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Before

House of Representatives

Committee on the Judiciary

Sub-Committee on Crime, Terrorism and Homeland Security

Hearing on

"Online Pharmacies and the Problem of Internet Drug Abuse"

June 24, 2008

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Overview

The "Ryan Haight Pharmacy Consumer Protection Act" S.980¹ (hereinafter the "Proposed Bill"), if implemented, would have a negative impact on the policy issue of safe delivery of controlled substances to United States patients at a reasonable cost. Additionally, the Proposed Bill through criminalization of the sale of controlled substances without a "valid prescription" by "online pharmacies" fails to attack the source of addiction to prescription medication. Drug users have multiple superior sources to acquire prescription medication and do not receive adequate treatment while incarcerated.

The Proposed Bill would disproportionately effect millions of Americans who cannot afford medical care and prescription medicine by impacting the significant benefit U.S. patients receive from the purchase of medications through online pharmacies without what the bill and DEA term a "valid prescription." Furthermore, the Proposed Bill directly impacts the ability of Americans to treat chronic pain, which affects up to 85% of adults at some point in their lives, and obesity, which affects 66% of the population. An estimated 300,000 premature deaths are caused by obesity each year, while an estimated 146,377 deaths from the period 1979-1998 are caused by arthritis. We do not seek to marginalize the 26,000 citizens who die from the total effects of all drugs each year (Nonmedical use of prescription medicine included), however for the greater pubic good, the ability to purchase prescription medication from "online pharmacies" without the need to visit a doctor grossly outweighs the cost to society.

Finally, the Proposed Bill follows the erroneous policy path of increased prison sentences for drug offenses that has so clearly been the hallmark of the failed "War on Drugs". As such the provisions of the Proposed Bill which call for increasing maximum sentences and a review of the guidelines by the Sentencing Commission reflect thinking that is more in tune with 1980 than 2008.

I. The Proposed Legislation Detracts From The Policy Goal of Safe Delivery of Controlled Substances To Patients At Reasonable Cost

The Proposed Bill would negatively impact the safe delivery of controlled substances to patients at a reasonable cost because many Americans would be forced to purchase medication from offshore sources which have a higher propensity to purchase counterfeit medication. Additionally, the restrictions would raise the cost of obtaining prescription medication. In 2005, the United States spent 16%, 1.7 trillion dollars (up from 14% in 2000) of Gross Domestic

¹ S. 890, 110 th Congress § 2 (as passed by Senate, April 1, 2008).

² Joseph Curran, *Prescription For Disaster*, State Office of Attorney General (September 2005) (internal citations omitted).

³ Health, United States, 2007, U.S. Department of Health and Human Services, 40 (2007) available at http://www.cdc.gov/nchs/data/hus/hus07.pdf. (Internal Citations Omitted)

⁴ Id. Health, United States, 2007.

⁵ Arthritis Types- Overview (2008), http://www.cdc.gov/arthritis/generic.htm

⁶ S. 890, 110 th Congress § 2 (as passed by Senate, April 1, 2008).

⁷ Marv Shepard, *Vulnerable Points In the U.S. Drug-Distribution System*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

Product (GDP) on health care. 8 Of this money, 12% was spent on prescription drugs, 25% on physician care. Out-of-pocket expenditures for health care cost Americans \$236 billion. 9

The majority of Americans choose not to report healthcare problems to health care providers due to costs. Over 40 million (19%) Americans 18 years of age and over failed to receive one or more of the following health care services in the past year because they could not afford them; medical care, prescription medicines, mental health, dental care, or eyeglasses. From 1997-2005, the percentage of adults rose from 6%-9% because of the inability to afford prescription medicine. ¹⁰

These combined financial considerations make "online pharmacies" that do not require doctors visits an attractive source of healthcare for millions of Americans. Therefore, the Proposed Bill is not the appropriate response to drug abuse in the United States.

A. The Proposed Bill Would Increase U.S. Patient Costs.

The Proposed Bill would negatively impact millions of Americans that are presently unable to afford medical care and prescription medicine. The act would contribute to the disparity between Americans that can afford medical care through the traditional channels and those that cannot. In total, Americans spend an estimated \$1.7 trillion in health care. ¹¹ Specifically, an estimated \$236 billion was spent out-of-pocket because of lack of insurance coverage, deductible, or copayment. Furthermore, an estimated \$200 billion was spent on prescription medication, including an estimated \$40 billion being spent out-of-pocket. ¹²Interestingly, Americans have spent \$650 million dollars a year in purchases from Canadian Internet Pharmacies. ¹³ This is attributed to the significant aging of the U.S. population, a U.S. pharmaceutical free market that permits drug manufactures to determine the market price, and the limited U.S. public and private health insurance plans. ¹⁴ 77% percent of Americans deem it unreasonable for Congress to stop Canadian pharmacies form selling drugs to Americans over the internet. ¹⁵ The following are significant groups that would be adversely affected by the Proposed Bill.

1. <u>Nonmetropolitan Areas</u>

Americans that live in nonmetropolitan areas have substandard access to physicians and have no other alternative than to forego medical care and prescription drug use or make costly trips to doctors in other counties. According to the CDC, the shortage of physicians in

¹⁵ See Cohen, supra note 13.

⁸ See id. Health, United States, 2007, supra note 3

¹⁰ See id. Health, United States, 2007, supra note 3

See id. Health, United States, 2007, supra note 3

¹² See id. Health, United States, 2007, supra note 3

¹³ Jillian Claire Cohen, *Public Policy Implications of Cross-Boarder Internet Pharmacies*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

¹⁴ Paul Saatsoglou, *Pharmaceutical Reimporation: Magnitude, Trends, and Consumer*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

nonmetropolitan areas is a deterrent to timely and appropriate healthcare. ¹⁶ 50 million Americans (17% of the U.S. population) live in nonmetropolitan counties. Additionally, 4% of counties in the U.S. have no physicians and an additional 7% classified as health profession shortage areas ("HPSA"). ¹⁷

The Proposed Bill would increase the deterrent of Americans in nonmetropolitan areas seeking any medical care or prescription drugs at all. "Online pharmacies" that do not need "valid prescriptions" enable these individuals the ability to interact with doctor's and healthcare providers online to receive prescription medicine at a reasonable cost. The "online pharmacy" is a new innovation that would avail individuals in nonmetropolitan areas access to healthcare and reduce the deterrent factor to seeking healthcare. The Proposed Bill would increase the overall cost to the 50 million lower- income Americans by having to get transportation to other counties. These, individuals should not receive substandard care because of the proportionately smaller risk of the use of prescription medicine for nonmedical use.

2. Americans Without Insurance

"Online Pharmacies" that do not require a "valid prescription" decrease the cost for uninsured Americans to receive medical care and prescription medicines. Americans with low incomes do not have consistent insurance coverage throughout the year. As recent as 2005, 20% of people under 65 have been uninsured for at least 12 months prior to the CDC study. 18

Uninsured Americans are more likely to forego the use of medical care and prescription drugs. ¹⁹ These individuals are three times as likely not to have had a doctor's visit in the past three-years. The Proposed Bill would foreclose any chance for the uninsured population to receive medical care and prescription medicines. The ability for the uninsured to purchase cheaper medications from U.S. "online pharmacies" without a "valid prescription" is a valid option for the uninsured to obtain prescription medicine. If the uninsured were forced to go to doctors to get a "valid prescription," the uninsured would not go at all because these individuals can clearly not afford medical care. Thus, "online pharmacies" give uninsured Americans a unique benefit not offered elsewhere.

3. Lack of Sufficient Insurance Coverage

An estimated 62% of U.S. population that purchase prescriptions outside of the U.S., even though these individuals had prescription drug coverage. Studies suggest that Americans need to buy medical prescriptions through "online pharmacies" because of high copayments, annual deductibles, and the rising cost of prescription medication. Individuals in the range of 65-74 age group are 22% more likely to purchase prescription medicine outside of the U.S. All

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¹⁶ See, Health, United States, 2007, supra note 3

¹⁷ See, Health, United States, 2007, supra note 3

¹⁸ See, Health, United States, 2007, supra note 3

¹⁹ See, Health, United States, 2007, supra note 3

²⁰ See Saatsoglou, Pharmaceutical Reimporation: Magnitude, Trends, and Consumer, supra note 14.

 $^{^{21}}$ Id

of these factors contribute to the estimated \$650 million dollars spent a year in Canadian "online pharmacies."22

Individuals That Have Forgone Medical Care Due To Cost 4.

Individuals with and without insurance tend to forego needed medical care because of cost. The cost of health insurance, deductibles, copayments, and prescription medicine financially prevents an estimates 2%-10% of Americans from receiving any medical care. 23 The following represents the percentage of people and age demographic that did not receive healthrelated services because of cost;

	Americans That Have Forgone Medical Care Due To Cost			
		Age Demographic		
		18-44 years	45-64 years	65 years and over
Service	Medical Care	8.10%	7.70%	2.50%
	Prescription Medicine	9.80%	8.70%	5.10%

The Proposed Bill would potentially increase the already substantial number of Americans that do not receive any medical care and prescription medicine. More Americans could succumb to this category if prevented from purchasing prescription medicine from "online pharmacies" without a "valid prescription." If the concern is overall health of Americans, the Proposed Bill would potentially work to the detriment of the whole, for the illusory benefit of requiring a prescription to purchase pain medication and other controlled substances online.

В. Safe Delivery of Controlled Substances

Although the FDA could potentially have greater control over the delivery of controlled substances to Americans, the effect of the Proposed Bill would force more Americans to purchase prescription medicines offshore, where the risk for counterfeit medications is higher. U.S. pharmacies and wholesalers are subject to rigorous prescription drug access and control.²⁴ A counterfeit drug is "deliberately and fraudulently mislabeled with respect to identity and or

²³ See, Health, United States, 2007, supra note 3.
²⁴ Michael Dickson, International Pharmaceutical Expenditure Differentials: Why?, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

source."²⁵ Marv Shepard, PhD, the Director of the Center for Pharma-economic Studies at the College of Pharmacy at the University of Texas, states that this is a global problem, with the leading countries China, India, Russia, Brazil, Pakistan and Mexico.²⁶ Dr. Shepard continues to state that Americans are continually searching for cheaper and cheaper prescription drug access in these leading countries and exposing themselves to risk.

The proposed bill would further exacerbate the problem. Americans cannot presently afford the price of prescription medication provided through traditional sales channels available in the U.S. The requirement to receive a "valid prescription" would increase the overall out-of-pocket expenses for medical care and prescription medication. Therefore, if the Proposed Bill is passed, the increase cost of prescription drugs to Americans could actually force them to purchase greater numbers of prescription medication offshore. The countries listed above have significantly higher rates of counterfeit drugs. This could, according to Dr. Shepard, "result in more deaths, disabilities, and continued destabilization of our safe drug-distribution system." 27

In conclusion, the Proposed Bill would have the cumulative effect of increasing the cost of controlled substances to U.S. patients. Additionally, the Proposed Bill would force Americans to pursue unsafe international channels of prescription drug trade and cause more deaths and disabilities.

II. The Benefits and Risks of Controlled Substances Sold Through "Online Pharmacies" without a "Valid Prescription"

Acting under the assumption that controlled substances used for medical purposes improve the lives of the patient, the benefits of prescription medicine sold by "online pharmacies" without the need for a "valid prescription" significantly outweigh the risks of abuse for nonmedical purposes, especially in teens. According to the U.S. Senate Resolution of the 109th Congress, 2D session, an estimated 26,000 citizens die from the effects of drug abuse each year. ²⁸ In 2006, 17.4% of the seventeen-year old population had used pain relievers for nonmedical use. ²⁹ However, a majority of the pain medication used for nonmedical use are mild pain relievers, i.e. Vicodin rather than "Dilaudid." In addition to pain medication, diet pills are commonly purchased through "online pharmacies." Although a percentage of youths have tried pain relievers and diet pills for nonmedical purposes, the majority of these drugs are obtained from friends and relatives, not online pharmacies. The benefit to low-income Americans, obese Americans, and elderly Americans to have the ability to purchase prescription medicine from "online pharmacies" without the need for a "valid prescription" grossly outweighs the risk to adults and teens purchasing pain medication from "online pharmacies."

²⁵ Marv Shepard, *Vulnerable Points In the U.S. Drug-Distribution System*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (*citing* World Health Organization, (1999)).

²⁷ Marv Shepard, *Vulnerable Points In the U.S. Drug-Distribution System,* Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

²⁸ National Vigil for Lost Promise, 109th Cong. § (2006).

²⁹ Nonmedical Use of Pain Relievers in Lifetime, Past Year, and Past Month, by Detailed Age Category: Percentages, (2008) http://www.drugabusestatistics.samhsa.gov/NSDUH/2k6NSDUH/1ab
³⁰ Id.

The Risk To Teens Α.

Implementing the Proposed Bill would not change the drug seeking behavior of teens or the supply of prescription medication for nonmedical purposes. Youths receive a majority of prescription medication by theft from friends or relatives that have a prescription, "doctor shopping," prescription fraud, and irresponsible doctors.³¹

The Office of National Drug Control Policy reports that seventy-percent (70%) of teens get the products from friends and relatives.. Furthermore, sixty-four-percent take the prescription pain relievers without the knowledge of the friends or relatives. More than three in five teens say they got prescription pain relievers from parents' medicine cabinets. Lastly, users 12 and older received prescription pain relievers and used them for nonmedical purposes from their doctors.

The National Drug Control Strategy comments upon the Ohio Prescription Monitoring Program that attributes "doctor shopping" as a predominant factor and means of getting prescription medication for nonmedical use. 33 Additionally, the Attorney General of Maryland cites prescription fraud, i.e. pharmacy intern stealing pills from the pharmacy, as a means of obtaining prescription meds.³⁴ Lastly, doctors individually contribute to the distribution of pain medication for nonmedical purpose. Recently a New Jersey doctor was found guilty of conspiracy to distribute oxcycodone.³⁵

Therefore, the minor impact of requiring "online pharmacies" to only distribute controlled substances with a "valid prescription" would not be attacking the true and majority source of nonmedical use of pain relievers. The most efficient means of attack are through parenting, education and supervision. Moreover, those adolescents who are inclined to purchase controlled substances through "online pharmacies" will continue to do so. Only now the drugs they are purchasing will be from off-shore pharmacies and will be more likely to be adulterated or counterfeit.

В. The Benefits to Patients

1. Chronic Pain Management

Conversely, with a new record high in 2006 of life expectancy at birth 78.1 years and a 22,117 decrease in preliminary number of deaths from the 2005 total, individuals are living longer with the need of prescription medicines.³⁶ In 2005, Stanford University Medical Center in

³¹ Office of National Drug Control Policy, *Prescription for Danger*, http://www.whitehousedrugpolicy.gov/drugfact/prescrptn_drgs/index.html (internal citations omitted). ³² *Id.* ³³ *Id.*

³⁴ Joseph Curran, *Prescription For Disaster*, State Office of Attorney General (September 2005) (internal citations

³⁵ Office of National Drug Control Policy, Prescription for Danger,

³⁶ U.S. Mortality Drops Sharply in 2006, Latest Data Show, U.S. Department of Health and Human Services (2008), http://www.cdc.gov/nchs/pressroom/08newsreleases/mortality2006.htm.

conjunction with ABC News, released a study that states, "[n]ineteen percent (19%) of all Americans suffer from chronic pain lasting three months or more, and 34% endure recurrent pain. Roughly 70% of the 10 million cancer patients in the U.S. suffer from moderate to severe chronic pain. In 2006, the CDC estimated the average annual arthritis prevalence in the civilian "21.6% (41.4 million) adults reported arthritis (50% of persons aged > 65 have arthritis). Adults over 65 account for 80% of the use of at least one prescription drug in the past month. In total, \$15.6 billion dollars have been spent on prescription medicine to treat arthritis, and \$100 billion annually on chronic pain management, including direct medical expenses, lost income and lost productivity.

The need for more cost effective means for Americans living with chronic pain to have access to pain medication is substantial. Referencing the cost factors listed above, millions of American forego doctors visits and prescription drugs because of the prohibitive costs. The increasing population of elderly Americans on a limited income that suffer from disabling arthritis and chronic pain can more aptly afford "online pharmacies" in the because of the lower prices. A significant amount of the elderly are living below the poverty line because of unexpected out-of-pocket costs and rising healthcare costs. Visiting a physician is not an option for most, and the elderly are in the greatest need for prescription medication. The Proposed Bill would greatly inhibit the financially challenged from obtaining essential medication without solving the problem of teen prescription drug abuse in the U.S.

2. Obesity

Obesity is an epidemic that causes "more than 300,000 premature death each year in the U.S. second only to tobacco-related deaths." Obesity medical expenses account for 9.1 percent of total U.S. medical expenditures in 1998 costing an estimated \$92.6 billion dollars in 2002. Obesity is directly related to socioeconomic status, i.e the people that can afford diet pills the least. If anything, the benefit of "online pharmacies" that do not require a "valid prescription" would help curb the increasing trend of obesity in America. Therefore, the Proposed Bill would contribute to the obesity trend in America, the second leading killer of the U.S. population.

In conclusion, although 26,000 citizens die from <u>total</u> drug use, pain medication included, this number pales in comparison to the 300,000 Americans dying from obesity each year, and the 49.2 millions suffering from arthritis. The combined effect of the Proposed Bill would be to force elderly and socio-economically disadvantaged citizens to purchase the cheapest available medication offshore, increasing concerns about counterfeit medicine.

IV. <u>Criminalization of Drugs</u>

³⁷ See Curran

³⁸ NHIS Arthritis Surveillance, http://www.cdc.gov/arthritis/data_statistics/natioanl_data_nhis.htm

³⁹ Cost Statistics, http://www.cdc.gov/arthritis/data_statistics/natioanl_data_nhis.htm

⁴⁰ Id. Health, United States, 2007

⁴¹ Contributing Factors, *Department of Health and Human Service*, http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors

The Ronald Reagan administration, launched the "war on drugs" policy in 1982. 42 The 1970's left America with high rates of drug abuse, and the Reagan Administration responded with stringent punishment policies rather than drug abuse treatment. By 2004, the number of drug arrests has risen to a record level of 1,846,351, with four of five (81.7%) arrests for possession and only one in five (18.3%) for sales.⁴³

A. **Increased Sentences**

The Anti-Drug Abuse Act of 1986 and the Anti-Drug Abuse Act of 1988 have created a host of severe mandatory minimum sentencing laws for drug offenses. The original legislative intent for the mandatory sentences were to go after "major traffickers" and "serious traffickers." Contrary to the legislative intent, only 1/13 cocaine defendants were classified as "high-level suppliers" and the rest were low-level assistants and purchasers. Between 1988 and 2004, a disproportionally exists between the increases in the average prison sentence for all offenses (8%) and the average prison sentence for drug offense (18%). 44 In 1980, roughly 19,000 (6%) drug offenders in state prisons and 4,900 (25%) in federal prison represented the inmate population. The mandatory minimum sentencing and the abolition of parole has resulted in drug offenders serving much longer sentences.

In 1986, the average drug offender served an average of 22 months in prison. Since the adoption of the mandatory sentences and sentencing guidelines, the average period in 2004 increased to 62 months in prison. As a result of the punitive movement and lengthier sentences since 1980, a twelve-fold increase in drug offenders are doing time in state prison representing 20% of the total inmate population. In federal system, drug offenders represent 55% of all inmates. In total, between state, federal, and local jails, the number of drug offenders in jail has increased by 1100%(493,800).

The Proposed Bill reflects the failed policy position that longer sentences and further criminalization is an effective policy for combating the social problem of drug abuse. The oftstated definition for insanity is to continue taking the same actions and expecting different results. 25 years of data indicates that legislation of this nature will not solve the problem of prescription drug abuse.

В. **Solving The Problem**

Currently, more than half the persons in state prison suffer from substance abuse and/or dependence. However in 2004, only one in seven (14.1%) of persons that suffer from substance abuse have received treatment, compared to one in three (36.5%) in 1991. In federal prisons in 2004, 15.2% of persons in with substance abuse have received treatment compared to 33.7% in 1991. Thus, persons in prison that actually need treatment are not receiving it.

⁴³ Quagmire 25 Year Report
 ⁴⁴ Bureau of Justice Statistics, Compendium of Federal Justice Statistics, 2004, December 2006 NCJ 213476

Although the shift in incarceration to treatment is reflected by Congress in 1994 when it adopted the "safety valve" provision that permits judges to sentence offenders below the applicable minimum penalty period if conditions are met, there is still a lack of treatment options in prison. This proposition is reflected by the increase in probation and parole violations as the result of drug use from 1980 (17.6%) to 2004 (34%). It is clear that punitive measures and prison sentences are not fixing the problem.

The Proposed Bill would not solve the problem of prescription medication for nonmedical use in the United States, especially among the young teens demographic. In 2006, the National Survey on Drug Use and Health estimated 12% of 17 year olds have used pain relievers for nonmedical use. However, amending Section 309 of the Controlled Substance Act (21 U.S.C. 829) would not change this. Pain medication abusers have multiple sources for the prescription medicine.

Although stories of teenage prescription medication abuse are well-known in our society, the American public is much less aware of the numbers of Americans that are able to afford prescription medicine through "online pharmacies." Additionally, the American public is not aware of the stringent incarceration rate on minor drug offenders that have no treatment options while in incarceration.

The solution to these problems is not the Proposed Bill. In fact, the Proposed Bill would contribute more to the problems the country is facing, while only solving a small fraction of them. The answer to drug abuse is education, rehabilitation and opportunity for advancement, not stigmatization of offenders and incarceration. By creating a model where a licensed physician reviews an on-line questionnaire and a valid prescription is filled by a licensed pharmacist, some control is maintained over the delivery process. The Proposed Bill would send that system overseas and underground thus exacerbating the problem.

I would like to recognize the assistance of Jason Manfrey, Summer Law Clerk, Villanova Law School Class of 09, in the preparation of this testimony.