

March 21st 2018

Chair: Greg Walden

SUBJECT: Energy and Commerce Committee

RE: Subcommittee on Health hearing entitled,
"Combatting the Opioid Crisis: Prevention and Public Health Solutions"

Thank you Mr. Chairman and members of the Committee for giving us the opportunity to testify today. My name is Wm. M. Simpson, President of DisposeRx, Inc., the country's leading site-of-use medication disposal company. My colleagues and I are both dedicated and passionate about stopping the cycle of addiction, overdose and death that begins with leftover opioids in the medicine cabinet, and we are here today to share our understanding in combating the opioid crisis and how we are delivering innovative solutions to safe drug disposal and prescription drug abuse.

With more than 90% of consumers (*Science Daily – August 2, 2017*) that have unused prescription medications failing to dispose of their medications in currently recommended ways, there is an obvious need to allow for the development of at-home site-of-use disposal solutions. Drug overdose is the leading cause of accidental death in U.S. According to the National Institute on Drug Abuse, overdose deaths involving prescription opioids have quadrupled since 1999, and with each day, more than 190 Americans are dying and an additional 1,000 people are being treated in emergency departments for not using prescription opioids as directed. In 2016, more than 64,000 people died from drug overdoses, with the majority involving opioids!

The failure to properly dispose of unused, or expired prescription drugs from our home medicine cabinets, managed care facilities, hospitals and hospices centers has dramatically contributed to the rapid

increase of prescription drug abuse, accidental poisonings, opioid overdoses and the pollution of our nation's public drinking water supplies. (*Washington Post* November 2016).

The death statistics on the opioid epidemic keep increasing, killing more people today per year than we lose on our national highway system (~59K), and surpassing the HIV/AIDS epidemic numbers of the '90's. With nearly 95M Americans using prescription painkillers last year and more than 650,000 opioid prescriptions dispensed daily, the problem continues to grow. Accordingly, WE FEEL it is urgent to stop the high cost of incineration, leachate into water supplies and unreliable disposal recommendations, but instead dispense with all prescriptions a reliable solution that permanently sequesters leftover drugs and stops diversion for abuse.

- 70% of addiction begins at the medicine cabinet (National Institute on Drug Abuse)
- 45% of homes have expired, unused or off-therapy medications (NY Times)
- Misuse of prescription medication is the #1 Emergency Department admission. (CDC)
- Cost of addiction treatment can be up to ~\$40,000 per patient per year, with Medicaid reimbursing up to two treatments (2018 Legislative Issues).
- The annual cost of managing the opioid epidemic is estimated by the U.S. Government to be in excess of \$504B in deaths, rehabilitation, lost wages and economic costs.

If you take into consideration all of the methods that are currently recommended for leftover medication disposal it shows that none of these methods are convenient, responsible, secure and certainly do not prevent diversion of controlled substances. Any consumer can research how to dispose of their unused medication and they will be given choices such as drug take-backs, kiosks, mail-in, combine with kitty litter or coffee grounds to make the mixture "unpalatable", or simply sewer by, flushing down the toilet or pouring unwanted medications into the sink. National policies may have long encouraged improper drug disposal. These methods have been around for two decades and during that time we have

continued to see an exponential increase in prescription drug abuse. Over 70% of people studied reported not using the take-backs or kiosks to dispose of their medications (*CVS -Public Opinion of Prescription Drug Abuse and Disposal -updated September 2017*). According to the American Journal of Drug and Alcohol Abuse, it is evident that annually, those controlled medications that were disposed in drug take back locations were estimated to only account for 0.3% of those dispensed. (*Kathleen L. Egan MS, Eric Gregory EdD, CPS, Michael Sparks MA & Mark Wolfson PhD (2017) From dispensed to disposed: evaluating the effectiveness of disposal programs through a comparison with prescription drug monitoring program data, The American Journal of Drug and Alcohol Abuse, 43:1*)

There is a better way! Today we are proud to be working with Walmart leading all retail pharmacies in fighting both our nations opioid epidemic as well as the dangers of prescription drug abuse. This is being done by giving patients a choice that works and allows them to safely, conveniently, and securely dispose of their unused medication at home. Effective at-home disposal (Site-of-Use) offers a far more convenient solution to drug disposal than take back programs and a more effective solution than disposing medication in an unpalatable mixture, which does not prevent the opportunity for diversion. Looking at data alone, it is very clear that there is an overwhelming need to offer a true and easy to use solution for consumers. Data has shown that items returned to drug take back locations often times include such things as nasal sprays, ointments, and creams. (*Steward, Malinowski, Ochs. Inside Maine's Medicine Cabinet: Findings from the Drug Enforcement Administration's Medication Take Back Events, Am J Public Health, January 2015*). In fact, in a North Carolina municipal collection point (2018) only 2.62% of the total items collected were actually controlled substances. A survey in the Journal of Drug Abuse revealed that 1.4% of consumers returned their unused medication to their pharmacy and 54% threw their medications in the trash. More than a third, 35.4% disposed of their medication in the sink or toilet. And what is more surprising is that fewer than 20% of patients reported having received any education from a provider as to correct methods

for medication disposal. (*Journal of Drug Abuse, Proper Drug Disposal: Studying a Solution to Household Prescription and Over the Counter Drug Abuse, 2016, 2:2*)

Home medication disposal is an example of a negative externality. In order to be most effective in bending this curve, education on proper drug disposal and simple home solutions are essential. The success of any program is determined by whether or not the patient, caregiver, and health care provider community is educated on proper disposal methods. Structured and simple education on drug disposal has to be a part of all solutions that are offered.

Safe drug disposal is also critical for maintaining public health. Flushing or throwing unused medication in the sink has been shown to contribute to the presence of pharmaceutical compounds in the water supply and a continuous exposure to these compounds could have a cumulative toxic effect (*Journal of Drug Abuse, Proper Drug Disposal: Studying a Solution to Household Prescription and Over the Counter Drug Abuse*).

Our country is in a tremendous crisis. Not only from opioid addiction, but from the growing dangers of prescription drug abuse. Prescription drug abuse is responsible for the largest percentage of deaths from drug overdosing. (Kinrys G, Gold AK, Nierenberg AA. *Proper Drug Disposal: Studying a Solution to Household Prescription and Over-The-Counter Drug Abuse. J Drug Abuse. 2016, 2:2*). The number of prescriptions written for benzodiazepines alone (drugs such as valium and Xanax) have more than tripled between 1996 and 2013 (*Psychology Today; Benzodiazepines: The Danger Lurking in the Shadow of Opiates, June 29, 2017, Dr. David Sack*), with nearly 50 million prescriptions are written for benzos each year.

DisposeRx has invested in developing a solution that can help eliminate one of the root causes of prescription drug misuse and abuse which is exposure to unused, unwanted medication in the home. DisposeRx is the gold standard for at home drug disposal. We have developed a product that safely, conveniently and securely allows consumers to dispose of their unused medications in their own home and when it is convenient for them. This will ensure that there is no time lag between dispensing and disposal, eliminating the opportunity for diversion. One study showed that there is, on average, a 34-month time gap between dispensing of a medication and disposal when the choice is take-backs or kiosks (*Am J. Public Health, Prescription Disposal Practices: A 2-year Ecological Study of Drug Drop Box Donations in Appalachia, September 2015*). DisposeRx allows the consumer to dispose of their medication when it is convenient for them, therefore making it more likely that there will be no opportunity for someone to misuse or abuse the drug.

Consumers are reaching out for a solution that is simple and safe to use, DisposeRx provides patients with an easy solution for drug disposal. Each packet contains a patented blend of non-toxic ingredients that will create a viscous gel when mixed with warm tap water. You simply take your pill bottle with the unused medication, add the warm tap water and the powder, shake for 30 seconds and then throw away in the household trash. The components of the gel sequester, or encapsulate the drug so that it cannot be diverted for misuse or abuse. It creates a barrier between the drug and the consumer therefore rendering the drug(s) non-useable.

DisposeRx is the most tested and trusted product on the market today. Our patented cross-linking polymer drug disposal solution has been subjected to rigorous third-party testing for both extractability and environmental friendliness. Extractability testing has shown that, once encapsulated or sequestered

by our product, drugs cannot be retrieved from the gel using common household solvents that an addict would have readily available.

DisposeRx is non-toxic and the majority of the components are listed as “generally regarded as safe (GRAS)” by the FDA. Environmental testing has proven that DisposeRx is neither dangerous nor hazardous to the environment. We have successfully passed the Toxicity Characteristic Leaching Procedure, the CCR Title 22 Fathead Minnow Hazardous Waste Regulation Bioassay as well as the 96-hour Washington State Hazardous Waste Regulation Bioassay. We are proven to be safe for the environment.

Incorporated into the mission of the DisposeRx team and lead by Dr. John W. Holaday, is the commitment to educating the community on the cycle of medication management, from dispensing to compliance and then ultimately proper and safe disposal. We realize that any program’s success is dependent on the inclusion of targeted instruction. With 89% (*Henry J Kaiser Family Foundation, “Total Number of Retail Prescription Drugs Filled at Pharmacies”*) of prescription medications filled face-to-face, this allows a wonderful opportunity for the pharmacist to practice at the top of their license and offer patients, family members and caregivers important details regarding medication lifecycle management, including safe usage, storage and disposal. We are proud to be working with Walmart leading the way with retail pharmacy dispensing, and soon we will be offering our solutions through other retailers and wholesalers. In addition we are partnering with Sheriff’s departments and pharmacies to bring the message of the importance of proper medication management to parents and students. Our initiative with drug disposal focuses not only on the mechanism for disposal but expanding the understanding, through educational initiatives, of the importance of the complete cycle of medication. We are developing tool kits for our website to teach viewers what prescription drug abuse is, how it can lead to addiction, and how you can

minimize drug misuse and abuse in the home. These are absolutely critical pieces for any drug disposal program to be successful.

Until the 1980s, medication management was done disease by disease. Treatment protocols were developed for each disease, and for patients with multiple diseases it was common to see both duplicate and conflicted medication therapies. This was called disease state therapy. In the early 1990s it was recognized that modern medicine could provide maximum benefits and minimal costs by treating the patient as a whole, not just each disease. This required the interaction of all of the medical profession treating the patient, often including multiple physicians and pharmacist all practicing at the top of their licenses. Medication for each evaluated patient may be changed, added or deleted from therapy. This results in the potential for partial remnants of medication to no longer being used, but remain in the medicine cabinet. It is those unneeded pharmaceuticals and those prescriptions not used, despite physician instructions, that are the core of misadventures that begin in the home medicine cabinet. This includes the evolution of drug addiction, diversion and pollution of the water supplies.

DisposeRx, recommends a change to the traditional lifecycle of a pharmaceutical:

We challenge the industry to adopt a responsible medication lifecycle that includes the following:

- Scientist Discover new medications
- Medications are tested and approved by the FDA for patient use
- Physicians are educated on proper prescribing guidelines
- Medications are prescribed by physicians for patient therapy
- During dispensing patients receive medication education which includes proper and safe usage, storage and disposal
- Patients use medication to treat diagnosed disease
- Unused medication(s) are safely and properly sequestered with site-of-use solutions by the patient once it is determined they are no longer needed.

In closing, DisposeRx is supportive of any directive that will encourage the development of medication disposal systems that will allow the consumer to make the choice on how to dispose of their unused drugs. To be effective, a system must be simple, secure, convenient and consistent with preventing the diversion of such substances. Cleaning out the medicine cabinet will become second nature if the mechanism to do-so makes it a realistic, obtainable goal for consumers.

Respectively,



Wm. M. Simpson, President

Ben Donaldson, VP Government Relations

Ann Hamlin, Director, Training and Science

Dr. John W. Holaday, CEO and Chairmen

[DisposeRx](#) is an anti-medication misuse company which has developed a site-of-use drug disposal solution for unused, unwanted, expired or off-therapy medications. Our technology solution offers an effective method for drug disposal, both chemically and physically sequestering medications into a viscous gel. Our Gold Standard disposal technology is the most tested in home drug disposal history, ultimately empowers users to safely dispose of medications in their home environments.