a question about health care, go talk to your doctor or go talk to your nurse. Where can you go talk to a doctor or talk to a nurse? You can go talk to a pharmacist. The pharmacist is there in the corner, ready to interact with you and ready to talk to you.

So my point is that the pharmacist is there, readily available, and is a natural person to be engaged with regard to the entire drug disposal process.

The Accountable Care Act, which is sometimes called Obama Care, embraced the concept of medication therapy management, that the pharmacist can play a role in helping patients understand their therapy.

I would submit to you that drug disposal is an extension of medication therapy management, teaching people how to use their medication, but likewise, when it goes unused, how to get disposed of it, and do it in an environmentally friendly manner.

So, I look at the whole disposal process as a patient education process that the pharmacist can play.

I work as a consultant to Sharps Compliance, and I'm speaking for them specifically this afternoon. I have worked with them -- I was with Walgreens for 40 years, left them, and have now been working with Sharps over the last year and a half to help develop their drug disposal program.

Our initial pilot was done working with the Iowa Pharmacy Association, the Iowa Board of Pharmacy, that would develop a program that would allow some type of a mail-back option for the patients.

It was a two-prong program. One were boxes that were actually put into the pharmacies, either 10 gallon or 20 gallon. Those boxes were tamper-resistant, were able to be then put into the pharmacy.

The program was designed so that the pharmacist would directly interact with

the patient. These boxes weren't just set out in the waiting room somewhere. These boxes were back behind the pharmacy.

Patients would interact with the pharmacist. The pharmacist would take in the medication.

If it was a controlled drug, we'd give it back to the patient and say, no, we don't take controlled drugs, but here's a list of sites where you can drop off the controlled drug. For the non-controlled drugs, they then would counsel the patients with regard to why they were bringing back this medication.

So, for the patient that would bring back the three-year-old amoxicillin, in front of the patient, that would be put into the box.

To the patient that was bringing back the Lipitor that was only a month old and half the bottle was still full, it was a golden opportunity for the pharmacist to be able to say, why are you bringing it back?

I got leg cramps.

Oh, well, then maybe I can call your doctor, see if I can switch you to Crestor, and maybe you won't have the leg cramps.

So really, it was a part of the whole process of helping patients understand their drug therapy, and then also getting those drugs off of the street, out of the medicine chest, and taken back into a safe environment.

The second part of the program was an envelope program that's been referred to earlier that was an actual envelope that the patient could be given.

It was a postage-paid, process approved through USPS so that the patient could take the envelope, clear instructions that this was for non-controlled drugs, place it in the envelope, and then they'd put it into the postbox.

The minute they put it into the

postbox, that immediately becomes federal property with all the laws and regulations that impact our mail.

That pilot program was very successful, and has now gone to its second year. That program expanded to NCPA, the National Community Pharmacy Association, and has been rolled out throughout the country, and have had very positive results.

The program earlier, they had talked about North Dakota, the take-away program that was talked about earlier, that also was an envelope program that Sharps supported. We're involved with a lot of the different programs that people are looking at, how they expand those envelope programs.

We see the current programs for non-controlled drugs to be a template to DEA to look for controlled drugs, to take that same program, that same control process.

It needs to be properly monitored. The envelopes or the boxes are tracked

electronically. There needs to be very clear processes whereby when that merchandise, when those packages are received, that there's law enforcement involvement, that there is controls, tracking, all of those things need to be in place, but it can be done securely and safely in an environmentally friendly manner with those tight controls.

Most recently, Walgreens has gotten involved with regard to this program. Only in the last three months, they've kicked off a program, and in those -- a lot of, we've talked about weights and all, the weights of measures, and the weights of drugs.

What makes the Sharps program different is that the envelopes are never opened, so we don't know how many -- the weight of the medication, we know the weight of the envelope, and we do weigh each envelope and track those envelopes.

Just in the three months of the Walgreens program, we have now destroyed over

four tons of envelopes with medications inside. So, those drugs are coming off of the street.

Earlier, there was comments about, you know, what percentage is that? Is that really helping diversion?

I can tell you, we're pulling four tons of drugs out of the street in just the last three months, just in Walgreens.

It is imperative that whatever option we have, and this has been said several times before, that the options are going to be so that it makes it easy for people to be able to use. So there's that, one size doesn't fit all, has been said earlier.

But for senior citizens who don't have readily available access to transportation, to inner city that don't have readily available transportation, there needs to be a mail-back option. It can be done in a safe and secure environment.

I was very heartened by some of

the comments made by the fellow from Maine, because obviously, again, they've got a very good success rate shown with regard to their mail-back program.

I think that our program that we're recommending falls directly in line with Dr. Condon's guidelines, or I think ideals was the word he used.

We welcome the opportunity to continue to provide input, and thank DEA for the chance to be able to talk to you.

Thank you very much.

(Applause.)

MR. CAVERLY: Thanks, Phil.

Dave Galvin?

MR. GALVIN: Thank you for the opportunity. My name is Dave Galvin. I'm an environmental program manager for King County in Seattle, Washington.

So I speak today from three perspectives, really. First, as a representative of local governments, who

typically end up holding the bag, so to speak, with handling leftovers in our society, whether they be the general garbage, the waste water, or more problematic products at the end of their useful lives or when they're unwanted.

Secondly, I speak as somebody who has some expertise in the field of managing hazardous and other problematic wastes. I was actually the one who coined the term household hazardous waste exactly 30 years ago this month.

Thirdly, I speak as representing a wealth of on-the-ground experience from Washington State. You've heard some references already to what we've been doing out in the Northwest corner.

We have over four years of experience now with direct collection of unused medicines at pharmacies of various kinds and other facilities.

So we've provided extensive

written comments already, for the record. And today I want to hit on a few key points. I have nine in total, if time allows.

So, number one, and some of these we've already heard. There will be kind of common themes.

One is, we need options, so we shouldn't go with a single national mandate of one solution, because one solution won't fit all. I think that's a point that many other speakers have already made, so I don't need to reinforce that.

Mail-back, drop-off, law enforcement events, we need a whole suite of options to be available for the variety of communities that exist across the country and even in any given state.

Second point is that to be effective, we need take-back systems that are capable of collecting large volumes. There's an incredible amount of these unused medicines out there. Any of you that have been involved

in any type of collection are aware of that.

We're convinced, based on the very limited studies that have been done and our own anecdotal information in Washington State that somewhere in the vicinity of more like 30 percent of medicines that are sold go unused. I don't think the figure of just a few percent really makes sense when you see the quantities that are available out there.

So one-day and small mail-back envelope kind of options are options in a suite, but they're certainly not the ones that are going to be sufficient to collect the large volumes of unused medicines that are out there.

We refer to these kind of options in the waste management business as boutique services. Yes, they're useful, but they're not the only thing if you're wanting to be dealing with hundreds of tons, not just single envelopes.

Single envelopes also don't work

when the deceased hospice patient's relative have to deal with the quarts of morphine and things like that. So there needs to be various options to handle the quantities that are available.

We estimate in Washington State alone, for example, that a convenient collection system could easily take in 150,000 pounds of unused medicines per year, just based on the data that we have from our own experience. We need systems that are capable of sweeping out large quantities.

And cost is an issue when you're dealing in the large quantities. So we need to think beyond boutique. And you look at the cost information available today on mail-back versus pharmacy drop-off, and there's orders of magnitude difference in the cost per pound.

My third point is that unused medicines need to be collected together, co-mingled, over the counter in with controlled substances.

It's not going to be cost-effective to have to separate these out and handle them separately, so we need a commingled system.

Ultimate users, as many people have said, do not know the difference, and so any mandatory kind of separation of medicines will complicate the take-back systems, add expense, and therefore decrease the convenience and therefore decrease the participation and therefore decrease the ultimate effectiveness.

So all bulked waste medicines need to be handled as if they were all controlled substances, and handled in a safe and secure manner from there.

The fourth point is that we don't need to count every pill. I think other people have already made that point. That will also severely complicate any kind of take-back system and increase the cost exponentially.

We can set up very secure systems that deal in bulk, and that prevent tampering, but you don't have to count every pill once they're being turned back in.

Fifth point, options for transport and shipping need to be addressed in the new regulations. It's a complicating area right now, those of you that are in the business.

We need to allow for secure bulk shipping via common carriers. And there are complications in the regulations now when you're dealing with the controlled substance regulations and the RCRA environmental regulations and the DOT regulations. We need to align those so that we can easily and conveniently ship these materials in bulk at a reasonable cost.

The sixth point is that unwanted medicines can be safely and securely collected at pharmacies. We have shown that in the Washington State examples. You'll hear more in a few minutes from Shirley Reitz about the

specifics of the group health collections in the Washington State area.

Using tight controls approved by the Washington State Board of Pharmacy, we have demonstrated that this can be done. We've had 25 clinical pharmacies, 14 retail stores and other facilities available.

In the last few years, we've collected over 60,000 pounds of unused medicines in Washington State with zero tampering, with zero diversion. It can be done.

So the DEA regs need to recognize that pharmacy collection is an option, and it will be one that will get us the largest volumes.

Seventh point is that pharmacy take-back will promote less diversion. Surveys show that people are most comfortable returning unused medicines to the place where they bought them.

People go to drug stores. People

go to the pharmacy as part of their routine errands. They don't typically stop by the police station, and they don't typically stop by the household hazardous waste facility. So if we want convenience and we want participation, pharmacies are the place to go.

My eighth point is that disposal, and you just heard this from one of the previous speakers, should be by high-temperature incineration in regulated facilities.

In other words, we believe in the Washington State model that all of these collected drugs should be shipped for hazardous waste destruction. It's the safest way, absolutely. It's licensed, permitted, secure, highly regulated, and it's the best option we have. We should just bulk these things up and get them destroyed as efficiently as possible.

So the DEA and the EPA need to get together to align the regulations to allow

this to happen, because there are some barriers right now to allowing that to happen.

And my final point is that the long term care facilities really need to be looked at and be part of the regulations. You've heard some comments on that, although the bulk of the discussion has been on household medicines.

But long term care facilities are a huge area of volumes of unwanted medicines that don't have good options right now for collection and disposal, so we definitely need to include those.

So, in summary, thank you very much for this opportunity to have this kind of public comment and input. I think this is really good, and we've come a long way in the last few years in our awareness of this issue and our coming together on a lot of common themes.

Regulation should provide for secure and convenient options that will result

in the collection of all unwanted medicines for safe destruction.

Thank you very much.

(Applause.)

MR. CAVERLY: Thank you, Dave.

Doug Herbert, please?

MR. HEBERT: My name is Doug Hebert. I'm with Environmental Pharmaceuticals, which is a reverse distributor located in Scottsdale, Arizona.

And I want to start off by just kind of repeating a little bit about the Secure And Responsible Drug Disposal Act of 2010, when it addresses the delivery of controlled substances by ultimate users, that an ultimate user, without being registered, may deliver a controlled substance to another person for the purpose of disposal of that controlled substance if (a), the person receiving the controlled substance is authorized under this title to engage in such activity, and (b), the disposal takes place in

accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

The requirements set forth in (a) and (b) of the aforementioned act currently exist within DEA's Office of Diversion Control, and they are referred to as reverse distributors. And by design, reverse distributors are DEA registrants, although the current rules restrict them to only servicing other DEA registrants to ensure the system remains closed and prevents the diversion of pharmaceutical controlled substances.

Unfortunately, current regulations exclude long term care facilities and ultimate users.

The requirements for the DEA registered reverse distributor are similar to those imposed on all registrants. They include physical security controls, extensive record keeping, accountability in the receipt, the transportation, storage, and ultimate

destruction of pharmaceutical controlled substances.

Reverse distributors were created by DEA to service registrants for the same reason that the Secure And Responsible Drug Disposal Act was passed for the long term care facility and the ultimate user, and that is to ensure the establishment of effective controls against the diversion of improper disposal of pharmaceutical controlled substances.

The topic of pharmaceutical drug disposal relating to long term care facilities and the ultimate user is one of great importance to our health and welfare of our nation.

Long term care facilities' inability to legally and safely dispose of controlled and non-controlled pharmaceutical drugs is destructive to society and the environment.

The physician's changing of a resident's prescription medication or the

untimely passing of a resident leaves the long term care facility in a dilemma.

Since the long term care facilities have been precluded from using a reverse distributor, they oftentimes transfer the controlled pharmaceuticals to a family member or simply discard them into the community water system.

With the passing of the Secure and Responsible Drug Disposal Act, it is recommended that DEA establish a separate long term care facility registrant category that is unique to the long term care facility industry.

Most long term care facilities are currently required to keep medications administration logs on all residents. Strict record-keeping, accountability, and security requirements of all medications are mandated by individual State Department of Health Services.

Requiring long term care

facilities to become DEA registrants will federally necessitate the long term care facility to account and properly dispose of the resident's controlled medications in their possession. This would occur if a resident's prescription is changed by a designated physician, or the resident passes away.

The long term care facility would also utilize proper disposal methods currently required by DEA and complete required documentation, or utilize the services of a DEA-licensed reverse distributor to store and properly destroy controlled prescription drugs.

DEA rules could also mandate the documented transfer of prescription controlled pharmaceuticals when a resident is transferred to another medical facility and/or the resident is released.

DEA's creation of a long term care facility registrant category would comply with the Secure and Responsible Drug Disposal Act

and federally regulate the industry's accountability and the accounting, storage, and disposal of controlled pharmaceuticals.

When it comes to the ultimate user, we focus on two major issues, obviously, diversion and the environment.

The first issue is the intentional or unintentional diversion by the ultimate user and/or his inability to properly dispose of unused or outdated controlled pharmaceuticals.

This is the nation's largest contributor to controlled pharmaceutical drug abuse among teens. Seventy percent of all teens illegally obtain controlled pharmaceutical drugs from the medicine cabinet in their own home.

Pharmaceutical drug overdoses in the United States outnumber overdoses on cocaine, heroin, and methamphetamine combined.

And the second issue is the environmental concerns associated with the

improper disposal and the introduction of prescription drugs into our nation's water supply. Pharmaceutical contamination of our nation's water supply has concerned environmentalists and other environmental agencies. It is estimated that 80 percent of the nation's water supply has levels of detectable pharmaceutical contaminants.

So to address the issue, we've done community take-back programs. These sporadic community -- the nationwide take-back programs of unused or outdated pharmaceutical drugs, like the one conducted last year by DEA on September 25 and the one scheduled for April 30, 2011, promotes community inclusion and educates the public on the larger issue of unused or expired controlled prescription medications in our homes.

What take-back programs fail to do is resolve the fact that the ultimate user has no convenient alternative method to safely and routinely dispose of pharmaceutical drugs at

little or no cost.

A limited number of pharmacies currently accept non-controlled prescription drugs as a service to the customer. The dilemma is the average person cannot differentiate between controlled and non-controlled prescription drugs, and cannot begin to comprehend the rationale as to why a pharmacy can't take back the -- can only take back the non-controlled substances.

The pharmaceutical industry is in the business of dispensing drugs, not taking them back. But most pharmacies shy away from taking back unused non-controlled substances for several reasons, including the time spent by a pharmacist sorting out the pills or addressing the controlled versus non-controlled legalities.

The focus of DEA's rulemaking process must address convenience, and it must address cost for the ultimate user and the DEA registrant.

The ultimate user needs a convenient location to drop off unused and outdated pharmaceutical drugs, or obtain access to a pre-addressed return mailer that delivers them to a reverse distributor for proper destruction.

The likely location for an ultimate user to return controlled or non-controlled pharmaceutical drugs or obtain a pre-addressed return mailer is the neighborhood pharmacy. This would include independents, chain pharmacies, grocery store pharmacies, and retail warehouse pharmacies.

It is imperative that DEA rules require registrant pharmacies to directly and/or indirectly provide the means for the ultimate user to safely and securely drop off unused or expired prescription, controlled, and non-controlled pharmaceuticals.

This can be implemented with little or no interruption of pharmacy operations and at a minimal cost.

This requirement could be accomplished by two methods. The first direct method requires the pharmacy to provide a convenient drop-off location within the pharmacy for the ultimate user to deposit controlled and non-controlled pharmaceuticals in a commercially designed drop safe.

When the safe is full, the pharmacy would contact the reverse distributor to schedule a pickup or a mailing of its contents for transportation and storage and eventual destruction at a DEA/EPA approved incineration facility.

The cost to the pharmacy could be reduced by DEA rules specifying that the container and its contents be permanently sealed and labeled as ultimate user returns.

The sealed container is then submitted to a reverse distributor by weight. The sealed contents of the ultimate user returns would be secured and handled as other scheduled controlled pharmaceuticals.

Biannual inventory reporting of ultimate user returns would be submitted to DEA and State Boards of Pharmacies by weight and not dosage units.

The second indirect method, and probably the optimal method for the ultimate user, involves the registered pharmacy to provide either through funding by drug manufacturers or sell for a nominal fee a pre-registered return mailer that delivers controlled and non-controlled pharmaceuticals to a reverse distributor.

The ultimate user obtains the pre-addressed return mailer from a local pharmacy, and from home, the user places the unused or expired controlled pharmaceuticals in the mailer. The return mailer is then permanently sealed, and ultimate user would drop it in the mailbox.

The permanently sealed return mailer is received at the reverse distributor, who segregates and secures the bag as ultimate

user returns.

Per DEA rules, the ultimate user returns mailer remains sealed and would be processed by weight, segregated and secured with other controlled pharmaceuticals.

Using the sealed return mailer method in lieu of a drop safe affords the pharmacy the ability to circumvent the direct handling of ultimate user returns, providing the means for the consumer to mail their pharmaceuticals directly to a reverse distributor, and further reduces the advent of diversion by eliminating the pharmacy's role and liability in taking back, processing, storing, and mailing of ultimate user returns.

I'd like to thank DEA for affording me this opportunity. And also, I think, in summary, I think the pharmacy is probably the most convenient place for the ultimate user to return drugs.

And I think by having more than one option, using a return mailer or a drop

safe, I think are the two best methods available.

Thank you.

(Applause.)

MR. CAVERLY: Thank you, Doug.

Shirley, is it Rietz or Reitz?

Reitz. Shirley Reitz.

DR. REITZ: Thank you.

I do have some slides to get everybody awake again, because I know it's just before break, so if we can have the slides up, that would be great. I'll be using those intermittently during my presentation.

So, good afternoon. My name is Shirley Reitz, and I'm the Associate Director for Pharmacy Clinical Services at Group Health Cooperative in Seattle, Washington. So I am also a pharmacist. It's good to see a large panel of pharmacists here today.

So thank you for allowing me to speak today about Group Health's successful program. You've heard a little bit about it,

but I'm going to spend a little bit more time going into some details about how we actually did this program.

I also want to, before I start, really share with you that Group Health did support the legislation that went forward. And we really do appreciate the leadership of the Group Health delegation members, particularly Congressman Jay Inslee, Senator Patty Murray, and Senator Maria Cantwell with their continued efforts to extend the reach of secure, effective drug disposal programs to keep our children, environment, and community safer.

So, just a little bit about Group Health. We are a non-profit tax-exempt health system that provides both coverage and health care to over 650,000 patients in the State of Washington and also in the upper corner of northern Idaho.

About two-thirds of those patients actually receive care from our owned and

operated clinics that are throughout Washington and in northern Idaho. So actually, we have about a thousand physicians that work for us. We contract with about another 6,000 physicians in 44 hospitals across the state.

Group Health also supports a foundation who supported or provided some of the seed money for the pilot that we did four years ago on the medication disposal, and also the world-renowned Group Health Research Institute.

So, earlier this morning, Dr. Condon had -- from ONDCP gave a brief description of our program when he talked about the Group Health and the Bartell take-back program, so I want to go into a little bit more detail about that.

So, in 2005, in the Seattle area, a multi-disciplinary team that included representatives from health care, governmental agencies, law enforcement and non-for profit

agencies came together for the purpose of exploring a way to provide a secure and environmentally sound program for managing the ongoing disposal of medications no longer wanted or needed by their users.

We had data from a 2006 King County survey of over 400 residents that led this development team to understand that consumers were far more likely to safely dispose of their medications if the disposal site was easily accessible to them.

In this survey, 84 percent of the respondents stated that the pharmacies fit that bill. So we went about designing a process for which medications could be collected from the consumer easily, using a system that was available at any time and on any day, that the collected medications could be stored securely, and that they could be disposed of using an environmentally sound method, in our case, a high heat incinerator at a waste energy facility.

Now, as a practicing pharmacist, I know that consumers do not often know which medications are controlled and which ones are not.

And in fact, in our experience, we found out that there are also health care professionals that sometimes don't know what controlled substances are and are not, mainly because patients are bringing back stuff to us when we did screenings of them that were from the 40s, the 50s, the 1960s, drugs that are no longer commercially available, and they'd look at them and say, I have no idea what this is.

So there are lots and lots of old drugs out there.

So, when we set up our program, we hoped to allow patients to use it for all medications, and we designed this system to meet the security requirements of a controlled substance collection.

So under the oversight and the direction of the Washington State Board of

Pharmacy, we developed a protocol that included the following security measures.

So, I want the next slide to come up, and what do I need to do to have that happen? It's not happening. Ah, there we go. Good. Okay.

So, first of all, we had to design a disposal bin. This disposal bin had a locking top and a front that contains interior baffle that allow consumers to drop containers of medications into the opening while preventing unauthorized access.

This disposal bin was mounted to the wall or to the floor of the clinic pharmacy waiting area, was within visual line of sight from the pharmacy windows, and was in an area that had security camera surveillance.

Signage on the outside, as you can see, of the metal container told the patient what should and should not be placed into the receptacle.

Next slide. Thank you.

The container on the inside of the bin is accessible only by licensed pharmacy personnel, and required two people with access to a different set of keys to open that front.

The keys are logged in and out, and systems have been developed to prevent any single person from having access to both sets of keys.

Once the container on the inside is filled, it is sealed, and an individually-numbered tag is threaded through small openings on the seal.

Paperwork is filled out recording the container number and the tag number, and this is faxed to a centralized pharmacy warehouse to notify them that a filled bucket is en route.

The sealed container is placed inside one of our pharmacy totes for transportation back to the warehouse. And once there, the containers are checked in and placed in locked cages in a secured,

centralized pharmacy warehouse for a short period of time, until the contents can be quickly screened by licensed pharmacy personnel.

Now, this screen is done under video surveillance, again, with at least two licensed pharmacy personnel present.

During the screening, the pharmacist is looking to remove items as required by the incinerator that we use, namely, iodine-containing products that turn their plume pink and mercury-containing thermometers.

Once these containers are sealed in the pharmacy, at the clinic pharmacy, the only time they are opened again is during this screening in the centralized pharmacy warehouse. And again, as I said, this is done under video surveillance.

The screened medications are then placed into 15-gallon boxes, sealed for transportation by a state-licensed reverse

distributor to the incinerator.

Using the tags that I mentioned earlier, we can track each bucket from the clinic all the way through screening, into the boxes, and ultimately to the incinerator.

Since 2006, we've had this program up and running continuously on our 25 pharmacies across the State of Washington. And in addition, Bartell's Drugs, a retail pharmacy group in the Seattle area, also has a number of pharmacies doing this as well.

Despite the fact that we have done little to no promotion of this service, during that time, we have collected and incinerated over 47,000 pounds of medication, averaging about 1,000 pounds per month, about 33 pounds per day, day in and day out.

Most importantly, during the past four plus years of this program, we have had no instances of diversion, and are confident that we have built a program that is both convenient for the consumers and secure.

Now, because this was a newly-developed program, we carefully tracked our costs. In 2009, we collected and incinerated 14,206 pounds of medication. Our cost, including personnel, materials, and disposal was approximately $66,700 for the program, or about $4.70 per pound.

On average, this program costs our pharmacies about $2600 for the year. Now, half of this cost is due to incineration costs, which can be substantially reduced by relaxing requirements of the hazardous waste incinerator companies around accepting controlled substances.

Now, a number of speakers have already addressed the issues of long term care facilities, so I'm not going to go into any detail there, but I do want to let you know that we, over the course of our two-year pilot and the subsequent continuation of this program, we have had many long term care facilities contact us and ask us if we were

developing a process that would work for them.

These patients are often on ten or more medications, and changes in dosing or drug can be frequent due to side effects, adverse drug events, or drug interactions, which result in large quantities of medications that will not be used and need to be destroyed securely and effectively.

Programs such as ours have demonstrated that there are secure and effective programs in existence already, and that the regulations this committee developed should not impede these current programs from continuing their impressive work.

Our experience over the past four plus years show that consumers have a lot of medications in their homes that they do want to discard in a safe manner.

Options for consumers must be made available, including physical drop-off sites that are convenient to the public, such as pharmacies.

As demonstrated over the past four years, programs such as ours, which are accessible to consumers, security protocols are in place, overseen by an authorized agency such as the State Board of Pharmacy, can and will result in consumers taking advantage of this service and removing these unwanted and unneeded medications from their medicine cabinets, reducing the potential for diversion that can and is happening in the home.

I am confident that these same secure protocols can be implemented in other pharmacies as well, so I strongly encourage the DEA to consider and to allow pharmacy medication take-back programs that follow strict protocols and are under the overview of an agency such as the state's Board of Pharmacy, such as our program.

I believe we have demonstrated this program is both effective and secure.

Thank you for your time.

(Applause.)

MR. CAVERLY: Thank you, Shirley. Our last speaker for this block is Daniel Turissini.

MR. TURISSINI: So I'm the tenth guy. I've got a good arm, good glove, no bat.

(Laughter.)

I coached high school baseball, so I know how that is.

My name is Dan Turissini. I'm not directly involved with this industry. I'm a local entrepreneur and technology developer. My wife spared you, I don't have my pocket protector with me, but I think I can speak to this.

We've heard and we are going to hear a lot of speakers in the disposal, law enforcement, and medical fields. I'm speaking to you not only as a technologist but a parent who unfortunately has been close to this subculture of recreational pharmaceuticals, and I've seen what it can do.

I also want to tell you that I do

believe that it's not limited just to the home medicine cabinet. There's a lot more going on and there's a lot less accountability in even that closed system than we believe, and we need to address that.

I think he's going to speak this afternoon, but Dr. Gressitt summarized the problem very well, and I quote, "Unused medication that needs to be destroyed is the product of numerous individuals and interveners."

These include the pharmacists, the prescribers, payers, insurance companies, manufacturers, and various industries and influences within the drug use process.

As a technology perspective, I think part of the problem and part of the issue has to be addressed in accountability, and it's a common problem throughout our nation. Like many of the events in recent history, this phenomenon highlights how the processes and infrastructure have failed our

citizens.

As examples, numerous disasters have been witnessed, medical doctors being used to carry sandbags and pass out water instead of being used to address injured persons.

In an effort to protect airline security, we are frisked before getting onto airplanes, and 100 percent of us now have to partially disrobe and go through the security line.

The frustration of traveling in the public increases as the transportation industry struggles to stay financially solvent.

And in the financial industry, we are constantly jeopardized by our personal information being lost by organizations like TJ Maxx and the Department of Veterans Affairs, resulting in hundreds of millions of records of personal data and information being lost.

So where am I getting? Like the other guy, I've got ADHD too, so I wandered a little bit, but now I'm coming back.

In considering all of these, and including this problem we're addressing here, we are missing one of the crucial foundations of our federal government.

While we perform many checks, there is no balance. There is no accountability. One of the big challenges we face today is the conflict between public and private safety. How do we protect the individual and protect the public concurrently?

Sadly, there are solutions available now that would allow us to promote the practice of accountability, if we would only employ them.

The mechanism for implementing the technology exists. It's relatively inexpensive and is widely available through various federal-sponsored programs that could

offer improved citizen access to government information and services, the flow of information within and among different industries and verticals, and reduce our customers' operating costs.

And we talked a lot about cost here. Cost is not just cutting corners. Cost is being more efficient, cost-efficiency.

If deployed properly, the individuals and interveners described by Dr. Gressitt and others would allow the sharing of required information without sharing other privacy and specifics, providing both public safety and privacy.

This is not something that is 100 percent preventative, but is a huge step that would address 90 percent of the problem.

We have not taken action on this because we were looking for the panacea, the 100 percent solution. I don't think that's available. And I think we've got to get moving, and I know the drawbacks in getting

things through the government, but I think we need to apply these technologies even in work flows such as this. This approach is different than trying to protect private data. Currently, we take great strides in trying to protect information and protect who is providing the information and who's putting the drug in the box.

But it's a lot easier to protect the transactions themselves, and a lot more pragmatic. And much of that data is already in the public domain anyhow, so protecting it is kind of counter-intuitive.

Simply applying this technology to work flows that we've heard, and all of these work flows are great, but without accountability, they are somewhat useless.

They would dramatically increase the accountability of the work flows, like those needed to secure responsible drug disposal. More importantly, it would decrease the fraud within these work flows, and we all

know that when we decrease the fraud, we dramatically decrease the cost of the work flow.

So what is required to make this happen? Simply, action. Serious review and balance of policy, not just changing happy to glad, to build public confidence and to establish clear lines of accountability and responsibility. Complete and comprehensive electronic, editably procedures, cut out all the paperwork. Make it electronic. Use digital signatures. Make it quick and easy and more efficient.

Education of all sectors, both public and private, leveraging forums for discussion and action like this, and funding significant applications that address a non-controversial problem, for example, the secure and responsible drug disposal, work flows described in this forum.

This can easily be initiated. There are three specific actions that serve as

the catalyst for industry and government alike to fully adopt accountable workflow solutions that leverage existing digital signature technology.

Appropriate funding, one, of secure and responsible drug disposal work flow applications that are enabled to use and transact business with strong mutual authentication, strong identity identification, and digital signature to ensure non-repudiation of these transactions. And this can be accomplished leveraging current OMB initiatives.

Number two, appropriate promotion for the deployment of strong identity credentials, not only within the industry and the government, but out to the citizenry of the United States, as well as increase education and awareness of accountability transactions for public, private, and government sectors.

And third, enforce the requirement

for digitally signed transactions and mutual authentication for all related transactions, and provide incentives to the industry for commercial sector to leverage these and implement similar initiatives.

To coin a phrase, trust but verify. And I think the verify piece is very important. Our kids are very smart, and no matter what we put together, they're going to find a workaround.

As a bonus, this approach will afford efficiencies that our efforts to address disposal and diversion can benefit from in terms of minimizing the overall cost of operation. You don't have to cut corners to cut costs.

As an expert in the field of information management and accountability work flow, non-repudiation of systems, I stand by, ready, as is my organization, to do our part in ensuring what I believe should be the secure, responsible, and accountable drug

disposal systems.

I thank you for the opportunity to speak, and I thank you for your dedication to this very important initiative.

(Applause.)

MR. CAVERLY: That ends our block of speakers, so let's go ahead and take a break.

We're running a little ahead of time. I have about 25 minutes to 3:00. Let's try to come back at, say, five minutes to 3:00.

(Whereupon, the above-entitled matter went off the record at 2:36 p.m. and resumed at 2:58 p.m.)

MR. CAVERLY: Can you hear me? Okay.

I got caught up here, I apologize. I try to keep us on time. We're a little bit ahead, so that's a good thing. But I apologize. I got caught up in some conversations.

Amanda is doing the time. Is that right? Amanda, raise your hand so the speakers can see you.

If you think John Purcell is mean, oh, man.

(Laughter.)

So watch out.

As we start into our next block, we have our speakers. We have four speakers and five chairs.

We're missing someone. It'll be the first six. We only have five chairs, so how can we do the -- oh, we're missing -- okay, never mind.

So who is six? Jeanie?

Why don't you come join us up -- here we go. It's like musical chairs, isn't it, almost.

Well, this is the home stretch. We've been using sports analogies this morning, and baseball players, and I guess we're now in football team area. We're past

nine -- we're actually past eleven.

I was in the Louisville, Kentucky, office for 16 years, and of course, the Kentucky Derby is celebrated the first Sunday in May. So we're on the home stretch. We'll use a racing analogy this afternoon.

So, Steve Gressitt is our first speaker. Dr. Gressitt, if you're ready?

DR. GRESSITT: Thank you, Mark. I tore up my speech. So much of it had already been said, I thought I'd try to go elsewhere.

There are five primary models of consumer unused drug return. I'm the medical director for an institute that was set up in Maine between two schools of pharmacy, a school of medicine, and the Center on Aging, which was the administrator for the Maine mail-back program.

Our institute supports three of these models to continue with clearer articulation by DEA of rules, namely law enforcement site drop-off, law enforcement

pickup, as Roy McKinney referred to, Chief Gahagan, and law enforcement controlled drop-off events.

We declined to support efforts to return drugs to pharmacies for end collection, and note that even if the DEA did authorize this, FDA rules on banning samples from pharmacy would make this problematic.

We recognize the value, however, of pharmacy consultations, and believe that can be encouraged with the fifth model, the mail-back.

Consumers can bring [drugs] into a pharmacy for a consultation, but at that point, after the consultation, a mailer could be provided for the drugs not to be stockpiled there or in a box, but shipped on immediately and gotten out of harm's way.

This, however, -- and this also avoids any of the OSHA, EPA, DOT, FDA issues.

There are other distribution site possibilities. There has been discussion

about whether the post office could distribute them.

There's been discussion about whether or not they shouldn't be distributed throughout the school system as a way to educate children in prescription drug abuse, and to normalize the behavior at an early age of getting rid of excess medication.

As far as the mail-back program, in 2007, the U.S. EPA awarded a grant to study a mail-back process based in part upon the passage of state law to codify enabling language for the MDEA.

Agreements between the MDEA and the U.S. DEA and the U.S. Postal Service followed after extensive discussions, meetings, and testing of the envelopes to be used, and I lost track of the number of lawyers.

Several verification methods were used to monitor for the diversion, which has not, to the best of our knowledge, occurred.

In addition, by using the Postal Service, inspectors are able to assess diversion independently.

Recently, there has been a suggestion to incorporate either 2D barcode or RFID chips in the envelopes to permit even more secure tracking and tracing.

This technique could eventually meet the electronic tracking standards as specified by the 2007 FDA Amendment Act, which specifies unique device identification capability, following the FDA's issuing its pharmaceutical barcode role in 2004.

An opportunity exists to maintain product identity throughout the entire life cycle of the drug, including destruction, as well as ensure personal accountability for each pill.

I'm saving that paragraph because Roy went over it.

The questions that are asked about how we feel the best way to go or the safest

way to go implies that there's one, and I'm going to join the group of people who have stood here and said that there may be multiple different secure solutions in varying geographic areas or population areas.

We do believe, however, the mail-back is the safest with the least handling involved, which, by itself, limits the risk of diversion.

Universal ability of Postal Service exceeds the availability even of pharmacies across the country.

That said, local, municipal and state and pharmacy board regulations are going to impact or permit or curtail in various ways what the DEA comes up with at the end of the day.

And so it's likely that, for instance, in Maine, our strict environmental rules are going to cause great costs, and that's not something that necessarily DEA may have authority or ability to help us out with.

We'd love you to.

We believe that disposal at long term care facilities, which hasn't really been addressed yet, can be addressed with the mailers, working on the following principle, that they are not DEA registrants.

By using two trusted identities at a long term care facility, the drugs left over from the MAR, which is on site, can be logged and with two trusted identities, the data can be sent to a central repository, and the two trusted individuals are responsible for the drugs until they are logged into the post office.

The post office logs them, tracks them throughout the system, and the end point, a newly created reverse distributor, who we shall perhaps name the Terminator Class, receives them, and at that point, also sends verification back to a central database.

This would give the DEA tracking traceability from actual dispensing of the

drug to the long term care facility through to its very destruction and incineration.

Research is necessary to continue. We appreciate the reports of 22 elephants being picked up by the DEA. However, I don't know that they were male or female.

We have tried to count what came back, because we're a research group. Well, we did 100 percent of about one box, then it went to 75 percent, then it went to 50, and Roy, it's down to 10 now.

It's going to drop lower. But that's for our research. That's not an industrial-scale program. And so, we would like to see a program where there is not each pill counted, but that there's a secure system of getting from the consumer to the destruction point.

Finally, we also need to address veterinarian, agricultural, aquacultural, and dental sources. And then we need to address programs that do not take all classes of

drugs.

There should be a black box warning on any advertising, the size of an FDA warning, because it's confusing to the public. And when one program was put in place that did not take controlled drugs, and the typeface was so minuscule that people couldn't read it, it was confusing to people within the state of Maine.

We need to look at creating a national center on drug disposal, work for independent provision of education, and/or advertising of the availability.

We need to consider expanding the Maine program while rules are being made so that there's better data available to the rest of the country for when that can be moved forward.

We need to address prevention of the problem in the first place. Why are we having this problem, and should we be changing prescribing policies and/or insurance policies

which mandate huge dispensing quantities?

And our state has taken into account what the data is that we've created, and CMS is now addressing that nationwide with Medicare Part B, which may, however, come in to be another source of conflict for the DEA if drugs are going to be required to be returned to the pharmacy by CMS regulations.

Finally, hospice is a group that needs assistance, and that can be handled, we think, with a mailer, safely.

And finally, there are school nurses who have collections of drugs at the end of the school year.

And finally, most importantly, no business model has yet bubbled up, and folks who are trying to do the research are beginning to feel that it needs to come soon, that there may be a variety of different funding mechanisms.

I thank you for your time. I might have time for one question.

Okay, thank you.

(Applause.)

MR. CAVERLY: Thank you, Dr. Gressitt.

Nadine You?

MS. YOU: Good afternoon, everyone. My name is Nadine You and I'm the President of EXP Pharmaceutical Services. We are headquartered in California, and we are a licensed reverse distributor.

We are in our 17 year of business. And our company and others like ours are in the business of taking back expired and unwanted drugs every day.

That's our core business, from pharmacies, Department of Defense locations, Department of Veterans Affairs locations, hospitals, anywhere that drugs are dispensed, we handle their expired and unwanted drugs, but they are all registrants. We aren't able to help right now in the consumer take-back or with our long term care facilities.

I want to thank the DEA for giving us the opportunity to speak today and to give our opinion on what we feel is a good option or several options, as people have said today, for this problem.

We also are very excited about the passage of the Secure and Responsible Drug Disposal Act, and we appreciate the opportunity to take a greater role in ensuring the safe disposal of unwanted pharmaceuticals.

Reverse distributors already handle these drugs, including controlled substances, every day, as a normal course of business.

As an industry, we are licensed and regularly audited and inspected by the DEA, the EPA, the FDA, and our state and local authorities.

We also have pharmacy licenses from almost every state, or every state that requires a reverse distributor to have a license.

Most reverse distributors are also verified, accredited, wholesaler distributors, which is a certification given by the National Association of Board of Pharmacies, which requires a very extensive audit, inspection, and renewal process every couple of years.

So as you can tell, we're very highly regulated. People with badges show up at our facilities whenever they feel like it, and we welcome it, come on in.

We also receive requests every day, whether it be over the phone or onsite service representatives from our customers who have patient-owned medications, these are the medications that have been dispensed to a patient but then not used, to help them with that problem, and we cannot do it.

We get requests from long term care facilities, veterinarians, dentists' offices, doctors' offices, Department of Veterans Affairs.

Ultimate users get our phone

number from agencies and they call and say, you know, Grandma passed away and I have these drugs. Can you do something? And we say, sorry, ma'am, we can't, or sorry, sir.

We are very glad that that could change.

We strongly support a mail-back program as has been described by other speakers today. We believe it's the easiest and safest manner to dispose of controlled substances.

An ultimate user living outside of a residential care facility could use a mailer, a secure mailer, as people have said, tamper-proof, postage-paid, sent to a reverse distributor.

We believe it should not be opened, that we should just receive them sealed, weigh them, log them, and have them incinerated.

Also, in our business, every day, we have -- well, every year, hundreds of

thousands of pounds of disposed pharmaceuticals are incinerated by reverse distributors.

We use medical waste incinerators, and for controlled substances, we send witnesses to these incinerators to witness that destruction.

We believe we would use [the] controlled substance incineration process for all returned, unwanted pharmaceuticals from consumers. We would just assume controlled substances are in there and witness it.

The mail-back program, we believe we could have pre-addressed envelopes to the reverse distributor that the pharmacy uses.

Almost every pharmacy in the United States uses [a] reverse distributor. They do not handle their own expired pharmaceuticals from their stock themselves.

This industry was born over 20 years ago, almost 30 years ago now, because it became too laborious for pharmacies and for

pharmacists to do it. There is not enough time.

So, for it to come directly to us, we already have personnel who are trained and who are background-screened and drug tested and the whole thing. We already exist.

I know a lot of people want to add new registrations, and that's the DEA's choice to do that, but there is a resource that exists already, and that is the reverse distributors.

Long term care facilities are in dire straits. They really need a viable option. We also believe that we can be that option.

In our case, we have a contract with the largest long term care facility pharmacy services organization to handle the stock from their distribution centers. But they can't even take the drugs back from their homes that they manage or that they supply, and therefore, we can't help them with that

either.

We do believe that there is a high risk of diversion in the long term care homes, leaving those drugs there. And as people have said, either when a patient leaves, dosages are changed, or someone passes away, they're left with these drugs and no viable way to do it. Flushing it is not a good choice.

The volume generated from a long term care facility would probably require common carrier usage rather than the Postal Service, so we encourage DEA to discuss that with the other agencies involved with that kind of regulation or guideline. It wouldn't be regulation, probably a guideline.

We also feel that the other take-back models that have been discussed today, whether it be pharmacy, and again, almost every pharmacy in the United States uses a reverse distributor, so if a pharmacy is going to take-back in a secure drop box, they can still send it on to their reverse distributor

for secure and safe disposal.

We can be a resource and a partner in the solution for this problem.

Our industry has always been concerned about the environment and about diversion. We have always used medical waste incinerators. We do not landfill anything.

There is no chance for diversion. Everything is sealed, witnessed, and it's been proven, it's a proven model, because we do it every single day of our life.

So we really look forward to the opportunity to be a part of the solution, to help our youths stop diverting drugs and using drugs. I'm also a parent of a teenager, so I worry about that myself. Hopefully he'll just stick to baseball. Everybody's been making baseball analogies today, and I've been like, yes, I love baseball.

So, again, we look forward to having the opportunity to be a part of the solution. And we really thank the DEA for

allowing us to come here and speak.

And we're very happy that Congress passed this act and that the DEA has worked so far to get to this point, because in the end, it's all about reducing that diversion, keeping the environment clean, and reverse distributors are here to help.

So thank you again.

(Applause.)

MR. CAVERLY: Sierra Fletcher was kind enough to switch with Phil Burgess, so I won't introduce Phil Burgess, I'll introduce Sierra Fletcher.

MS. FLETCHER: My name is, in fact, Sierra Fletcher. I'm the Director of Policy and Programs at the Product Stewardship Institute.

We're a national nonprofit organization based in Boston, Massachusetts, and we have a membership of 46 states, more than 200 now local government agencies from around the country, more than 60 -- let me get

this -- corporate, organizational, academic, and non-US government partners that we work with.

And so as you can see, I'm never alone, anywhere I go, talking about anything. Many of those folks that we work with everyday are right in this room.

So I want to speak a little bit about the work that we've done on the pharmaceutical issue. We come from the perspective of being interested in reducing unintended impacts of various consumer products.

So, I am talking about pharmaceuticals, which, to me, fits in line with a number of other products that have unintended impacts, often on the environment, associated with their manufacture, use, and often disposal.

So a couple of years ago when I started working on this project, we pulled together a regulations work group which was

back before we knew it really needed to be a statutory change work group of people who are interested in figuring out a better way, or meandering through this system and developing a way that controlled substances and other drugs could be collected in compliance with all of the various laws that you're also familiar with from the federal down to the local level.

In working with that work group, last week we developed some recommendations which I submitted as part of PSI's written comments to the DEA. But I'm also glad to be able to present them now to you, in person.

And I'll be glad to share a copy of these, because I did send it out last Tuesday to our contacts around the country. And 119 organizations, companies, or agencies or individuals signed on in the past week, the last one right about noon.

Now, so before making the remarks which are going to be very repetitive, which

is a bit inevitable, because I'm identifying areas where I hear a lot of consensus, we've heard a lot of consensus on some of these points already today, I'd like to tell you a little bit more about some of the people on whose behalf I am speaking directly in these remarks.

It includes six state government agencies, from states including Georgia, New York, and Tennessee. Two state legislators, 32 local government agencies from around the country. A couple of examples are the City of American Canyon, California; the Redding Health Department in Redding, Connecticut; the Waste Commission of Scott County, Iowa; the City of Lincoln Public Works in Nebraska; the City of Oklahoma City in Oklahoma; the Northeast Kingdom Waste Management District in Vermont; and the Marathon County Solid Waste Department in Wisconsin.

There are six groups that represent either law enforcement or

specifically substance abuse organizations, the Chief of Police from Chittenango, New York and the Utah County Division of Substance Abuse are among those.

Also, 31 organizations related to the environment and health, which is, when I introduce PSI, you probably understand that we work a lot with these kinds of groups. It includes the California Association of Sanitation Agencies; Healthcare Without Harm; the P2D2 program started by Paul Ritter and Eric Bohm in Illinois; Physicians for Social Responsibility in Austin, Texas; Practice Green Health; the Texas Campaign for the Environment, and the Washington State Nurses Association.

Also, eleven companies including pharmacies, those in the waste industry, and consulting firms, including Bartell's Drugs, who we've heard about from Washington State's program, and the Iowa Pharmacy Association, and then more than a dozen individuals, which

is actually 31.

I did eventually count, because I had a few moments there, signed on on behalf of themselves, and they gave their affiliations, but weren't able, within a week, to run these things up the chain.

So, in making the -- I acknowledge somewhat repetitive remarks I'm about to make, I'd just like you to bear with me in understanding that this is not just me talking, these are -- I represent a lot of people who wish they could be here today, but especially among the local government folks, weren't able to travel to come and represent their interests directly themselves.

So we think, as you've heard before from many others, that a wide range -- not a wide, a range of options is needed to be able to meet both the cost concerns and the logistics and the priorities and the demographics within our diverse communities.

These should include mail-back

from the home, and we look to the Maine model as providing a good example in many aspects, including tamper-resistant, tamper-evident envelopes, nondescript envelopes using track and trace technology, etcetera.

We like the idea of collection at retail pharmacies. We've learned a lot from the program in Washington State.

I'd like to make it very clear that from PSI's perspective and as stated in the document endorsed by these groups, not all pharmacies might want to choose to play this collection role, and I think that that's fine. I think it needs to be voluntary.

And for the pharmacies who do choose to do so because their staffing allows it, because they're able to demonstrate that they can comply with strict security protocols and be overseen by the appropriate regulatory authority in their state, many of them are, in fact, well-placed in their communities to provide this kind of service, and we've heard

some of the other benefits of pharmacy involvement as well.

We think these same kind of security protocols can be applied in other settings and communities. Law enforcement collection for sure should continue. I really like the work that's been done around this issue around the country, but I also think that fire stations, clinics, and hospitals, again, are other options to choose to provide a take-back collection site or collection events under security protocols.

Collections should include all prescription drugs or all pharmaceutical drugs, I should say, not only the controlled substances. It's much more efficient.

The consumer doesn't know the difference, as we've acknowledged, and I think a container of drugs is much less attractive for diversion than a container known to contain only controlled substances.

Those drugs that are shipped by a

common carrier for the purpose of disposal should be tracked throughout the process using track and trace technology. I think the common carrier option is one that should be available.

And I've heard an awful lot of requests that the information, and I think that this is exactly what the DEA intends to do, that the information coming from the new rulemaking should be communicated clearly and consistently around the country, and so, recognizing that for now, we have a patchwork of programs that are happening all over the country, and they need to understand how to comply with the new regulations.

And also, as we've heard, the drugs that are collected should not have to be inventoried.

And finally, we suggest and echo as others have done that the regulations should be developed in consultation with the EPA and recognize the local, state, and

Federal environmental requirements.

Separate from this endorsed statement that I've just presented to you, I'd like to just make a couple of remarks on other aspects of the issue that PSI is very interested in and we've been working on.

I think there's a lot of work to be done on waste reduction. I'm very excited by the new language that I see developing, short-cycle dispensing, initial prescription limitations, partial fills of prescriptions.

And I see the industries that deal with these very complicated transaction sets already working to figure out how to make this happen, not just in the context of the new rulemaking from the centers through Medicare and Medicaid services, but perhaps even more broadly than that, and I support those efforts.

And it's also been alluded to and mentioned a number of times today, who should pay for these programs? And I think that

there do need to be a range of options.

But the model that we would look to at the Product Stewardship Institute is a shared responsibility throughout the system, and everybody having a role to play, but putting the primary financial responsibility for doing take-back programs of whatever stripe they may be on the companies that are the brand owners that produce the drugs.

This isn't all that far-fetched. As we heard this morning, it's being done in British Columbia, under a law. It's also being done in a couple of Canadian provinces, the same companies that sell the drugs here in the U.S. are implementing it voluntarily in a couple of provinces in Canada.

And a few companies have already started collecting the medical sharps devices that go along with their self-injected drugs in California, and providing for their collection there, here in the U.S. So this is an option that we're interested in exploring

with those who would like to join us in doing so.

And I thank you again for your attention to the issue, your expeditious response after the passage of the law, and I look forward to continuing to comment on the rulemaking.

(Applause.)

MR. CAVERLY: Thank you, Sierra.

Next up is Mary Hendrickson.

MS. HENDRICKSON: My name is Mary Hendrickson, and I am the Director of Quality and Regulatory Affairs for Capital Returns, doing business as GENCO Pharmaceutical Services.

I am also a pharmacist, and have spent many years of my career working in a variety of practice settings, including long term care pharmacy operations.

On behalf of Capital Returns GENCO Pharmaceutical, we commend the DEA for expediting its action associated with the

Secure and Responsible Drug Disposal Act of 2010. We appreciate this opportunity to present at this meeting.

GENCO Pharmaceuticals Services is one of the largest reverse distributors in the United States. We receive unused, expired, and/or recalled medications from multiple large pharmacy chains in the US, as well as managing pharmaceutical returns on behalf of many pharmaceutical manufacturers.

I recognize that you've heard from a lot of reverse distributors today.

Currently, only a small subset of reverse pharmaceutical distributors have systems in place to manage processes on behalf of pharmaceutical manufacturers. GENCO is one of those reverse distributors.

As a result, GENCO Pharmaceutical Services has made significant investments in technology to manage pharmaceutical returns from a variety of sources.

We have systems in place to not

only handle a large volume of product, but we also have systems to handle patient returns in the event of a recall.

In fact, we currently manage multiple recalls simultaneously. While many recalls are not at the patient level, we have managed patient-level recalls, including controlled substances, from patients who are ultimate users with the DEA exemption provided for swift retrieval of the product in this circumstance.

As we have heard throughout the day, it is important that we acknowledge the significant need for consumers to have a method to dispose of unused medications to decrease the likelihood of abuse, misuse, and accidental poisonings.

In addition, while the cause of pharmaceutical contaminants in our environment is likely from a variety of sources, removing any contributory sources, such as consumers flushing their medications, is an important

factor for consideration when reviewing the problems associated with unused medications from patients or ultimate users.

As a company that supports the collection of unused medications from consumers or ultimate users, we have been actively engaged in national and local meetings, work groups, and other events associated with the collection of consumer medications.

We have received feedback. The consumers thought highly of a mail-back method for their unused medications.

However, we have heard, as we have throughout the day, that there are interests expressed in other methods that were equally convenient for consumers, such as a drop-off box or kiosk in a location that is easily accessible.

In recognizing that it is paramount that rules be created which support a consumer medication collection program, we

support multiple methods for this activity if the methods meet the standards of security, safety, accountability and reporting to prevent the diversion of collected product.

We further recommend that utilizing the most environmentally friendly method of disposal renders the controlled substance and other pharmaceutical product non-recoverable. At this time, this method would be incineration at a regulated incineration site.

Based on our experience, a mail-back method currently meets this requirement, and removes the medication from people's homes the quickest.

As you have heard earlier, we did manage a pilot program for medication collection utilizing a mail-back method in Wisconsin during 2008.

For clarification purposes, we actually utilized a common carrier at the time, as opposed to the U.S. Postal Service.

The program was successful as a feasibility trial to determine if consumers would utilize a mail-back method. In addition, it gave our business the opportunity to evaluate incoming consumer return compliance.

Specifically, we were able to determine if consumers would follow the general instructions regarding the return of the product and to what extent the labeling would remain on the product.

During this program, we managed the returns exactly as we would manage any return to our business. This included tracking the receipt date, inspecting the container upon receipt for damage or compromise, as well as capturing the medication name, NDC number, and quantity returned.

In addition, we segregated this product based on the rules of the Resource Conservation and Recovery Act, or RCRA, into

its appropriate non-hazardous or hazardous categories, although it's important to note that this is not actually necessary, since household waste is exempt from RCRA.

It's important to note that, on average, over 90 percent of pharmaceuticals that are returned through reverse distribution, whether its household or trade returns, are actually non-hazardous as opposed to hazardous, so we would not want to categorically send household returns all to hazardous incineration, since, again, household returns are federally exempt. State-level exemptions may vary.

After processing, we send these medications to the appropriate incineration site, as I indicated.

While processing the unused medication in this matter may sound labor-intense, the use of advanced technology, including RFID technology, barcode scanning, automatic certification, among other

technologies, enables efficient and cost-effective methods of accomplishing these tasks.

In addition, technology also provides a high level of security and traceability in handling controlled substances to detect any compromise or diversion.

As a result of easily managing a mail-back method directly from consumers, we are a proponent of this type of method for the collection of consumer medications.

We believe this provides a mechanism to remove the medications from people's homes in the quickest time.

Because we have systems in place to manage the detail associated with ultimate user returns, we can provide full accountability of those returns and recommend that reverse distributors be the DEA registrant category that consumer medications are shipped to, either directly from consumers or after collection.

As a reverse distributor, we have had many of our large pharmacy customers, chain customers, as well as some of the pharmaceutical manufacturers we are contracted with, ask about consumer collection programs for their products.

In addition to the actual collection of the medication, there has been some interest expressed in the data that would be collected as part of the program. Specifically, a consumer collection program managed to the product level could collect significant data about medication utilization.

One of the many examples of the value of the data is associated with antibiotic resistance trends. If the returning zip code or general region is captured along with the specific product information, it could be correlated to antibiotic resistance data.

While we recognize that antibiotic resistance can be attributed to a variety of

sources, including their use in agriculture, providing information about unused antibiotic use in people would be valuable to the pharmaceutical industry, the CDC, as well as other health care professionals.

It's important to note that there may be times or even settings where it would not be necessary or even desirable to collect any detail associated with the return of medications.

In these instances, the product or quantity-level detail would not be necessary as part of the program, but instead, only appropriate security, personnel, and container traceability of a collected return would be necessary.

The collection of unused medications from long term care facilities would be an example of one of these instances, as long term care facilities already have documentation regarding the discontinuation of the medication at the patient level through

the existing rules existing already in long term care.

A mail-back method could work for long term care facilities.

If the DEA chooses to allow for more than one method, and does allow for collection sites, a mail-back system could also work for collection sites utilizing standard collection containers or secure kiosks.

Since pharmacies currently send a collection of unused medications through a one-box method to reverse distributors, the same concept would work for returns from a consumer collections site.

A secure container provided by the reverse distributor or other source could be packaged and shipped to reverse distributors. We believe a drop-off method or collection site may not be utilized as quickly as a direct mail-back method from consumers, but wanted to address the feasibility of both

methods as it relates to reverse distribution.

It is important to note that the materials would have to be shipped via ground transportation and comply with DOT reviews and the carrier's requirements, although we have noted that DOT is having limited transportation with concern with pharmaceuticals in consumer-level packaging.

With the concept of sending consumer collected medication to reverse distributors, we are requesting that the DEA review some key factors for rulemaking. These include the registrant category, the term non-recoverable, as well as the safety, security, and accountability of the program.

First, we are asking the DEA to review the DEA registrant category. We review documentation maintained at our site from a Federal Register notice, Volume 60, Number 163, published in the 1990s.

At that time, the DEA was in the process of reviewing registration category,

and was considering a disposal site DEA registrant category.

Based on a review of a letter from the DEA, we recognized the activities -- they recognized the activities of a reverse distributor will be reviewed.

The disposal facility registration was not utilized at that time because the activities of the reverse distributor [who] was also registered as a wholesaler distributor with the state agencies more closely met the definition of distribution.

In greater detail, the DEA cited the level of accountability and reporting services provided by reverse pharmaceutical distributors and found the information valuable in monitoring diversion.

It is important to note that when I use the term reverse distributor, I am referring to those that are licensed as wholesaler distributors.

Since the DEA utilizes this

category for waste or incineration companies also, we have at times experienced confusion in the industry, including misunderstandings by state environmental agencies that regulate these activities.

It is important to note that the same services for incineration reverse distributors are not the same as those for wholesaler distributor reverse distribution sites.

Because of the confusion that we experience with our activity, we ask that the DEA may want to consider a new registration category, if the DEA chooses to allow for collection site locations.

Refraining from using the term reverse distributor or something similar may provide a greater understanding within the industry.

If the DEA chooses to use a new category, utilizing an ultimate user collection site registrant category would

allow DEA to refine the requirements for security, personnel, collection activities, and transfer to another DEA registrant, such as reverse distributors.

It is important to note that we are not advocating for a dual registration for those registrants that already receive unused medications, such as reverse distributors. We request a refinement of the already existing definition of activities for those registrants, to include take-back from ultimate users in all circumstances, not just recall.

Clarification of the reverse distributor versus an incineration site may also be necessary and may help to clarify the activity. However, we would need the same level of accountability between DEA registrants, so there is a level but competitive playing field.

Specifically, if the DEA refines the DEA registrant category to distinguish the

difference between reverse distributors who are wholesalers as opposed to incineration companies, we want the same level of safety, security, accountability, and record-keeping requirements for both.

In addition to the DEA registrant category, we are asking that the DEA further define the term "non-recoverable."

Reverse pharmaceutical distributors are very familiar with requirements for managing any waste generated at their sites. We have systems in place to segregate waste appropriately and send it to witnessed incineration.

It is important for DEA to consider and to define the terminology it currently uses for rendering a controlled substance non-recoverable.

As a result of participating in multiple meetings and work groups, we have realized that many people are not familiar with appropriate disposal methods after

holding a collection event.

Household waste is exempt from RCRA in categorization at least at the federal level, but we are aware of people mixing the product with other substances to consider it non-recoverable, or using methods like backyard burn barrel, which is not appropriate from an environmental standpoint.

As a result, we ask the DEA to review their definition of non-recoverable, and recommend only incineration based upon applicable federal and state regulations.

Finally, we want to reiterate that a method of unused consumer medication collection is an important topic in the U.S. We are a proponent of a mail-back to reverse distributors to provide a high level of accountability.

We ask the DEA to ensure that the requirements of safety, security, and accountability be met for any take-back site as required by all DEA registrants, decreasing

environmental contamination as well as removing unwanted medications from people's homes is ultimately the goal for all of us.

On behalf of GENCO Pharmaceutical Services, we commend the DEA for the quick response to the act, and thank you for the opportunity to be heard.

(Applause.)

MR. CAVERLY: Thank you, Mary.

Now, I'll tell you how I pronounce your last name, and then you tell me how you pronounce your last name. Jeanie Jaramillo? All right.

DR. JARAMILLO: Wow, you speak even faster than I do.

My name is Jeanie Jaramillo. I'm a Doctor of Pharmacy and a licensed pharmacist, and I currently serve as the Managing Director of the Texas Panhandle Poison Center and Assistant Professor for Texas Tech School Pharmacy.

I'm also a co-founder of

Medication Cleanout, a community medication take-back program in our area. We've had six events since September of 2009, collecting more than 2500 pounds of unused medications.

Five to eight percent of those have been controls, and to put that in perspective, Amarillo has a population of about 180,000. Some of our small, rural communities that we had events in had populations that ranged from 2,000 to 30,000.

As reiterated several times today, there are multiple approaches that are needed to address this problem. What I want to talk about, briefly, is just the role of the community take-back programs. And I want to start with a human interest story.

We tend to focus on controls because we're here with the DEA, but it's really much bigger than that. Our poison control center has received multiple calls, two within the last year and a half, in which small children have been exposed to

medications that have almost resulted in their death.

These two calls were the direct result of ingesting Tessalon Perles. And these are a cough suppressant. They're not a controlled substance.

In one such case, dad dumped these extra pills in the trash can in the bathroom. Mom was running bath water. She brings an 18-month[-old] in the room, continues to run the bath water, finds the 18-month-old child with the Tessalon Perles in their hand.

So, she takes them away, throws them back in the trash, and puts the child in the bath.

Within five minutes, the child was gray and shivering. At that point, she decided he had ingested these medications. So she took him out, fortunately called 911.

Within another five minutes, the child was seizuring, and within 10 minutes, the police officer had arrived, and the child

went into full cardio respiratory arrest.

So that's within 15 minutes of ingesting this product, this child could have been dead, had mom not activated EMS quickly.

It's just an example of what can occur due to unused medications sitting in the home. Something we think that's fairly harmless can be fairly dangerous.

I have to tell you, in my lifetime, I've never been part of an effort that is so necessary, so needed, and so justified, and so hard to implement. So many barriers out there, it's unbelievable.

Our first attempt, when we contacted DEA, poor Cathy had to live through this. We contacted local DEA, they said you need to call regional. We called regional, they said, you need to call national.

I was blessed enough to get Cathy at that point, and she helped me out, although she did have to refer me back to regional.

So it's quite a process.

My hope is that the new rules will be specific enough to provide a consistent approach nationwide.

It shouldn't matter who your Special Agent in Charge is. How an event's going to be managed, if it's going to be managed, should not be at the discretion of a Special Agent in Charge. They should have some sort of consistent policy to follow.

Basically, we contacted DEA and said, we want to send you a letter telling you where our event's going to be and when it's going to be, what law enforcement officers are going to be there.

And they said, no, we don't need a letter.

Now, that concerned me from the point of diversion. No one is tracking these events, which I think is a huge red flag. Basically, anyone can have an event.

And if we're talking about preventing diversion, that's got to stop.

Somebody should be tracking the events and making visits periodically, unannounced.

So as the DEA moves forward in facilitating the removal of unused medications from homes and communities, I also want to push for collaboration between the DEA, the EPA, boards of pharmacy, the Department of Transportation, and DPS and local law enforcement or national local law enforcement associations. We need guidance on how to responsively do programs.

There is a need for them. There will always be. Even if these become available through pharmacies nationwide, something that's available all the time, people tend to stop thinking about it. So I think there will always be some need for community take-back events.

I do recommend that we no longer separate controls and non-controls. I propose that the sorting process itself may lead to diversion.

We're sorting all the components and saying, hey, these are your heavy drugs, and we're putting them in one nice little box, which seems counter-productive.

Some pharmacies, including those in Texas, in order to deter theft, will actually disperse controlled substances throughout the stock. That seems like a reasonable approach for these events as well, particularly for dumping them out. It's much harder to identify an oxycodone that's in a box with 50,000 other pills than it is if it's separated.

I would also like to suggest that you consider credentialing pharmacists or other professionals to manage collections that may include controls. Law enforcement agencies are stretched very thin right now. It's a barrier to events right now.

One out of every three law enforcement agencies we contacted declined to participate due to the burden of storing the

medications in their evidence lockers or evidence rooms and then destroying them.

Some of them require line-item inventories for controls that go into their evidence rooms, and it's a very onerous task for them.

Okay. This obviously would require waste management companies to be able to accept not just non-controls, but the controls as well.

Should the DEA continue to take the stand that the management of controls must remain in the hands of law enforcement?

We suggest that the DEA provide the opportunity for law enforcement to turn these items over to the DEA for disposal, so that local law enforcement agencies aren't burdened with having to store these locally and destroy them with local funds.

So, in that case, I would suggest the DEA accept controls and facilitate disposal to remove the burden.

I've already mentioned keeping a list, maybe a national public registry of events that the DEA maintains for tracking purposes, but also to notify the public.

I strongly feel that no event or system should exclude controls. We've discussed over and over and over today that the public doesn't know what they are. Frankly, we don't want them to. It's a red flag that these items can be abused or sold on the street.

There was one program that was conducted at a health department, and it excluded controls. And they said, I'm sorry, these are controlled substances, we can't take these.

And one of the participants simply walked out in the lobby and put them in a chair and walked out the door. So situations like that will be repeated if controlled substances are excluded. In terms of data collection, multiple presenters today

have discussed the cumbersome nature of cataloging collections. I agree wholeheartedly that there should be no requirements for data collection, besides perhaps weighing the items.

However, there are programs that can collect data and need to. There's a great need for data collection to assist with a root cause analysis. This whole conference or public meeting is focused on the back end of the problem. The meds are out there, they're not being used.

In order for us to address this at the front end and do a root cause analysis, we've got to know what these items are, and the only way we can do that is to catalogue the items.

Again, I'm not proposing that every program do this. I'm proposing that programs who wish to collect data be allowed to, and not discouraged or prohibited, as was done with the last DEA take-back event.

From our experience, from cataloguing the items that come in, we've identified problem areas.

Samples are a huge problem area. Nebulizer solutions generally come in a box of 100 unit doses. If you have a child with an acute respiratory illness, they may need three or four doses. You're stuck with 96.

Laxatives are marketed in 24-count or 30-count boxes, and generally people bring those in to dispose of, there's 21 or 22 left.

Five hundred count bottles of aspirin or Tylenol, these are just examples of what we're finding by cataloguing the items that come into our event.

Without data, this is really a losing battle. This can be compared to the argument by the pharmaceutical industry that it's okay to put medication in landfill. There was a big stand that landfills do not result in medications in the water until studies were done that showed that is not the

case, that leachate does result in medications leaching into the water.

The pharmaceutical industry denied that. I think we're in the same situation here.

So again, I suggest that the DEA not prohibit or discourage data collection.

Other obstacles. We currently, with our program, with our university, have a contract with a waste management company. We pay about 25 to 30 cents per pound for incineration.

I suggest that we not require items to be incinerated as hazardous waste. If they have to be incinerated as hazardous waste, they can cost up to $8.00 per pound, so incineration that for us costs $250 could be $6,500, making many programs cost-prohibitive.

I also think that the DEA should be cognizant that there's a potential conflict of interest with waste management companies, just for this reason, $8.00 per pound for

incineration versus 25 cents per pound, just something to consider.

Education is very necessary. We've all discussed this. We need to educate the public about the problem. I suggest a partnership with public health organizations or established network of poison control centers to assist with these efforts.

And lastly, suggest that -- people laugh at me with this one, I'm sorry -- drug seizure funds be used, in addition to pharmaceutical industry funds to fund these programs.

All right.

Again, thank you all for having us and allowing us to speak and give our opinions.

(Applause.)

MR. CAVERLY: Derrick Bell?

You were afraid to sit up there with the rest of them, weren't you?

MR. BELL: There were no chairs.

I'm bringing up the rear.

MR. CAVERLY: I'm just giving you a hard time.

MR. BELL: I'm bringing up the rear, with the Kentucky Derby. I was kind of hoping we would keep with the football analogy, and two-minute warning sounds a lot better, but as my wife tells me, I kind of resemble the fleshy part of the horse sometimes, anyway.

(Laughter.)

You can see on the slides there, I've got five slides, ten minutes, two minutes a slide, so I think we're good.

I am Derrick Bell, work with the North Carolina Department of Agriculture and Consumer Services. The program I manage is the pesticide disposal assistance program.

We are part of the Structural Pest Control and Pesticides Division, but in the Department of Agriculture, which is kind of a little bit offbeat for what everybody's here

for, we also have a Food and Drug Protection Division as well as a Veterinary Division.

At times, we do get requests to dispose of veterinary medications, and people will also bring their own human medications, so, next slide please.

Just a little bit about our program, and like I said, we do have a little bit of tie-in. Our pesticide disposal program was the first in the nation in 1980. There are lots of similarities between our program and what were termed by Mr. Galvin in -- what year was that, for HHW, household hazardous waste programs, there's a lot of similarities between pesticide programs and HHW as well.

Waste streams included in HHW could easily roll in pharmaceuticals as well. We typically get about 140,000 pounds a year of pesticides.

We have a competitive bid. We try to -- we have 100 counties in North Carolina, and we try to be in every county once every

other year. We're usually in a neighboring county every six to eight months.

We are proposing to add pharmaceuticals to our collection program and waste streams, but we know we're not going to be the be-all, end-all. We're not going to be everywhere at once. We're not even going to be everywhere every six months, so we're just trying to help.

We're trying to find a way that we can help. We've got an infrastructure in place to do collection programs, and we thought it was a real good fit.

And through our Commissioner, who has backed this, we were going to fund or will fund the pharmaceutical waste stream.

Next slide, please.

I kind of hinted a couple of times, I think it must have put the bullets in -- there you go, just go ahead and hit it. There you go.

HHW, household hazardous waste

collection, these are some older numbers. Thirty-eight counties out of 100 in North Carolina had HHW events in `07. That varies, obviously, depending on funding, resources.

The permanent facilities in the state, there's about eight to ten. A couple would like to come online here soon. DEA can kind of consider those permanent HHW facilities as well, hopefully, like they do a reverse distributor or whatever.

But I am involved with a Household Hazardous Waste Council in North Carolina. We try to jumpstart or kick start HHW programs around the state.

We have a good method for doing that, because we pay for the pesticides to be disposed of, so everybody likes the guy who's going to pay the bill. So we're pretty popular in getting HHW started or helping to get them started.

The cost efficiency's improved when HHW and Ag collections are combined. As

I said before, pharmaceuticals can roll right in with HHW.

The ultimate user is obviously the household. Several -- for lack of a better term, loopholes in laws and regs include the HHW exemption that hopefully the pharmaceuticals will be rolled in on that.

Next slide, please.

The problem with the situation in North Carolina, there's no procedure for the public to get it done, including the veterinary medications.

Like I said, we have collection days where people will bring their veterinary medications lots of times and in addition bring their own.

Utilizing the existing infrastructure of what we have in place for state-wide pharmaceutical disposal would go to help, especially those rural counties that do not have HHW programs.

Funding, we are prepared to fund

the pharmaceutical waste stream for disposal through these HHW programs as well as at our collections. That does not include long term care facilities or any businesses or anything like that.

Products that are flushed or added to household trash, that's the whole reason HHW started out. It was a problem at the municipal solid waste facilities with people getting injured or whatever, taking the HHW out of that, so it stands to reason that you can add pharmaceuticals to that as well.

Establishment of the infrastructure of the PDAP and HHW programs through the state could help eliminate that problem and reduce diversion as well.

The collection itself, partnering with local law enforcement to oversee, we've had support from several sheriffs in the state, and the Sheriffs' Association as well, and everybody's ready to do it.

Nobody has the money to do it.

That's the big problem, so that's where we hopefully can come in and at least fund that waste stream, pharmaceutical waste stream.

We agree with lots of other folks that have been up here. It should be co-mingled due to the lack of funding to supply the personnel needed to get it done, so it's going to be much easier, not only on the front end to collect it, but on the back end, to dispose of it.

Incineration, we have a licensed haz waste incinerator that follows us through the state collecting from HHW as well as our single-day events. Everything we collect gets high temperature incineration at a licensed, EPA licensed haz waste incinerator.

Universal waste rule, hopefully, EPA's on the agenda for tomorrow. I've been in touch with them several times as they put public notices out. They're trying to add pharmaceuticals to the universal waste rule, which pesticides are included in the universal

waste rule. That's another caveat of the RCRA, along with HHW, that hopefully we can utilize to make this a little easier to collect.

Cost-effective, we've been practicing this program since 1980. We have the funding in place. We're ready to go. The problem has been we've just got to be able to manage it per DEA regs to allow us to take it to the incinerator.

Our problem is, as someone mentioned before in Wisconsin, our licensed incinerator currently is in Ohio. Before that, it was in Texas. Before that, it was in Arkansas. None of those places are close to North Carolina.

So what we're looking for is an easier method to get that material to the incinerator without having to witness burn.

Next slide please.

So we're just looking to help. That's all we're trying to do. We know we're

not going to be the be-all, end-all.

We hope that we can come to the table and help hash out things that we've run across before. You can't believe the similarities between pesticide programs and this whole issue of pharmaceuticals. I feel like I'm running over the same ground sometimes.

Maintain disposal cost efficiencies. We're around 84 cents a pound right now. I've heard other programs say, for pharmaceuticals, they're up over $4.00 a pound. If we can roll that in to what we're doing, we're less than $1.00 a pound. That's pretty efficient.

We recommend -- only recommend to the DEA that during the proposed rulemaking, please consider the potential for rendering pharmaceuticals on-site as an intermediate state, reexamine that situation to allow secure, cost-effective, environmentally conscious and convenient disposal and

transportation of commingled pharmaceuticals, including controlled substances prior to final destruction at an EPA-licensed hazardous waste incinerator.

I think it's very important -- when we're putting our programs together, we work a lot though the cooperative extension in each county, and we tell them, time and time again, it's your program. How do you want to do it? What fits your needs best?

I think several people have touched on it before. The way we do things is not going to work everywhere, but we need to be allowed to try to use things that will make it cost-effective, environmentally conscious, and ease the burden for the people who are trying to do the right thing. And that's it.

Thank you very much.

(Applause.)

MR. CAVERLY: Thank you, Derrick.

And in the unenviable position of being the last speaker of the -- last

individual speaker, at least, of the afternoon, John Waffenschmidt. Did I get that right?

Waffenschmidt.

Ah, there's Ts here. That's our mistake. My apologies.

MR. WAFFENSCHMIDT: And here, I've got three copies, and also, they're written so that when you guys are resting in your room later, you can read it.

Thank you very much. I appreciate the opportunity to comment. Covanta Energy is an energy from waste company, with extensive experience in the ultimate thermal destruction of pharmaceuticals.

Starting in the beginning of 2010, we offered free disposal to any community that would do a collection of pharmaceuticals from households. We did that in order to help accelerate the various programs throughout the United States of trying to collect these pharmaceuticals.

As a result of our program in 2010, we destroyed an excess of 30,000 pounds of such pharmaceuticals, some of which came via the DEA programs.

Looking specifically to the questions that were posed for this meeting with regard to the safest manner for the disposal of unwanted controlled substances, we, like others, would talk more broadly about pharmaceuticals in the general sense. And we think that when you look into environmental and drug diversion concerns, and that ultimate destruction is via thermal combustion, at either an energy from waste facility, a hazardous waste incinerator, or a medical waste incinerator, which all offer the same level of thermal destruction.

The reason is simple. This destruction precludes any chance of diversion and precludes these chemical compounds from entering surface or drinking waters.

With regard to collection and

transport, which are also relevant to these DEA considerations, we will leave specific recommendations to others more directly associated with such collection and transport.

As has been stated repeatedly, we would only suggest, number one, that appropriate security protocols be in place. Number two, and perhaps in some ways most important, that the convenience to the consumer be a very important consideration so that we can collect as much material as possible and that different communities will prefer different options.

The follow-up question to that is: Why do we believe that the proposed solution is the best to protect human health, public health and safety, and can curtail diversion?

Thermal treatment facilities, whether they be energy from waste facilities, hazardous waste incinerators, or medical waste incinerators, are extremely effective at destroying organic compounds, performing at

destruction efficiencies of 99.9999 percent.

What that means, in practical terms, is that once the pharmaceuticals are subject to thermal destruction, such pharmaceuticals are rendered into a condition which precludes their diversion and eliminates the potential impact to the environment, particularly associated with surface and drinking waters.

In a couple of the earlier presentations, they talked about some of the local obstacles to running different programs. I'm going to speak more specifically to that.

And the one that I think is a direct obstacle, that doesn't have an associated benefit, is that in order for us -- meaning, an energy from waste facility, to be able to accept pharmaceuticals, which include the hazardous component from households, we need that local state to accept that the household hazardous waste exemption applies to that particular program and those specific

products.

If such exemption is not granted, the incoming pharmaceuticals must either go exclusively to a hazardous waste facility or those pharmaceuticals must be separated between the hazardous and non-hazardous component, with the hazardous component being directed to a hazardous waste facility.

This increases the cost to the communities due to the greater costs of separation and the increased costs of hazardous waste disposal, given that such disposal is more expensive than disposal at an energy from waste facility.

In effect, this is cost without benefit since the thermal destruction capabilities of an energy from waste facility mirrors that of a hazardous waste incinerator.

These issues should not be taken lightly. When a potential take-back program or any organized pharmaceutical program, including those associated with long term care

facilities, is burdened with additional regulatory hindrances, as well as increased costs, the potential to enact these programs is reduced.

It is suggested that the DEA coordinate with the U.S. EPA so that the EPA can initiate an appropriate complimentary -- I was aiming for five minutes, so I almost made it -- would allow for an appropriate complimentary rulemaking process, which would allow for any pharmaceuticals which are directed for ultimate disposal at a thermal treatment facility to be determined as non-hazardous on a de facto basis.

Thank you very much for the opportunity to comment. And I can't say I like being last, but I'm glad I was able to be here.

(Applause.)

MR. CAVERLY: Thank you, John, and my apologies for your placement. But, your comments, as everyone's comments, are

absolutely essential to us in this process.

So, we're running a little ahead of schedule, but that's okay. I have a friend who still works in the DEA Chief Council's Office who places the analogy of your span of attention with the length of time your bottom can rest on a seat.

So, I know it's difficult. We've spent a long day listening to people. It's been very productive for us, to DEA, so I want to thank those of you who spoke, and those of you who are just here.

We do want to afford the opportunity for individuals who would like to add comments to this public record. Again, I want to repeat that a transcript of these proceedings will be available.

So we've got, I guess, two microphones here set up. So if -- Erica?

(Off-mic comments.)

I would be happy to.

So, we'll give folks the

opportunity to add comments to the record. If you would like to do so, I would recommend that you would kind of queue up behind one of the mics, and we'll alternate from side to side.

So now we have three microphones, so, yes. So the far left, or my far left, far right?

MS. SCHLOSBERG: Thank you. My name is Claudia Schlosberg, and I'm a consultant to pharmaceutical companies, nursing home facilities, and long term care pharmacies.

And I just, thank you, first of all, for holding this public forum. I think we've heard many very important comments. I think there's a lot of consensus you're hearing among stakeholders.

But one point that's been made, and I just want to underscore, is the critical need for DEA, as it moves forward with its regulation, not only to coordinate with FDA

and EPA but also with CMS.

As we are here today, CMS is reviewing comments to a proposed rule in which they would require all unused medications from long term care facilities to be returned to the pharmacy to be inventoried and counted and reported back to Part D plans.

At the same time, EPA is finalizing its guidance to health care facilities on disposal of unused medications, which, if it goes forward and there is not dialogue and coordination, could result in continued conflicting guidance to health care facilities and providers.

And so while I think a lot of progress can be made as you move forward because clearly, controlled drugs have been kind of a sticky point in the process, without that coordination, we're still going to see a lot of confusion and conflict and additional costs to providers and additional obstacles.

So I just want to underscore that

point. I think it's been made a few times. Thank you.

MR. CAVERLY: Thank you.

Please.

MS. BOEHME: My name is Susan Boehme. I'm with the Illinois and Indiana Sea Grant.

Sea Grant is in every coastal state in the nation, including the Great Lakes. We are involved with coastal issues and water issues. We focus on education, outreach, and research, so we've been involved in the unwanted medicines issue for about five years now. We've been working with Great Lakes communities to start collection programs.

We have a tool kit that we've been refining over the years, the DEA has reviewed it in the past, that we provide, free, to anybody who wants to start a collection program and try to help them.

We also interact with them quite a

bit on a personal level to make sure they're doing the safe and right thing. We provide small financial support for their advertisement of their programs or purchasing of collection boxes.

So our goal is really to get as many collection sites around the Great Lakes as we can. We were very active in an Earth Week EPA initiative to collect about 4 million pills in the Great Lakes in 2008 over the course of about 10 days.

More recently, we've also started to develop education materials, including state-approved curriculum, some 4-H guides, to start reaching a younger audience, and we work with the P2D2 program. Paul Ritter's already been mentioned.

I should note that he was just named one of the outstanding teachers of the year by SeaWorld, and will be honored by them for that and for his P2D2 program.

We've been working on this issue

with funding from EPA and working with a lot of Great Lakes communities.

And there's a couple things I just wanted to mention. Probably in this very highly educated room on this issue, maybe, what, 10 percent, if that, could distinguish a controlled from a non-controlled. So even us, who work with this day after day after day, can't, on the ground level, distinguish them.

And I think what we also need to start to see is some statistics on what's being abused in the non-controlled world. We know that it happens with a lot of different cases, when we talk about a pharm party. They're not just taking controlled substances to those parties. They're taking everything.

So the distinction goes out the window the minute you walk out this door, and for most of us in this room, we can't distinguish.

So, while we can talk about the

statistics for what's happening in the controlled world, we should also be focusing on what's happening in the non-controlled world, so that whatever we do doesn't just focus on the controlled substances.

I also wanted to mention that it's important that the DOT does see whatever the rules are, because we have had collection programs that have been stymied by DOT regs. And so while we've done everything we can to make the program happen and the communities have actually collected the medicines, they've been stuck in a police station for a very, very, very long time because of DOT regs. So it's important that they understand, specific state-wide regs, what comes out of this.

And I just want to again sort of reiterate the issue of minimization, that one of the things we'll get from some of the data that can be collected, and we don't think every collection program needs to be counted pill by pill, but we need that data to

understand what is being thrown away, so that we can start to talk to people about why they're throwing away, time and time again, thousands and hundreds of Tylenols or whatever it turns out to be.

And I think the point about understanding what antibiotics and some of those, if we start to see certain antibiotics being thrown away on a regular basis, there might be some really, really important information there that we should not -- that we need to collect.

So I think we really need to, as we move to the next step of this problem, which is minimizing that waste, is we need to understand how people are disposing of medicines.

And just going one step back to the tool kits, it was clear from the first DEA collection event that there was some misinformation out there.

And we really think that the tool

kits that we have, and there's a few others out there, that the agents should all have those tool kits, because they can help educate them, and get them up to speed on the environmental issues. They know the DEA rules, but on the environment components and some of the other components.

The tool kit includes about 30 or 40 different case studies of different collection programs that people can use. And so it's a way to do this in the most creative way we can with the dollars that we have.

Thanks.

MR. CAVERLY: Thank you.

Back over?

Do we have someone over here?

No, back over to you, then.

MS. HOBOY: Good afternoon. My name is Selin Hoboy. I'm with Stericycle, and I also am part of the Healthcare Waste Institute which looks at health care issues as it relates to different waste coming out of

the health care environment today.

And I want to first thank DEA for giving us this opportunity to speak and be here today. We heard a lot of great things today, and I think some overwhelming support for some high-level topics, like no pill counting but still having some way to have some assurance that these wastes are not going to get diverted somehow, commingling the waste, which would capture more than just the controlled substances, as I think someone just mentioned.

The fact that you would get some of the other things that are high on your priority list, but haven't necessarily made it into a scheduled drug thus far, so I think that would be really helpful.

I think some things to consider, when you're looking at these issues too, is to make sure that there's good instruction to the consumer so that they understand. I think that was brought up earlier.

But I also think I'm hearing, we want flexibility. In some cases, people are saying, well, we want programs to be well-prescribed.

I think the more you can be prescriptive, I think it would be better for there to be consistency, and I think somebody else earlier said level playing field for compliance purposes with these requirements, because there may be opportunities here for some people that might see this as an opportunity to do the wrong thing.

So providing additional guidance would be beneficial, I think, both on the consumer side, but also on the programs that are going to be implemented.

The other benefit to that would be that you would have consistency state to state. So there are nursing homes, there are home health care providers that are across state lines that may be trying to implement programs.

And if there's a lot of variety from one state to the other, it may be very difficult for them to have a cost-effective program.

It will also help from a compliance standpoint with EPA regulations and DOT regulations, perhaps.

So I think there's going to have to be some balance between things that are flexible enough to give people options but prescriptive enough so that there's consistency maintained throughout.

One last thing that I just wanted to bring up is, we heard a lot about reverse distributor today. We heard from some great reverse distributors. We also have a reverse distribution part of our facilities in our company.

I think one thing that needs to be clarified between the DEA and EPA is that, today, reverse distributors are not waste handlers. So if we're asking for reverse

distributors to become the repository of this type of material, we need to be careful that we don't end up having issues from an EPA perspective.

Are they going to be required to have solid waste permits? Is that going to put them in jeopardy in their communities? Because today they're not -- maybe they're just a quiet part of the community, and you go for a solid waste hearing, and there's going to be a lot of people coming out of the woodwork.

So, there's some things like that that need to be considered if reverse distributors are going to be looked at. I think it's a good idea. I think that we already have controls in place, as many have already said, so I'm not going to repeat all that.

But I do believe that it's not a bad option. I just think that that needs to be taken into consideration, because today,

there are several states that are already looking at the fact that if a hospital or health care provider is sending waste that's considered hazardous waste back to a reverse distributor which is ultimately just going to dispose of it, they're saying that that has to be identified at the point of generation at the hospital.

So there are just some things like that, some nuances that probably need to be taken into consideration. And those folks from EPA here today, and they'll be here tomorrow, and hopefully you'll have additional discussions.

So, thank you.

MR. CAVERLY: Great. Thank you so much.

Any other comments?

During the -- then I'll conclude with this. During the national take-back, we encouraged -- our public affairs office within DEA encouraged the individual offices to send

us photographs of the collection sites. And we had some wonderful photographs.

The St. Louis office sent us a picture of a gentleman who had pulled out a kitchen drawer, and just pulled his kitchen drawer out, and showed up at the collection site with his kitchen drawer. He didn't throw it in a bag, he didn't -- he just took the whole drawer.

But one of the photographs that was sent to us was a sample bottle of Quaalude. This was material that was surrendered, and I can't recall where the collection site was, unfortunately.

But Quaaludes were withdrawn from the market in 1982, so this was a physician's sample container that was in someone's home. It was withdrawn from the market in 1982. Methaqualone became a Schedule 1 controlled substance in 1984 in the United States.

So here's a bottle that's been kicking around someone's home since at least

1982, is now -- was now a Schedule 1 controlled substance, and wound up being surrendered at one of these collection sites.

So the odd things that we hang on to, we, the American public, society, hangs on to.

But we have one more request for a comment, so, please.

MS. AIDUKS: Sorry, I'm going to hold everybody up. Just a second, I won't be long.

MR. CAVERLY: That's okay.

MS. AIDUKS: My name is Charlene Aiduks, and I'm with Eli Lilly and company. We're a pharmaceutical manufacturer, R&D.

And we heard a lot of comments today relative to commercially distributed products, and physician samples, that type of thing. But we haven't really talked at all, yet, at least, and maybe we will tomorrow, about clinical trial materials and investigational drug products that could be

controlled substances.

The FDA requires that when we are doing clinical trials, that study drug, at the end of a study, if it hasn't been consumed or used by the patients, that the patients have to return that to the investigational site.

And Cathy, I know we've talked about this at previous FDA meetings before. So, I just want to be sure that this gets captured as -- sorry?

MR. CAVERLY: We actually, believe it or not, DEA changed its mind. Can you believe that?

(Laughter.)

We actually changed our mind at one point.

MS. AIDUKS: All right.

MS. GALLAGHER: There was a conference, and we went back and said, we really need to re-look at this. And working with our chief counsel, they agreed, which was nice. So we have gone back to --

MS. AIDUKS: Excellent.

MR. CAVERLY: The issue is, if you're a clinical trial subject and you're given controlled substances, you're an ultimate user. You've been given controlled substances and FDA requires those controlled substances be returned to the clinical investigator.

DEA's original position was, sure, go ahead, it makes sense. And then as we got into this disposal issue, we recognized that there were some statutory issues or some statutory problems.

And we said, no, you can't, you're a clinical investigator, you can't accept controlled substances back from your clinical trial subjects, in opposition to FDA.

We actually realized that wasn't a reasonable point of view. And we went back and had a little internal discussion and reversed ourselves, probably three, four months ago, six months ago. Time flies.

But, so, anyway, if you're a clinical trial subject, you may return controlled substances, consistent with FDA's guidance, to your researcher.

MS. AIDUKS: That's good news.

MR. CAVERLY: Okay.

MS. AIDUKS: Thank you. The only other comment I would make --

MR. CAVERLY: Sure.

MS. AIDUKS: We've heard, several times, that for funding for this and requesting that pharmaceutical companies have some responsibility in funding this, since we put these drugs out there, and I don't think probably any of us would deny that.

But I think it shouldn't just rest with the branded companies. It should also rest on generic companies, because they produce a lot of material, and with these insurance and Medicare and Medicaid, generics are more probably prolific on the market. I can't verify that, but they're certainly out

there, and they're just as much a problem, I think, as the branded drugs are, so I think they should bear in that responsibility as well.

MR. CAVERLY: Okay.

MS. AIDUKS: Thank you.

MR. CAVERLY: Thank you.

All right. I hope no one will object to getting out early, because that's what we're about to do.

We have one more question? Oh, boy. He is a brave soul.

MR. PARHAM: Thanks, Mark.

I, too, join with everyone here in commending DEA for finally taking this step. I don't know if it's reluctant or not, but we're glad you're here, and we're glad we can count on the beginning of hopefully the good leadership from the federal government on this.

Having said that, maybe I'm old school, I don't know. I'm retired from DEA so

I share their pain in dealing with this. I think there's one component that is critical to maintain as the government.

I know we're trying to find quick fixes. The communities are doing whatever they can to deal with the reality of too many drugs out there, particularly prescription drugs.

But as you mentioned, from the very beginning, Mark, or the other gentleman on your panel, how the CSA was constructed and the fact that it's a closed system which has a component to it that I feel cannot be minimized or taken out, and that is accountability.

I would say, at least, DEA or whichever federal agency which stands up to take on this humongous effort for our society has to be the last standing or last bastion of accountability.

Right now, everyone's kind of accepting the funding, the issues, the

efficiency or lack of efficiency, whatever you want to call it, trying to find the quick and easy way to handle something that's very enormous. And I recognize that.

But as I think Jeannie, if I remember correctly, I think she was from Texas, mentioned, that you should not discount the pill-counting aspects of it, because there is data and things like that that is vital to where this program is going to be in the future.

Someone has to stand that line. And if DEA or other government agencies decide to dismiss that and say, bring your drugs, we don't care what it is, how much it is, we'll weigh it, get the public attention, through the media thing, we seized 500 tons of whatever, or collected 500 tons, then, to me, that's reprehensible for the government to take that position, the federal government.

States, you all can do whatever you want, but, the federal government I think

at least has to stand that line of maintaining a system that's accountable to the American public.

Thanks.

MR. CAVERLY: All right. That concludes our public meeting for Wednesday, January 19.

We are scheduled to begin tomorrow on the 20, hopefully with representative Inslee, and/or his staff. They've expressed an interest in addressing us as a group, and hopefully, should Congressman Inslee's schedule permit, he'll be with us to kick us off at 9:00.

So, I hope you have a good evening. We appreciate your attendance, and hope to see you tomorrow.

Thanks very much.

(Whereupon, the above-entitled matter was concluded at 4:29 p.m.)

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UNITED STATES OF AMERICA
DRUG ENFORCEMENT ADMINISTRATION

+ + + + +

PUBLIC MEETING

+ + + + +

PROCEDURES FOR THE SURRENDER OF UNWANTED CONTROLLED SUBSTANCES BY ULTIMATE USERS

+ + + + +

THURSDAY
JANUARY 20, 2011

+ + + + +

The Public Meeting was held in the Grand Ballroom of the Renaissance Mayflower Hotel, 1127 Connecticut Avenue N.W., Washington, D.C., 20036 at 9:00 a.m., Cathy Gallagher, Moderator, presiding.

T A B L E O F C O N T E N T S

P-R-O-C-E-E-D-I-N-G-S

8:56 a.m.

MR. CAVERLY: If people could start settling in, please. Congressman Inslee is on his way. He's been delayed just a few minutes. We've been told three to five minutes. So if everyone could come in and settle down we'll get ready for the congressman. I hope you found yesterday's meeting informative. Certainly it's our intention to hear - to listen, but I know it's interesting sometimes for folks to hear other people's points of view as well. So I had several individuals come up to me afterwards and express interest I guess in hearing some of the issues that were brought up yesterday.

For those of you who are just joining us this morning, welcome. This is the second day of our conference. I see a lot of familiar faces out there this morning so I suspect most of you are returnees as

opposed to new additions, but for those who are joining us, welcome this morning. We'll be starting out with Congressman Inslee here in the next few minutes. As you look through our agenda we've got a little different perspectives that we'll be presenting. The Food and Drug Administration, EPA, the Environmental Protection Administration, our Postal Service brethren are here as well in addition to NABP and the Army is in here in force too, so.

As we wait for the congressman to attend here this morning I'll make an admission. I mentioned yesterday that we had been discussing this issue in the office for probably several years. The advance notice of proposed rulemaking was published in early 2009, but really we had been talking about it and exploring this issue for the last couple of years, but we describe it as trash-talking in the office. So you may have heard me say that before but it's true. So we've been

trash-talking for several years.

Thank you. Our first speaker this morning is the Honorable Jay Inslee who represents the First District of the State of Washington in the U.S. House of Representatives. Representative Inslee was an original sponsor to House Resolution 5809 which was a companion to Senate Bill 3397 that became Public Law No. 111-273, the Secure and Responsible Drug Disposal Act of 2010. Representative Inslee has been a champion for a regulatory scheme to securely and safely dispose of prescription drugs and we welcome his remarks here today.

(Applause)

REP. INSLEE: Thank you. This is a real treat for me to see us moving forward on a real problem we have. I'm sorry to keep you waiting a few moments. We have some Chinese friends in town and I was just meeting with the leader of the Chinese renewable energy industry about how we can

get into the game with China to start developing solar and wind power, and we are in a great game with them so my apologies keeping you waiting. When you deal with 1 billion Chinese you need to be gracious, so I was this morning.

This is a treat for me because this has been a passion of mine for some time to try to move forward, to try to deal with both issues of drug abuse in our country and some environmental consideration of how we really safely dispose of pharmaceuticals. This came about, my interest came about as many things do in Congress in just kind of a local story when people brought to me this problem that we couldn't find a way to dispose of these drugs in a safe and environmentally friendly fashion.

And I sort of looked at it through the eyes of my grandmother who worked at Bartell's Drugs in Seattle, Washington, for decades when she raised four sons as a single

mother through the Depression, and she gave me one piece of advice. She said always do good, Jay, it'll pay off eventually. And she also said never mess with my Social Security. I'll never forget that as well which may be an issue here for us. But I had people come to me and just say look, this is just a homegrown problem, we don't have a way of disposing of these drugs and they are sitting around in people's medicine cabinets and grandparents are letting their grandkids get into it and their grandkids' neighbors, and this is a significant problem. And I heard from both just constituents, I heard from drugstore owners, I heard from some of my great friends locally and law enforcement who had really taken a laboring order to try to figure out a way to deal with this and it was clear that we needed some federal legislation. So we got together on a bipartisan basis to try to move something forward and I'm pleased to say we've got a

bill that helps us move forward.

I wanted to make five points this morning. First, the obvious one which is that we have a growing problem in prescription drug abuse. And this is sort of a - kind of a quiet epidemic because my colleagues and I really are still getting attuned to how fast this has broken upon us with an increase in prescription drug abuse. We knew that every day the statistics show that 2,500 teens use prescription drugs to get high for the first time, every single day. That is an epidemic. It's not a small problem in the country, it is an epidemic. And we know that obviously the largest contributing factor is just the availability of these drugs. And the worse and harder it is to dispose of them, the more that that principal factor really drives that epidemic, so the take-back programs obviously have a huge demand.

Number two, and I want to talk

about this a little bit because it's very important to me and that is the real legislative intent of our act that we passed, and that's to allow for accessible with a capital "A," convenient with a capital "C," and cost-effective drug take-back programs with a capital "C" and "E." And I want to stress that because it is our goal that when we adopt the procedures and the regulations for this they really are consumer-friendly, and I like to think of either Nordstrom's or Starbucks. We have two great retail leaders of customer-friendly procedures here in Washington State.

We want to have take-back programs that are the Nordstrom's and Starbucks of drug take-back programs. That means that they respond to the needs of the users, they are very sensitive to their time and geographic constraints, they do not impose unnecessary restraints on their ability to access the service, and that really go out

and ask the consumer, because if you look at Starbucks and Nordstrom's, the reason they succeed is they ask the consumer what works for you, and that's what we really hope to - in how we design a drug take-back program. And I think this is a bit of a challenge for us because we come from a culture that is rule-driven and isn't always sort of responsive to the needs of the consumer. So when we design these systems I think a real principal goal is to think of ourselves almost as retailers, retailers of a service. We are a service provider. And I hope that you will find a way to help us in that regard because if we're going to do that that's the only way it's going to work.

Now, accessibility. We're talking about really making sure that the programs meet the accessible needs of individual communities because we know they're so different, from urban to rural and the like. When we talk about convenient we're talking

about both traffic and availability from a traffic perspective, but from different places. Different people have different parts of their life. Some people have a lot of pharmaceuticals in their life and pharmacies work well, some are more comfortable with hospitals, fire districts, and others sort of brick and mortar locations. Some may want a convenient place on the way to work. But we want to think how Starbucks thinks which is that we want a coffee shop on every corner in the United States and China. So I hope that that becomes a principal sort of goal of the programs that we develop.

Cost-effective. Obviously important because in today's situation we know how tough budgets are. Third principal. We really have examples of programs that have worked across the country, so I think that if we can just use the not inventing the wheel principle it works, and if we can find

some - in fact, if this room can find, you know, a half dozen best principle examples I hope we can spread them nationwide. We certainly have some suggestions in that regard.

Fourth. I hope that the need to keep this material out of our water is not thought of as an afterthought when we design these systems. I live on Puget Sound. The water is intrinsic to me, but we all drink it no matter where we live and we know that endocrine disruptors, hormones and a lot of other really, really nasty stuff can cause real, real problems in the human physiology. And we really have to think about ways to handle these materials appropriately from an environmental perspective. If you've done any sort of reading about endocrine disruptors and what they may or may not be doing to us in the future and right now it'll make you really, really aware of the need to find out a way to not allow this to end up in

our biosphere and in our ecosystem because it eventually ends up in us. And there's a lot of concern right now in the communities, the scientific communities, about these particular chemicals. So finding a way to really dispose of them in an environmentally sensitive way, we hope this is not going to be an afterthought.

Fifth thing I'll mention is we need DEA obviously and for a lot of different reasons, but we need the help of this organization from a local community standpoint. And you'll hear this from every local leader in America. The more that our national organization can be responsible to the local leaders' sort of viewpoints and understanding their local communities, the better. And again, this is not easy. This is a challenge when we try to have national policies to try to respond to local needs. It's a tension in all of our lives from a national organization standpoint. But

because we are in a - by necessity have to be a user-friendly group - I think this is a time as much as any time for federal officials to try to be responsible for those local needs.

So I'm just going to conclude in thanking you personally for your efforts on this. I've worked with some folks, Pat Slack, is Pat here today? Did I see - Pat. Pat who's been a great local leader. If you want to know any great idea just call this guy right here, Pat Slack, he has all the answers, along with Sheriff John Lovick, John Gahagen who's been a great, great citizen who lost his son to drug abuse. And when you know a guy like John you know how important this issue is. So again, I want to thank you. I look forward to maybe a year from now we'll get to come back and celebrate some success and good luck, good hunting. Take care.

(Applause)

MS. GALLAGHER: Good morning. Mark was our emcee yesterday. I'm Cathy Gallagher, I'm going to try and emcee today. Mark is such a natural at this. I want to reiterate what was said yesterday by Mr. Joe Rannazzisi, Colin and Mark that we thank you so much for taking time out of your busy schedules, traveling far distances to come and be a part of this discussion. We took a lot of - we heard the same common themes yesterday, but from - coming from all different varieties of interest on this issue it really does help us, and we're getting the message options, options, options, various options, so that was really helpful.

I wanted to put my little two cents on disposal if you don't mind and some of you have all probably heard this story. My coworkers are going oh, here we go again. But I'll tell you, five years ago I started in my position as - in liaison and policy, and I went out to attend a conference and I

heard Dr. Gressitt, if he's in the audience. Those of you who know Dr. Gressitt, he's very passionate about this issue. And I thought, you know, disposal, is this really a big deal? I didn't get it. About six months later I was at another conference and there's Dr. Gressitt, you know, stumping his message and I thought this is going to be an issue. This is an issue and we need to look at this.

And I came back to our group and I said I want two people to start looking at this issue because I want DEA to be proactive, I want us to be the heroes here. You know, we're going to be ahead of the curve for a change which, you know, for federal government is not the way - even though we want to be, it doesn't happen that way. And we deal with a lot of different issues, obviously disposal isn't the only one. And the staff worked feverishly on this, started reaching out. They worked with Washington State looking for options, we

looked at pilot programs, we were, you know, eager, and then boom, we hit the wall because we realized it was a statute issue that was holding us back. Regulations, for those that - you know, we can change regulations, we can't change the statute. It's an act of Congress and that's why we say an act of Congress was necessary for this.

So from the outside it looked as if we stopped, and we sat around and we said well, we've got to signal to the outside world that we're really engaged in this activity, so what can we do? So we did an advance notice of proposed rulemaking because we wanted to go out and ask questions. We could still learn about this issue, we'd have the data, we'd have the information, so when the act was passed - it wasn't a matter of if, it was a matter of when because you could see what was coming - we would be ready. And so we did do that in 2009 which you heard yesterday, and I know I'm being repetitive.

But the second thing we said, okay, what else can we do? We need to do something now. And it was this little thing, the law enforcement exemption, which is a little bit of a loophole, it wasn't intended to be used in the way that we creatively nurtured it out in the field. And I think what was amazing was to watch these communities across the country say okay, this is something we can do. Let's reach out to law enforcement, and if law enforcement had the resources as well as the passion for this they could start doing some community efforts. And it was to sit back, looking as if we were doing nothing, but to watch what was going on across this country was exciting. And then from take-back it turned into how can we educate. And we saw sheriff's departments in North Carolina go out into the school systems, do a poster contest.

We have pictures of these posters

of, you know, the big foot stepping on the pill, and that's what came out of this. And I think yesterday we heard that. It's education, it's communication, it's not just the disposal. That's critical, but it's getting the message out. So through the law enforcement take-back programs we've seen that. And never when we sat, just Mark and I kind of talking about law enforcement take-back, did we ever think DEA would do a national take-back program. We almost were dumbfounded that that's where we ended up. But we know that it wasn't just DEA doing this, it was the state and locals across this country for many years doing these take-back programs. We were glad to jump on the bandwagon and get a national take-back program out there because again, it got the message out, and we're just continuing to grow from that. But we know we didn't do that on our own. We know that was because of you guys out there doing it.

And the only other thing is - this is the story everybody gets tired of me saying. Five years ago I said I see two trains and they're eventually going to come into the station together and one is diversion, misuse, abuse and environmental issues, and it's not a train wreck, it's both trains coming into the station. And I sat here yesterday and I said both trains are in the station right now. And I talked with EPA and they said okay, but where are we going? Where's the train going when they leave the station? I thought this morning and I said, well, we need to hook them all up together. I know this is so corny, but this is how I see things. And we're going to come together and we reached out to other agencies as you see, those who have come and done some presentations and will continue today, we're bringing people into the station. I love that it's in the Mayflower Hotel, it's historic for me. When I was 10 years old in

this very room I sat at my grandfather's retirement party right here, amazed about this room. It's so eerie that here we are. But we are in the station and we're going to get this right. It won't be perfect, but I think we all are so committed and it's the passion of these trains that we can't - we have to resolve the issue as best we can. So there's my little story. You can tell this is an issue, I've been trying to move this train for a long time in the frameworks that we could, that Colin laid out. There are obstacles for us and I can tell you too, I said when I thought we were - when I was being full of myself five years ago saying we'll be ahead of this, I said I don't want to be legislated. I want to be in charge.

And then when we couldn't, all I kept saying was please legislate us, please give us something so we can move forward, and we're here. And so I applaud the efforts of Representative Inslee, Stupak, all the people

who pushed it, pushed the congressmen to get on this issue. So now we can move forward. So okay, I'm off my soapbox and so we'll move on to the program. Our next speaker is Jim Hunter with FDA. The trouble that FDA has - not trouble - they have to look at all the drugs. DEA, we look at controlled substances, but we've been the blocker to moving forward and now we're ready to go. So I'm going to invite Jim Hunter up here. Thank you.

MR. HUNTER: Thank you, Cathy. I know we have something in common now because I'll have to credit Dr. Gressitt also for my initiation into drug disposal. I was given the assignment to work with Dr. Gressitt because my director at the time just said I need someone else to deal with Dr. Gressitt.

(Laughter)

MR. HUNTER: So it's been a very, very positive engagement with Dr. Gressitt and things have moved forward since that

time. And I am a pharmacist reviewer within the controlled substance staff within the Center for Drug Evaluation and Research, and aside from my review duties I am also the agency - or one of the agency contacts and one of the agency experts on safe drug disposal and take-backs in particular because of my many affiliations and collaborations and discussions with all the stakeholders, many of the stakeholders from the very beginning several years ago. And I am ecstatic, as ecstatic as a regulator can be that the passage of this particular bill which will enable us to really move forward.

Let me start by thanking DEA for having the meeting and this meeting is soliciting ideas and procedures that will allow the ultimate users of prescription medicines to surrender prescription medicines containing controlled substances for environmentally responsible destruction. Let's see if I can get my slide thing to work

here. Oh, is it up there? Oh, good. Okay. As we heard yesterday, since most of you were here yesterday, we heard from an Office of National Drug Control Policy speaker about the fact that the intentional use of controlled prescription drugs for non-medical purposes is the fastest growing drug problem in the country, and to add to that it's the second most common form of illicit drug use among our teens, teens who when surveyed say that they get their medications, most of their medications from friends and family which includes the medicine cabinet. It's certainly no wonder with 3.9 billion prescriptions written per year for all medicines that many of these medicines for very legitimate reasons become unwanted and unneeded, unused, and sitting in medicine cabinets where they become a potential risk for accidental ingestion that could result in harm.

The timely and the proper disposal

of these medicines that are unwanted and unneeded takes away all of that potential risk and that's the heart of my message today, one of them. So FDA applauds the passage of the Secure and Responsible Drug Disposal bill because it's going to be enabling legislation, it's going to allow some new possibilities to help prevent prescription drug abuse, misuse and accidental poisonings.

We are - FDA is very hopeful that this legislation will promote the development of a wider availability, safer disposal systems for all prescription medicines. As Cathy alluded to, we - our charge is for all prescription medicines in terms of our core mission being that we - to the American people, the Center for Drug Evaluation and Research, one of our core missions is to make safe, relatively safe and effective drugs available to all Americans, and part of that is maintaining the integrity of our supply

chain and making sure that everyone is confident when they get a prescription that that drug is what it should be.

Also, not to be too empathetic, but FDA recognizes the difficulties that DEA has in implementing the regulations that strike that right balance, the balance between protecting the public health and safety with those other considerations of ease of use, cost and participation, enabling participation in communities. Congressman Inslee's message was to that effect as well very strongly, and we support that. Also, in the spirit of the shared goal to empower and encourage citizens to use these programs to empower citizens to take action to make their homes safer. We lend our support and we also lend our - any sort of consultation that you might need. We stand ready to help move this forward and it's in all of our best interests to do that, and I want to make that clear.

Today I'm going to talk about the

roles regarding medication disposal. I'll quickly go through some public health efforts that we have initiated on the consumer level, and then I want to talk about patient disposal directions and our product labeling, and the reason I do that is to sort of set the background and context for the - later on the concerns and issues to consider - we think DEA should consider as they develop the parameters for take-back programs.

If all medicine dispensed is not consumed by the patient, then disposal becomes that final chapter in the life cycle of prescription medicines. And we hope that for most medicines the life cycle ends with the patient taking the drug as prescribed and it having its intended effect, but again, for lots of legitimate reasons when these medicines are no longer needed and wanted by the patient they remain in the home and then they become a safety risk because the patient no longer needs them, and we know

prescription medicines by definition are written for a particular illness, for a particular patient, for a particular condition and so anyone else taking that medicine is really what we consider a form of misuse and a potential for harm because then someone is playing doctor.

Also, there are safety risks associated with improper disposal methods, and disposal methods which might not make the drug completely unavailable. It could still stay in the garbage can where it could be, you know, taken by children, it could be taken by pets and with the high-risk medicines - and I like the DEA word "unrecoverable" - with the high-risk medicines it's very important that when those are disposed of that they are unrecoverable and they can't cause harm.

So FDA has a role in educating consumers about these risks and providing information on how and why to dispose of

medicines properly to avoid these risks. Again, these are educational efforts geared to the consumer, to the patient and to date most of these efforts have focused around our reasons why and frequently asked questions and how to dispose of unused medicines in the context of why we have a certain subset of medicines, high-risk medicines that we still recommend flushing as a disposal medicine. And I think it's important that I sort of explain why because then I hope that you understand that it's really not that the drug is - that we are driving the train to flushing, it's really the point is that we and the companies have identified risks of that particular product to non-patients. Again, disposal is to benefit the non-patient. The patient takes the drug for effect; the non-patient can only get in trouble with the drug. So to protect the non-patient this is why some drugs have such undue high risk that we think that those

drugs need to be gotten rid of immediately and that the patient should have access to the modality of that at the time it's needed.

So our consumer pages, we have a fact sheet, frequently asked questions and we continuously update our flushing instructions on those few medicines that have flushing instructions, and I'll get to that later. I also included here something that's not on our webpage which is the proper disposal of prescription drugs and as probably most of you know, that is the guidelines on the ONDCP website for the disposal of most medications except for the ones that are on our list, and that was put together by ONDCP yet it was also - the EPA believe it or not and the FDA, we also collaborated on that disposal guideline. We have also assisted other government agencies with their disposal messaging, Partnership for Drug-Free America. We helped EPA internally with their new

guidelines on - the disposal guidelines for healthcare facilities, and very early on we worked with the American Pharmacists Association on their SmartRx program which was quite an adventure for me because I got to critique some Madison Avenue logos, and - when they had pills like taking over the world and things like that, and we were going wow, maybe not, maybe not. Oh, sorry, that was supposed to be on that slide when I was talking about those things.

And another point and role really to drug disposal, as I said before I wanted to sort of get into the weeds a little bit on is to talk about disposal instructions and our product labeling. First off, disposal directions are recommendations for - to be put into our labels, and they're not a regulatory requirement. We don't have a section in our labeling regulations that say you must put disposal directions, you know, in the patient - information for the patient

part of the label. That's not a regulatory requirement. I won't say as a result, but as it happens disposal directions are not routinely included in most products. Out of the 8,000 or so products that are prescription drugs we have probably less than 30 that have consumer-directed or prescriber to talk to consumer directed labeling for disposal. And what drives that is that this specific disposal directions in those products, and some of them are in the form of the patient package insert, maybe at the bottom of the package insert there will be information for the patient to relate to the patient. Also, in some of our products under REMS this information is in the medication guide.

And in that case, that medications guide is required to be given to the patient at the time of dispensing. But in all cases the product labeling for these small number of medicines contains the disposal directions

because we have determined that these instructions are necessary to protect that non-patient from undue harm associated with the accidental use, misuse and sometimes abuse of the product, and especially in overdose situations. In this context the safe medicine disposal instructions are actually a necessary element to increase the overall safety profile of the drug. We have benefits, we have risks. In these particular products we say we need more on - we have to lower the risk side a bit, and the way to do that with these products that one pill can kill is to - you must instruct the consumer or the patient to get rid of these drugs as soon as they're no longer needed. For example, FDA reviewed data on accidental death of children from exposure to certain opioid medications, and we concluded that the safest disposal option at present was one that makes them immediately and permanently unavailable. Again, it's - our need was

driving the directions. Those are the medicines that are included on the FDA flush list, and the headline here of course is to make that point and fortunately the story behind this headline is a happy one. It was a close call of accidental ingestion of a prescription opiate, but unfortunately many cases of accidental exposure do not end happily.

To summarize, our current recommendations for drug disposal is for the vast majority of medicines that do not have specific disposal directions in their labeling our recommendation is to follow the federal guidelines at this point. However, when specified in a medicine's labeling FDA recommends to flush only those higher risk medicines as an interim measure. Again, this is an interim measure. This is not perfect, this is not - I think now with the passage of this Safe and Responsible Drug Disposal Act this will be revisited, but at this point we

think it's still the safest method to use for these particular high-risk medications. We think that, and we believe that any potential risk to people and to the environment from flushing this small select group of medicines is outweighed by the real possibility of life-threatening risk from accidental ingestion of these medicines. I want to leave on a positive note. We are very hopeful that following the implementation of the regulatory provisions of the Secure and Responsible Drug Disposal Act that a variety of legal collection methods and environmentally sound disposal methods will become more widely available that will accept both controlled and non-controlled medicines. These options as we've been hearing certainly include take-backs, mail-backs and other innovative disposal systems. This will in turn allow FDA, and we will, reassess our current disposal recommendations on the flush list.

Let me shift gears a little bit, make sure I'm on the right slide here. This morning when I was looking at my roles of FDA I realized I'd really left one out, and I talked about it earlier. It's that core mission of making sure that the drugs that are dispensed by pharmacists are - they're pure, they're quality and they're what they say they are. That is our core mission at FDA. So our number one concern with developing provisions for this act is that security of the drug collections for disposal is our number one concern. It's based - and also based on reports from several take-back programs across the country. I think it is a fact that those that collected both controlled and non-controlled substances, the non-controlled substances are medicines where the majority of the drug is returned. And so FDA is concerned not only with the security from diversion of the controlled drugs, but also about the security of the non-controlled

drugs. We're certainly encouraged by all the speakers who were advocating for tight controls on all of these medications and we would also be in support of that.

So why are we concerned about the reentry of previously dispensed medicines? Well, these previously dispensed medicines just like your mother may have told you when you were a little kid and you picked something off the ground and put it into your mouth, she says put that down, you don't know where that's been, and that's exactly the way we feel about some of these, that any drugs that have been returned, have been dispensed, have been out in the world. No one can attest to their strength, quality, purity, or identity, they're just things you can't know, and reuse of these medicines may cause harm. Therefore, we certainly support provisions that ensure that the medicines are intended for disposal and destroyed. The idea is surrender and destroy, and with as little

time lag in between.

I want to mention that prescription drug samples, we have a law, the Prescription Drug Marketing Act of 1987. We've interpreted that act to say that drug samples cannot be received or stored in retail pharmacies. They can never be sold. They're not intermingled with retail drugs. This is the same concern with retail pharmacies receiving or storing previously dispensed medicines, so receiving surrendered drugs at retail pharmacies opens up that possibility of inadvertent resale of drugs and could lead to drug diversion. We have no doubt that the DEA provisions will provide parameters to assure the security and ultimate destruction of surrendered control medications. Diversion and reuse of non-controlled medication does occur. We have cases that have already occurred. I'm not aware of any that have involved any of these community programs, but we do have some

prosecutions of some individuals under the guise or under the impression to their consumers that they were collecting these drugs for destruction. They resold these drugs and they were caught and prosecuted. So it does occur. So diversion and reuse of non-controlled medicines does occur, so protecting the legitimate drug supply we think is reasonable. It is reasonable that similar security requirements apply to all prescription drugs surrendered for destruction.

I'd like to join the chorus of many people before me who have talked about the difficulty in segregating controlled medicines from non-controlled medicines at these - for take-back. Consumers really can't be relied upon to segregate these controlled substances from the non-controlled, and a separate system we think would be confusing for consumers. Returns to long term health facilities might not have

the same problem because those are sort of within the provider medical realm, but we think the programs developed should be easy to understand. That will make them more likely to be utilized. So I think we're joining the chorus on that one.

Another concern - a consideration, I should say. We only had one big concern. These are considerations. It's important that FDA know that safe disposal programs are available to consumers before we can recommend them as a first option. I said before that for those high-risk medicines, our standard for those right now is that you have - the patient has access to a method that is readily available and that's immediate to get rid of these medicines. So we think effective disposal programs should minimize the time that the medicine remains in the home after the point it is no longer needed or wanted, and that timeliness, access and availability of safe and effective

disposal methods is an especially important element, again, for those products that are on our flush list. Availability and access to safe and secure take-back program for disposal is also an important consideration when recommending these programs in our product labeling. We have to know what we're recommending. We have to know that, yes, these are safe programs, yes, these are something that we want consumers to use for these high-risk medicines.

Another consideration we have I think is a little more general, and really we would like the provisions to be flexible enough to allow for innovative methods. We might not have all the answers today and we rely on drug sponsors to come up with the solutions to the problems that they recognize and we recognize. In this arena we're talking about when a problem with a drug comes up or a risk is identified that needs to be mitigated, and that risk needs to be

mitigated by making sure that non-patients are protected, then we rely on industry and we encourage industry to solve your own problem. Heretofore that solution has been the flush directions, but we think that this legislation will enable a lot more innovative approaches, and we don't want to stifle that so it's important that we allow room for creative and innovative methods for disposal. I was one ahead of myself, how did that happen?

So in summary, which you've all read, FDA strongly supports the DEA in developing these procedures to allow individuals to dispose of expired, unused and unneeded prescription medicines through take-back programs. We really hope and we think that procedures will empower and encourage the citizens to take timely, safe and responsible action to make their homes and communities safer. And again, effective security provisions that assure the ultimate

destruction of all the returned medicines are critical to protect the public. And we look forward to continuing to work with the DEA and all our federal partners to encourage the development. We want these things to go, we want them to work. We are - I'm trying to figure out in your train analogy exactly where we might be. Maybe we're dragging a stick? But no, no, we want to move forward. And the core message here is that our directions that are in labeling for these products are there for safety reasons. They're driven by a need that was recognized early on before anyone thought about what would be sort of the most environmentally friendly I'll say method. They were driven by that need for immediate and complete unrecoverability for drugs. So at that I'll close and thank you very much.

(Applause)

MS. GALLAGHER: I think Jim was the brave one because the dirty word "flush"

is now out in the room, we can talk about it, and I thank you because that's a difficult word. We don't really want to promote it, but there are reasons that maybe it needs to be looked at. A common theme yesterday was communication, and I think your message in the labeling and how we communicate to the public how to dispose of it will also be a charge to DEA to make sure we're really getting the message out, and I think we look forward to working with FDA on that.

So our next speaker is - and I'm not going to say the last name right, I apologize. So this is Emil Dzuray from the U.S. Postal Service. Thank you.

MR. DZURAY: Good morning. Good morning, everybody. As Cathy said my name's Emil Dzuray and I'm the Acting Chief Sustainability Officer for the U.S. Postal Service. I want to thank DEA for holding this public meeting to get our ideas on how to best implement the Secure and Responsible

Disposal or Drug Disposal Act of 2010. I'm really thankful for two reasons, one a very personal one. I'm a parent of a new teenager and the evidence and the stories about the growing abuse of unused prescription drugs among our teens and our young adults scares me, quite frankly, as a parent. So the more we can do to stem that diversion for that use I personally want to make sure that we're part of the solution set. And second, as the Chief Sustainability Officer I'm charged with making sure that the Postal Service does its best to operate in an environmentally responsible and socially responsible manner. In addition to that, we're charged with helping our customers do the same so that they can use our products and services so that they can be more environmentally and socially responsible. So working with the DEA and mail-back programs around the country fits this sweet spot very well. So today I want to talk about how the Postal Service and

mail-back can be a part of the disposal of unwanted medications and prescription drugs. I'll be talking about specifically why mail is a safe, secure and environmentally responsible solution for transporting prescription drugs for disposal. We've been working and we look forward to continue to work with the DEA on the rulemaking process so that mail can be a more robust part of the solution set.

So why mail-back? The DEA asked to hear about different solutions for disposal that focus on safety and ease of use, and we believe that mail-back offers three main points for a take-back program: convenience, safety and security, and cost-effectiveness. First, as it relates to convenience, we deliver and pick up from every address in the United States and also, using our merchandise return service, it has the unique feature so that mail programs or mail take-back programs can make the

envelopes and packages free through postage paid, free to the ultimate user. So there's a convenience that they don't have to pay and they can participate with that. Second, the drug shipments, the unused prescription drug shipments through our networks are safe and secure. They're tracked throughout our network using our intelligent mail bar code system. They're protected by our independent Office of the Inspector General and they're watched over by our law enforcement agency the Postal Inspection Service. And third, mail is cost-effective. For example, our merchandise return service that I talked about as a means for implementing mail-back programs costs about anywhere about $1, $1.22 for a mail-back. So let me talk about these three features in a little bit more detail.

Convenience. As I said, mail is convenient. First, mail-back programs can utilize the postage paid feature that I talked about through the merchandise return

service where it's free to the ultimate user. And second, the ultimate users - and I should thank Representative Inslee for kind of teeing up my slides here, he did a good job - we're everywhere, obviously. The ultimate users can take their packages to over 33,000 postal retail outlets, they can drop them off at 180,000 secure blue collection boxes, or they can use carrier pickup from their residence or business and there's no additional charge for this pickup service.

As it relates to safety and security, mail is safe and secure. Our Postal Inspection Service oversees the safety, security and privacy of the nation's mail networks. Postal inspectors work closely with pharmaceutical, retail, financial and other shipping companies to investigate mail-related crimes. They can investigate and arrest persons for illegally mailing controlled substances such as

narcotics, steroids, drug paraphernalia as well as controlled prescription drugs. In addition to our Postal Inspection Service, we operate an independent Office of the Inspector General. Their role is to make sure that our network is safe and secure and they maintain the integrity and accountability of its employees as well as its revenues and assets. We have special agents monitoring the network at all times throughout the country with - stationed in 90 offices around the country.

When it comes to cost-effectiveness, as I mentioned, we envision mail-back programs primarily utilizing our merchandise return service. As I said, it's about $1, $1.22 for a typical return package and this service is well positioned to handle the return of prescription drugs. Our MRS, or Merchandise Return Service, not only is cost-effective but as I said it has that unique feature where postage is paid by a

third party such as a mail-back program coordinator so that it's free to the end user. Again, not only being cost-effective where they only pay for what is actually shipped back, but it's again convenient for the ultimate user. As I mentioned, our intelligent mail bar-coding system enables us to have visibility of the package throughout our network from pickup to reception or delivery, and that tracking is available for both our first class and our priority mail services. On the screen you can see an example of how our Merchandise Return Service looks, what a typical label looks like with its bar code, and you can also see underneath it an example of how we used the merchandise return label in a plastic, sealed, padded envelope for the main mail-back program. I think Dr. Gressitt is in the audience here. I heard somebody talk about him earlier. So this is an example of how we can use this particular service for mail-back programs in

a way that is easy and easy to track and easy to use for the end user.

Mail has been part of the solution for quite some time now. We've been conducting operational test agreements with different states, Maine being a prime example, to ensure the safe transport of controlled and non-controlled prescription drugs. Through these operational test agreements we've gained valuable insight on how pharmaceutical returns can be used and conducted through the mail programs, or mail networks. And last year on the other side we've been delivering pharmaceuticals through the mail for quite some time and last year alone we delivered more than 90 million pharmaceuticals to end users. So the mail has been used both for the distribution of pharmaceuticals to customers as well as in certain cases to take back unused drugs. So we have experience. Another key feature of using mail is the privacy. For the past six

years we've been voted the most trusted federal agency for assuring our customers' privacy by the Ponemon Institute and we were also in Ponemon's top 10 list of the most trusted American businesses. So we think that's an important feature of mail.

As I mentioned, we are working closely with the DEA to provide safe and secure mailing regulations to handle the return of prescription drugs. Currently we have three options available. In the first option the DEA-approved reverse distributors take back unwanted controlled and non-controlled drugs only from manufacturers, distributors, pharmacies and practitioners, and we have programs where they use the mail to do that. The second option is where an ultimate user returns the drug or unused prescription to a DEA-approved reverse distributor. This option is only available for non-controlled substances currently and the Postal Service requires instructions be

included that explain that controlled substances are excluded from this type of shipping option along with information on how to correctly dispose of controlled substances. The third option is where ultimate users use the mail to return controlled substance to a DEA-approved law enforcement agency willing to accept them, and these substances are then catalogued and properly disposed of. As I mentioned, the Maine pilot program was an example of that.

So to wrap up I really just wanted to make the point that mail can be a part of the solution, the set of solutions that we look forward to stem the diversion of unused prescription drugs for the wrong reasons. So mail is part of the solution, it's convenient, it's cost-effective, it's safe, it's secure and environmentally responsible. So with that I'd like to thank DEA and we look forward to continue working with DEA on the rulemaking process. So thank you.

(Applause)

MS. GALLAGHER: It's 10 o'clock. We're about 15 minutes ahead which isn't a bad thing, so why don't we go ahead and take our break now and we'll start back up at 10:15. Thank you.

(Whereupon, the foregoing matter went off the record at 10:01 a.m. and went back on the record at 10:15 a.m.)

MS. GALLAGHER: If I could use Mark's terminology, there's a porch lag. So if people could start taking their seats so we can get started. Okay, I think we'll get started. Give people another minute to get to your seats. Okay. Our next speaker is Bill Winsley. He's the president of National Association of Boards of Pharmacy. I think he'll bring a good perspective from the pharmacy. We hear about how everybody wants this in the pharmacy and I'm anxious to hear what NABP is - how you all are looking at this issue. So thank you.

MR. WINSLEY: Thank you very much, Cathy. Is this on now? Okay. And I appreciate the opportunity to be here. You'll see from the first slide I'm actually wearing two hats today. I'm here as President of the National Association of Boards of Pharmacy. That term expires in May. My real job is as Executive Director of the Ohio Board of Pharmacy. Now, the reason I point that out is as President of NABP when I get up and talk those of you that know Carmen Catizone well know that I'm expected to be polite, politically correct and not antagonize anybody. On the other hand, as the Executive Director of the State Board of Pharmacy in Ohio, I have been known to sometimes be downright rude, very politically incorrect and somewhat mean in my statements. So I would ask you all please to use some judgment as I'm up here talking. There will be times when I'm going to talk about what NABP is doing and during those times I will

do my best to antagonize no one, but I'm afraid I may step on some toes at other times and please understand that's Mr. Ohio coming out. If I mess this up, Carmen will send me back to the minor leagues and I'm not wanting that to happen, so I'd like to finish my term.

Just so you know, NABP is an association. NABP is not a government agency. They are an association of government agencies and you can see the NABP mission statement there. Basically, NABP's prime directive, if you will, is to assist the boards of pharmacy not only within the United States but several of those boards outside of the United States as well in protecting the public health, and that's critical. It's not to protect pharmacists, it's not to protect doctors, it's to protect the public health. In fact, the mission of all licensing boards - I try to get this into most of my talks when I have a mixed audience

- the mission of every licensing board in the country is not to protect their licensees, contrary to what a lot of the public opinion is. It is instead to protect the public primarily from their licensees who act in illegal, immoral, incompetent or impaired ways. Do not go too far with the immoral, but we do, most of us, have moral turpitude clauses in our practice acts. DEA in many regards, at least for the illegal and impaired, that also applies to DEA -- to protect the public from those people who act in these ways. The licensing board's role is not to protect the licensees. That's the job of the associations and they do a very good job at it. Our job is to protect the public from those licensees who act in one of these ways, and if we do our job right, and the same holds true for DEA, if we do our job right, we protect the public in a way that still lets the good guys operate as best as they can. Now obviously, if you have laws

and rules you have restrictions, but we, at least in Ohio and most of the boards of pharmacy, try to look at separating the good ones from the bad ones, and let's make sure we can take care of the bad ones. Let's leave the good ones alone.

The Ohio Board of Pharmacy is a little different, and I want to make sure you understand that. We are a licensing agency like every other board of pharmacy in the country, but in Ohio we do not have a state police so the Ohio Board of Pharmacy is also a law enforcement agency. We are the state agency charged with enforcing the drug laws, the criminal drug laws, throughout the State of Ohio. Now obviously the local police, sheriffs and so forth also have that responsibility in their jurisdictions, but we are the state agency with statewide drug law enforcement. So we enforce the criminal drug laws. We share with the Department of Agriculture the Ohio Food and Drug Act.

Obviously, we don't mess with the food part. We are the controlled substance authority in Ohio so the rules we make about controlled substances apply to everybody and then, of course, we enforce our own practice act.

Now, this is where Mr. Ohio comes out. I've been to a bunch of talks over the years on drug disposal, drugs in the water, and we had a lot of really good speakers yesterday. I've spent a lot of time - and I'm serious - spent a lot of time to be well prepared. Some of you that came for the 10 minute segments obviously put a lot of work into what you wrote. Some of you had more words in your 10 minutes than I'm going to have in my 30, but they made sense. You did a very good job. However, you all disappointed me. Every talk I've been to, every meeting I've been to there's one subject that comes up. It is a critical subject and everybody gets all bent out of shape about it. I didn't hear one word about

Prozac fish yesterday, not one word. At least one speaker at every meeting I've been at for the last several years has brought up Prozac fish, ha ha ha ha, and it just irritates the daylights out of me. So, during my four hour layover in Columbus Airport waiting for my plane to arrive to bring me here Tuesday night, I got on the laptop and decided this time I was going to be prepared. When one of you guys that spoke yesterday brought up Prozac fish I was going to be prepared to address it. You really disappointed me, nobody brought it up. We did hear about the fish yesterday that doesn't know whether it's a he or a she, and the same principles apply, and I'm sorry to waste your time, but I put a lot of work in the airport while I was bored getting these facts and figures I'm about to give you, so we're going to go through it anyway. 2003, an article that I found, "Fish on Prozac." Two other articles, "Fish on Prozac: How

Depressing," antidepressant ingredient detected in Texas lake water. As a 60-year-old, the one that really got me, antidepressant Prozac inhibits sex drive in fish. Now this is serious. That article goes on to say that Prozac-like pharmaceutical products - and I'm not picking on Prozac, folks. Please don't file a lawsuit. This is what everybody likes to joke about so that's why I was addressing it. But drugs in the water are obviously a problem. Prozac's taken, however, by more than 54 million people around the world. That was also in that article.

Now, I did some calculations. I told you I was bored. I found an article that was trying to relate suicide rates and Prozac use and it came out to the benefit of Prozac and that wasn't what I was looking for. They had dispensing figures on it-- from 1988 to 2002 the number of prescriptions for Prozac that had been dispensed. Then I

went to Drug Topics. If you're familiar with the Drug Topics website they do a survey every year and they list the top 200 dispensed brand name drugs and the top 200 dispensed generic drugs. And so I had the Prozac scripts from `88 to `02 and if memory serves me correctly it was right around 2002-2003 that the generic fluoxetine became available. So in 2003 Prozac had dropped to No. 197 out of 200 on the Drug Topics list and then `94 on Prozac was not there. So I don't have Prozac figures from `94 on, and I have fluoxetine from `93 to 2009. But the bottom line is in all that time, brand and generic, 423 million prescriptions were issued for fluoxetine, brand or generic. Now, I think Drug Topics, and some of you can tell me if I'm right, but I think they kind of adjust the figures to make them all consistent, and I think it's to a 30-day supply, but I'm not sure. So at a minimum, being conservative, if you figure that each

of those scripts was for 30 capsules, Prozac sometimes is BID, twice a day, but usually it's once a day and so you figure it's 30 capsules a script, 423 million scripts, that means in that time period there were 12.7 billion BID doses of Prozac dispensed. That's a lot of Prozac. We've got troubles in this country. And when you consider the fact that all that time I was looking up fluoxetine dispensing, the number one drug on the list which was about four times higher in dispensing was hydrocodone. So I mean, you pick any drug you want and this calculation works. Now, depending on where you look, and I've been looking at this for some time and it depends on what source you use, but somewhere around 10 percent of every dose of fluoxetine that's consumed is excreted as fluoxetine. Every dose. Now, it depends on where you look. Some people say it's slightly less than 10. The Epocrates software I have on my cell phone says 11.6

percent unchanged. Ten percent is close enough. Every dose that was consumed was excreted into our water system by the patient at least 10 percent. But in addition to that, there's an active metabolite that adds another 5 to 7 percent more, so somewhere around 15, maybe even as high as 20 percent, of every dose of fluoxetine that is taken by the patient ends up in our water supply. So the question I have for you is where is the Prozac, the fluoxetine, in the water coming from? Where are the hormones that made that fish wonder if it was a he or a she coming from? And is there anybody in this room - no, I'm not going to ask it that way because somebody will raise their hand and embarrass me. I don't think there's too many of us in this room that think that patients in large part are going out shelling out all that money for the fluoxetine, for the birth control, going home, standing over their toilets and shucking them out into the

toilet. So no matter how big a deal we make about flushing, my suggestion is that that's a very tiny part of the environmental problem. And not wishing to hurt anybody's feelings, but I'm going to use the dirty F word again. When you look at the fact that we have drugs in cabinets, and, as a law enforcement agency, we deal with those kids that are getting hooked on those drugs. I've had countless phone calls from parents, from spouses who have lost a loved one because they OD'd on drugs. And having three daughters and five grandchildren I have to tell you, and I'm not being dramatic, this is the absolute truth, that pain comes across the phone lines and it ties your stomach in knots. So when I get people that call me and say I've got these drugs left, what do I do with them, the first thing I ask them is is there a drug disposal program in your community coming up. I don't know of all of them, I hear of some, but I ask them is there

some way that you can take it somewhere. Right now the answer is almost invariably no. So I want you to know that in the State of Ohio--and this is Ohio, not NABP--in the State of Ohio we tell them to flush those few doses. And I don't care whether it's a controlled substance or whether it's a cardiac drug or a blood pressure med because the side effects - a lot of the people that we deal with, pardon the phrase, but a drug is a drug. They don't really know the difference. They just take it, and the side effects of some of our non-controlled substances are sometimes just as severe or more severe than the side effects of the controlled substances. So, for what it's worth, until we get a better method--and I hope it's real quick because I philosophically agree with everybody--I don't like flushing. But, until we get a better method in the State of Ohio, we tell people to flush them--small doses, small quantities.

We're going to talk about nursing homes in a minute.

NABP -- okay, nice guy. NABP has dealt with this issue on several occasions, but the two most recent. In 2008 at our annual meeting, the membership passed a resolution on medication collection programs, and I'm going to spend some time covering that. And then that report came in to our annual meeting at 2009 and yet the membership came out with another resolution on over-prescribing and excessive use which addresses another major part of the problem. And I'm just going to go through this quick, but the resolution basically addresses the fact that unused, unwanted, expired medications threaten public health--and this phrase got in because I, even though in spite of all my diatribe recently about flushing instead of holding onto them, I didn't stand up and argue about this--so we do have an environmentally friendly statement in this

resolution. But we also tie it to the fact that there is an increase in drug abuse which we all know. Some of us have known for 22 years or more that there's been a problem with prescription drugs. And, so in a way, we're -- some of us -- are kind of glad that everybody else is finally becoming aware of it. But, nevertheless, there is. And NABP has recognized that the collection programs provided for safe and efficient disposal, so they asked the executive committee of NABP to convene a task force to review the medication collection programs and also recommend some changes to our model rules. Like most associations we have some model rules that states can use if they wish. So they came out -- the task force met and they came out -- with two recommendations. Well, they came out with several, but I want to cover two of them with this group here. First of all, they asked that we keep an eye on what DEA is doing, which we all do, but particularly in

this particular instance about addressing the return -- and the key phrase I want is at the bottom there -- to comment at the appropriate time, which I assume is now, to advocate for DEA to allow licensed pharmacies to be repositories for unused controlled substances. That's a common theme that ran all through yesterday. I want to add NABP's voice to that as well. As boards of pharmacy, we deal with those pharmacies and we understand that the majority, overwhelming majority of them -- of pharmacists -- are honest, just as everybody in every other profession. We do have some bad apples and most of us are pretty capable of dealing with those bad apples. But pharmacies already possess a carload of controlled substances that pharmacists and technicians have ready access to and if this is done in a safe and secure manner as I've heard before in order to minimize the chance of diversion, in order to minimize the chance of resale, then we

think that retail pharmacies should be given the opportunity to participate. Please not a mandate, but I will tell you in the State of Ohio I have a whole group of pharmacists who are more than willing to help their communities out by accepting some of these returns and helping them to get destroyed. And so I think if pharmacy is given the opportunity, they will grab it. So please, I'd ask DEA to consider that as the rules are being done. Get pharmacies into that process.

The other recommendation which kind of leads into the next resolution is to work with appropriate entities to research methods reducing the amount of unused medications. We all know that patients are part of the problem. They get an antibiotic and they start to feel better so they quit taking it, which is not real good, but they do that. They get medication to be taken as needed and they don't need it. So those are

all problems, but there are other problems as well that need to be used to address this issue, some of which are a little outside of the scope of this meeting so I'm just going to quickly touch on -- leading into the next resolution which dealt with overprescribing, which is one of the big reasons we've got drugs in medicine cabinets. Overprescribing and excessive use of prescription drugs compromises patient safety. So what the membership asked us to do, the executive committee, is continue NABP's efforts in any way possible to address the issues related to the excess drugs in the medicine cabinet -- dealing with disposal, consumer education, prescription drugs and abuse -- and work with other stakeholders really to reduce the incidences of over-prescribing. And I've still got 11 minutes so I'm going to tell a story. I'm going to give you some HIPAA-protected information. About a month and a half ago, I had a little cyst or nodule right

here at the base of my thumb and it was fine until I grabbed something and then it put pressure and it smarted so I went to my family doc. He said I'm not going to take that out right there at the base of your thumb. There's nerves running up, I'm not getting in there, you've got to go see a hand surgeon, which seemed a little excessive, but I went. The guy was really good. So I'm in there and I'm talking to the anesthesiologist because I don't know if you know it or not, but even small procedures now, instead of clamping off your arm and putting in a local and making your arm dead, they like this drug called Propofol that takes you out and then you come back. So anyway, I'm talking to the anesthesiologist about what he's going to use and we're negotiating the amount of Versed he's going to use, because being 60 I've had it several times and I don't like it, when in walks this young PA -- physician assistant. Introduced herself and she's working with the

surgeon and she wants to go over my discharge instructions beforehand when I'm still sane and sober. And so she's talking to me and she said and when you leave I will give you a prescription for a pain med. She didn't know who I was, what I do and she was young. And I said yes, what are you going to write. And she kind of looked at me and she said, well, I like to use Norco because it's got a lower level of Tylenol in it and Tylenol - I said I know what Norco is. How many are you going to write? She said, well, 30. And I looked at my hand and I looked at her and I said now wait a minute. I just have this little lump here. He can't be going to amputate my thumb. Why in the world do I need 30? And she was thinking when I said how many are you going to write I'm going to start whining I want a whole bunch. I said that is ridiculous. I said now I don't know whether there's going to be any pain or not. Historically, I probably -- based on other

things I've had done -- I probably won't even fill the script, but, for heaven's sakes, there's no excuse for you to write it for 30. Make it for no more than 10. Are we clear? Yes, sir. I get in the operating suite and she's in there, and she comes up to me right before they knocked me out or did whatever they did to me -- there's a gap there. I hope I didn't tell them anything. But anyway, she comes up and says I'm in here and I'll be assisting and so forth and I just looked at her and I said - well, I couldn't point at her because they were painting my hand, you know, and that kind of stuff. I said 10. She said yes, sir. And she gave it to me. Now, the end result was I didn't fill it and I couldn't have because she didn't write the script right and that happened to me once before and I filled the script. It was just for a prep but I filled the script and one of my inspectors found it in the pharmacy and pointed out to me that I had

filled an illegal script so I didn't. Bottom line is overprescribing is the biggest issue that we have and somehow, some way those of us in the audience have got to get to the docs and convince them that they don't need 30 hydrocodone every time somebody comes in with a sore toe, but that seems to be the common quantity. I'm sorry that the insurance companies don't like small quantities, but there are times when small quantities are more appropriate and I wish we can get that message across. I can tell you that we're doing it in Ohio as we go out and talk to doctor's groups. Some of them don't like to hear it, but I'm real sorry, they hear it anyway, okay?

So that's basically what NABP has come out with. Certainly want the message across that pharmacies need to be part of the take-back issue. And please understand, I don't like flushing either. Philosophically, it's bad, I don't like it, but I've got bad -

people dying from drug overdose. . . I've got bad flushing. And to me, there's no balance at all. The dead people far outweigh the flushing. Let's get this rule done, let's get a better method to do it and then I'm going to quit saying flush.

Everybody has talked about retail pharmacies as part of the take-back. I don't want to waste anymore time. Long term care has come up. Long term care is critical. They are a special situation. From personal experience, because when I started with the board I was in the field, I was in long term care facilities quite frequently. They have lots of problems with excess drugs and what works for the general public - somebody yesterday suggested that mail-back would even work for nursing homes. With all due respect, I suggest that for most nursing homes that is not going to be an appropriate way to deal with it. Nursing homes routinely generate lots of drugs that are excess.

We're back to overprescribing again. When I was in the field and I would go into a nursing home - and I'm not picking on the VA but I am picking on the VA - I would see vials of Darvocet-N that had 720 of them in a vial for an elderly patient. Now, can anyone here justify an elderly patient getting 720 vials of a drug that FDA finally has recommended come off the market because it doesn't do any better than Tylenol for pain? And those drugs were just accumulating in the nursing home because in some cases they were on automatic renewal. And it's not just VA. This goes on across the board. So basically long term care needs some special solutions.

I want to talk to you about what we do in Ohio. Fasten your seatbelts because I'm going to shock some people maybe. In Ohio for years we've allowed long term care facilities to ship the drugs -- unused drugs -- back to the pharmacy for the pharmacy to

take care of. In fact, we even allow the reuse of those drugs because they are not in the possession of the ultimate user. Instead, for us, they go from a licensed facility pharmacy to a licensed facility nursing home. We're in the nursing homes to make sure that they're secure, they're in a stable temperature, so -- and you'll see from the rule -- they're in tamper-evident packaging. So we do allow pharmacies to reuse the nursing home meds that meet certain criteria. I've given you a rule number. I understand these slides are going to be posted so if you go to our website, which was on the first slide, you can get to this rule if you really need it. But, basically, you'll see that routinely we do not allow drugs to come back to the pharmacy for re-dispensing except drugs dispensed for inpatients. And, again, that's one of the differences currently between DEA and the Ohio Board of Pharmacy. We regard nursing

home patients and hospital patients as inpatients rather than outpatients. And inpatients, which is right now under federal, that's kind of where we're at. So we say drugs dispensed for inpatients, so hospital or nursing home can come back for dispensing again as long as, as I already said, unopened, single-dose or tamper-evident containers and the drugs have not been in the possession of the ultimate user. We have a major concern with tampering. We also have a major concern with storage as you heard earlier this morning. So even those injectables that are still sealed that leave a retail pharmacy and go to a patient's home, we do not allow those to come back because we don't know where they've been stored. And so, you know, we are very careful to ensure that the only drugs that come back for reuse are those that have been stored properly, those that are in tamper-evident containers, those that have been under the control of a

healthcare professional.

Now, in order to come back they've got to jump through some hoops because we want it to be secure and accountable. I will also tell you that we have removed a lot of nurses out of nursing homes for diverting drugs so we understand that there is a problem there. We've also removed a few pharmacists for diverting drugs, so we want to make sure that it's accountable and secure. So we have a requirement that there's inventory lists at both ends. The same inventory lists and the pharmacists darn well better check when they come back. It's intensive, but it gets the drugs back to the pharmacy -- so verified by both. Then if they reuse that drug there has to be records. Now, keep in mind that the pharmacy packaged it up so they have the original lot number and original expiration date. We don't allow them to mix, but they can reuse if they want to, knowing the path of that drug, or if they

destroy them they're required to keep drugs. And they can destroy them any legal way possible. Many of them use return wholesalers so that they can just return the drugs and get rid of them. We do not suggest that they flush those large quantities, and I'm telling you, we're talking file cabinets full. But they are allowed to destroy them. The other thing I will point out is that those nursing home meds can also be contributed to the free clinic. Ohio was the first state in the nation to allow drugs to be donated to a drug repository program, but as we did that bill, again, we got in there that the only drugs that could be donated were drugs that were never in the possession of the patient or caregiver which basically drops it back down to nursing home meds and unit-of-use containers. But nowadays instead of reusing them, a lot of our nursing home pharmacies now are donating them to the homeless shelters and so forth, which are

also licensed with us, by the way. We license everybody that moves.

So that I got done with one minute and three seconds left. Oh no, one more. First of all, the return does not apply to controlled substances of course. I want that perfectly clear. I don't want to be arrested by DEA on the way out the door, but I have yet - because I really think that's something - if we can set up a safe and secure mechanism, accountable, that's one way to get rid of some of those PRN opiates rather than putting them in an incinerator, putting them down a drain. And as we heard yesterday I guess CMS is going to come out and mandate that pharmacies start crediting for some of those Medicare Part D drugs, and if that's the case maybe we ought to at least keep an open mind to some of that reuse. So now with that, that's my final slide. I appreciate it. Thank you all for your attention and I'm looking forward to the rest of the day.

(Applause)

MS. GALLAGHER: Knowing Bill I am sure when he was put asleep for his little cyst he did say things, they just didn't tell you. You can't help yourself. Two things before we move to the next speaker. Over-prescribing obviously is a big issue and the key - the challenge for DEA is that we don't tell doctors or we should not tell doctors how to practice medicine. So we get looked at as, well, doctors are overprescribing, they're underprescribing, then they look to DEA for guidance and we are - it is very clear that that is not our lane. We should not be there. But when there's over-prescribing and abuse, immediately they come back to DEA. So I just want you to know for those of you who aren't familiar with our issues, you know, the practice of medicine we try to leave that to the practitioners. The other issue is long term care. We are very clear, we know that the issues with long term

care facilities are something that we really have to take into consideration and we really are. It's not just the user at the home, the long term care facility is important. I think Bill gave us some good ideas.

Our next speaker is Robert Dellinger from EPA. He's the Division Director from the Materials, Recovery and Waste Management Division, Office of Resource Environment. EPA is new to us and I'm now noting my new vocabulary words for my winter vocabulary list. One of them was "thermal combustion," "high temperature burns," these are terms that DEA, we really don't discuss, so I have enjoyed - I don't know enjoy, because this is all a new area-- but I'm learning a lot about that area. We have reverse distributors, they destroy it. For us it's accountability, can you account for it, that's what matters to us. But now I'm like, okay, I've got to learn these new terminologies so my winter vocabulary list

and EPA list keeps growing and I probably will learn more today. So Mr. Dellinger, I'm not sure where you are. There he is, okay. Thank you.

MR. DELLINGER: Well, I want to start by thanking the Drug Enforcement Administration for inviting our agency to provide comment on the issue of developing safe and effective drug collection and disposal methods. EPA's involvement in this issue is prompted by several things. First, our areas of responsibility include ensuring that waste is managed safely and protectively as required by the Resource Conservation and Recovery Act which I'll give you another acronym, RCRA, and then people will know that you're an expert on waste management. And second, research has documented that active pharmaceutical ingredients are now widely established as ubiquitous contaminants in the environment at very low concentrations. Active pharmaceutical ingredients have been

found in a wide spectrum of environmental media including sewage, surface waters, ground waters, sediments, drinking waters, marine environments, sewage, sludge and bio-solids, tissues of crops and native vegetation when bio-solids or treated wastewater are used for irrigation or soil amendments, and tissues of aquatic organisms. The presence of active pharmaceutical ingredients in the environmental media can result in chronic ultra-low level exposure for wildlife and humans.

As it is the mission of EPA to protect human health and the environment, we've been working to understand the issues surrounding the disposal of pharmaceuticals and the presence of active pharmaceutical ingredients in the environmental media. We also respect DEA's responsibilities under the Controlled Substances Act and DEA's primary concern that controlled substances are not diverted from the waste stream. EPA and DEA

share a common goal of protecting public health. While our respective agencies' missions differ in focus, the missions are compatible when it comes to the disposal of unwanted controlled substances and other pharmaceuticals. DEA enforces against diversion directly to people and EPA enforces diversion - enforces against diversion to the environment and thus indirectly to people. EPA looks forward to collaborating with DEA on this issue and welcomes the opportunity to share our technical expertise in future collaborative efforts between our agencies on this issue. Our joint efforts should focus on making drug take-back programs available and easy to execute in a safe manner. EPA is working to stop flushing of drugs where appropriate and drug take-back programs can help keep drugs out of the environment. EPA has awarded two grants for take-back programs which I'll discuss a little bit later and has drafted best management practices for unused

pharmaceuticals at healthcare facilities.

I'd like to provide a quick overview of EPA's general recommendations for DEA's new regulations regarding disposal of controlled substances from ultimate users. First, EPA recommends that DEA develop a national set of options for drug take-back programs to encourage the use of these programs. Second, EPA notes that controlled substances collected and commingled as both hazardous and non-hazardous solid waste must be managed as a hazardous waste and be managed according to the Resource Conservation and Recovery Act and also the Clean Air Act, and all other applicable federal, state and local regulations. Third, EPA recommends that DEA define what constitutes destruction of a controlled substance and identify the method or methods that DEA believes achieve destruction by providing specific examples such as incineration. Our agency has quite a bit of

experience with incineration and those types of destruction technologies, and we'd be happy to provide any help that you all need in the future. Our last recommendation is that DEA consider streamlining or modifying drug take-back recordkeeping and inventory requirements. EPA also encourages DEA in its new regulations to provide flexibility consistent with the policies underlying the Controlled Substances Act to enable a national set of approaches that can be widely implemented for drug take-back programs that in practice may or may not involve the collection of controlled substances. This may require a menu of options each perhaps suited for different geographic locales. Options include but are not limited to mail-back programs, consumer returns to DEA registrants, secured boxes at pharmacies and other locations, or any combination of those, and any other approach that may come about as a result of this public meeting. EPA is

mindful that any take-back program needs to be designed to prevent diversion of controlled substances in accordance with the Controlled Substances Act. In regard to the specific issue of the collection of pharmaceuticals from the public, EPA awarded two grants to test two different approaches for prudent disposal of unwanted pharmaceuticals and both of these pilot drug take-back programs were very successful. And I'm going to go over in just a little bit more detail on both of these in the next two slides.

The first grant that I'll be discussing is a grant that was awarded to the Regional Excess Medication Disposal Service in St. Louis, Missouri. The model for this take-back program was for pharmaceuticals to accept returned drugs and pharmaceuticals. During the grant period this take-back program collected over 244,000 capsules, tablets and suppositories. No controlled

substances were collected through this program as the grantees were not able to obtain permission from the local DEA. No diversion or theft of the pharmaceuticals occurred and all of the collected pharmaceuticals were incinerated.

The second grant that EPA awarded was for a pilot mail-back program and this program has continued to operate after the grant period and is currently collecting over a hundred pounds of drugs a week. The program is administered by the University of Maine Center on Aging in cooperation with the Maine Drug Enforcement Agency and also the U.S. Postal Service. And there are also numerous partners within the state and also national partners. The program distributes postage paid medicine return envelopes to selected pharmacies and organizations, and staff at these locations give envelopes and instruction packets to interested participants. Then the participants mail

unwanted medications via the U.S. Postal Service which provides secure delivery to the Maine Drug Enforcement Agency and the envelopes received are logged, catalogued and destroyed under Maine DEA custody. All non-controlled drugs are incinerated as hazardous waste and the controlled drugs are witness incinerated as municipal solid waste at a waste to energy facility. No diversion or theft of the pharmaceuticals has occurred and the amount of drugs collected illustrates the success of the mail-back model for take-back programs.

Once collected, unwanted controlled substances and other unwanted pharmaceuticals, whether hazardous or non-hazardous solid waste, must be managed and disposed of according to the Resource Conservation and Recovery Act, the Clean Air Act and all other applicable federal, state and local regulations. States may have more stringent or broader regulations than the

federal government as the federal environmental regulations set the baseline, the minimum that needs to be achieved. Thus EPA strongly recommends that organizers of take-back programs contact the state and local environmental regulatory agencies for their locations to see - to make sure that they're doing what's supposed to be done in those particular states or counties. EPA's comments focus on the federal regulations as they apply to the disposal of household pharmaceutical waste, and first I'll discuss RCRA requirements and Clean Air requirements. These regulations apply differently depending on the situation.

The Resource Conservation and Recovery Act regulates waste management in the United States. Non-hazardous waste such as municipal solid waste are regulated under Section Subtitle D of RCRA which is - and it's implemented basically at the state and local level. Hazardous wastes are regulated

under Subtitle C of RCRA and Subtitle C regulations are issued at the federal level although states can issue more stringent hazardous waste regulations than the federal regulations if they choose to do so. Virtually every state in the union is - has been approved, their Subtitle C hazardous waste permitting programs and enforcement programs have been approved. There are a few states that did not do that. So the states are also involved with the federal government in making sure that hazardous waste regulations are met.

We often get questions asking whether pharmaceuticals are hazardous wastes under RCRA. The short answer is that there are only a very small percentage of pharmaceuticals that are regulated as hazardous waste. This includes three DEA controlled substances that are also listed hazardous waste. A waste is considered hazardous if it has been specifically listed

by EPA as a hazardous waste or if it exhibits a characteristic of hazardous waste, and those characteristics are ignitability, corrosivity, reactivity and toxicity. The regulations applicable to hazardous waste pharmaceuticals depend on whether the generator of the hazardous waste pharmaceuticals is a household, conditionally exempt small quantity generator, small quantity generator, or large quantity generator.

DEA is interested in the disposal of controlled substances from ultimate users or households. The federal waste management regulations include an exemption for all hazardous waste that's generated by households. Thus, under the hazardous household waste exemption, pharmaceutical waste that would otherwise be regulated as hazardous waste that are generated by households are not required to be managed in accordance with the federal hazardous waste

regulations. The municipal landfill regulations that were issued by EPA back in 1991 were developed under the requirement that they be able to manage any hazardous waste that would get there through conditionally exempt small quantity generators and by households. EPA has interpreted the exemption to apply even when the household hazardous wastes are collected by a third party. In other words, that exemption travels along with those materials and that third party could be a take-back event. It should be noted, however, that not all states recognize this exemption as applying once household hazardous wastes are collected and consolidated. EPA recommends that organizers of collection events contact their local and state environmental regulatory agencies to ensure that the collected hazardous pharmaceutical wastes are managed in accordance with all local and state environmental regulations. And while

we don't regulate household hazardous waste under our hazardous waste regulations, we recommend strongly that the collected pharmaceutical household waste be managed and disposed of in accordance with those regulations. States also run hazardous waste collection programs and we've offered that same advice to the states in those types of take-back programs where they're taking in paints, solvents, or different things like that at collection programs. If the collected pharmaceutical household hazardous wastes are managed and disposed of as hazardous waste then the waste shipments must be manifested, and the hazardous waste manifest is a tracking document that accompanies the waste from the generator to its ultimate disposal site and there are different elements in between -- sign-offs. The waste may need to be treated as well, and burning in a permitted incinerator would be the likely treatment step prior to disposal

of the remaining ash in a permitted hazardous waste landfill were these materials to be hazardous.

The Clean Air Act standards do not apply to the direct disposal of controlled substances by their ultimate users. Under the Clean Air Act EPA has issued emission standards for hazardous waste incinerators and for non-hazardous solid waste incinerators. Specifically, our agency has promulgated standards for hazardous waste combustors, whether they be boilers or industrial furnaces, municipal waste combustors, hospital, medical and infectious waste incinerators, and commercial and industrial incinerators which potentially could be applicable to the destruction of controlled substances. In addition, EPA has issued emissions standards for municipal solid waste landfills. And if DEA is interested in obtaining those regulations we can put you in touch with the people that are

running those programs and are familiar with those regulations.

Due to concerns over the possible impacts of active pharmaceutical ingredients in our nation's waterways, EPA suggests that DEA affirmatively discourage disposal of household controlled substances to sewers except in the few instances where the Food and Drug Administration recommends flushing. The FDA recommends sewering a short list of drugs that are extremely dangerous to those for whom the drugs have not been prescribed, such as children and pets. For all drugs including controlled substances that are not included on FDA's list, EPA recommends against sewer disposal. I know that's different from what the gentleman is doing in Ohio.

In addition, EPA suggests that DEA define and constitute -- define what constitutes destruction of a controlled substance and identify the methods that DEA

believes achieve destruction by providing specific examples.

Finally, we note that any approved destruction methods must be in accordance with the Resource Conservation and Recovery Act, the Clean Air Act, and all other applicable regulations including federal, state and local environmental regulations.

And again, we'd be happy to help DEA figure out what some of these regulations mean. Some of them are quite complicated, so. And we know - I work in what is the Office of Solid Waste and Emergency Response, but we have - we know people that are dealing with air issues and also water issues and the like.

EPA supports DEA's drafting of regulations that would allow for the disposal of unwanted controlled substances by some entities that are not now registered with DEA. Based on EPA's draft healthcare study on the management and disposal of unused

pharmaceuticals, a common means of disposal for unused controlled substances at long term care facilities is to flush them down the drain. Employees of long term care facilities typically are not DEA registrants and therefore cannot return controlled substances to their pharmacy or transfer them to a reverse distributor or to any other DEA registrant for disposal. This means that long term care facilities usually dispose of controlled substances by flushing them. By developing a means of allowing long term care facility personnel the ability to become DEA registrants or developing some other type of authorization mechanism, the facility could have additional disposal options. And Ohio seems like they have done a lot of work to try to - to make that happen.

EPA recommends that DEA consider streamlining or modifying drug take-back recordkeeping and inventory requirements. Inventory and record-keeping requirements for

controlled substances at take-back events are currently applied in various ways, including pill by pill identification, separation and tracking prior to disposal. These requirements could present obstacles to the organizers of drug take-back programs that would collect controlled substances from ultimate users. And in developing your regulations, we recommend and I think I'm going to repeat what I started with at the very beginning, develop a set of flexible options for pharmaceutical take-back programs. I move that from the bottom to the top, you know, just - that's the thing that we're very much interested in. Ensure that destruction and disposal of pharmaceuticals are in accordance with the federal, state and local environmental regulations and define allowed destruction methods and disposal options. And again, I, you know, if - you know, just let us know and we'll do the best that we can to help you all work through

that. And then streamline recordkeeping requirements for take-back programs.

Again, I'd like to thank DEA for inviting us to participate in this public meeting and to provide comments on the disposal of pharmaceuticals, including controlled substances. We look forward to working with DEA and welcome the opportunity to share our technical expertise on destruction and disposal options. And for more information on EPA's efforts to improve management of drug waste, our main contact would be Lisa Lauer. Her phone number is 703-308-7418. And I want to thank DEA again for inviting EPA to share our views with you on developing safe and effective drug collection and disposal programs. Thank you.

(Applause)

MS. GALLAGHER: During the last five years one of Mark's and I discussions - we have lots of discussions on where to go - one of my biggest struggles has been, you

know, we don't define what's non-recoverable, what's non-retrievable. We need to define it, you know, but it's not in our regs. Do we define it? How do we define it? Do we do a study? You know, I keep coming back to this because we receive letters from industry or companies that have great ideas. You know, if we have this tub and we have all these solutions in it and we just put the drugs in there, is it rendered disposal, you know, is it gone? And we've never been able to say yes, no, this method. So we've heard it twice now. You need to define what this is. So that's a huge undertaking, but I think we'll try and maybe take a look at it. I can't make promises on that one, but clearly that's something that I'm hearing, a reoccurring theme.

As we move to the next speaker, we've talked about the individual at the home getting rid of their medication and getting it out of the medicine cabinet and why that's

important. We've talked now about long term care facilities and their needs. But we've also now - just has been brought to our attention, last week we met with the Department of Army and the issues that they're dealing with. We heard about the VA and the Army-- all the armed forces -- have with suicides and unintentional overdose, they have a huge burden to tackle this. And so I'm interested - I think you will find - Bruce Shahbaz from the Army is here. He is in the Army Health Promotion and Risk Reduction Task Force. He met with us and his cohorts met with us last week. It was very moving because of what's going on in the world today and so I welcome you to come and speak.

MR. SHAHBAZ: Good morning. Thank you to the Office of Diversion Control for allowing the Army to come. On behalf of General Chiarelli, the Army's number two four star general, we appreciate this opportunity.

As you mentioned, we do have a serious urgent requirement for the ability to deal with medication take-back, particularly the controlled substance take-back. I'm going to talk about the challenge that the armed forces is facing, the Army is facing, explain our unique population requirements and why we think we're a different subgroup for which we have a unique solution that presents itself to us. I'd like to caveat and say I am speaking on behalf of the Army only, not the entire Department of Defense nor the VA or any of the other associated uniformed services.

I'd like to begin by reading you a portion of a spot report that I received yesterday morning. "On 19 January `11 Command was notified of the on-post death of Private - a 22-year-old single white female assigned to a medical unit in Yongsan, Korea. Preliminary investigation revealed that at about 5:50 in the morning, the private was

found unresponsive in the barracks room by another soldier. EMS responded. The soldier was pronounced deceased at the scene at 6:45 a.m. The private was last seen alive at 1600 hours on the seventeenth. Examination of the scene found nine bottles of prescription medication and several empty beer cans. The amount of medication and indications of possible misuse is in play. There were no obvious signs of trauma to the body. Autopsy has been scheduled." I would love to be able to tell you that this is a unique and isolated incident. It is not.

I apologize for not being here yesterday. General Chiarelli had a press conference where he announced the Army's 2010 suicide numbers. In the active Army, we had 156 soldiers die by suicide. In the Army National Guard, soldiers not serving on active duty, we had 101 deaths. This is a doubling from last year. In the Army Reserve we had 44 deaths which is about a 35 percent

increase. We had 28 Department of the Army civilians and 14 active duty family members. Within the ranks, overdose is an increasing problem. Within suicide, it's our number three cause of death for suicide and the percentage has been increasing over the last several years. In addition, we recently wrote a report, the Army Health Promotion Risk Reduction Suicide Prevention Report, a small little examination of the problem. And in our accidental deaths, from Fiscal Year 01 where we had less than 40 accidental deaths to FY 09 where we had more than 100 accidental deaths during that time period. Fifty percent of those deaths were the result of some sort of overdose and 74 percent of those overdoses were the result of prescription medication overdoses. So, in addition to my suicide issue, I have the accidental overdose issue, a significant problem within our force.

Why is this happening to us? In

large part it is because we are an Army at war. It seems somewhat obvious, but the implications for the Army are pretty grand. Last year, 45,000 soldiers left Ft. Hood, Texas, and went to Afghanistan for a year and then came back home. Forty-five thousand people moving in their entirety, conducting combat operations, carrying 150 pounds of gear through small towns, villages and the mountains, doing their job, coming back where they hope to be home for approximately 18 months, God willing two years, before they deploy again. Eighteen months is an increase for us. For the last several years most of our soldiers have been fortunate to get 14 months at home before they deploy again. So we have this constant workload that is accumulating stress on the force, both physical and psychological injuries that are requiring a substantial amount of medication intervention. Colonel Labadie here from the Office of the Surgeon General tells me that

in any given moment in time about a third of our force is taking a medication of some sort, and one of those medications, a narcotic pain medication specifically, about 7 percent of our force is taking a narcotic pain medication. Another 3 percent is taking a behavioral health medication. Now when you have a workforce of 1.1 million people with 7 percent and 3 percent taking a medication at any given moment in time with the obvious turnover over the course of a year, that's a large number of medications. The Army Surgeon General has attempted to address this problem, and in May of last year wrote a pain management report which we are now implementing in an effort to get to some of the issues that some of our previous speakers talked about in terms of the overmedication, the appropriate medicating and those issues. But again, remember as a force at war, we're deploying and if you're going to an outpost on top of a mountain in Afghanistan there's

no CVS nearby where we can write a two-week prescription of medication for that individual and hope that they go to the corner CVS in Afghanistan to get it refilled. We have to prescribe sometimes in larger quantities than we would normally like to do. Additionally, within the Army we have a smaller subset population of exceptionally high-risk individuals that we call our wounded warriors. This population are people who are taken out of their infantry and armor normal Army units and assigned to a hospital unit because their injuries, either combat injuries or other injuries, prohibit them from doing their job and deploying with their unit. So we've got a sub-population, a small population of people who all have very serious both physical and psychological injuries. This has become an incubator of problems for us within this small group. Many of them are receiving many, many multiplication medications and constantly

having those medications altered. You can imagine for multiple amputees, the surgeries that they're undergoing, the things that they're doing, their medications change on a regular basis. These are also individuals who frequently are suffering from traumatic brain injury and post-traumatic stress and have medications associated with them. So an instance like the spot report I read you this morning of six, eight, ten various pill medications in a barracks room is not uncommon. We work hard to try and control that, but our ability to dispose of it is limited at this time.

So as a result of this confluence of problems, the Army's senior leadership has become engaged and they are actively seeking solutions to this problem. General Chiarelli is by training and background an armor officer which means he grew up in the Army driving tanks, and he likes shooting at things and making things blow up. Of late I

think I'm one of his favorite targets for shooting at because for an armor officer, you know, what's going to happen in an hour is kind of their long-range plan and to be able to say to him well we think that we're working on a solution and in 18 months to two years we'll have policy promulgated which will address this problem is wholly unacceptable. So I've described part of our problem.

How is the Army healthcare system, the Army environment, different? In general, the Army's healthcare system is a closed access system. We have universal access for all of our service members and family members serving on active duty and an integrated healthcare system inasmuch as we have an electronic medical record that is a worldwide electronic medical record. If a prescription is written for a soldier today in Korea and that person goes next week to Germany, the pharmacist has the ability to see that. The

primary care doctor has the ability to see that prescription. So we have excellent situational awareness of what medications soldiers are taking if they're receiving it within the military health system. Even if we have to refer that soldier to a provider on the economy we will have awareness of that because we're paying for that medication and it will be annotated in our pharmacy records in a relatively short period of time. We have an integrated health system, as I mentioned, so our primary care docs and our specialty docs are all using the same electronic medical record, gaining that same level of visibility.

And also, one significant difference within the military arena is that our hospital CEO, if you will, is a uniformed officer who has legal authority given to them by the Uniform Code of Military Justice in that - in terms of diversion, of controlling we have the ability to court martial people

and send them to a place in Leavenworth, Kansas, for breaking those rules and regulations and diverting. And so not only is our healthcare system - it's a closed system -- but it's a closed system that has very tight controls on it, the ability to put very tight controls. The military doesn't do everything very well, but we follow rules really, really well and, if we're told that you have to count these things every week, we count them every week and have very good inventory lists and maintain those policies and procedures.

So the Army really desperately urgently needs the authority to conduct pharmacy take-back programs so that when those medications for soldiers are changed out we have the ability at the pharmacy to say okay, well we would like you to return your Percocet before we increase you to Oxycontin. So bring back your unused Percocet, turn it in and we'll issue you the Oxycontin. We need all of that

to occur within the healthcare system so that we maintain continuity of care, it can be annotated in the medical record, providers have situational awareness of it, pharmacists have situational awareness of it and we don't want necessarily to bring the law enforcement community into it because soldiers by nature will not willingly go into a military police station for any reason ever.

The Army is wholly committed to the safe and ecologically safe disposal of those medications and ensuring the appropriate tight controls on those medications as we take them back and we think that we will be able to put systems in place to meet the most strict requirements.

That in general concludes my very brief presentation. Again, thank you for the opportunity. I'll be here for a little while if anyone has any additional questions for me.

(Applause)

MS. GALLAGHER: Well, we were listening last week to the issue that they're having to deal with. My heart - you know, I'm a parent too and I have college kids and I have a high school kid and so this is close to me as well. And I think of the parent who's lost their soldier as well as the parent who's in their hometown and their child has overdosed. The pain is absolutely the same and that's, just like Bill Winsley, I mean it just, it can't help but impact you. And so it was a little - I'm an emotional person if you haven't picked up on that -- but listening to your charge in what's the burdens that are now placed on you, I'm with you in thought and prayer because I know it's intense. With that, enough emotion.

Why don't we break for lunch. We're a little ahead of schedule, that's not a bad thing, but why don't we come back at 1 o'clock and instead of doing baseball analogies I thought maybe we would do

passengers on a train to kind of connect with my train thing this morning, or crew. My son's a rower so maybe we'll switch to rowing on the Potomac or something. So we'll see you at 1:00.

(Whereupon, the foregoing matter went off the record at 11:26 a.m. and went back on the record at 1:00 p.m.)

MS. GALLAGHER: We have a couple of minutes here, but I wanted to see if - we're going to call it our train over here. We've got some passengers. I need James Lovitz, Dave Maness, Kendra Martello and Joyce Nalepka - am I saying that right? If you guys could take your place here. And if Kevin Nicholson, David - you'll have to tell me how to do your last name - Ralph Orr and Patric Slack, if you could just kind of move to the front here and then as these groups are done we'll rotate you out.

I want to welcome you back to the public meeting. We're kind of near the end

here and, again, it's been very informative and very helpful for us in our planning process. Just like yesterday, if you were here yesterday, you'll know the drill. This will be people who have indicated that they wanted to make a comment to the record. We've given everybody 10 minutes and John Purcell's back to be the nice timekeeper which is a thankless task - job, I know. And on your list, you'll see Phil Burgess. He actually spoke yesterday. We had a little oops in our agenda. So Ronna Hauser will be the first and then we'll just move on there. So Ronna? Thank you.

MS. HAUSER: Good afternoon. Thank you for allowing me this opportunity to share the community pharmacy perspective regarding the proper disposal of unused or expired medications, especially in regard to the safe surrender of controlled substances. My name is Ronna Hauser. I'm a registered pharmacist. I'm also the vice president of

policy and regulatory affairs for the National Community Pharmacists Association. NCPA represents America's community pharmacists including the owners of more than 23,000 independent community pharmacies, pharmacy franchises and chains. NCPA has long supported efforts to properly dispose of unused, unwanted or expired medications through safe, secure and environmentally responsible take-back programs. That is why NCPA began participating in the national effort to find sensible solutions while working within existing laws and regulations by creating a prescription drug disposal program for our members.

Echoing the comments that have been made over the past two days, consumers want ongoing, convenient and clear disposal options as evidenced by surveys showing that local pharmacies are the most convenient locations where consumers say they would return unused or expired medicines. NCPA's

prescription disposal program, Dispose My Meds, helps participating independent pharmacies do just that. As active members in the community, pharmacists are in a prime position to ensure the safe and proper handling of medications from dispensing to disposal. The NCPA prescription disposal program highlights the pharmacist's role as a respected and knowledgeable resource on medications. Additionally, involving pharmacists in medication disposal allows for the identification of adherence problems during direct patient counseling. NCPA's prescription disposal program, launched in 2009, offers information and resources for pharmacies to create medication disposal programs. After a successful start, our program expanded in 2010 to include a low-cost turnkey program as well as a consumer outreach website. Through our program, community pharmacists utilize the Sharps take-away environmental return system which

allows the return of unused medications in postage prepaid envelopes for patients to mail on their own as well as 10- or 20-gallon pharmacy collection boxes at participating community pharmacies. As part of a consumer outreach effort, NCPA also launched DisposeMyMeds.org, an online resource to help consumers learn more about medication disposal programs. This online resource also has a pharmacy locator for consumers to find local pharmacists who are participating in drug disposal programs.

To date our program includes over 1,100 community pharmacy locations across 47 states and has collected more than 20,000 pounds of unused prescription and over-the-counter medications from consumers. The medications that are being returned via the take-back programs of participating pharmacies were originally dispensed from many other locations, especially mail-order facilities. It is important to note the

NCPA's prescription disposal program strictly prohibits the return of any controlled substance prescriptions. To help ensure compliance with all applicable laws and regulations the following recommendations are provided and reinforced in communications with all pharmacies participating in the prescription disposal program:

Determine that your participation complies with state pharmacy regulations.

Do not allow the return of controlled substances.

The pharmacist should be directly involved to ensure that controlled substances are not being placed into the return boxes.

And the medication take-back boxes should not be freely accessible to the public.

The intent of the Secure and Responsible Drug Disposal Act of 2010 is to encourage the Attorney General to establish regulations which prevent the diversion of

controlled substances but still allow public and private entities to develop a variety of methods of collection and disposal of controlled substances. NCPA contends that community pharmacies as both state and DEA licensed entities provide a safe and viable manner by which consumers can dispose of unwanted controlled substances. Community pharmacies are well equipped to handle controlled substances and are held accountable on a daily basis for ensuring these substances are not diverted. Therefore, those pharmacies who volunteer to participate in take-back programs should be considered by the DEA as appropriate locations to receive unwanted controlled substances. There should be no requirements to keep controlled substances separate from other prescription medications being returned as take-back receptacles should not be accessible to the public.

NCPA's current disposal program

allows for either the United States Postal Service or United Parcel Service to transport unused pharmaceuticals from take-back programs to their ultimate destruction site. These same carriers currently transport millions of doses of mail-order prescriptions, so any concerns regarding diversion via these carriers should be unwarranted.

Regarding regulations impacting the take-back of controlled substances by long term care facilities, NCPA requests that no requirements be placed on pharmacies to take back unwanted controlled substances from long term care facilities with which they contract to provide pharmacy services. Long term care facilities should have mechanisms by which they currently document and keep records of waste which could, among others, be utilized for the disposal of controlled substances.

Despite the success of the NCPA

prescription disposal program, significant challenges remain, making it difficult to increase the program's scope. With passage of the Secure and Responsible Drug Disposal Act of 2010, NCPA asks that DEA address the following issues during the regulatory process:

Convenience for the consumer. Programs that allow for drop off of unwanted controlled substances at multiple public locations, including community pharmacies under the supervision of a licensed pharmacist as well as programs that allow for patients to utilize prepaid mailers to dispose of medications should be allowed.

Legal and regulatory feasibility. In addition to current laws in place that prevent take-back programs from accepting controlled substances, the DEA must address those that may impede the transit of controlled substances or the handling of hazardous waste.

Also, there should be liability protections in place for pharmacies that choose to operate these programs.

Program financing. Adequate funding is necessary for any drug disposal program to succeed and grow, whether it is through states or grant programs.

Effective outreach and education. Thorough education for all involved stakeholders is necessary for understanding of a drug disposal program and to ensure that all applicable laws are recognized and respected.

In conclusion, NCPA advocates for funding sources at the local, state and/or federal levels to assure that pharmacists and/or pharmacies are appropriately compensated for drug disposal programs. Such programs will assist in deterring abuse and diversion of medications and will foster public involvement in protecting our environment and in poison prevention efforts.

Additionally, involving pharmacists in medication disposal allows for the identification of adherence problems during direct patient counseling and provides a way to address waste in the healthcare system from medications not being taken as prescribed.

NCPA appreciates the opportunity to comment and looks forward to working with the DEA and other stakeholders during the regulatory process. Thank you for your time.

(Applause)

MS. GALLAGHER: Next we have James Lovitz. I didn't check your tickets down there.

MR. LOVITZ: Thank you. For those of you that don't know me, and most of you don't, my name is Jim Lovitz. I'm a technical director for a company called PSC Environmental Services and we're a waste management and disposal company. And we've recently taken on the endeavor of trying to

help service the pharmaceutical and healthcare waste industry in regards to a lot of these things. Our experience is really of the EPA, of the DOT, OSHA, and other things. So when we decided to go about this endeavor, they tasked me with really kind of identifying the groups that we'd have to work with from a regulatory perspective, that being state BOPs, departments of health, the DEA -- which is administration, not agency, learned that one. And so over the last two years I've really worked to try and educate myself on these practices. And I actually believe that doing all this research also helped me personally become a legitimate ultimate user myself so I've got some personal vested interest in this as well. But what we wanted to convey to you today was really what we believe we need to have to be able to properly dispose of the materials. Now, the reality of it is at the entry level or the receiving level of these wastes it's

going to be a little different than what we have to do at the other end. And I've heard many people talk about incineration only, I've heard many people talk about high prices and everything else like that, but for us to be able to do this in a cost-effective manner we have to be able to do what we do best, and that's efficiently manage waste.

And a lot of the regulations that I've read in regards to this data, state boards and even the DEA and everything, really never - the modern rules anyway never really took into consideration the disposal of waste and how we were going to regulate those people. And in many cases, and I've talked to, you know, probably a hundred different regulators in states from boards of pharmacy and the DEA and everyone else, and it became clear that there really wasn't one set of guidelines for our type of agencies, or our type of entities I should say. They either told us we don't have a mechanism in

place for you so we're not going to require you to have a permit or we're going to put you in where we think you fit best which is the wholesale distributor/reverse distributor. Now, historically the reverse distributor has been one that takes returns and through that then they either determine if something is credible and can be sent back to a manufacturer or whether they're going to dispose of the material. Well, that's not necessarily what we're doing here. We are intending to take everything and everything we take will be managed as waste. And so we wanted to come forward and give you a couple of recommendations as well so that we can actually hopefully give some guidance on what needs to be done so that we can properly dispose of the material and do it in an efficient and cost-effective manner for everyone.

One other thing I wanted to note before I went into my -- what I thought were

the challenges and recommendations -- is I wanted to talk briefly about the diversion. To me, it seems that diversion has always been or these materials have always been regulated in a very controlled environment. I believe you use the term "closed system distribution." We're talking about something completely different here. We're talking about something that's been out of the control, all right. It's been out of the system so many things could have happened to these materials along the way. They might not have been stored in sanitary conditions. Maybe someone has tampered with something. Maybe they are just unused materials or something like that. So as far as diversion for me, I think simply by doing this program we're preventing diversion. As opposed to before where it was essentially to keep it in the closed system, now we're trying to get it back into the closed system. And so for every single pill we take, you know, that's a

pill that we can prevent that baby from taking, or prevent that pill from ending up in that bowl at the pharm party and things of that nature. So I think just this program alone is preventing diversion.

All right, with that said, some of the challenges we saw, and I've heard these over and over this week. One of which is that - some of the words I think we need to use here: ease of use, simplicity. I think the program has to be practical, it has to be accessible and it has to be affordable.

I also think we need to think about what I call small town America. I've heard some great programs, I've seen some great things up here, but I think a lot of those are probably directed at probably more established, more developed communities. If you really want to have a successful program, I think we have to build a program that essentially anyone could be a part of and anyone could implement. So whatever

regulations we put in place should really take into account the small town America, too, because I think we're going to find that - I would bet we'd find that the percentage of use in small town America is probably a little greater than in the larger metropolitan areas.

As far as regulatory compliance, I also want to note that we're dealing with a whole lot of entities here. I've heard a lot about mail-back programs. You know, there's entities and agencies that are going to be part of this as well, the EPA, and even the DOT. I haven't heard the DOT mentioned much, but the reality of it is even if something isn't regulated by the EPA that doesn't mean that it's not a DOT hazardous material. Even if it's a household hazardous waste and exempt there are states that still regulate it as hazardous waste and once you regulate it as hazardous waste, a mail-back program is no longer an option. You cannot mail back

hazardous waste no matter what it is, all right? So you need to have several options.

I like the idea of the pharmacy, I like the idea of a mail-back. I think a bigger option is going to be the household waste collections. Our company has specialized in that for many areas. Last year alone, our company alone collected over 20 million pounds of household hazardous waste. We serviced over 300,000 households at these programs. So I guarantee you the minute we tell them we can take those things, the amount of material we're going to get at these things will be exponentially larger than anything we'd see at an individual pharmacy or a single mail-back program. You're going to see those 4,000 pound numbers escalate to 40,000 in no time. So I think there needs to be numerous options.

So along with that, some of the other recommendations we had:

One, the type of program I

mentioned.

Two, I think you have to have the ability to mix the waste, the prescription versus controlled substance. There's no way you're going to be able to eliminate that, all right? And so I think the regulations need to authorize us to be able to incorporate prescription into that as well as over-the-counter somehow. If you don't, I'm not sure just calling everything controlled substance will satisfy the tracking requirements for a board of pharmacy, especially if you're going to make the tracking requirements more lenient, which I'm going to ask for in a minute.

Additionally, I think we need to have a separate classification. I think you have to have a separate classification for this, whether you want to have a Schedule EU or UU or something like that because I think we need to be able to readily identify these materials. We have to be able to distinguish

between a normal material product and the ultimate user product simply for no other reason because it was out of our control. We certainly don't want something like that accidentally getting back into a controlled system. So I also think that by classifying it it'll simplify your ability to write the regulations because instead of trying to add excerpts to every single portion of your regs maybe you could just have a separate ultimate user regulation, and I think it should include all Schedule 2 through 5, anything with medicinal value.

As far as collection points I think that's - I've talked about that. I think with collection points when you look at it, collection points are going to have a lot of problems. They're going to have limited space. We're going to have mobile sites, all right? So you're going to have mobile temporary collection sites. These sites are not going to be able to meet present security

and storage requirements as outlined by the DEA and probably not even the board of pharmacy. And it's going to have limited capabilities of inventory and tracking and of course, receipt of uncontrolled items as well, prescription items. So maybe we focus on maybe having a set standard of packaging, you know, at these mobile sites, these temporary sites, a set of packaging that you can lock when it's not in service and that can be ultimately locked and tamper proofed and then shipped out for disposal. I don't think you'd find any disposal company that would complain if we picked it up, could not open it and then shipped it on for final disposal or whatnot. I think that would also help diversion quite a bit.

Tracking and reporting and record-keeping. I think one of the goals if you want to keep costs down, you've got to make it easy to track this stuff. The reality of it is when you collect this stuff you're not

going to have the means of doing that. So we need to have - by doing like a Schedule UU or whatnot, all right, we've got this many pounds of it in this container and we track it by that means.

And then of course I also think that licensing, there should be some licensing requirements. Maybe you have an ultimate user collection registrant. I also think it might not be a bad idea to think about having an ultimate user technician or manager certification, especially if you're going to have a lot of mobile sites. I think it would be a good idea to have someone that's trained and well versed to be able to manage these that would help in your compliance and also within your diversion practices.

And I want to close with this. This is really my first visit to D.C. It was a fun visit to say the least. I very much enjoy this town, but I was very interested to

find out as I walk along the streets there are many people that want to stop me and kind of sell me on what they're going with, you know, try and educate me on something or get me to go for their cause. And I had about three instances yesterday, one was Greenpeace and there were a couple others, and I didn't stop and give them the time of day and I like to think I'm an okay guy. I like to think I believe in doing what's right. And I didn't stop, and I kept going. And I saw everybody else do the same thing, and I bet I'm not in the minority here. I bet every one of us has seen that and has done that. And the reality of it is these people were actually promoting and trying to sell you on some really good things that's going to help us out, that could help save this place, but none of us gave them the time. And why is that? Well, for me, I didn't give them the time because one, it wasn't convenient for me, and two, I thought they wanted something from me. And

so I think that's a fine example or maybe an anecdote on what we need to make sure we do here. The reality is we're dealing with quite a large and temperamental beast in the American public, all right? They're not going to do everything we want them to and so if you want them to cooperate and do this program it has to be done in a convenient manner and at absolutely no cost to them. The minute you start asking them for something, they're going to get pushed off no matter how good or how great this thing is. Unfortunately, I've done the same thing.

So that's really all I wanted to say today. Thank you very much for giving me the time, I appreciate it. Thank you for listening. Everybody have a good day.

(Applause)

MS. GALLAGHER: Thank you. Next we have Dave Maness. How do you say your last name? Maness. Okay, I was close.

MR. MANESS: Good afternoon. My

name is Dave Maness. I'm CEO with Cactus LLC based in Charleston, South Carolina, and Bill Winsley's here from Ohio. Bill, if you're still around, I promise I will not bring up Prozac fish.

I'd like to thank you for the opportunity to offer comments regarding the surrender of unwanted controlled substances by ultimate users and long term care facilities. In order to gain a clear perspective on the issue of drug disposal and diversion, Cactus attended several meetings this past year that specifically addressed this concern. We attended the International Symposium of Safe Medicine in Portland, Maine, the annual meeting of the National Association of Controlled Substances Authorities. In addition, we sought feedback from state and federal regulatory agencies. We heard opinions from multiple environmental groups. We gained knowledge from leading experts on the topic of unused

pharmaceuticals, including the Charleston County Coroner's Office, which was quite an interesting meeting. After attending these meetings, Cactus concluded that there is a serious need to address the concerns of the diversion of controlled substances and drain disposal of unused drugs in the environment.

With approximately 20 years of experience in the medical business, Cactus is a specialized company devoted to improving the process by which unwanted or unneeded drugs are disposed. Our primary mission is to address the environmental impact of unwanted pharmaceuticals and the concern for diversion of unused drugs. Our technology provides a solution for capturing unused raw pharmaceuticals by acutely securing and safely rendering drugs unusable and unrecoverable. Cactus is dedicated to providing a secure, economical and easy to use system for the capture and disposal of pharmaceuticals without impact to our

environment. Our goal is to help reduce the confusion, the errors, diversion that occur within drug wasting and to provide the healthcare and consumer markets with a secure, safe and effective alternative to drain disposal.

We support the DEA's efforts to improve the process for surrender of controlled substances by ultimate users, the DEA's initiatives with community take-back programs to keep drugs out of the hands of our teens. Cactus has found that healthcare facilities have very few alternatives to drain disposal of controlled substances and other pharmaceutical products. In addition, we've learned these facilities find the current federal and state policies concerning the environment and diversion to be conflicting and confusing. Due to the complexity of sorting, classification and the lack of disposal options, many medical employees waste unused pharmaceuticals in

inappropriate locations and containers outside the protocols of the facility.

As a solution, Cactus developed the Smart Sink system to provide a simple, effective and easy to use to accept and properly dispose of drugs in a Go Green manner, thereby diminishing the use of drain disposal. In addition, the Smart Sink has the potential to be used as a disposal method for controlled substances with DEA approval. We believe that the Smart Sink system will allow for medical facilities to render unused drugs unrecoverable in the acute setting while securely and safely disposing of unused controlled substances through their approved waste haulers. We believe this system would provide an easy solution to drain disposal and prevent diversion at the same level of flushing. Moreover, we stand beside the DEA in our belief that the ultimate responsibility lies with those in possession of controlled substances, whether the waste

drugs are disposed of down the drain or in the Smart Sink system. We believe this new technology is one of the few systems that address both the DEA diversion issue and the environmental concerns of the EPA along with other environmental organizations and state agencies.

Regarding take-back programs. Cactus realizes educated consumers and patients tend to embrace Go Green initiatives that are - and are fully aware of the negative impact waste pharmaceuticals have on our environment. In addition, they are also concerned about unused drugs getting into the wrong hands at home. We clearly understand the growing problem with access to prescription drugs by teens and recognize the increase in the number of cases that validate this concern.

Cactus is also addressing in-home diversion with a new, inexpensive secured product for home use. This product can be

sold through retail pharmacies to help fund ongoing pharmacy-based take-back programs.

We also believe there should be secure disposal alternatives that provide easy and convenient methods for consumers to return unused medications to medical facilities, retail pharmacy through mail-back programs and to their physician practices. This form of a micro take-back program will provide a more economical and sustained method to remove unused drugs from the market.

We believe the tendency and stewardship of patients and consumers is to return unused prescription drugs back to the point of origin, which is their pharmacist, their family physician or medical facility. That's their tendency. We also believe this potential engagement with a pharmacist or physician will provide additional opportunities to address overprescribing and modification of their prescriptions. This

engagement could also address the economic and negative effects that overprescribing causes to patients.

Cactus supports the initiatives for secure and effective take-back programs of unused prescription drugs in order to keep them out of the hands of our children, drug dealers and drug addicts. Cactus requests the DEA to provide a more acceptable definition of "unrecoverability." We believe the federal and state agencies should agree on reasonable alternatives to drain disposal and accept their technologies or other technologies, such as the Smart Sink system. This will ultimately allow for authorized personnel and waste companies to safely and securely accept controlled substances that have been rendered acutely unusable or unrecoverable. If needed, Cactus has designed a tracing method to track individual containers from initial shipments to final destruction and ultimate destruction.

In summary, Cactus believes the Smart Sink system provides an excellent option to drain disposal. This system can provide for capture, conversion, secured removal and ultimately proper destruction of unneeded drugs. By acutely rendering waste pharmaceuticals to an unusable and unrecoverable form, we feel that long term care health facilities, physician practices and consumers will be able to utilize this system versus drain disposal and help protect our teens, our community and our environment.

We respectfully request an opportunity to meet with the DEA to share additional proprietary information, gain evaluation and feedback on the Smart Sink system and its appropriate applications. Thank you again for this opportunity to speak before you today. Thank you.

(Applause)

MS. GALLAGHER: Next on the train is Kendra Martello.

MS. MARTELLO: Thank you very much. My name is Kendra Martello. I'm an Assistant General Counsel with the Pharmaceutical Research and Manufacturers of America or PhRMA. We represent the nation's research-based pharmaceutical industry. Last year, in 2009, our member companies and the biopharmaceutical research industry as a whole invested more than $65 billion in the research and development of innovative and life-enhancing medicines for patients. And I wanted to say at the outset that we appreciate the DEA's attention to the problem of prescription drug abuse and we share the concerns expressed by the DEA. As a matter of fact, we've partnered with DARE and PDFA and others for a number of years now to help educate the public on the dangers of prescription drug abuse.

We also appreciate the opportunity to comment to the DEA as it begins the process of implementing regulations

authorized under the Secure and Responsible Drug Disposal Act. And as we engage in the regulatory process, I want to remind folks of the four statutory parameters in the regs that we should keep in mind as we drive the development of regulations. We need to consider the public health and safety, the ease and cost of program implementation, participation by communities, and the legislative direction not to mandate or create - so not to require anyone to create or operate a disposal program.

PhRMA since 2007 has engaged in a partnership with U.S. Fish and Wildlife Service and the American Pharmacists Association to help educate consumers on how to safely, quickly and easily dispose of their unwanted and expired medicines using the household trash. This program, called Smart Disposal, has actually over 200 participating organizations as of the latest count. Through the Smart Disposal program,

consumers are educated to seal any unwanted medicines in a plastic bag, to mix it with an undesirable substance such as coffee grounds or kitty litter and dispose of it in the household trash. This would, to use DEA's terminology, make the prescription medicine unrecoverable and it would also be immediate and easy for consumers to use.

When considering prescription drug abuse more broadly, we also encourage that any public policies aimed at curbing prescription drug abuse must not create new barriers for diversion or prohibit access to needed medicines. The ultimate decision for a patient to receive a medicine is one that's engaged in consultation with their healthcare professional. And we heard speakers this morning talk about not regulating the practice of medicine. It's important for those interactions to continue uninterrupted.

So as DEA considers developing regulations to implement the Secure and

Responsible Disposal Act, there's three main considerations that we'd like to set out, and I'll talk about each one of those in detail.

First is diversion, education and information collection. With respect to diversion, and I mentioned this at the outset, any regulations must protect against diversion and not create new avenues for diversion. The DEA mandate under the Controlled Substances Act is to create a closed distribution system for controlled substances, and that should not be compromised in the regulatory process.

In addition, we need a strong consumer education component, and that consumer education component should focus on three things: appropriate use of medicines, secure storage of medicines and prompt and safe disposal. So what do we mean by appropriate use of medicines? Well, when used appropriately medicines can help patients live longer and healthier lives.

For example, with chronic disease, it's a leading driver of healthcare costs in the United States and of death to patients. Appropriate use of medicines can help patients manage chronic conditions and live longer, healthier lives. We also need to educate patients about the importance of adhering to prescribed treatment regimens. Adhering to medicines can help patients feel better and if they stop taking their medicines that can have public health consequences. Adherence to prescribed treatment regimens can also lead to better health outcomes, minimize the interactions with the healthcare system and lower healthcare costs overall.

Consumers need to be educated about secure and responsible storage and use of medicines. We've heard some discussion already about sharing of medicines. Statistics show that about 56 percent of people who misuse prescription drugs actually

obtain them from a family member or friend. Consumer education can go a long way to addressing this problem. Consumers should understand that they should store the medicines properly and not share them. And again, as I said, a particular medicine is prescribed for a particular patient in consultation with a licensed, qualified healthcare professional. We should not disrupt that system.

And then consumers need to be educated about prompt and safe disposal. There are a number of potential options that we've talked about. There can be legitimate reasons why a patient stops taking their medicine. They may have changed their prescription, or they may have side effects that they can't tolerate. In that event - or they may actually be expired. So in that event, they need to know about the various options to dispose of their medicines quickly and safely. We talked about one, Smart

Disposal. The household trash disposal is one mechanism that's quick, easy and convenient for consumers to use. It promotes flexibility and it's immediate, to echo the words of the FDA. We've also heard about other types of collection events today, mail-back, ongoing collection events at a pharmacy, or collections at periodic events such as the DEA event in April. Another option that we've heard about is permitting consumers to use household hazardous waste collection facilities when they drop off their paints or expired batteries.

It's difficult to assess the impact of these various programs and models without robust data and information collection. Some key questions that need to be answered include the ease of program implementation, participation rates, the impacts of the particular options on the policy goal of reducing prescription drug abuse, the costs and benefits of the various

options, and the overall public health impact. In addition, we note that with respect to long term care facilities, the mechanisms to allow ultimate users to take back controlled substances for disposal may not be appropriate for long term care facilities.

Finally, we believe that any drug that has specific label instructions in the FDA mandated labeling should not be eligible for inclusion in a secure disposal program.

So the final thing I want to talk about is recordkeeping and data collection. Robust data collection and information collection will help inform public policy and make sure that any public policy is grounded and supported by sound data and information. The next DEA event in April is an opportunity to engage in some of that data collection. An inventory of what's collected, understanding what is collected and why, why patients stop using their medicines, can go a

long way to improving the public health. Prior reports of the amount of prescription drugs collected could be clarified by providing context whether that includes pill bottles and/or packaging materials, and exit surveys could be considered to help collect some of this data. In closing, we appreciate the opportunity to comment and look forward to continuing to work with the DEA and other stakeholders as it develops the regulations. Thank you.

(Applause)

MS. GALLAGHER: Next - I guess last in this group we have Joyce Nalepka. So the rest of you all can go back to your seats and then the next group, if you guys could come line up, please.

MS. NALEPKA: Good afternoon, everyone, and I thank all of you for the opportunity to speak to you. We are - I represent the national parent movement in this country, and I'm here specifically today

to deliver a message from one of our California groups who is interested in this particular issue. Their idea is to form corporate partnerships with pharmacy retailers and drug manufacturers for a concept that will make it easy for people to drop off unused meds at pharmacy locations, which will draw traffic to their stores and cover the cost for that, and a state of the art drug demand reduction resource conference center on the West and East Coast by having them stock and sell items with our 21 Drug Free campaign slogan. The gentleman, by the way, who is heading this up was formerly the president of Caterpillar Tractors so he speaks from probably a little more technical term than I would, but I'll try to make it clear to you. The wholesale profits will enable us to provide literature and training that could be sold or dispersed through the stores with the items and enable us to hire state representatives who will continue to

build a membership base nationwide. The center will use video conferencing, social media and e-learning to get grass roots Americans with factual information about drugs and prevention. The misuse of prescription drugs is obviously a major problem and one that we've recognized for a very long time, but since most of us as parents got involved in the anti-drug movement when our children were small, most of us go back 30 years in closing drug paraphernalia shops and trying to keep drugs away from kids, and joining others to make it successful. And we were very successful in the grass roots movement. We invited Nancy Reagan to be our honorary chairman. She graciously accepted and was very helpful in making connections for us, helping us raise money. I just wanted to show you briefly, I know you won't be able to see it much from there, but this is a chart that the government, the Health and Human Services

division drew about our efforts during the 1980s. And here's where we started, drug use was very high. We began organizing and educating parents, which we're starting to do again, and hoping that our pharmaceutical groups will join in this as well as other companies. And this takes a sharp drop. The title is "How Successful Has Prevention Been?" and shows a 50 percent reduction in drug use by kids mainly by forming parent groups, parents getting to know their children's friends, then getting to know the parents of those children's friends and go as a group to their schools, get rid of the pro-drug information that was in their schools. I could go on for days about what was going on there. It is getting better.

The main thing we need to do I think is one thing that after we got strong enough we began to change America's attitude about drug use during that time, including going over about two blocks away to the

National Association of Broadcasters and talking to Eddie Fritts, asking him, look, you need to help us. We are tired of hearing jokes on radio and TV that are teaching our kids that drugs won't hurt them, come join the fun, and he's a dad. He did not only join us but he joined our board of directors and put together a series of PSAs and radio tapes that they sent out to all 5,000 of their members, and then he helped us organize I believe it was 65 members of the Senate and congressional wives organization and we really began to sail along until a group that most of you probably don't know about even, because it's so bizarre, a group of people who want to legalize everything in this country. This is at the bottom of what's going wrong in your field as well. We really need your help, the Elks and any service organization that you know needs to know what we know.

The real objective, as I said, is

to reduce the level of drug use for both licit and illicit drugs. So far we aren't doing well with 5 percent of the world's population consuming 66 percent of the world's illicit drugs, and now the growing problem of misuse of prescriptions. We need to raise the level of awareness among parents, kids and the general public, particularly about marijuana. Their perception of pot today is that it is benign, a medicine of some sort and legal in some states, none of which is true, and the DEA has been without question our very top drawer, right side friends on all of these issues. In fact, if you read the 1974 hearing record from Congress from the Eastland hearings, we knew enough about marijuana's damage then to stop it then. Pot today is so potent it's been nicknamed "skunk." Whereas marijuana had a THC content of a half percent, half of 1 percent in the `70s, today it averages 10 to 21 percent THC.

It's like grain alcohol compared to near beer and it causes permanent damage, including depression, paranoia and schizophrenia in brains that aren't fully developed until age 21. The recent Tucson, Arizona, shooter is a classic example of marijuana-induced mental illness and try to go up here to Channel 4, 5, 7 or 9 and get them to write something about that. We absolutely are striking out when it comes to the media helping us to educate the public. Obviously marijuana isn't the only dangerous drug, although I continue to call it our most dangerous drug since kids don't believe it, most people on the street don't believe it. They still think it's a harmless giggle. And if you notice on the late night TV shows they're beginning to - the jokes are beginning to flow back again. If all drug-induced causes were included, the figure would probably be four times higher. One of the non-profit parent organizations I work with in

California has created a Take Back America campaign, and we have a proposal we believe will make it easier to take back unused meds by putting drop boxes at retail pharmacies like they have done successfully in Canada. By stocking and selling items with our campaign logo, we can largely cross the - cover the cost for disposal and one hundred percent of the wholesale profits will help finance the state of the art drug demand reduction center. I have a copy of - this is one of the hats they've designed. It simply has an eagle's face on the front, says "I am the future." And it will have another logo on the back that is an anti-drug slogan. Oh, I see. Here's the slogan. "If a young person arrives at age 21 prior to smoking, abusing alcohol or using drugs they are virtually certain never to do so." That's a statement by former Secretary of HHS Joe Califano who studied the issue for over 17 years at Columbia University. The intent of

the logo is to make an indelible mark on the minds of children and their parents. A refrigerator magnet, key chain, or other item could carry the message to others. These caps are very high quality. In volume the wholesale cap would cost about $6.50 and could have a corporate logo on the side as well. Based on keystone pricing they could be sold for $13.00. So the store could profit not only from selling the items, but also from the traffic that would be generated from the take-back program plus the advertising we will do and business directed to their store. Our goal is to create a person or persons in every state to speak to schools, churches, service clubs, corporations and others, building an ever increasing membership base where we can ask a little support from a lot of people and in turn continue to feed them information to keep the kids on the safe and steady path to adulthood.

In summary, we need retail pharmacy chains or other national chains as corporate partners so we can not only take back unused meds, but we can take back America from the brink of the abyss.

And I want to tell you just one more quick thing. What I do most of my time, I live here near Washington, and I spend a lot of time educating members of Congress. And we have an unfortunately large number of members of Congress who have supported bills that would essentially legalize marijuana or decriminalize it, whatever they call it. But, as I said, we have enough information now that it should be called our most lethal drug in the country. So we couldn't quite figure out why they wouldn't give us any attention and the media wouldn't give us any attention, and this marijuana the kids are talking about today is so strong the kids call it "skunk." It's 244.2 percent stronger than it was in the `70s and that is according

to the National Institutes on Drug Abuse. There are two ways in my view - now, this is not DEA or anyone here represented, this is in my view - there are two ways to get your Congressman's attention. You convince him or her that you outnumber them, or you embarrass them a little bit. So we named the drug "skunk" and any member of Congress who introduces, supports, or votes for a bill to legalize marijuana gets one of these little guys and a wall hanging to go along with it. So I hope I haven't embarrassed anyone. We are absolutely non-partisan. We don't mind if we embarrass a Republican or a Democrat if they're going to hurt our kids. And I want to tell you that I'm here for you. I'm here for every kid in this country. I just met with the NAACP three times in the last month and I said I don't understand why you're not hearing what I'm saying. I'm here for your child. You see those three little black faces over there on your desk who are your

sons? I'm here tramping the streets for them, and I want you tramping the streets for me. And we're making a little headway, but unless we all pull together at our local community and it's the basis for what you all are doing here, too, with your pharmacy program. One of my sons, by the way, was a pharmacy rep for years, a very good one.

And I thank you for your time. If ever I can do anything for any of you who live in the area, need someone to speak, we'll tell you the real scoop. Thank you all.

(Applause)

MS. GALLAGHER: Our next speaker is Kevin Nicholson.

MR. NICHOLSON: Good afternoon. As Cathy just mentioned, I'm Kevin Nicholson. I'm Vice President in Government Affairs for the National Association of Chain Drug Stores, and as many -- similar to many of the other speakers today -- I'm also a registered

pharmacist. I thought I'd throw that in as well. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Our members operate 39,000 pharmacies, they fill nearly 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the U.S. NACDS is committed to pursuing effective strategies to help prevent the diversion and abuse of controlled substance medications and the devastating effects that the abuse has on people's lives.

With an emphasis on the pursuit of effective strategies, we thank DEA for the opportunity to share our perspectives on the return and disposal of controlled substance medications dispensed to consumers. We share DEA's goal of working toward a safe and appropriate means for consumers to return their unused medications to authorized entities for destruction.

To advance this goal, we support

the following four principles. Number one, the integrity of the closed system must be maintained. As DEA recognizes, the Controlled Substances Act established a closed system of distribution to prevent the diversion of controlled substances. All persons who handle controlled substances must be registered with DEA or exempt from registration in the Controlled Substances Act or through DEA regulations. In addition, DEA registrants must maintain strict records of all controlled substance transactions. We believe that the recently enacted Secure and Responsible Drug Disposal Act does not and should not amend this closed system.

Number two, protect patient health and safety by maintaining a physical separation between the delivery of care and unused drugs. Although pharmacies can and do serve as take-back locations for consumers' unused prescription drugs, they are only one option. As other speakers have recommended,

multiple solutions should be pursued. Pharmacies have stepped up and accommodated consumers who need to dispose of their unwanted medications. However, we have concerns about pharmacies being expected to accept this role on a national scale. As mentioned by other speakers, there are numerous regulatory hurdles that must be overcome, including rules by FDA, EPA, DOT and state agencies. We fear that imposing on retail pharmacies a mandatory take-back requirement could risk compromising the integrity of the medication dispensing system. Requiring pharmacies to take back prescription drugs could create potentially hazardous circumstances as some prescription drug waste is classified as hazardous waste. Moreover, pharmacies accepting prescription drugs from consumers have no knowledge about where the drugs had been stored or under what conditions. The drugs could be contaminated with infectious diseases or other hazardous

substances, yet these potentially contaminated and hazardous substances may have to be stored in the pharmacy in close proximity to pharmacy personnel and medications being provided to patients. Retail pharmacies are generally not designed to store returned medications that may be classified as hazardous waste. We are also concerned about the contamination of food. Many pharmacies carry food products and/or are located inside of food stores. Consumers could carry potentially contaminated products in shopping baskets and shopping carts that would then be used for food shopping potentially contaminating other consumers and the food they purchase. For these reasons we believe it would be unwise to mandate that retail pharmacies serve as take-back sites for unwanted drugs. Only pharmacies that can safely and properly take back and store unwanted prescription drugs should voluntarily participate as drug take-back

sites.

As mentioned by other speakers, pharmacies have also participated in law enforcement sanctioned collection events. These programs and events meet the key principle of separating the location taking back consumer medications and the delivery of care. We appreciate the opportunity to work with law enforcement in these collection events and look forward to future collaboration in these events.

Our third principle is that we need to provide consumers with safe and convenient methods to return their unused drugs. A consumer drug return and disposal program should be easy for consumers to understand and use. This will foster public acceptance and involvement. The programs must comply with federal laws - with federal and state laws applicable to drug take-back and disposal, including environmental and drug enforcement. Examples include providing

consumers with prepaid mail-back envelopes to return their unused drug to law enforcement approved secure facilities for disposal and destruction and municipal collection programs. An effective program would be readily understandable to consumers through public service announcements and education campaigns.

Our fourth principle is to ensure necessary funding by establishing feasible and sustainable funding sources. Drug return and disposal programs are best suited for funding through sustainable resources such as state municipal waste disposal programs, ongoing grant funding or product manufacturers. Pharmacies are not suitable for bearing the cost of these programs. Pharmacies' reimbursement for dispensed drugs is continuing to decline and there's no leeway for us to absorb the cost for drug take-back and disposal.

With these four principles in

mind, we believe that there are at least four viable options for the safe disposal of controlled substances. Number one, periodic collection events such as DEA conducted last year and has already scheduled for this year. As DEA recognizes, these events should be conducted by law enforcement officials in tightly controlled environments to maintain a closed system and minimize the risk of diversion.

Permanent collection facilities including secured containers that are under the direct control of law enforcement officials.

Mail-back programs. Under this option, patients could ship to manufacturers or DEA approved disposers directly via the U.S. Postal Service. Theft or tampering with shipped returns would be subject to federal criminal penalty as we heard earlier today.

DEA could establish a voluntary disposer registration category or similar

registration for the disposal of controlled substances which could include pharmacies and reimbursed distributors.

We believe that these solutions would best maintain the current closed system and minimize the risk of diversion by keeping temptation to divert to a minimum. These solutions also allow for the separation between healthcare delivery and product return and disposal. Postal shipment, as I mentioned, is a secure method currently used by mail order pharmacies. It would provide for the imposition of additional penalties for those who engage in theft or diversion by postal regulations. However, as I mentioned, the establishment of a disposer registration category probably would require regulation and security measures for those who voluntarily seek that registration.

In conclusion, we share DEA's concern about controlled substances being diverted into the illicit market. We also

recognize that there must be a mechanism for consumers to dispose of unwanted controlled substances in a safe and environmentally sound manner. We appreciate the opportunity to present our views on these issues and we hope we have been able to share with DEA helpful information as you determine the best methods for disposal and destruction. Thank you.

(Applause)

MS. GALLAGHER: I'm not going to be able to say your name. This is David Oostindie. Okay, thank you.

MR. OOSTINDIE: Good afternoon. I am David Oostindie and I'm with the City of Wyoming. I'm the Environmental Services Supervisor for the city and we're located in southwest Michigan. First I'd like to thank the DEA for this opportunity to make these comments and I look forward to the outcomes of this process.

Our city owns and operates both a

drinking water plant on the shores of Lake Michigan and a clean water wastewater treatment plant, and we use a land application biosolids for our solids residual. So our interest in protecting all of these assets and functions that we do led us to start a pilot program in November of 2009 where we partnered with 25 local pharmacies and our own Wyoming Police Department to do a take-back program. And in the 14 months since we started that program we collected over 5,500 pounds of medication and safely destructed of it all with the help of our police department.

The success of that program quickly gained a lot of attention and I started getting calls from neighboring municipalities and decided that we would form a partnership and expand it regionally. So as of December 1 of 2010, about a year after we started, we now partnered with four neighboring municipalities and we now have

over a hundred pharmacies and 17 police departments involved in our program. It's been a great success and we just hope that, you know, someone small like us can do this, look what we can do on a larger scale is what our hopes are.

We're fortunate to have an incinerator right in our county where we're operating our program that the police departments already use for evidence destruction and their other needs, and typically they only bring in 200 to 300 pounds of evidence each time they go to make a burn. So, by coordinating our efforts with them, we can now add all of the medications that we take to that because they pay a minimum of one ton no matter how much they bring in. And so us bringing in another 400, 500, 600 pounds each time that they make a burn doesn't cost us an extra cent. So coordination with them has been the key to keeping our costs down.

Our new expanded program is called West Michigan Take-back Meds and it's our goal to keep our waste, streams, landfills clean and keep the drugs out of the unintended user's hands, and create a convenient and safe means for disposal.

So this is where we're asking for your help in streamlining the regulations and creating the options for this program. To keep our costs down, involvement in the program should accommodate all types of medications, both controlled and non-controlled.

It also should be readily available and utilized so the pharmacist has a resource and a partner. They've been a great help in our program and they were all very willing to take this on. I heard story after story from the pharmacists that said people come in all the time with bags full after a loved one has passed away. So it's been a great help to those people in need.

The meds should be commingled to save the expense and sorting would be a burden on the partners that are running this program with us.

The short list of controlled substances that are currently recommended for flushing should be removed. We don't want anything going down the drains, at a plant like ours especially.

Law enforcement involvement should be minimized, should not be required if possible. They're already overwhelmed and underfunded these days, although we have great support in our area. But I'm sure they don't want to take anything on more than they have to right now.

The system should also include long term care facilities of course.

And lastly, no federal rule should preempt state or local rights to apply more stringent requirements to maintain our own NPDES permits that we need to follow as the

last line of defense to the environment. Thank you very much.

(Applause)

MS. GALLAGHER: Next we have Ralph Orr.

MR. ORR: Good afternoon. Thank you for the opportunity to present information on behalf of the National Association of State Controlled Substances Authorities, otherwise known as NASCSA. My name is Ralph Orr and I am Secretary/Treasurer of this organization. In my real job, I work for the Virginia Department of Health Professions, and I'm the program manager for the prescription monitoring program there.

NASCSA is a 501(c)(3) organization representing the majority of state controlled substance authorities in the country and was created to provide a continuing mechanism through which states, federal agencies and others can work to increase the effectiveness

and efficiency of state and national efforts to prevent prescription drug abuse. NASCSA members include boards of pharmacy, licensing agencies, departments of health, public protection agencies and state controlled substance enforcement agencies. Associate members and sponsors include drug manufacturers, technology vendors, pharmacy chains, managed care companies and other interested parties. NASCSA has three primary objectives as an organization: one, to provide a forum for discussion and communication between government agencies and the private sector on controlled substance issues; two, promote adequate and uniform controlled substance laws throughout the various states; and three, facilitate and coordinate the gathering and distribution of controlled substance information, trends and issues.

Our organization has addressed the issue of unused and unwanted pharmaceuticals

with resolutions in 2007 and 2010. Presentations at recent annual conferences have included the Maine mail-back program, the Washington drop-off program and in 2010 we heard information from Charlotte Smith of PharmEcology Services who we'll hear from later today, and Jeff Gloyd, Manager of Community Programs for Waste Management Healthcare Solutions. So we've received a great deal of information on this topic.

It is very clear to our members that pharmaceuticals stored in residential households, in long term care facilities have contributed to increased drug overdoses, diversion of these substances, increases in childhood poisonings and increased healthcare cost. Pharmaceutical take-back or other return programs can reduce the availability and thus the diversion of dispensed controlled substances. NASCSA recognizes that the improper disposal of pharmaceuticals may lead to negative environmental impacts

and that medications should generally not be flushed down the toilet or drain unless the label or patient information instructs doing so because of safe handling concerns. We are aware of federal guidelines that encourage consumers to take advantage of community pharmaceutical take-back programs. However, such programs are not widely available to most residents. We support the implementation of medication collection and disposal programs that meet local, state and federal regulations that include safeguards to prevent diversion. These programs should provide safe, convenient, low-cost or no-cost service to residents and use environmentally sound means of disposing of the collected medications.

Flexibility is encouraged when it does not have an impact on the accountability of the drugs to be disposed of, especially in mandating any specific mechanism for disposal or destruction of these medications to allow

for use of possible new technology or other processes that may be currently utilized. And the reason for that is because we want to have those substantial cost savings. Many states, as you are very well aware, have severe financial issues and we do not have a lot of flexibility with spending.

We encourage the promotion and funding of collection programs that meet the needs of citizens on a permanent, year-round basis.

Furthermore, NASCSA recommends that there be an enforcement process established for programs that do not properly follow existing Controlled Substances Act protocol and the regulations that will be promulgated under the Secure and Responsible Drug Disposal Act of 2010.

NASCSA welcomes the opportunity to comment in the development of regulations for collection and disposal programs. Further, as we are able to communicate quickly with

our members to not only disseminate information but also to solicit feedback, we offer our assistance to DEA as you examine this issue in the months to come. Thank you again for the opportunity to comment.

(Applause)

MS. GALLAGHER: Our last speaker is Ralph Slack and then we'll probably take a break after that. Thank you.

MR. SLACK: Thank you. First, I apologize, public speaking is not my forte. I want to thank Congressmen Inslee and Stupak for their diligent work on bringing this bill forward and getting us to this point and I want to thank DEA for allowing me to be here to speak. My name is Pat Slack. I'm the Commander of the Snohomish Regional Drug Task Force. I've been in law enforcement for 42 years. Today I represent an entity called WASPC, which is the Washington association of chiefs and sheriffs. They represent 39 sheriffs' departments and over 200 law

enforcement agencies.

I participate in a group called the Snohomish County Partnership for Secure Medicine Disposal. They have members from solid waste from Snohomish and King County, health districts from Snohomish and King County, and some EPA representatives. In our partnership we have developed the largest collection sites in the Pacific Northwest. Our county has a population of approximately 700,000 and I manage 29 of those sites. And when I mean I manage those 29 sites, I go out and I'm the individual that participates in training of staff on how to collect these items. I go out and put the boxes in place. I go out and put the cardboard boxes in. I go out and pick up the boxes. I then transport the full boxes to the evidence room, and, when we get a large enough stash of those, I load them up in a trailer and I haul them to Covanta in Oregon for destruction. I've also participated in the

Group Health take-back and observed theirs, and I've also participated in the Bartell's take-back.

We do not count pills, and if law enforcement is forced into a situation to count pills, law enforcement will not participate in the State of Washington. I can tell you that now. It's just cost-prohibitive. By our rules, we would have to write lengthy reports listing every type and the amount of pills that were in that, and then we'd have to book those into evidence and that would be evidence sheet after evidence sheet and that's just cost-prohibitive.

The bins that we currently use are similar to the ones that you saw yesterday from Group Health. They're a double lock box. The people onsite have one key and the task force has another key. The boxes are sealed onsite and signed off by someone from that site and someone from the task force,

and then transported to the evidence facility. In our 29 locations, I have locations at federal law enforcement, tribal police, county sheriff's office, state police and local law enforcement, and even in the jail. And the jail turns out to be one of our biggest participants because of the meds that are handed out to the inmates there and then they leave and they're not allowed to take them with them.

What DEA is tasked with is I think a formidable job. I do not see where one shoe will fit all for the challenges that we have before them. One of the models that I believe in is the British Columbia model. The British Columbia model was formed 13 years ago by legislation and in that legislation it mandated that the brand names, the generics and the over-the-counter drugs would fund that program. They put it out to the pharmacies as a voluntary. At that time, British Columbia had a population of a little

under 4 million people and they had about 850 pharmacies and under 200 participated. In 2009, their population is just under 5 million, they have 1,000 pharmacies and they have 985 participating, and they adjudicated over 50 metric tons of unused medications. One year. And it cost them under $400,000. I went up there, I reviewed the process at the pharmacies, I talked to some of the pharmacists and something that I never expected came out of that. I'm a law enforcement officer. If I come across an event that leads me to believe that a doctor has overprescribed and I contact the doctor, I believe it kind of falls on deaf ears. The pharmacists though are more on an even keel, level playing field with the doctors and in British Columbia the pharmacists are saying Joe, you know, I keep getting these pill bottles that are three-quarters full from you. You know, you want to look at this? And they're actually starting to see an

impact in that way. I think that's another part of this process that we're trying to work on.

The pill count. I went to British Columbia and they do a pill count. Every three to five years the brand names, the generics and the over-the-counter come to BC and they sit down and they set out 80 special buckets, and then they bring those buckets in and they break those buckets down. They have a computer and they count them all out. They do that to determine what their cost is going to be. So you can tell of the product that's coming in how much is over-the-counter, brand name or generic. It works very effectively. They would not disclose any of the counts to me for their own reasons, but it seems to work very, very well.

Collection and disposal problems. Diversion is all of our greatest issues, but I can tell you, if we do not set up a good program and we have a lot of diversion, the

cost of prosecuting and investigating the diversion will far outweigh the cost of the disposal program itself. It is very problematic and concerns me greatly. The program needs to be ongoing. The DEA, God bless them for what you guys do on the yearly thing, we participated in the one last September. It was very problematic for my partners in law enforcement in the county. Why? Because our law enforcement stations are normally in the smaller departments not open to the public on a weekend. So they had to bring in staff for four hours. I had four people on overtime for that day to go out to each one of these sites and pick up all the boxes that were being filled up. DEA was gracious enough for us, we were very lucky that we were able to load up a trailer and transport those to DEA and then be able to hand them off. Other entities had to book them in and then book them out and transport them later. The Maine model talks about

officer pickup. Again, cost-prohibitive to us.

Flushing and landfills. In Snohomish County, in the State of Washington, there's 39 counties. Three of them have regulations that are against flushing scheduled drugs or putting them in the landfill.

The program needs to be convenient for the public. Mail-back, I am very concerned about mail-back unless it has tracking to it and I want to know who's going to be responsible if Envelope 111 doesn't come in. Who's going to be making the phone call and who's going to find out where it goes? Local law enforcement does not want to be involved in that. Again, that's a burden on us and staffing is a huge problem now.

The other thing with mail-back is last week I pulled one box and checked the contents of one of our boxes. It had 27 bags in it. Of the 27, 17 would fall into the 1oz

to 13oz. The other 10, because they were liquid medication -- which one of our largest groups are the elderly and the elderly have a challenge with taking pills, so a lot of their medication comes in liquid -- would require the larger box that would cost almost $11.00 to mail.

A comment yesterday that has me concerned is drug seizure funds money that was represented could be pulled to pay for this program. I don't know about the other 49 states, but in Washington State under the Revised Code of Washington drug seizure dollars can be only used in the enhancement of drug investigations.

Again, prior to coming here I spoke with my U.S. Attorney's Office and asked them about the prosecution of diversion in a mail-back program. They think it's very, very problematic. They do not think - it would have to be a large-scale operation for it to rise to a prosecution level, and

they said that it would be, in their request, that investigation would be passed off to the DEA diversion unit in that entity. I think that's the totality of my comments. I thank you very much.

(Applause)

MS. GALLAGHER: It's 2:18. Let's take a 15-minute break, be back about 2:35. Is that about 15 minutes? Thank you.

(Whereupon, the foregoing matter went off the record at 2:19 p.m. and went back on the record at 2:38 p.m.)

MS. GALLAGHER: Why don't we settle back into our seats for the home - not home stretch. I've got to come up with a train analogy for the end of the line. Could the next group of speakers come up and sit up at the seat, in order if possible? We added a chair so we have one through six up here. Is Sal here? Oh Sal, okay. So Sal, we have Scott Kuhn, sorry. Charlotte, I see Charlotte's there. Bernard Strain, is he

here? Angelo, I know you're here. We'll get to you. And then Stefanie. So okay. We're at the end of our registered public presentations and we switched from John Purcell to Amanda, and now Amanda's the timekeeper. She'll be signaling you five minutes out, two minutes out and you get the big zero when it's - your time is done. So we appreciate your comments. So we'll start with Sal.

MR. CALI: Good afternoon, ladies and gentlemen. I'm pleased to have the opportunity to address this forum for a very important subject which is the collection and disposal of unused medicine. I'm a technology company.

We have looked at other initiatives going on within the healthcare arena in which accountability, tracking and verification is of very same, similar importance. I wanted to bring to the attention of the group, and I'm not sure if

this is going to be redundant or not, but I'll take the chance. The FDA back in 2007 and 2008 had laws passed for the pharmaceutical tracking and tracing of medications entering the supply chain. That's everywhere that the medicine travels, from the manufacturer identifying their source material, putting it through the production lines, every movement of the medication is part of this requirement. So this is law now. So from the beginning, the birth, from cradle to the grave of monitoring what's going on with drugs and medication. Part of what they have included was a standards group, and they published standards on what was going to be used as part of that initiative. And these are, again, rules and regulations that will be coming forward as far as it begins to be implemented.

Technology plays a role. The automatic identification technology is part of the specifications and standards used.

This is a global initiative. So it's not just the U.S., it's global. So drugs and medication coming in from the global arena needs to comply. So manufacturers of drugs will be ID'ing every product that they are producing and bringing into the supply chain. The technology again that they have selected is singular bar coding, much what you would see on a pack of cigarettes or bottle of Coke or whatever -- a two-dimensional bar code and RFID. So they, those particular technologies, will start to show up within the supply chain. That follows through from again the manufacturer down to when they move it to the transportation, down when they move it to the distributors, the warehouses, regional warehouses and then down to the prescription fillers, the pharmaceutical areas or the drug stores. We'll have those unique IDs and there will be a unique ID assigned to it from the time it was created at the birth of the product down through the

whole supply chain.

When you start seeing them on this end, there's a unique opportunity here to tie into what's already started. The prescriptions that are issued will have these IDs, will have a two-dimensional bar code on it. When the pharmacy issues that there will be a two-dimensional bar code or a bar code of some kind assigned with that RFID. It's a selection process. So there's an opportunity now where when you're identifying drugs that are being presented for disposal you can quickly identify it by scanning or reading the RFID, or if it's a manual process the same thing there. So you can capture this information at the time the pharmacy is issuing this prescription. The only thing you won't have will be how many pills were really used from that, but you'll know how many was issued.

And as far as deployment of technology, much of that technology is

already deployed. It's a matter of linking in, making some adjustments to accommodate what you want to accommodate. And the reason that I've gotten involved with this end of the process was that we're looking at the manufacturing side down through the whole supply chain and providing the track and traceability capability to accommodate that. We are discussing some opportunities with the U.S. Postal Service in track and traceability. That's who led us to this organization to see how we might be able to play a role to enhance what's going on, and I see there's opportunities to enhance this. When you think about the Postal Service, how many cities and towns are they in? They're all over. How many trucks and vehicles are on the streets? They're all over. They've got their internal police to investigate what's going on within the mail system. And again, one of the points I want to make is that when this enters the system - this is

the envelope Maine is using. When this enters the system it's now in the custody of the Postal Service so all the laws and regulations and their police force comes involved with a breach. So when that happens you have them going in and saying where did the breach come from, investigating that. That's a byproduct of using the mail. The other thing I wanted to mention is that enhancing this would be somewhere in this area would be a two-dimensional bar code that can be scanned. So pertinent information can be embedded in that, and if there's particular information that could be a HIPAA violation we can encrypt that so it can't be used by anybody unless they have the ability to unencrypt it. So you have security, accountability. So I think that lends for a very interesting process for this kind of mail-in system. And for bulk you'd have to address that a little bit differently, but I'm sure that can be accommodated. I think

that's basically - I'm done. Thank you.

(Applause)

MS. GALLAGHER: Next we have Scott Kuhn.

MR. KUHN: Good afternoon. My name is Scott Kuhn. I'm Vice President of Environmental Compliance for Clean Harbors Environmental Services. Clean Harbors is North America's largest hazardous waste disposal company, providing customers with technical solutions for the safe and effective recycling, treatment and disposal of hazardous waste, including unwanted medicines and pharmaceuticals. We operate over 50 waste management facilities, including four hazardous waste incinerators in the U.S., two hazardous waste incinerators in Canada, four hazardous waste landfills, two industrial landfills, eight treatment and recycling facilities and a network of collection and treatment facilities.

Clean Harbors has been involved in

the management and disposal of controlled substances for many years and has extensive experience in the proper management of these materials. Three of the hazardous waste incinerators that we operate in the U.S. routinely receive Schedule 1 through 5 controlled substances from registrants, law enforcement collections and reverse distributors, destroying them in what we call witness burns. Our fourth U.S. incinerator facility located in Aragonite, Utah, is also an authorized reverse distributor for Schedule 1 through 5 controlled substances and listed chemicals, receiving these materials from pharmaceutical manufacturers and distributors throughout the country. The company has also participated in the cleanup of clandestine drug labs for state and federal agencies, including DEA.

The problems dealing with disposal of unwanted controlled substances from healthcare facilities and households are

complex. On one hand, disposal of these waste materials into the municipal garbage is not desirable as they could easily be removed from trash and be reintroduced into the population for unintended and illegal use. To combat this potential diversion, individual users and healthcare facilities have been encouraged in the past to flush unwanted pharmaceuticals down the drain. While this has provided households and these healthcare facilities with a convenient and cost-free method of disposing of their unwanted pharmaceuticals, as we have heard numerous times today and yesterday, there is considerable concern that these pharmaceutical residues and the metabolites, including controlled substances, that are introduced into the aquatic environment be it discharge of treated domestic and commercial wastewater can cause adverse environmental effects, including increased antibiotic resistance and endocrine disruption. There

is no doubt that action is needed in this area, but exactly what type of action is needed and what type of programs should be established? That's what we're here to discuss today and yesterday.

The issues associated with collecting expired and unused pharmaceuticals including controlled substances from healthcare facilities and households are different from those associated with collections from manufacturers and distributors. DEA has an established program for regulating the collection and disposal of waste or unused controlled substances from manufacturers and others in the pharmaceutical supply chain. This program is designed to prevent the diversion of the controlled substance for illicit uses and has requirements for participant registration, security, tracking of controlled substances movement and reporting. As we have heard during this meeting, this program works well

up to the point of controlled substance pharmaceuticals distributed or prescribed to individuals. This distribution can occur at hospitals, long term care facilities, or the neighborhood pharmacy. As we know, once the controlled substance has been prescribed to individuals, current regulations do not allow them to be effectively and efficiently collected and brought back into the existing reverse distribution chain. For this reason we applaud the Congress for passing the Secure and Responsible Drug Disposal Act of 2010 and the efforts of the DEA over these years to revise current requirements and develop an effective process to facilitate the safe disposal of controlled substances.

The establishment of programs for collecting prescribed controlled substances from healthcare facilities and from individuals pose their own unique problems and there is no single program that will be effective for these different sources. For

healthcare facilities, including long term care facilities, we believe that expanding the scope of existing programs for the collection of non-controlled substances that are already in place at hundreds of hospitals and long term care facilities would yield the best chance of success for the least amount of cost. These existing programs generally collect between 25 and 50 pounds per bed per year of non-controlled pharmaceutical waste. Typically, these non-controlled substances is gathered in bins strategically placed in employee-controlled areas near the dispensing machine, nurses' work area or on mobile work station. When full, the contents of these small containers are transported by facility staff to larger drums which are sealed and stored in appropriate storage locations, awaiting pickup by companies such as Clean Harbors. In some cases, healthcare facilities have found it cost-effective to contract a turnkey operation where Clean

Harbor's personnel are stationed onsite and do all the waste management for the facility, allowing the facility staff to concentrate on healthcare responsibilities. Simplicity has been the key to the success of these programs and we believe the existing infrastructure can be used with some modification for the management of prescribed controlled substances. All we lack is the authorization to collect these materials.

A second major segment of the company's business is also devoted to collection and disposal of household hazardous waste and the company has contracted with states and municipalities nationwide to provide this service. This is typical of what the company does. We have very - a lot of experience in this area. Unfortunately, we have found that during these events that we are given by households pharmaceuticals and other types of controlled substances which we are not allowed to take.

Generally what happens there is that we turn the materials over to the organizer of the event, who then tries to arrange it through law enforcement, but generally law enforcement doesn't want to take custody of that because they have no manner of disposing of it or managing it either. As a result, in all but a few events, controlled substances are not collected from the households and they have to go back with the patient or with the person.

These collection events could be used as a mechanism for the collection of the - effective collection of household waste along with pharmaceutical and controlled substances. They already are set up where we have trained people working at these events. They document the collection and the disposal of these events, and we can do this very easily under our reverse distributor authorization and document and track controlled substances received from these

households, and make sure that they are disposed of in an approved facility.

From an operational standpoint, I would like to just make a few comments on some of the things I've heard presented here during the meeting. In a number of presentations, there were concerns over the need to segregate controlled and non-controlled substances as well as those that may be hazardous waste. I wanted to clarify that from the perspective of destroying these materials in a hazardous waste incinerator it doesn't matter whether these materials are segregated or not. The destruction efficiency in our incinerators is not dependent on the mix of the chemicals that are fed to it. To maintain our operating permits we are required by EPA to demonstrate at least 99.99 percent destruction on a periodic basis in performance tests using the most difficult to burn industrial materials that are fed in quantities that stress both

the incinerator unit and the pollution control devices. For the substances of concern to the DEA and this group, we would obtain the same 99.99 percent destruction whether these materials are mixed in a single container or segregated into separate containers. It is the nature of the hazardous waste incineration that we can provide customized collection and destruction for customers to meet all of their needs and requirements.

One last point I would like to make in closing is that I heard some statements during the meeting today about the cost of hazardous waste incineration and that they are cost-prohibitive, most people dealing with these materials. Truthfully, in talking with our salespeople and our customer service people, we don't understand this because the figures that I have heard today and that my colleagues and I have heard at other events are not the rates or charges

that we charge customers, and they appear to be very over-inflated. We're not sure if you're given pricing from your brokers, your consultants or your contractors or any other intermediaries, but I would want to assure you the prices that you're hearing that we heard today for disposal are not what we charge, and knowing others in the industry that is a similar thing for the other companies. The numbers that we've heard and that we continue to hear out in the market are not what we - our normal charge is.

So I appreciate the ability to come and address the group here in DEA on this area and applaud the work DEA is doing on this.

(Applause)

MS. GALLAGHER: Thank you. Our next speaker is Charlotte Smith.

MS. SMITH: Thank you. Hi, my name is Charlotte Smith with PharmEcology Services Waste Management Healthcare

Solutions. I have the dubious distinction of being a pharmacist who practiced in the bad old days where we told people to flush their drugs. I also have the distinction of being in practice before there was a Controlled Substances Act. That's really scary, isn't it? But the last 20 years I've had the privilege of working on the waste side of the industry, first as a co-founder of Capitol Returns in Milwaukee, Wisconsin, and then in 2000 founding PharmEcology Associates which was acquired by Waste Management in 2009. And it's really been a very satisfying type of pharmacy practice that I never anticipated.

Waste Management appreciates the opportunity to submit oral comments in conjunction with the Drug Enforcement Administration's public meeting to discuss procedures for the surrender of unwanted controlled substances by ultimate users. Waste Management is North America's leading

provider of integrated environmental solutions and the healthcare industry is an important customer. Waste Management Healthcare Solutions is a special services division of Waste Management that provides operational and consulting services required to handle healthcare's complex waste streams from a compliance, safety and risk assessment related to waste management to in-house operational logistics collection and processing for a variety of waste streams, including hazardous and non-hazardous pharmaceuticals and controlled substances.

We have six points we would like to express today. First of all, Waste Management supports the creation of a new disposer category of DEA registrant. Implementation of the Secure and Responsible Drug Disposal Act of 2010 affords DEA a regulatory opportunity to create a new category of DEA registrants for those entities solely engaged in receipt and

disposal of controlled substances generated by non-DEA registered end users. This category would be distinguished from existing registrant categories of reverse distributor by function and regulatory responsibilities. Reverse distributors primary function is to evaluate outdated drugs for their credit-worthiness and arrange for disposal of non-creditable drugs, but do not conduct actual disposal or destruction. To facilitate the safe and secure disposal of unwanted controlled substances originating from end users who are not DEA registrants, Waste Management strongly recommends the development of a new DEA registrant category for entities that are not in the business of reverse distribution and whose sole function is the receipt and appropriate disposal of controlled substances and other unwanted medications by dedicated end users. The DEA registered disposer could receive returned medications and controlled substances through

the mail in pre-approved shipping containers mailed directly by end users, or from consolidated collection programs such as from secure, locked collection kiosks used as part of approved take-back programs. Entities that perform this disposal function and are currently registered as reverse distributors should be reclassified as disposers to avoid confusion in functions and legal responsibilities. There is some precedent for this new category of DEA registrant as proposed by DEA in the 1990s when it created the reverse distribution category originally.

Since EPA does not regulate household-generated pharmaceutical waste as hazardous waste under RCRA, Waste Management recommends that all incineration facilities permitted to accept non-hazardous pharmaceutical waste be eligible to apply for this new category, including waste to energy facilities, regulated medical waste facilities and hazardous waste facilities to

offer all take-back scenarios the opportunity for the most cost-effective disposal option regardless of market factors or geographical location. DEA should ensure these regulations are consistent with current federal EPA regulations.

Further, Waste Management recommends that both the new category of disposer and current reverse distributors should be authorized to receive controlled substances from consumers.

Our second point is that Waste Management supports clarification of the definition of "non-recoverable." We encourage DEA to provide either definitive conditions by which a controlled substance would be considered to be non-recoverable, or in the absence of such statement definitive conditions DEA would not consider to render a drug as non-recoverable.

Our third point is that Waste Management supports secure inventorying of

returned and unopened packages, envelopes and containers. To facilitate safe and secure disposal of unwanted controlled substances and to reduce the opportunity for illegal diversion, Waste Management strongly recommends that secure unopened containers, packages and envelopes used for the return of unwanted medications, including controlled substances for disposal from end users be the designated level for inventorying medications discarded by end users. Secure containers and envelopes can be tracked using standard bar code technology now used by the shipping industry, for example, FedEx, UPS and U.S. Postal Service. Inventorying of consumers' discarded medications should focus on ensuring the packaging is secure and has not been tampered with or opened. Waste Management is strongly opposed to any proposals that require opening containers or packages of end users' discarded medications destined for disposal for purposes of

identifying and inventorying individual medications. Whether the receiving entity is a disposer or a reverse distributor, shipments of end users' discarded medications should not be opened for inventorying.

We also recommend that disposers of end users' unwanted medications be exempt from automated reports and consolidated order system, or ARCOS reporting, established for tracking suspicious orders of Schedule 2 and 3 drugs. Inventorying at the individual medication level will increase the risk of illegal diversion by exposing the drugs to human intervention, pose occupational risks for disposal personnel handling unknown substances, make consumer take-back programs prohibitively costly and serves no useful data collection purposes. There will be no initial inventory from the end user.

Our fourth point is that Waste Management supports transporting discarded pharmaceuticals via U.S. Postal Service or

common carrier with track and trace technology, or via collection and transport by entities that are DEA registered disposers. Waste Management supports safe and secure collection and transport of controlled substances and other medications returned by end users for the purpose of disposal. We believe this can be accomplished by common carrier or U.S. Postal Service personnel who pick up secure packages, mailers or shipping containers from residential customers, long term care facilities, or from consolidated collection programs. Alternatively, DEA registered disposers should also be able to serve as collectors and transporters to the ultimate disposal facility. As described above, Waste Management supports the use of track and trace technology utilized by the shipping sector to track unopened secured packages mailed by end users to a DEA registered disposer.

Our fifth point is that discarded pharmaceuticals be returned - regards discarded pharmaceuticals being returned directly from residential customers. Waste Management envisions developing a system whereby residential end users are supplied with an appropriately sized pre-addressed mailing package with track and trace labels. All the customer would need to do is insert their unused drugs, both controlled and non-controlled substances into the mailer and ship it via the U.S. Postal Service or other carrier. The receiving facility would, in a secure, caged area, document receipt and ultimate destruction of the unopened package. Documentation of unopened mailers would minimize handling and help preclude opportunities for theft and diversion.

We also address the discarded pharmaceuticals from take-back programs. Waste Management envisions a mail-back option for shipment of larger amounts of discarded

pharmaceuticals collected by approved take-back programs or in long term care facilities. Pharmaceutical and long term care facilities would be provided with pre-approved, tamper-resistant shipping containers with track and trace labels. The shipping containers would be retrieved by common carrier, the U.S. Postal Service or DEA registered disposer. We also recommend that similar processes be approved for hospitals that routinely come into possession of consumer-generated controlled substances brought in and left behind by their patient population.

Waste Management looks forward to the opportunity to work with DEA to establish a secure system for appropriate packaging, shipment and final disposal of discarded controlled substances by patients who currently have few options for ensuring their unwanted drugs - that their unwanted drugs are safely destroyed. We thank you very much

for this time.

(Applause)

MS. GALLAGHER: Thank you. The next speaker is Bernard Strain. Are you here? No. Okay, well then we'll move to the next speaker, Angelo Valente.

MR. VALENTE: Thank you. Good afternoon. My name is Angelo Valente. I'm the Chief Executive Officer of the American Medicine Chest Challenge. I'd like to begin by thanking the Department of Justice, the Drug Enforcement Administration for affording me the opportunity to address this hearing on procedures for the surrender of unwanted controlled substances by ultimate users.

We have all heard throughout the past two days about the serious issue about prescription drug abuse and the alarming research that demonstrates that the number one access point is the family medicine chest. Three years ago the Partnership for a Drug-Free New Jersey, the parent organization

of the American Medicine Chest Challenge, in response to statewide research that showed 47 percent of parents of middle school children knew little or nothing about the issue of prescription drug abuse created the first statewide comprehensive public health campaign to highlight this growing epidemic among our young people. The public service campaign entitled "Grandma's Stash" brought heightened awareness to the issue of prescription drug abuse and the easy access point that exists in each of our homes met with great success. This two-time national award-winning campaign not only increased awareness but also started a movement among New Jersey residents to take action in protecting their children and grandchildren by disposing of their unused, unwanted and expired medicines. The only problem that existed was at this point there was little direction, confusing regulations and no disposal locations for residents to utilize.

As a direct result of this newfound need, the Partnership for a Drug-Free New Jersey partnered with the DEA New Jersey division, the New Jersey Office of the Attorney General and hundreds of local law enforcement, government and non-profit media and corporate partners to create the first in the nation statewide day of disposal of prescription and over-the-counter medicines called Operation Medicine Cabinet New Jersey.

Operation Medicine Cabinet New Jersey accomplished three main goals. First, it brought unprecedented media attention to the issue of prescription and over-the-counter medicine abuse. It caused tens of thousands of residents of New Jersey to look at their cabinets as a potential source for young people to access highly addictive and deadly drugs. And finally, it created a way for adults to safely dispose of their unused, unwanted and expired medicines. In four hours on Saturday, November 14, 2009, more

than 9,000 pounds of medicine with a street value of more than $35 million were collected. Eighty percent of New Jersey residents had an easy access to a local collection site resulting in participation by more than 25,000 people. More than 450 local police and law enforcement agencies established local collection sites. The success of this first in the national statewide public health initiative was featured in the White House Office of National Drug Control Policy 2010 National Drug Control Strategy. The success of this initiative could be summed up in three simple words: cooperation, collaboration and communities.

Building on the success of the New Jersey pilot, keeping in mind cooperation, collaboration and communities, and responding to calls from community leaders throughout the country for guidance on implementing this initiative, the American Medicine Chest

Challenge was created. The American Medicine Chest Challenge is a community-based public health initiative with law enforcement partnerships designed to raise awareness about the dangers of prescription drug abuse and provide a safe day of disposal at a collection site or in the home of unused, unwanted and expired medicines that was held across the country. The American Medicine Chest Challenge provided a unified, national, statewide and local focus to the issue of medicine abuse by children and teens. It was designed to generate unprecedented media attention to the issue of prescription and over-the-counter medicine, and to challenge all Americans to take five simple steps, the 5-step American Medicine Chest Challenge: take inventory of the prescriptions and over-the-counter medicines in your home, secure your medicine cabinets, dispose of your unused, unwanted and expired medicines safely in your home or at an American Medicine Chest

Challenge disposal site, take the medicines you have exactly as prescribed and talk to your children about the dangers of prescription drug abuse. With cooperation and collaboration from national organizations such as PhRMA, the Partnership at drugfree.org, the American College of Emergency Physicians, the Consumer Healthcare Products Association, the Generic Pharmaceutical Association and NIDA, this initiative provided without any cost to any community government or law enforcement agency in the country and did not utilize a single tax dollar, something I think we can all appreciate in these difficult economic times.

The 2010 Inaugural American Medicine Chest Challenge reached and surpassed its goals in establishing this national public health initiative with coalitions and law enforcement partnerships in 37 states. Not only did thousands of

local community residents dispose of over 10 tons of unused, unwanted and expired medicines, but more importantly the lifesaving AMCC 5-step message was delivered as a result of over $10 million of in-kind media exposure received without any cost for the taxpayers. This was made possible due to the cooperation, collaboration and communities where each of these entities were able to bring their unique capacities to compliment each other's abilities, law enforcement to safely collect, store and dispose, community leaders and organizations to increase awareness and promote local participation, corporations and national organizations to provide support, and the American Medicine Chest Challenge to orchestrate and facilitate and assist all cooperating partners, and most importantly, leverage its in-kind media support.

As you develop the procedures for the surrender of unwanted controlled

substances by ultimate users, the American Medicine Chest Challenge believes that cooperation, collaboration and communities should be the main ingredients to assure success in community programs. This new procedure for the surrender of unwanted controlled substances by ultimate users should encourage cooperation among all stakeholders, foster collaboration between community and non-profit organizations, local, county and state government agencies, and law enforcement to maximize effectiveness of surrendering unwanted controlled substances by ultimate users, and finally, to be community-driven where local, community and state leaders can and will have the capacity to lead their constituents in this very crucial public health crisis. Thank you very much.

(Applause)

MS. GALLAGHER: Thank you. Let's do Stefanie Wiegand and Mr. Strain is here.

Do you want to just come on up here to the front and we'll pull you up in a minute? So Stefanie, why don't you come up first.

MS. WIEGAND: I'd like to first start out by thanking the DEA for the opportunity to comment. My name is Stefanie Wiegand and I'm a dual degree PharmD/JD student at the University at Buffalo. Today I would like to present about drug take-back events and permanent take-back programs as a possible solution. I'm going to be talking from the perspective of someone who's volunteered at numerous take-back events and as a co-investigator of a medication waste study from the University at Buffalo along with Rachel Giroux and my professor Karl Fiebelkorn.

In many ways, western New York where my university is located is like any American community. We are battling a huge adolescent drug abuse problem. Kids Escaping Drugs, a local organization supporting the

treatment and prevention of drug abuse in the adolescent population reports that prescription drugs, not marijuana, heroin and cocaine, are the most common substances exchanged and used in western New York schools. That would be in the bathrooms, the hallways, even in the classroom with the teacher present. I'm glad to say though that western New York is answering the call to this problem. We're constantly and desperately and aggressively trying to find a solution. With some measured success we have held take-back events under the supervision of law enforcement. These events have taken countless controlled substances from the household medicine cabinet where they are easily accessible.

I would especially like to thank the DEA for coordinating the National Take-back Day last September 25, 2010. Western New York had six sites for consumers to surrender unused, unwanted and expired

medications into the possession of DEA and appropriate law enforcement officials. I'm proud to say that our community also offered the DEA a great deal of support. Literally an army of volunteers came out, including other law enforcement divisions. A local ice cream manufacturer helped out, grocery stores, community pharmacies, a car dealership, advertisers, TV and radio stations, teachers and school district administrators, the Kids Escaping Drugs organization that I previously mentioned, an incineration facility and of course the University at Buffalo School of Pharmacy. All these individuals helped to properly dispose of over 2,000 pounds of pharmaceutical waste the public surrendered to the DEA that day. As you can see, it did also take a considerable amount of coordination and there was no small cost either, and unfortunately we're sometimes reminded that it's not enough. The day after

one of our take-back events in May 2009, we found out the day after an event that three young adults overdosed after chewing just one fentanyl patch. They had obtained it from a relative, I believe it was a grandmother, which underscores that while we collect from hundreds of cars at a 4-hour event once or twice a year, we just simply aren't doing enough. The Substance Abuse and Mental Health Services Administration estimates as much as 70 percent of people above the age of 12 who abuse pain relievers obtain the medications from family or friends, just as the case I mentioned. If we could help the public clean out more family medicine cabinets, the diversion occurring there would be greatly reduced.

The September 25 take-back event successfully disposed of over 230 pounds of controlled substances, and we patted ourselves on the back and - but we still want to do more. We want to reach more people.

We only had a total of 915 vehicles drive through and drop off medications which means we only reached that small portion of 1.1 million residents of Eerie and Niagara County. We had everything on our side. We had advertising. We even have a public awareness campaign in New York which mandates posters and pharmacies to tell people to first try a collection event and then to follow FDA guidelines. So we had everything on our side except I want to say convenience and accessibility for the public. And take-back initiatives we all know will only be successful if people actually use them.

So with the passage of the Secure and Responsible Drug Disposal Act of 2010 I became excited by the prospects that we may no longer be limited to only hosting a take-back event. I believe permanent take-back programs at convenient locations will be more effective than the occasional collection event. Several efficient, secure and

environmentally sound protocols for take-back programs have been developed by various private and government entities across the country. With these advances, relying only on take-back events would risk doing too little for the enormous public health problem of prescription drug abuse.

And now I'm going to talk about some research we did at University at Buffalo. This summer I joined a project on medication waste. We designed a survey that we administered to the participants of the September 25 events and my hope is that we can take the results of the survey and just help inform everyone as we try to write regulations.

With over 780 consumers anonymously reporting to us how they currently dispose of medications, whose medications they are disposing of and which medication locations - which disposal locations are convenient for them, we have

some data to guide us going forward. And given the recent recalls of Darvon and Darvocet, many consumers were really seeking this best procedure for the disposal of controlled substances, so this is a very pressing issue and I hope we can have resolution soon.

I'm just going to summarize some results we had. Most consumers reported that they were disposing of either their own medication or a family member's, but other answers included a friend's or deceased person's medication. So I think we need to recognize that all good faith attempts to surrender should be accounted for.

And then prior to this event the most common method for disposing of medications were flushing and dumping down the sink, and throwing in the trash as is, which are considered improper disposal methods. And only 10 percent reported disposing of medications according to the FDA

guidelines which is to mix the drugs in something undesirable like coffee grinds or kitty litter. And then I did mention earlier we do have a public awareness campaign in New York, "Don't Flush Your Drugs," so we'll be evaluating if that is working because it does look like only 10 percent are properly following those guidelines.

Another 24 percent reported they just store their medications at home. Sixteen percent reported they never dispose of medications at all. So, I mean that's kind of telling us what we probably already know, that people are accumulating drugs in the household whether they're unused, unwanted or expired.

And then we also determined that local pharmacies and events similar to the National Take-back Day were considered the most popular disposal locations with 48 percent reporting pharmacies were convenient and 52 percent reporting take-back events

were convenient.

On the other hand, we found that police departments, hazardous waste facilities and other disposal locations were markedly less favored, with only 5.6 percent or 3.4 percent and 2.9 percent respectively responding to these options.

What this data tells me is that proper drug disposal continues to be a challenge, even for those who are willing to drive out and participate in take-back events. We need to further bridge the gap between what consumers demand and what options are currently available for unwanted controlled substance disposal. I think if we listen to what consumers are telling us in these surveys, we can see that the intuitive solution for the general public would be to return controlled substances to where they obtained them, the local pharmacy. In fact, the pharmacist is usually the most readily available resource patients go to for

questions about proper disposal. The New York pharmacies post a notice at the pickup counter about proper drug disposal methods. The notice tells patients don't flush unwanted household medications. Instead, return them to collection events where available or mix with something undesirable. In addition to the convenience a local pharmacy would offer consumers, the pharmacy profession has demonstrated a strong desire to promote the safe handling and disposal of medications by patients. The National Community Pharmacists Association has launched a prescription disposal program in community pharmacies, and a consumer outreach website, www.disposemymeds.org. The American Pharmacists Association, on the other hand, has launched Smart Disposal as a public awareness campaign in partnership with the U.S. Fish and Wildlife Service and the Pharmaceutical Research and Manufacturers of America. And at a more local level,

pharmacists and pharmacy interns from the University at Buffalo have volunteered at all the pharmaceutical collection events in western New York.

Still, convenience has to be tempered with appropriate diversion controls. Should surrendered unwanted controlled substances enter into the illicit market, the goal of the Secure and Responsible Drug Disposal Act would be circumvented. Therefore, any permanent location for take-back has to adhere to secure protocols. As pharmacies already securely handle controlled substances in their daily operation, it would be easier for them to follow additional diversion control measures for a drug take-back program. Certain parameters could include tamper-evident technology, one-way openings and witnessed destruction.

My last concern is how best to ensure that ease and cost are considered in the development of regulations. I think it

best to defer to each state as the final design and implementations.

I hope this presentation has been helpful and I look forward to seeing a resolution to this issue. Again, thank you for the opportunity to present.

(Applause)

MS. GALLAGHER: Mr. Strain? Thank you.

MR. STRAIN: Good afternoon. Everybody still with us? Sorry I was a little late from arrival but just drove in from Philadelphia. Let me start by saying good afternoon members of this committee.

My name is Bernie Strain. I have traveled here from our home in Philadelphia. You might recall us from our appearance on the Today Show. You might have seen or heard of this case on the news with Katie Couric or from an Associated Press story. This story is about our beloved son 18-year-old Timothy Michael Strain, a great athlete, a beautiful

young man, a loving son. Our loving son died from an accidental prescription drug overdose. He had severely burned his hand on a lawnmower and was prescribed pain medication by a doctor. He was then given additional meds, medication, from an ill-advised adult. Those additional meds were left over in her medicine cabinet. This became a fatal combination that killed our son and this person is currently being tried in a court of law in the City of Philadelphia.

We are not here today for additional notoriety, but instead to end this scourge that killed our wonderful son and to spare others from endless and agonizing pain that we continue to feel almost a year and a half later. Since his death we have made it our life's mission to find a way to end this practice of diversion and misuse of prescription drugs, and find a safe and effective way to dispose of medications.

Tiny pills that were the size of a dime killed my son.

Further, the tragedy again struck recently. Who says lightning does not strike twice in the same place? Last Sunday my sister's stepson after a long battle with prescription drug addiction was found dead. The drugs that took his life were not prescribed to him, but to someone else.

On May 24 of last year, our Tim's birthday, United States Senator Robert P. Casey passed a resolution calling on all 50 states to start the conversation about how to properly dispose of prescription drugs.

In our hometown of the City of Philadelphia after many weeks and conversations and lobbying our council members, our city council passed a resolution named Timmy's Law to honor my son and to begin the process of creating a prescription drug take-back program that would help rid our water and contamination from people

flushing these pharmaceuticals into our drinking water. According to the Philadelphia Water Department, we currently have 53 different pharmaceuticals in every glass of water that we drink, let alone what's in our rivers and streams. In the City of Brotherly Love, we recently held public hearings on this topic with the Health and Welfare Committee of our Philadelphia City Council, and we are ready to pass Timmy's Law.

Timmy's Law will be a 24/7 prescription drug give-back program. At the time of those public hearings, your DEA representatives asked us to hit the pause button until the federal laws are written because, as you know, your federal laws will supersede our local laws. We, the City of Philadelphia, are asking, since we and the mayor of our city and city council are willing to start a pilot program, for guidance from you about what to do in the

meantime until our laws are written. Time is of the essence. As I mentioned, another one of my family members is deceased let alone countless others. Where better to start this program than in the city that our nation was founded in?

We are asking our government to start this pilot program where our citizens could dispose of pharmaceuticals in a safe and secure manner. We have been willing with two great organizations - sorry about that. I can blame it on it being cold outside, but that's not the reason. These are programs - we have been working with two great organizations and we don't necessarily plan on reinventing the wheel because these programs are up and running in the Chicago, Illinois area. These organizations as I stated are both from Illinois. The program started by Paul Ritter, an environmental teacher and his students, is one of the leading drug disposal programs. It is called

P2D2 program, Pill Prescription Drug Disposal program. Paul Ritter and his students have helped to initiate and support several up and running programs in a number of towns and states throughout our country.

We also have been working with David Katz, a DEA board member and a father like me. His son Daniel - who lost his son to this epidemic of prescription drugs. You can't have a successful drug take-back program without an education program. That's why I offer the P2D2 program as one example. It is not until our young people take ownership, like Mr. Ritter's class in Illinois, that we can reduce the deaths and reduce the diversion problem. Education programs have not, to my knowledge, been mentioned in the Responsible Drug Disposal Act of 2010. Education programs need to be necessary as part of that act and/or law.

I know Washington has no money for another program. Some might call it pork,

but I call it saving lives. It would be wise for our pharmaceutical companies to step up and volunteer to fund the education component of this effort.

In the City of Philadelphia our law could easily be written to make those pharmaceutical companies who sell and dispense these drugs mandate it, like a law in San Francisco, to consume all the costs in the drug give-back program and the education side of this effort. We are not trying to place the burden on businesses and would strongly encourage them to step up voluntarily. We have several sponsors in Philadelphia who have stepped up already - that have stepped up already. We are looking for drug companies in or around Philadelphia to do their part before we mandate them to do so.

There were 409 prescription drug-related deaths in Philadelphia in 2009. My Timothy was one. More teenagers die in the

United States of America from legal drugs rather than illegal drugs. Prescription drugs are increasingly sold illegally on the street and crimes related to the theft of prescription drugs in medical facilities and pharmaceutical companies as well as the trafficking of illegal drugs and pharmaceuticals across the nation, our borders are on the rise. It is critical to provide individuals with safe and secure means of disposing of expired, unwanted, unused medications. We in Philadelphia are ready, willing and able to take the lead with your help and guidance.

We have significant objections to certain proposed solutions for the collection and disposal of unused medications because we feel that they increase the likelihood of diversion and at the same time threaten public safety. We also feel the potential for the destruction of public property that would greatly be increased where these

solutions are implemented.

As we know currently, controlled substances cannot be collected and disposed of unless they are done so in a 24-hour security law enforcement setting such as a police station or a sheriff's office. After collection of the drugs may also be transported to those facilities by law enforcement personnel to decrease the likelihood of diversion. We, therefore, feel that the safest and most secure method for the collection and disposal of wanted medications would be through the installation of collection boxes in law enforcement facilities willing to provide 24-hour secure and control these collections. This program will save lives and protect the public's health while reducing diversion. Enclosed with my presentation, we have inserted a photo of our drug collection and disposal boxes.

Portions of this written testimony

were taken from David Katz, the President and founder of Save a Star, Inc. In February 2011, we will unveil the P2 educational curriculum at Timmy's old high school, in W.B. Saul High School in Philadelphia. This will be the first of its kind in the State of Pennsylvania. United States Senator Robert P. Casey, Mayor Nutter and various state and local officials will be attending a press conference. We will unveil the union between Saul's new environmental program and Mr. Ritter's existing environmental program in Illinois that day. These two classes will be working together as one with television sets in each classroom using Skype technology. In this virtual classroom setting the two groups of students will begin their efforts to change our environment for the better, together learning the dangers of prescription drugs.

We welcome all members of this committee and the DEA officials to join us on

that day. We will keep everyone apprised of that date and time as information becomes available.

It is with all my heart and in the memory of Timothy Michael Strain and David Lee Katz that we have traveled here today to make their young lives not have been in vain.Thank you very much.

(Applause)

MS. GALLAGHER: Thank you, Mr. and Mrs. Strain, coming to talk about your painful story. It just reminds us how important this issue is, and how it affects all of us. And one thing - I've been with DEA 26 years, I started when I was 10, and I take it seriously that we're mandated to protect the public safety and sometimes that sounds corny but I can tell you the people I work with at DEA, we take that seriously. And we've got this issue on the front burner. We have lots of burners, everything's percolating. Disposal is on the front burner

and we are working on it full time. So I assure you, we are moving as fast as we can. Of course it's never fast enough, I know, but I just want to assure you that this is a priority for DEA. So that closes the registered speakers.

We're now ready to do some open mic speaking so we invite - we've got three places. I'm going to give up my lavaliere here. Three microphones on the floor. What we ask, if you are interested in giving some public statements, to line up behind the microphone and we'll just kind of move accordingly. Let's see if people are lining up. Why don't we start over here. Thank you.

MS. SLAVIN: Hi, Dale Slavin from the Safe Use Initiative, Food and Drug Administration. I wanted to thank you all for hosting this, it's a terrific thing. One of the things I think I want to understand or learn more about is about the idea of when

these drugs come back in. I'm hearing a lot about, well, there's overprescribing from the prescribing community, and remember that physicians are only one prescriber. PAs can also prescribe, which we heard about, and in some cases nurses can prescribe depending on the state's rules.

So realize that it's a larger community, but there's overprescribing. But how are we going to explain to the prescribers, yes, you are overprescribing. How can we show them that that's really happening? Is it because the drugs come back to the take-back program? Are there justoverabundance of certain particular products that come back in? So consider pill counting in that way, and how can pill counting be done. Is it the British Columbia model where they go in every year or five years or whatever it was and the industry reps count the pills because that's how they divvy up how much each of them is going to

pay for it and they also get an idea of what's coming back in.

The other thing that I wanted to mention is how to get that information out to the public, how to make sure that they understand that they have options for getting their drugs taken back. How are you going to disseminate this and make sure that it penetrates all the way through into all of our psyches so to speak, and to make it easy.

I do agree, I think it was Mr. Lovitz as well as a few others that did say, you know, asking the consumers to pay is a certain way that probably we will turn them off from doing it. If it's not easy we're probably not going to get them to do it. You know, and think about the three clicks. When you're on your computer, if it takes more than three clicks to get to a site you usually start getting turned off and you don't go to that site.

The other thing is I attended a

few prescription drug monitoring program conferences and at one of them the official from Connecticut was talking about getting unused, unwanted drugs out of the medicine chests. And when he made it an issue about drug abuse nobody wanted to participate because it makes you feel about yourself or about your family. You just, you know, not in my family, not my patients, they don't abuse. So when he made it a green issue, which we've heard a lot about it being green, then it became something that everybody seemed capable about getting behind because now they were saving the environment. They were doing something good. So just another thought. Thank you.

MS. GALLAGHER: Thank you. Anyone else interested? I'm going to ask Mark to close us out because Mark Caverly is going to be retiring in weeks here, February 26, and he's done amazing things, thirty five years with DEA. So I thought it would be fitting

that he would close out.

just want to thank you again for your participation. I need to thank our staff who kind of I think, I'm hopeful this was somewhat seamless. We have Erica Gehrmann in the back, Bonnie Knopka up here who helped put your presentations if you had them. Maxine Booker in the back who welcomed you, John Purcell who welcomed you and did the timer, and Amanda Juhas for your support. Thank you so much because I know it's hard work.

(Applause)

MS. GALLAGHER: And I hope you have safe travels home and many of you I know will be continuing our dialogue so thank you. Mark?

MR. CAVERLY: So I get the benediction here. So on behalf of the Drug Enforcement Administration, and personally on my behalf and Cathy's, I want to thank all of you for your attendance and your

participation. If you haven't guessed by now, your input is very important to us -- it's crucial as we go through this rulemaking process and make some decisions as to how best to implement the Secure and Responsible Drug Disposal Act of 2010.

We've heard common themes and you've noticed despite the fact that we've had a transcriber here and there will be a transcription, we've taken copious notes. I think I've taken more notes during this particular session than I have in quite some time.

So what you're telling us is important. We're listening. We do anticipate a Notice of Proposed Rulemaking as quickly as possible and then we want you to tell us whether we got it right or whether we got it wrong, and tell us specifically. We understand we're not going to make everyone happy, we can't do that, but we're going to try to craft the best possible rule to

implement this consistent with what Congress has told us and what you folks have told us here today. So again we thank you.

Hopefully you will have a safe journey home if you're here locally or if you're traveling. Again, thank you very, very much for your participation today. Thank you.

(Applause)

(Whereupon, the above-entitled matter was concluded at 3:45 p.m.)