Statement of
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Before

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United States Senate

Hearing on
Prescription Drug Disposal

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Thank you Chairman Kohl, Ranking Member Corker and Members of the Committee for holding this important hearing on prescription drug disposal. Consumer drug disposal is a significant issue in the United States and we applaud the committee for its focus on the topic.

General Background

I appreciate the opportunity to provide this testimony today representing Capital Returns / Genco Pharmaceutical Services. Capital Returns was founded in 1991 by a pharmacist and business person and is now part of Genco, a 112 year old privately held third party logistics management company. I have been employed as the director of quality & regulatory affairs by Capital Returns / Genco Pharmaceutical Services (GPS) for the past 5 years. I am also a pharmacist and have worked in multiple pharmacy practice areas, including over 11 years in long-term care pharmacy operations.

I have been a first-hand witness to the surplus of unused medications in long-term care facilities as well as witnessed the destruction method utilized by these facilities. In my experience many facilities have limited resources to destroy products like controlled substances. They are frequently not familiar with the best standards of practice or environmental regulations for discarding pharmaceuticals. As a result many of these products are destroyed by flushing them down the drain or toilet. While the science has not determined what sources of medications have contributed to pharmaceutical contamination in our environment, it is clear based on the findings of the U.S. Geological Survey that pharmaceuticals are present in our waterways. Flushing medications down the toilet or drain, while not the single cause of pharmaceuticals in our environment, is certainly a contributing factor. Long term care facilities need a secure method to send back their unused controlled substances to minimize their contribution to pharmaceuticals in the environment and allow the facility staff to spend more time focusing on the care of their residents as opposed to the destruction of unused medications.

In addition to the long term care population I have observed unused medications in people's homes within the general population. I have heard individuals rationalize that they may have a potential need for the medication in the future or they simply do not know how to dispose of the medications properly. Unfortunately, in some instances these unused medications can fall into the wrong hands creating situations of misuse, abuse, and accidental poisonings.

After working in reverse pharmaceutical distribution I have a very different perspective of how unused medications can be managed. Currently, the reverse pharmaceutical distribution industry receives unused, expired, or recalled pharmaceutical product, including controlled substances from other business entities such as pharmacies and drug wholesalers. These unused medications are processed for potential credit from the manufacturer. Depending on the manufacturer's returns policy the product is sent back to the manufacturer or to incineration.

While a summarized description of the process is relatively straight-forward, reverse pharmaceutical distribution is an extremely regulated industry inherently making the process not only more complicated, but also producing an industry with a high-level of safety, security, and accountability. In addition an environmentally responsible method of destruction is used for unused product. Several federal agencies have regulatory oversight of the reverse distribution industry and/or the unused, expired, or recalled medications. These agencies include the DEA, EPA, FDA, DOT, and OSHA. Specific state pharmacy and environmental regulatory agencies also impact the industry.

In order to adhere to the regulations the pharmaceutical products returned to reverse distributors are subject to a several step process. The procedures include, but are not limited to, capturing the name and address of the returning entity as well as the DEA registrant number if it is a controlled substance return. In addition, the product is counted with the lot number and expiration date also captured. Reverse distributors are required to report the transfer of specific controlled substances to the DEA through the use of the Automation of Reports and Consolidated Orders System, or ARCOS report. An example of some of the controlled substance information regularly reported to the DEA includes the receipt, inventory and destruction of controlled substances, along with a requirement to report any product loss.

If the product is determined to be waste, the waste is segregated based on characteristics of the product and the requirements of the Resource Conservation & Recovery Act (RCRA). The outcome of the segregation process is an accumulation of non-hazardous waste and an accumulation of separated categories of hazardous waste such as toxic, corrosive, ignitable, and reactive as some examples of the categories. The waste separation procedures in place within reverse distribution provides for the safe storage and transportation of hazardous pharmaceuticals. The hazardous waste that is generated at GPS is shipped to an approved treatment, storage, and disposal facility for incineration. The non-hazardous pharmaceuticals are incinerated at a waste to energy facility.

The progression of the unused product being turned from waste to energy is initiated when the product is shipped from GPS to the incineration site. The pharmaceuticals are fed into a hopper for incineration. The product is combusted at a high temperature creating the steam which spins the turbines that generate electricity. The waste to energy facility utilized by GPS meets the federal environmental standards and utilizes a multi-step process to ensure appropriate environmental performance. The result of using a waste to energy facility decreases the use of oil or coal for energy as well as elicits a net greenhouse gas reduction. Currently, over 90% of the unused product that is determined to be waste at our facility is non-hazardous under RCRA and is sent to the waste to energy incineration site.

It is noteworthy to mention that there is some existing confusion with the term reverse distributor. The DEA does not have a separate registration category for incineration facilities that dispose of controlled substances and utilizes the reverse distribution registrant category for these incineration sites. Typically, the incineration sites are only destroying the product and do not have the same rigorous set of standard operating procedures as I have described in this testimony. When I am using the term reverse distributor it is not referring to a disposal-only facility registered by the DEA as a reverse distributor.

Unused Medications from Consumers

As I have attested to unused products generated by pharmacies and other business entities are processed at reverse distributors following multiple procedures and regulations.
It is important to reiterate that these procedures and regulations promote the safety, security, accountability and the most environmentally safe method of disposal. Simply put, reverse distributors core business function is drug take back. As a result, we are often asked if we can take back unused medications from consumers. With only a few exceptions, reverse distributors customarily do not take back unused pharmaceutical product from consumers
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Our primary barrier to entry into consumer take back is the Controlled Substances Act. This Act only allows for transfer of controlled substances among DEA registrants thereby creating the closed loop of distribution. The closed loop of distribution for finished pharmaceuticals starts with the manufacturer who ships to drug wholesalers. The wholesalers sell to pharmacies. The unused, expired or recalled product is shipped back to the reverse distributor. Each of these businesses is a DEA registrant. When a pharmacy dispenses the medication to a patient, the patient is not considered to be within the closed loop of distribution and is not a DEA registrant. As a result, reverse distributors as well as the other DEA registrants cannot take controlled substance product back from patients as they are not part of the closed loop of distribution.

The expenditures associated with the processing and disposal of unused pharmaceutical product from consumers has also been considered a potential barrier to a successful take back program; however, we believe that a resolution to this exists based on our customer requests for a program. GPS has received requests from our customers, including both large pharmacy chains and pharmaceutical manufacturers to provide a consumer take back solution. Regrettably we have not been able to develop this business opportunity due to the Controlled Substances Act.

A consumer take back program is not a new concept to GPS and other reverse pharmaceutical distributors. In 2006 GPS created and presented a model for the use of a mail-back consumer returns program at the 3rd Annual Unused Drug Return International Conference. This presentation not only included the proposed procedures for a mail-back program for consumers, but it also included the recommended changes to the Controlled Substances Act. The proposed changes allowed for controlled substance to be shipped to reverse distributors from non-DEA registrants or the patients.

In 2008, GPS conducted a small feasibility pilot to determine if consumers in two counties in Wisconsin would utilize a ship-back program for their unused or expired medications. GPS worked with the county waste departments, the Wisconsin Department of Natural Resources as well as other interested individuals. The program was funded by grants from the EPA Great Lakes Sea Grant Program as well as the Wisconsin Department of Agriculture Trade & Consumer Protection.

The procedures that accompanied the feasibility pilot included several key elements, including advertising, education, data collection, and proper safety, storage and disposal of the returned product. We advertised to consumers through the use of local media including newspapers, flyers, radio and television. GPS designated a specific 1-800 phone number for consumers to request an informational packet and the appropriate shipping materials for their product. We deliberately chose to engage the individuals in the return process through a phone conversation as this provided us with the opportunity to explain to the consumer that we could not accept certain materials including bio-contaminated product and controlled substances. Written directions were shipped to the address provided by the caller to reiterate the detailed message that was initially provided through the phone conversation. We also proactively informed the DEA that we were conducting the pilot program in the event that we did receive controlled substances from individuals.

The pilot program ended after approximately six months. In this time we received 1730 calls with 1259 households returning product. The 1259 households returned 15164 medications. The medications returned to GPS included a variety of therapeutic categories including cardiovascular medications, hormones, antibiotics, and diabetic medications as only a few examples. A small percentage of the returned product also included controlled substances despite the written and verbal education provided to consumers. Subsequently, the controlled substance returns were reported to the DEA .In the brief period we operated the pilot we concluded that there was consumer acceptance for this type of prescription take back program.

Since our pilot program we have received numerous requests to continue a consumer take back program covering a larger geographic area than our initial feasibility study; however, we have not been able to continue a program due to the potential to inadvertently receive unsolicited returns of controlled substances from non-DEA registrants. While we did our best to educate individuals on the definition of a controlled substance, including why we could not accept these products, we found that consumers did not fully understand and incorrectly sent us controlled substances.

It is noteworthy to mention that due to the multiple systems in place within reverse distribution we did manage the controlled substances to the same level of accountability as if received by a DEA registrant. This included counting the product, providing witnessed incineration and reporting the receipt and destruction of these products to the DEA. Again, we have not progressed with any other consumer take back program as we did not want to purposefully continue this practice when it was evident that individuals will return controlled substances even when educated not to return these products.

Our discontinuation of this program puts us at a disadvantage to those operating other prescription take-back programs that allow consumers to send back their unused or expired medications. Any take back program that accepts controlled substances is required to have law enforcement present; however, based on the questions that we receive about consumer take back it is evident that not everyone is familiar with the regulatory requirements and may not be reporting receipt of controlled substances to the DEA.

Clarifications and Exemptions to the Controlled Substances Act

Despite the challenges with the Controlled Substances Act for consumer returns, the DEA has been very helpful in providing some clarifications or variances for reverse distributors. These variances and/or clarifications have included the ability to receive a specific controlled substance product directly from patients and the ability to receive any controlled substance from a patient in the event of a patient level recall. In addition, a variance provided by the DEA was for the acceptance of controlled substances from long term care facilities in Kentucky.

First, a clarification provided by the DEA to GPS was provided when the take-back of one particular controlled substance was questioned. This product is fentanyl citrate transmucosal lozenge or the trade name Actiq. The product has the active ingredient at the end of a stick making it somewhat shaped like a candy sucker or lollipop thereby potentially making it extremely dangerous to children. In the clarification letter provided by the Drug Enforcement Administration the DEA determined that no special exception is needed as this situation is covered under the Special Exceptions for Manufacturer and Distribution of Controlled Substances in Title 21 of the Code of Federal Regulations (CFR), Section 1307.12. This states that the manufacturer or its designated registered agent may accept returns from a non-registrant who is lawfully in possession of a controlled substance regardless of the schedule of controlled substance. GPS is contracted with Cephalon, the manufacturer of the product Actiq and therefore may accept returns from non-DEA registrants for this product

The second clarification to the Controlled Substance Act mentioned and currently used is for reverse distributors and manufacturers to receive controlled substances from non-DEA registrants in the event of a patient level recall. All product that is returned from patients under these circumstances is brought into the highly regulated environment which results in the product being counted and sent for witnessed incineration with full reporting to the DEA. GPS has managed many recalls on behalf of pharmaceutical manufacturers.

Finally, a variance to the Controlled Substance Act, although not widely used at the time it was issued, is an exemption for reverse distributors to accept controlled substances from long-term care facilities located in the state of Kentucky. The Drug Enforcement Administration allowed for a variance for reverse distributors indicating that they were aware of a critical problem within the State of Kentucky regarding the disposal of controlled substances at long term care facilities. The DEA indicated that they were providing the variance as a result of controlled substances stockpiling within the long term care facilities and presenting a public health problem. In order to avoid the potential diversion of these controlled substances the DEA agreed to allow long term care facilities to ship controlled substances for disposal to DEA registered reverse distributors. Unfortunately, the program was not widely utilized as many facilities either did not know about it or did not want to pay for the disposal process.

As a result of these clarifications, reverse distributors are allowed to take back controlled substances from non-DEA registrants in certain circumstances. GPS would welcome the ability to expand its part in the take-back of unused consumer product including controlled substances and is providing recommendations as part of this testimony.

Recommendations and Conclusion

As the problem with unused medication continues to be an issue among consumers it is evident that the Controlled Substances Act needs to be amended to allow take-back of controlled substances from non-DEA registrants. Since reverse distributors' core business function is the safe and secure processing of unused medications, GPS is a proponent of unused products being processed through reverse distribution. Reverse distributors have systems in place to adhere to the highly regulated environment and utilize the most environmentally safe method to dispose of medications.

If the number of reverse distributors continues to be lower than other types of DEA registrants we believe that it may be easier for the DEA to monitor the take back of controlled substances by reverse distributors. In conducting a review of the DEA diversion website for total DEA registrants, the website listed only 55 reverse distributors as opposed to 66,257 retail pharmacies alone for May, 2010. As the DEA works to prevent the diversion of controlled substances, we believe that the fewer number of registrants or individuals that handle the product the less likelihood of diversion, although we fully recognize that diversion can occur in any setting and only takes one individual.

GPS previously submitted recommended changes, including proposed language for the Controlled Substances Act to the DEA. This was most recently submitted in 2009 when the DEA solicited information on the disposal of controlled substances through their advanced notice of proposed rulemaking. The general recommendation from GPS included the ability for reverse distributors to take back controlled substances from non-DEA registrants.

An additional recommendation to the DEA is to distinguish the reverse distribution registration from disposal-only facilities. The current terminology used by the DEA does not match other regulatory agencies use of the term reverse distributor and creates confusion for the industry and agencies involved. The use of disposal or incineration as a registrant type would help provide the necessary clarification.

It is also important to note that unused medication from consumers is considered household waste and therefore is currently federally exempt from the environmental regulations. GPS proposes that when these products are collected from households they undergo the same rigorous environmental procedures and destruction standards as utilized by the reverse distribution industry. The process of incinerating unused product, particularly at a waste to energy facility is the most environmentally responsible method currently available today and the procedure utilized by GPS for all non-hazardous pharmaceuticals.

In summary, GPS recognizes the significant problem of unused consumer medications in the United States. We believe with changes to the Controlled Substances Act, GPS, along with our customers and other reverse distributors can have a significant impact on reducing the amount of unused medications in homes across the U.S. As a result we anticipate the occurrence and prevalence rates of misuse, abuse, and accidental poisonings from prescription product would decrease. Finally, we also believe that a solution will minimize the contribution of pharmaceutical contamination in our environment.

Thank you Chairman Kohl, Ranking Member Corker, and the members of the Committee for your commitment to appropriate prescription drug disposal for consumers and your interest in resolving the problems associated with this issue.