# PRESERVING PROBLEM FOR DISASTER THE GROWING PROBLEM OF PRESCRIPTION DRUG BUSE IN MARYLAND





State of Maryland Office of the Attorney General

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#### **EXECUTIVE SUMMARY**

A seventeen-year old high school athlete dies of a drug overdose. The twins of a thirty-year old addicted mother are placed in foster care because her drug habit prevents her from caring for them. A computer programmer loses his job when caught using and selling drugs. A college student goes to jail for a robbery committed to feed his drug dependency.

All too familiar stories of lives ruined by drug abuse? Yes, but with a twist. These are stories not of people abusing marijuana, cocaine, heroine and other illegal drugs, but rather are tragedies born of abusing legal drugs manufactured by pharmaceutical companies and normally dispensed by prescription. Whether obtained initially for a legitimate medical purpose and later abused, diverted through fraud or theft, or bought with nothing but a credit card on the Internet, these are drugs which bestow great medical benefit when used as prescribed but present an increasing danger as vehicles of drug abuse and diversion.

The abuse of illegal drugs is, after decades of struggling to contain it, embedded in our consciousness as a widespread and intractable problem. We are acutely aware of the dangers it poses for the health and well-being of our youth and our communities. As parents, we try to educate our children about its destructiveness. As policy makers, we try to allocate resources to combat it and develop programs to help those who have already succumbed to it. As law enforcement officials, we battle to beat it back at its source. It holds a place of regrettable prominence in our public policy and private thoughts.

The abuse of *legal* drugs, however, has not received nearly the same attention. Yet it threatens to become a scourge as insidious and destructive as the abuse of illegal drugs. The U.S. Department of Justice calls the diversion and abuse of pharmaceuticals among the "leading drug threats to the country," and characterizes the risk to Maryland as a "serious but often unrecognized threat throughout the state."<sup>1</sup>

The proliferation of prescription drugs in recent decades has ushered in tremendous advances in medicine. New, more powerful, more effective medications regularly reach the market. Health care providers have made significant strides in palliative care and the treatment of pain. These innovations are invaluable, as they save lives, reduce suffering, and improve quality of life for millions.

Yet at the same time, medical advances have given rise to a new danger.

<sup>&</sup>lt;sup>1</sup>National Drug Intelligence Center, *National Drug Threat Assessment 2005*, U.S. Department of Justice, Document ID: 2005-Q0317-003, February 2005 at 3; National Drug Intelligence Center, *Maryland Drug Threat Assessment*, U.S. Department of Justice, Product No. 2002-S0379MD-001, August 2002, at 18.

Millions of prescriptions written every year give people access to a wide range of prescription drugs. As the *National Drug Threat Assessment 2005* notes, in the late 1990's, "legitimate commercial production and disbursal of pharmaceuticals, particularly prescription narcotics, increased sharply, making more of the drugs available for illegal diversion."<sup>2</sup> With this proliferation has come an enormous potential for abuse. Millions of Americans have already begun using powerful pain relievers and other prescription drugs for non-medical purposes, with results every bit as harmful to themselves and others as the abuse of cocaine, heroin, and other illegal substances. Especially given the Internet's open pathway to obtaining prescription drugs, this problem promises only to get bigger.

We must begin to pay more attention. We must do so in such a way as to preserve the benefits of drug innovation, patients' access to optimal health care, and the medical profession's freedom and ability to practice the best medicine possible. Yet we must recognize and address the growing impact of this abuse.

To that end, I recommend that we take the following steps:

- **Prescription Monitoring Program:** We should design and implement an electronic prescription monitoring program which is both safe and effective, drawing upon the input and expertise of all stakeholders, from health and pharmaceutical professionals to law enforcement and patient advocates. It should balance carefully our dual interest in providing patients optimal and confidential medical care while also assisting law enforcement and health professionals to combat and prevent drug abuse and diversion.
- **Illegal Distribution of Prescription Drugs:** We should strengthen our laws which prohibit obtaining prescription drugs with intent to distribute them for non-medical purposes.
- Regulation of Pharmacy Technicians: We should reduce the diversion of prescription drug retail inventory by enacting legislation to regulate unlicensed pharmacy technicians.
- **Coordination and Training of Law Enforcement:** We should work closely with the Drug Enforcement Administration to increase coordination among federal, state and local law enforcement agencies to combat and prevent drug diversion, including the development of training protocols.
- **Public Outreach and Education Campaign:** Marylanders, and especially parents, need to be more aware of the dangers and warning

<sup>&</sup>lt;sup>2</sup>National Drug Threat Assessment 2005, supra, n.1 at vii.

signs of prescription drug abuse and the increasing hazards of the Internet as a pipeline. We should launch a public outreach campaign to educate people about its growing prevalence, the ease with which teens and even children can purchase powerful prescription drugs on the Internet, and the steps people can take to protect themselves and their children.

- **Training for Health Professionals:** The health care profession can work alongside law enforcement in detecting and preventing abuse and diversion. We should develop and provide information resources and training to help health and pharmaceutical professionals identify and prevent doctor-shopping and the use of fraudulent prescriptions.
- Protection Against Unscrupulous Internet Pharmacies: With the Internet fast becoming a major source of prescription drug diversion, we must do everything possible to protect Marylanders from the rogue, online pharmacies which sell powerful drugs to anyone, without so much as a professional consultation, let alone a prescription. While most effective regulation will have to occur at the federal level, which we should strongly encourage, in the meantime we must educate people about how to avoid the pitfalls of purchasing legitimate drugs on the Internet, and how to protect themselves and their children from the online accessibility of controlled dangerous substances and other medications without meaningful medical oversight.

In sum, as prescription drug abuse and diversion threaten to become as deeply entrenched and destructive as illicit drug abuse, we need to begin addressing these issues more comprehensively. As with most endeavors, our efforts will be most effective if we can bring everyone involved in the many facets of this problem together. As health and pharmaceutical professionals, as law enforcement personnel, as patients, as advocates and as parents, we can come together to make a difference.

> J. Joseph Curran, Jr. Attorney General September 7, 2005

#### I. PRESCRIPTION DRUGS - OVERVIEW

#### A. Medical Necessity and Value of Prescription Drugs

Prescription drug abuse cannot be addressed effectively without recognizing and accommodating the medical necessity and value of these drugs. The most commonly abused drugs fall into four categories: narcotic analgesics or pain relievers; benzodiazepines or therapeutic tranquilizers; stimulants; and barbiturates or sedatives.<sup>3</sup> All four categories benefit many Americans suffering from a wide range of often debilitating and painful mental and physical illnesses.

Millions of Americans live with chronic or recurrent pain severe enough to interfere with their daily lives. The Maryland General Assembly a few years ago cited estimates that "as many as 34 million people nationwide suffer from chronic intolerable pain," which the Legislature called "a costly epidemic facing our nation."<sup>4</sup> Other estimates are even higher.<sup>5</sup> Nineteen percent of all Americans suffer from chronic pain lasting three months or more, and 34% endure recurrent pain.<sup>6</sup> Roughly 70% of the 10 million cancer patients in the U.S. suffer from moderate to severe chronic pain. Arthritis pain affects almost 43 million people every year, and about 45 million Americans have chronic, severe headaches. Between 70% and 85% of adults suffer back pain at some point in their lives, and 60 - 100% of HIV/AIDS patients experience pain. Pain sufferers are less likely to be satisfied with their lives, with about 40% of Americans reporting that

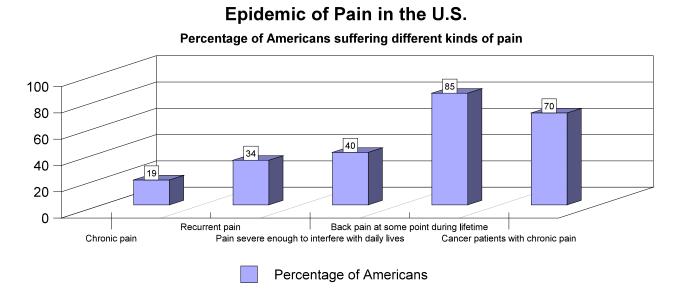
<sup>4</sup>Chapter 368 (House Bill 423) of 2002 (Preamble).

<sup>5</sup>Catherine D. DeAneglis, "Pain Management," *Journal of the American Medical Association*, 290 (2003): 2480-81.

<sup>&</sup>lt;sup>3</sup>Examples of narcotic analgesics include oxycodone and hydrocodone; common brand names are Vicodin®, Percocet®, OxyContin® and Darvon®. Some common benzodiazepine brand names include Valium®, Xanax®, Ativan®, and Klonopin®. Stimulants generally fall within three specific categories: (1) methamphetamine, (both prescription preparations, *i.e.*, Desoxyn® and Methedrine, and non-prescription or illicit methamphetamine); (2) prescription diet pills, such as amphetamines, Benzedrine®, Biphetamine®, or Fastin®; and (3) Ritalin® (or methylphenidate). Common brand names for sedatives include Nembutal®, Sopor®, Seconal®, and Restoril®. *See* Substance Abuse and Mental Health Services Administration, 2004. *Results from the 2003 National Survey on Drug Use and Health: National Findings*. (Office of Applied Studies, NSDUH Series H-25, DHHS Publication No. SMA 04-3964). Rockville, MD at Appendix C: Key Definitions, 2003, 121-147.

<sup>&</sup>lt;sup>6</sup>"Poll: Americans Searching for Pain Relief," ABC News, USA Today, and Stanford University Medical Center, April, 2005.

pain affects their mood, activities, sleep, ability to work or enjoy life.<sup>7</sup> Chronic pain may well be the nation's most costly health problem, with annual expenditures, including direct medical expenses, lost income and lost productivity, estimated to be \$100 billion annually.<sup>8</sup>



Source: ABC News Poll: Americans Searching for Pain Relief

Millions of American adults and children also suffer from serious mental illnesses which profoundly disrupt their capacity to function and are increasingly a leading cause of disability. Over 19 million Americans suffer from depression alone. The most severe conditions affect five to ten million adults, (2.6 to 5.4%) and three to five million children ages 5 to 17 (5 to 9%). In 2002, more than 10% of noninstitutionalized Americans were estimated to have had a major depressive disorder at some point in their lifetime, with 6.6% having one during the past 12 months.<sup>9</sup>

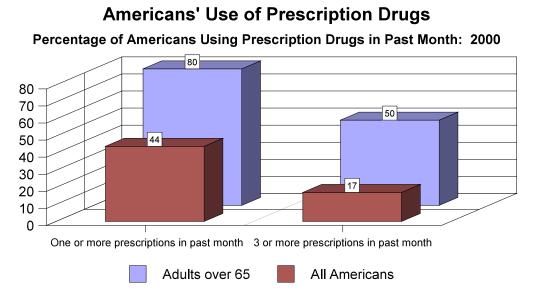
<sup>8</sup>Id.

<sup>9</sup>National Alliance for the Mentally Ill, "About Mental Illness," 2005, <u>http://www.nami.org;</u> see also, Health, United States, 2004: Chartbook on Trends in the Health of Americans, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, at 58 and Table 58.

<sup>&</sup>lt;sup>7</sup>*Id. See also*, "Pain as an Issue in Public Health Policy and Law," April 15, 2005; *see also*, University of Virginia Health System, "Chronic Pain," http://www.healthsystem.virginia.edu/uvahealth/adult\_spine/chronic.cfm.

The good news for these millions of Americans is the continuing advent of new and better drugs resulting in ever more effective treatment. Between 70% and 90% of people suffering from mental disorders can now benefit from the combination of drugs and therapy, and more effective pain relievers offer hope for the millions suffering chronic pain.<sup>10</sup>

As a result, many more people are using prescription drugs every year. Sixty percent of Americans have taken prescription drugs for pain.<sup>11</sup> Between 1988 and 2000, the percentage of Americans who reported using at least one prescription drug during the past month increased from 39% to 44%, and those using three or more drugs increased from 12% to 17%. The figures are even higher in the older age groups, with 60% of adults age 45-64 using at least one prescription drug in the past month, and more than 80% of those over 65 doing so. The number of people over 65 taking three or more drugs increased from about one-third in 1988 to almost one half in 2000. The use of antidepressants specifically almost tripled during the same time period, and prescriptions for stimulants treating Attention Deficit Hyperactivity Disorder in children increased from 2.6 million in 1994 to over 5 million in 2002.<sup>12</sup>



Source: Health, United States, 2004: Chartbook on Trends in the Health of Americans

 $^{10}$ *Id*.

<sup>11</sup>ABC News Poll, "Americans Searching for Pain Relief," *supra*, n. 6 at 2.

<sup>12</sup>*Health, United States, 2004: Chartbook on Trends in the Health of Americans, supra,* n. 9 at 50, 58, 62.

Public and private expenditures on prescription drugs have risen accordingly. The \$2.7 billion spent on prescription drugs in 1960 climbed to \$12 billion in 1980. These expenditures ballooned to \$40 billion in 1990, and then more than doubled to \$104 billion in 1999. In 2002, Americans spent \$162 billion on prescription drugs, a 56% increase in just three years. Similarly, Maryland *per capita* expenditures on prescription drugs rose between 1991 and 1998 from \$274 to \$449, a 64% increase.<sup>13</sup>

- B. Prevalence and Demographics of Prescription Drug Abuse
  - 1. Abuse of prescription drugs second only to marijuana use

Paralleling the increased therapeutic use of prescription drugs is an alarming increase in the abuse of these drugs. By 2002, according to federal data, almost *30 million people* had used prescription pain relievers non-medically at some point in their lifetime, and about 1.5 million were currently dependent on them.<sup>14</sup> In 2003, 6.3 million Americans, or 2.7% of people aged 12 or older, were current users of prescription drugs taken for non-medical purposes.<sup>15</sup> Pain relievers, used by 4.7 million people, accounted for the largest portion of the abuse; tranquilizers were second at 1.8 million; 1.2 million used stimulants; and .3 million used sedatives.<sup>16</sup> Prescription drugs are now involved in almost 30% of drug-related emergency department episodes.<sup>17</sup>

Comparing these rates to illegal substance abuse figures drives home the dimensions of the problem. Prescription drug abuse exceeds abuse of *all* other drugs combined except marijuana. Current marijuana use is 6.2%, with prescription drug abuse next in line at 2.7%. Cocaine is third at 1%, and use of hallucinogens, heroin,

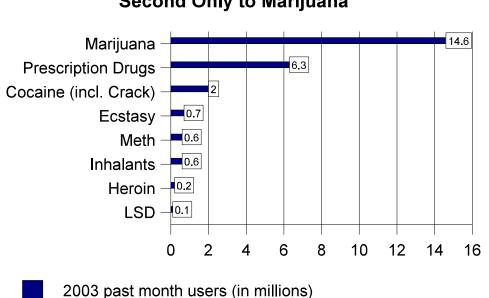
<sup>13</sup>*Id.*, Tables 119 and 146.

<sup>14</sup>National Survey on Drug Use and Health, *Nonmedical Use of Prescription Pain Relievers*. The NSDUH Report, May 21, 2004, Office of Applied Studies, Substance Abuse and Mental Health Services Administration, at 1-2.

<sup>15</sup>Results from the 2003 National Survey on Drug Use and Health: National Findings, supra, n. 3 at 1.

<sup>16</sup>*Id.* at 1. The statistics on prescription drug abuse include abuse of the non-prescription stimulant methamphetamine, and are thus necessarily included herein. This report and its recommendations, however, focus only on abuse of prescription drugs, and therefore include prescription methamphetamine but exclude illicit methamphetamine.

<sup>17</sup>Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002*, DAWN Series: D-24, DHHS Publication No. (SMA) 03-3780, Rockville, MD, 2003, at 25. and Ecstasy follow at fractions of a percent. In sum, almost twice as many people currently abuse prescription drugs than use all illegal drugs except marijuana combined.<sup>18</sup>



# Second Only to Marijuana

**Non-medical Use of Prescription Drugs** 

Source: Results from the 2003 National Survey on Drug Use and Health: National Findings

2. Prescription drug abuse on the rise

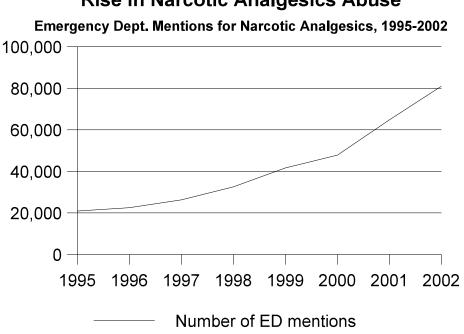
Prescription drug abuse is also increasing more consistently and dramatically than illegal substance abuse, particularly in the narcotics analgesics category. Overall illegal drug abuse did not change significantly between 2002 and 2003, and use of some specific drugs declined, e.g., Ecstasy past year use rates fell from .3% to .2%, and hallucinogen past year users fell from 4.7 million to 3.9 million.<sup>19</sup> The number of lifetime non-medical users of pain relievers rose, however, from 29.6 to 31.2 million.<sup>20</sup>

 $^{20}$ *Id.* at 2.

<sup>&</sup>lt;sup>18</sup>Results from the 2003 National Survey on Drug Use and Health: National Findings, *supra*, n. 3 at 1-2.

<sup>&</sup>lt;sup>19</sup>*Id.* at 1. "Past year users" are those reporting use of a drug at least once within the last year. "Current users" report using a drug within the past month. "Lifetime use" refers to the use of a drug at least once during the respondent's life. Id. at 132, 136.

Emergency department episodes involving narcotic pain relievers increased 45% between 2000 and 2002.<sup>21</sup>



## Rise in Narcotic Analgesics Abuse

Source: National Drug Threat Assessment 2005 Summary Report

These increases reflect the trend over the past fifteen years. Between 1990 and 2002, new abusers of pain relievers rose from 573,000 to 2.5 million.<sup>22</sup> Emergency department episodes involving narcotics pain relievers rose almost *300%* between 1995 and 2002.<sup>23</sup> The treatment admissions rate for primary abuse of pain relievers more than doubled between 1992 and 2002.<sup>24</sup>

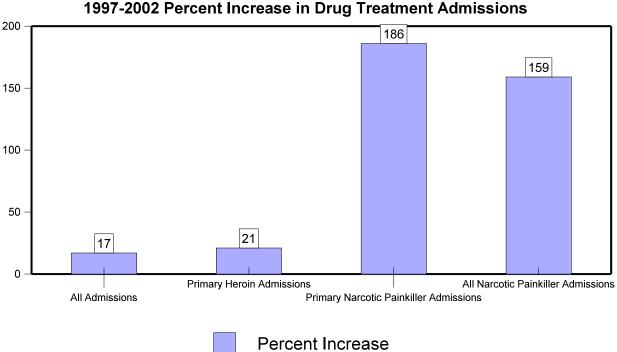
<sup>22</sup>Results from the 2003 National Survey on Drug Use and Health: National Findings, supra, n. 3 at 1-2, 14, 47.

<sup>23</sup>National Drug Intelligence Center, *National Drug Threat Assessment 2005 Summary Report,* U.S. Department of Justice, Document ID: Q0317-005, February 2005 at 29.

<sup>24</sup>Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS): 1992-2002. National Admissions to Substance Abuse Treatment Services,* DASIS Series: S-23, DHHS Publication No. (SMA) 04-3965,

<sup>&</sup>lt;sup>21</sup>Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002, supra, n. 17 at 29.

Similarly, between 1997 and 2002, the increase in treatment admissions involving narcotic painkillers was much larger than the rise in drug treatment admissions overall. All drug treatment admissions increased 17%, with admissions for primary heroin abuse rising 21%. By contrast, admissions for primary abuse of narcotic painkillers increased *186%*. Admissions for any primary, secondary or tertiary abuse of narcotic painkillers increased 159%.<sup>25</sup>



Abuse of Prescription Drugs Rising Fastest

Source: Treatment Admissions Involving Narcotic Painkillers: 2002 update

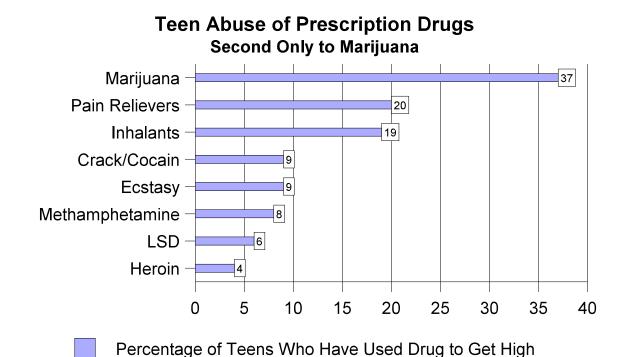
#### 3. Demographics

Abuse of prescription drugs cuts across gender, race and ethnicity, and virtually all age groups. Lifetime use is about 14% in men, 11% in woman, 13.6% in whites, 9.7% in blacks, 7% in Asians, and 11% in Hispanics. While more men abuse

Rockville, MD, 2004 at 2.

<sup>25</sup>Drug and Alcohol Services Information System, *Treatment Admissions Involving Narcotic Painkillers: 2002 Update.* The DASIS Report, Office of Applied Studies, Substance Abuse and Mental Health Services Administration, July 23, 2004 at 2. prescription drugs than women, women are more likely to abuse prescription drugs than other illegal drugs. Similarly, while whites account for more substance abuse overall, they account for a greater proportion of prescription drug abuse (*e.g.*, 88% of prescription drug treatment admissions, compared to 59% of all treatment admissions).<sup>26</sup>

Abuse of prescription drugs is highest and rising fastest among young people. The most recent study released in April, 2005 reveals an alarming one in five teens (4.3 million) has abused a pain reliever to get high. Eighteen percent report using Vicodin®, one in ten have used OxyContin®, and 10% have abused stimulants like Ritalin® or Adderall®. For the first time, "teens are more likely to have abused a prescription painkiller to get high than they are to have experimented with a variety of illicit drugs - including Ecstasy, cocaine, crack and LSD."<sup>27</sup>

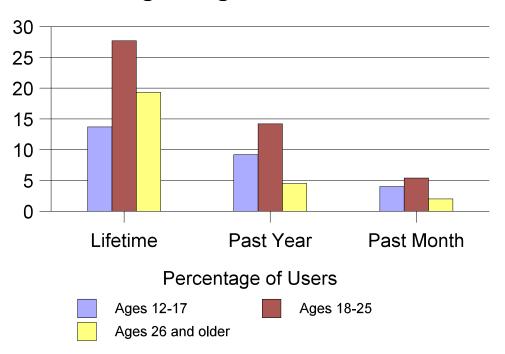


Source: Partnership Attitude Tracking Study, Teens 2004

<sup>&</sup>lt;sup>26</sup>Drug and Alcohol Services Information System, *Characteristics of Primary Prescription and OTC Treatment Admissions: 2002.* The DASIS Report, Office of Applied Studies, Substance Abuse and Mental Health Services Administration, November 19, 2004 at 2; *see also, Nonmedical Use of Prescription Pain Relievers, supra,* n. 14 at 2.

<sup>&</sup>lt;sup>27</sup>*Partnership Attitude Tracking Study: Teens 2004,* The Partnership for a Drug-Free America, (April 2005) at 6, 16.

Of the 36 million lifetime prescription drug abusers in 2001, almost 27% were aged 25 or younger. About 28% of young adults aged 18-25 were lifetime users in 2002, compared to 19% of people aged 25 and older. Similarly, 4% of 12-17 year olds and 5.4% of 18-25 year olds were current users, compared to 2% of those over 25. Among youths aged 12-17, girls were more likely to have abused prescription drugs than boys in the past year (9% compared to 7%). Among young adults between 18 and 25, men were more likely to have used than women (14% to 10%).<sup>28</sup>



# Prescription Drug Abuse Most Prevalent Among Young Adults and Teens

Source: Non-medical Use of Prescription-Type Drugs Among Youths and Young Adults

The rise in youth abuse of powerful prescription narcotics is particularly disturbing. Past year abuse rates among 12<sup>th</sup> graders almost tripled between 1992 and

<sup>&</sup>lt;sup>28</sup>National Household Survey on Drug Abuse, *Nonmedical Use of Prescription-Type Drugs Among Youths and Young Adults*. The NHSDA Report, Office of Applied Studies, Substance Abuse and Mental Health Services Administration, January 16, 2003 at 2; *see also*, Office of National Drug Control Policy, *Prescription Drug Abuse in the United States*, March 2004; <u>http://www.fed.gov/oc/initiatives/rxdrugabuse/presscharts.ppt</u>.

2004, from 3.3% to 9.5%.<sup>29</sup> Use of OxyContin® among  $12^{th}$  graders rose from 4% to 5% in just two years, from 2002 to 2004. One in 20 seniors reported abusing OxyContin® in the last year.<sup>30</sup>

#### C. Harmful Consequences of Prescription Drug Abuse and Diversion

As with abuse of illicit drugs, prescription drug abuse causes substantial harm both to abusers directly and to everyone bearing the indirect burdens on our systems of criminal justice and public health. The harm to abusers is evident in the statistics showing the almost 300% increase in emergency room visits involving prescription drugs in recent years, and the near doubling of treatment admissions for abuse of pain relievers.<sup>31</sup> The data by itself, however, sanitizes the full story. It leaves out the anguish of parents who find out too late that their teenager was abusing a fatal cocktail of narcotics obtained on the Internet. It fails to capture the lost promise of the student who drops out of college to feed his habit, or the despair of the father of three whose addiction to painkillers costs him his livelihood. As with illicit drugs, prescription drug abuse exacts a heavy price from those who become its victims.

The toll on our systems of criminal justice and public health is also profound. While law enforcement data shows that illicit drug abuse still accounts for a larger proportion of violent and property crime, the impact of prescription drug abuse on criminal activity is on the rise. One state investigator estimates that "at least 70% of the enforcement cases involve pharmaceuticals. The problem is as big or bigger than street drugs."<sup>32</sup> More than 4% of all state and local law enforcement agencies in the Northeast, in fact, reported in 2004 that pharmaceuticals were the drugs that contributed *most* to violent and property crime in their areas.<sup>33</sup>

<sup>30</sup>Johnston, L.D., O'Malley, P.M. Bachman, J.G. & Schuleberg, J.E. (2005). *Monitoring the Future: National Results on Adolescent Drug Use, Overview of Key Findings*, 2004. (NIH Publication No. 05-5726). Bethesda, MD: National Institute on Drug Abuse, at 4-5.

<sup>31</sup>National Drug Threat Assessment 2005, supra, n. 1 at 101; Treatment Episode Data Set (TEDS): 1992-2002. National Admissions to Substance Abuse Treatment Services, supra, n. 24 at 2, 10.

<sup>32</sup>Interview with Supervising Investigator Edward Howard in *A Closer Look at State Prescription Monitoring Programs,* Diversion Control Program, Drug Enforcement Administration, U.S. Department of Justice, (Feb. 2003), *available at* http://www.deadiversion.usdoj.gov/pubs/program/rx\_monitor/effect/eil.htm.

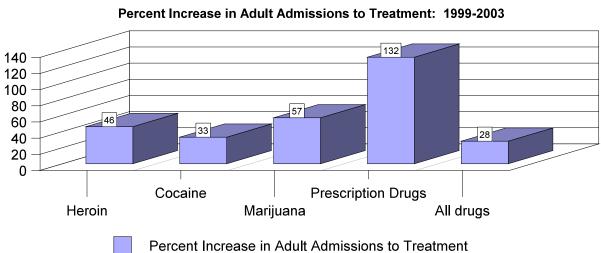
<sup>33</sup>National Drug Threat Assessment 2005, supra, n. 1 at 99.

<sup>&</sup>lt;sup>29</sup>National Drug Threat Assessment 2005, supra, n. 1 at 100.

This increased criminal activity results either in the diversion of law enforcement resources from some other need, or creates the demand for more resources. In 2003, for example, the Drug Enforcement Administration felt compelled to create a new task force solely to track the multi-million dollar Internet trade in narcotics, which it characterized as an escalating crisis. Senior DEA investigators, in discussing the enormous spike in illicit pharmaceutical websites, explained, "It's like rabbits. Every day, there are more of them. They're up, they're down, they're foreign, they're domestic . . . we're afraid it's going to overwhelm us."<sup>34</sup>

#### D. Prescription Drug Abuse in Maryland

Maryland is no exception to these national trends. The number of admissions for treatment of narcotic analgesics abuse rose 240% between 1992 and 2002. Maryland's 2002 rate of admission was sixth highest in the nation.<sup>35</sup> Adult admissions rose from 2,440 to 5,661 between 1999 and 2003, an increase of 132%, while treatment for overall drug abuse rose only 28% over the same period.<sup>36</sup>



Maryland: Prescription Drug Abuse Rising Faster Than Abuse of Illicit Drugs

Source: State of Maryland: Profile of Drug Indicators, April 2005

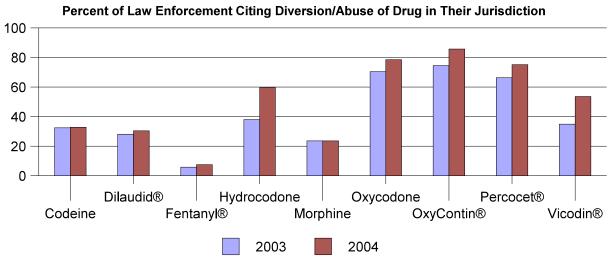
<sup>34</sup>"Internet Trafficking in Narcotics Has Surged," *Washington Post*, October 20, 2003.

<sup>35</sup>Treatment Episode Data Set (TEDS): 1992-2002. National Admissions to Substance Abuse Treatment Services, supra, n. 24 at Tables 2.5a and 2.5b, pp. 90-93.

<sup>36</sup>Office of National Drug Control Policy, Drug Policy Information Clearinghouse. *State* of Maryland: Profile of Drug Indicators, April 2005, at 11.

Central Maryland ranked first in the nation in *per capita* emergency department episodes involving narcotic analgesics in 2002. Such visits rose 47% in central Maryland from 2001 to 2002, compared with an average 20% increase nationwide. Baltimore ranked first out of 21 major metropolitan areas in *per capita* emergency department mentions of narcotic analgesics in 2002.<sup>37</sup>

A U.S. Department of Justice survey of Maryland state and local law enforcement also shows the rise in prescription drug abuse and diversion statewide. In 2003, for example, 75% of law enforcement officials said OxyContin® was being diverted and abused in their jurisdiction. Only a year later this percentage had risen to 86%. Similarly, the percentage citing hydrocodone as a problem rose from 38% to 60% between 2003 and 2004, and Percocet® went from 66% to 75%.<sup>38</sup>



**Prescription Drug Abuse and Diversion in Maryland Jurisdictions** 

Source: U.S. Department of Justice National Drug Threat Surveys 2003-2004

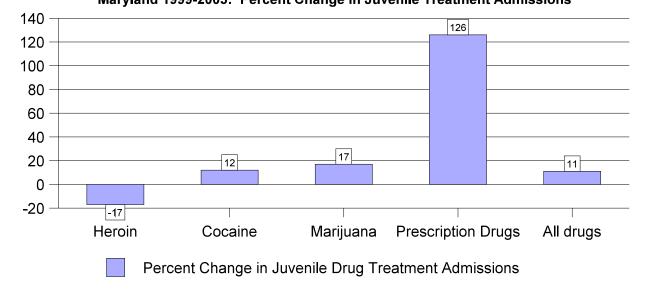
Maryland State Police and Drug Enforcement Administration ("DEA") data underscore the growing prevalence of prescription drug diversion, particularly oxycodone products. Nearly 85% of DEA arrests in 1999 for writing false prescriptions involved oxycodone products, including OxyContin®, and reports from almost all

<sup>&</sup>lt;sup>37</sup>Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002, supra, n. 17 at 84-85.

<sup>&</sup>lt;sup>38</sup>National Drug Intelligence Center, *National Drug Threat Surveys: Maryland 2003 and 2004*, U.S. Department of Justice.

counties signal its growing popularity among teens.<sup>39</sup> Maryland State Police reported a 182% increase in oxycodone cases between 1998 and 2000, and the Washington/Baltimore High-Intensity Drug Trafficking Area ("HIDTA") has recently cited concern that "Baltimore may be emerging as a source area for diverted OxyContin®".<sup>40</sup>

Abuse rates among Maryland youth also track national figures. Juvenile admissions to treatment for prescription drugs rose from 186 to 420 between 1999 and 2003. This 126% increase dwarfs the 11% increase in juvenile admissions for overall drug treatment. In 2002, 8.4% of 12<sup>th</sup> graders reported having used prescription narcotics, 11.4% had abused prescription stimulants, and 6.5% had used tranquilizers.<sup>41</sup>



Juvenile Abuse of Prescription Drugs Rising Faster Than Abuse of Other Drugs Maryland 1999-2003: Percent Change in Juvenile Treatment Admissions

Source: State of Maryland: Profile of Drug Indicators, April 2005

<sup>39</sup>*Maryland Drug Threat Assessment, supra*, n. 1 at 22.

<sup>&</sup>lt;sup>40</sup>See Maryland State Police, Criminal Intelligence Division, Maryland State Police Crime Laboratory Reports; *see also*, Office of National Drug Policy, Washington/Baltimore HIDTA, *available at*, http:// www.whitehousedrugpolicy.gov/publications/policy/hidta04.

<sup>&</sup>lt;sup>41</sup>State of Maryland: Profile of Drug Indicators, April 2005, supra, n. 36 at 6.

#### E. Methods of diversion

Legitimate commercial dispersal of pharmaceuticals has increased substantially over the last five to ten years. OxyContin® sales in particular rose 63% in just three years, from 2000 to 2003.<sup>42</sup> Thus, prescription drugs are increasingly accessible to abusers simply by virtue of their growing prevalence.

Easy access to pharmaceuticals is also enhanced by the relatively decentralized way in which drugs are acquired and used in the United States. While manufacturers, distributors, doctors and pharmacists are regulated, patients have virtually complete freedom to seek and use prescription drugs as they see fit. They may go to any doctor of their choosing for a prescription, and they may select any pharmacist they wish to fill it. They may use the same doctor and pharmacist repeatedly, or they may switch regularly. No single entity keeps any centralized records of medication acquisition and use, and physicians and pharmacists do not share information. As one researcher puts it, "it is impossible to identify what patient has acquired what medications from what pharmacy under the authority of what physician."<sup>43</sup>

Diversion of prescription drugs within this decentralized system occurs in primarily four ways: prescription fraud, "doctor shopping," theft and the Internet.

1. Prescription Fraud

Prescription fraud covers a wide range of schemes, from forging or altering prescriptions, producing counterfeit prescriptions, and impersonating physicians over the phone. In addition, while constituting only a small percentage of the medical community, some physicians and pharmacists create or dispense fraudulent prescriptions for personal use or, in exchange for a fee, for others who do not need the medication. In a recent case, a Maryland dentist pled guilty to unlawful distribution of Percocet®, and acknowledged writing prescriptions for Percocet®, OxyContin®, and other painkillers for no legitimate medical purpose, without conducting examinations or treatment, in exchange for sexual favors.<sup>44</sup> In another, a pharmacy intern wrote 100 phony prescriptions for controlled substances and stole 40,000 pills from the pharmacy in which he worked.<sup>45</sup>

<sup>42</sup>*National Drug Threat Assessment, supra*, n. 1 at 102.

<sup>43</sup>Brushwood, David B., "Maximizing the Value of Electronic Prescription Monitoring Programs," *Journal of Law, Medicine & Ethics*, 31(2003): 41-54, at 42.

<sup>44</sup>National Drug Intelligence Center, *Pharmaceuticals Drug Threat Assessment*, U.S. Department of Justice, Document ID: 2004-L0487-001, November 2004, at 6.

<sup>45</sup><u>http://ago.state.ma.us/txt/foresent.htm</u>

Often doctors caught up in these schemes will have serious addiction or financial problems themselves. In one case a Texas physician wrote himself repeated prescriptions for hydrocodone, Ambien® and Valium®, while writing thousands more for customers of an online pharmacy he had never examined or even met. One such customer was a mother in New Jersey who had prior problems with substance abuse and received over 800 doses of hydrocodone.<sup>46</sup> In another case a doctor lost his legitimate job as a staff physician and began working for an online pharmacy, writing 20,000 prescriptions for more than 4.7 million doses of mostly hydrocodone and Xanax®, earning almost \$1 million in fees.<sup>47</sup>

#### 2. "Doctor Shopping"

Drug diversion occurs through "doctor shopping" when individuals visit a variety of different doctors to obtain multiple prescriptions for a drug, and then have the prescriptions filled at different pharmacies. While the phenomenon was made famous by the revelation of Rush Limbaugh's addiction to painkillers, many people engage in this practice, either to feed an addiction which developed in the wake of legitimate use of a drug, or to procure drugs illegally for resale. One Maryland woman was prescribed the anti-anxiety drug Xanax® to cope with a tragedy in her life, but when her doctor stopped writing the prescription, she began going from doctor to doctor, fabricating panic attacks, backaches, migraines and other problems to get multiple prescriptions for tranquilizers and painkillers.<sup>48</sup> In a recent Florida case, a man made 34 visits in one year to 14 different doctors to obtain prescriptions for OxyContin and hydrocodone.<sup>49</sup>

"Doctor shopping" highlights one particularly troubling aspect of prescription drug abuse. In contrast to illicit drug abuse, people are more susceptible to fooling themselves into believing that abuse of prescription drugs is not as harmful as other substance abuse because they are using pharmaceuticals manufactured by reputable drug companies, and their abuse begins with bona fide prescriptions for legitimate medical purposes. As one woman who became addicted to drugs she took initially for legitimate reasons explained, "I would never do [street drugs.] I figured I had a prescription for what I was doing, which made it O.K."<sup>50</sup> A director of a substance

<sup>47</sup>*Id*.

<sup>49</sup>*Id.*, at 7-8.

<sup>50</sup>*Id.*, at 1-2.

<sup>&</sup>lt;sup>46</sup>"Doctors Medicate Strangers on Web," *Washington Post*, (October 21, 2003).

<sup>&</sup>lt;sup>48</sup>Meadows, Michelle. "Prescription Drug Use and Abuse," *FDA Consumer Magazine*, U. S. Food and Drug Administration, September-October 2001 at 1; *available at* <u>http://ww.fda.gov/fdac/features/2001/501\_drug.html.</u>

abuse treatment program who sees this phenomenon over and over agrees, explaining that "people tell themselves they aren't using something old Joe cooked up in a garage somewhere. They may figure a legitimate manufacturer made this, so what could be the harm?"<sup>51</sup>

#### 3. Theft

Millions of pharmaceuticals are also diverted every year through theft from pharmacies, manufacturers, distributors, importers/exporters, and people with legitimate prescriptions. The size and method of thefts vary widely, from a 2004 Boston case involving 11 defendants and millions of dollars worth of pharmaceuticals stolen from large U.S. drug manufacturers, to a series of pharmacy hold-ups in downtown Detroit by a lone addict feeding his Vicodin® habit.<sup>52</sup> Diversion through all kinds of theft is increasing, however; the number of dosage units stolen nationwide increased 16% between 2000 and 2003, reaching almost 3 million.<sup>53</sup> Between 2000 and 2003, the DEA reported 2,494 thefts of OxyContin®, with over 1.3 million dosage units stolen.<sup>54</sup>

In Maryland, there were 83 reports from pharmacies, distributors, hospitals, clinics and other businesses of drugs lost or stolen in 2001 and 2002. Almost half involved OxyContin® or another oxycodone derivative, and more than half involved thefts of pharmacies, including armed robberies, break-ins, and employee theft.<sup>55</sup>

4. The Internet

Finally, the Internet is fast evolving into a significant means of drug diversion. As described in an investigatory piece in the *Washington Post*, "[w]ith little notice or meaningful oversight, the Internet has become a pipeline for narcotics and other deadly drugs. Customers can pick from a vast array of painkillers, antidepressants, stimulants and steroids with few controls and virtually no medical monitoring."<sup>56</sup> The resulting abuse has been ravaging; "[s]tretching from Florida to California, the Internet pipeline

 $^{51}$ *Id*.

<sup>52</sup>"Trafficking on the Rise in Prescription Drugs," *The Boston Globe*, April 2, 2004; "Pills Behind More Holdups," *The Detroit News*, September 8, 2002.

<sup>53</sup>*Pharmaceuticals Drug Threat Assessment, supra,* n. 44 at 7.

<sup>54</sup>Joranson, David E. "Pain Policy in the U.S.: Are We Moving Forward?" American Pain Society, Boston 2005, *available at* <u>http://www.medsch.wisc.edu/painpolicy.htm.</u>

<sup>55</sup>"A New Form of Drug Abuse," Carroll County Times, (July 13, 2003).

<sup>56</sup>"Internet Trafficking in Narcotics Has Surged," *Washington Post, supra,* n. 34.

has left a trail of deaths, overdoses, addictions and emotionally devastated families."57

Many Internet pharmaceutical distributors, or "Internet pharmacies," offer prescription drugs to customers without requiring prescriptions or physician consultation and verification. One rogue Internet pharmacy operating out of Las Vegas shipped nearly 5 million doses of controlled substances to customers around the country in one year, increasing its sales from the previous year 100-fold. Shipments were based only on prescriptions written by a handful of doctors who, through middlemen, conducted brief telephone conversations with would-be patients. There were no face-to-face meetings, examinations, lab tests, or follow-up care.<sup>58</sup> In another case, an online pharmacy sold pharmaceuticals imported from Mexico without ever requiring a single prescription, reaping \$1.5 million in profits before being shut down.<sup>59</sup>

While estimates vary, the number of Internet pharmacies has risen from zero in the mid-1990s to as many as one thousand in 2003. Of 157 Internet websites identified by the Center on Addiction and Substance Abuse ("CASA"), 90% did not require any prescription or doctor consultation to purchase prescription drugs. Forty percent requested nothing, while 49% only required customers to describe symptoms in an online questionnaire before receiving drugs, with no physician verification of their symptoms. Only 1.9% required mail prescriptions, and 4.4% required faxed prescriptions.<sup>60</sup>

CASA's report is an interim release of the findings of a larger, ongoing study of prescription drug abuse and diversion. The researchers found the "astonishing availability of controlled, dangerous, addictive prescription drugs through the Internet" so "alarming that [they] considered it their obligation to release [the] information prior to completion of CASA's comprehensive study."<sup>61</sup> Of particular concern is that not a single website identified in the study had any security procedures to restrict children and adolescents from buying prescription drugs. As Joseph Califano characterized the study's findings:

"these drugs are as easy for children to buy over the Internet as candy. Anyone - including children - can easily obtain highly addictive controlled substances

<sup>57</sup>*Id*.

<sup>58</sup>*Id*.

<sup>59</sup>Id.

<sup>60</sup>National Center on Addiction and Substance Abuse, "You've Got Drugs!" Prescription Drug Pushers on the Internet," Columbia University, (February 2004) at *i*.

<sup>61</sup>*Id.*, at 1.

online without a prescription from Internet drug pushers. All they need is a credit card."<sup>62</sup>

In addition, some Internet pharmacies recruit physicians to write fraudulent prescriptions for customers. In a recent case, the FBI charged three companies and ten individuals in a massive Internet pharmacy ring that fraudulently distributed millions of drug dosage units and made over \$150 million. One Texas doctor had his license revoked and pled guilty to authorizing more than 20,000 prescriptions without ever meeting a single patient, performing an exam, taking a patient history, or verifying any medical information.<sup>63</sup>

The latest study signaling the recent spike in teen abuse of prescription drugs underscores the effectiveness of these various modes of drug diversion. Teens cited "ease of access" to prescription drugs as a "major" reason for the increase. In addition to other methods, teens described the ease with which they could obtain drugs from their parents' medicine cabinets or those of their friends.<sup>64</sup>

### II. AVOIDING UNINTENDED "CHILLING EFFECTS"

With prescription drug abuse becoming a bigger problem, and law enforcement recognizing the need to step up its efforts to crack down on it, there exists a collateral category of victims, *i.e.* the patients who need drugs for pain management or other legitimate medical purposes and the health care professionals who decide whether to prescribe them. Experts agree that many barriers exist to patients' access to effective pain management. Yet two of these obstacles, the fear of addiction and the fear of prosecution, are related directly to prescription drug abuse.

Patients in severe pain often do not receive the drugs they need. As the Federation of State Medical Boards ("FSMB") states, "there is a significant body of evidence that suggests widespread acute and chronic pain continue to persist in the United States."<sup>65</sup> In a nationwide study of pain among elderly nursing home residents, for example, researchers from Brown University found that severe pain was prevalent,

 $^{62}$ *Id*.

<sup>64</sup>*Partnership Attitude Tracking Study: Teens 2004, supra,* n. 27.

<sup>65</sup>"Development of the Model Policy for the Use of Controlled Substances for the Treatment of Pain," Federation of State Medical Boards, *available at* <u>http://fsmb.org/pain\_resources/main\_page.htm.</u>

<sup>&</sup>lt;sup>63</sup>"Doctors Medicate Strangers on the Web," *Washington Post, supra,* n. 46.

persistent and poorly treated.<sup>66</sup> The American Cancer Society estimates that up to 50% of seriously ill and dying cancer patients suffer from pain that could be treated adequately with available drugs.<sup>67</sup>

While many factors fuel this problem of access, the chilling effect born of prescription drug abuse is one of the most daunting. The effect is two-fold; it occurs both because reports about prescription drug abuse contribute to misconceptions among patients and health care professionals about the dangers of addiction, and because doctors might resist prescribing painkillers for fear of legal ramifications if they make a mistake, or even if they do not. Again, as the FSMB warns, "the most common barriers [to effective pain management] are lack of understanding in the medical community about the treatment of pain and fear among physicians that they will be investigated, or even arrested, for prescribing controlled substances for pain."<sup>68</sup>

First, misconceptions about pain management have a negative impact on patients' access to opioid treatment. Ironically, misunderstanding fed by stories of abuse are proliferating at a time when medical advances in palliative care have made that treatment ever more efficacious. Patients need to receive the opposite message. With over 50 million Americans suffering from chronic pain, and many millions more with recurrent pain interfering with their daily lives, patients need a better understanding that the likelihood of addiction as a result of medically prescribed pain medication is extremely low, "ranging from roughly 1 in 1,000 to less than 1 in 10,000."<sup>69</sup> With the impact of untreated pain estimated in the tens of billions of dollars, and the psychological effects of anxiety, hopelessness, depression and even thoughts of suicide often devastating, the stakes are high for patients who resist effective treatment out of misconceived fears of addiction.<sup>70</sup>

<sup>67</sup>Schmidt, Charles. "Experts Worry About Chilling Effect of Federal Regulations on Treating Pain," *Journal of the National Cancer Institute*, Vol. 97, No. 8, April 20, 2005 at 554.

<sup>68</sup>"Development of the Model Policy for the Use of Controlled Substances for the Treatment of Pain," *supra*, n. 65.

<sup>69</sup>Institute of Medicine, *Approaching Death: Improving Care at the End of Life* 193 (1997).

<sup>70</sup>Drug tolerance, when a higher dose of a drug is needed to achieve the intended therapeutic effect, and physical dependence, when withdrawal symptoms follow discontinuation of a drug, are quite different from addiction, which is a psychological and behavioral syndrome characterized by compulsive drug use despite harm. *Id*.

<sup>&</sup>lt;sup>66</sup>Joan Teno *et al.*, "Persistent Pain in Nursing Home Residents," *Journal of the American Medical Association* 285 (2001): 2081.

Second, physicians may resist prescribing painkillers, may under prescribe them, or may avoid taking patients who require pain management altogether for fear that writing these prescriptions will invite investigation, regulatory scrutiny, or even criminal prosecution. In the last six years, more than 5,600 physicians have been investigated and 450 have been prosecuted for illegal prescribing and drug diversion.<sup>71</sup> We do not doubt the good-faith law enforcement objectives involved, but this activity contributes to doctors' fears of unwarranted scrutiny. A 2001 Wisconsin survey of doctors found that over half knowingly undertreated pain out of fear of government investigation.<sup>72</sup>

Uncertainty and a lack of clear guidelines about what can trigger suspicion on the part of law enforcement exacerbates the chilling effect on treatment. Doctors worry that factors such as the number of patients receiving opioids, or the duration of therapy, dosages and number of tablets patients receive could all be considered potential indicators of diversion triggering an investigation.<sup>73</sup> In a California study, 40% of doctors admitted that fear of investigation affected how they treat chronic pain.<sup>74</sup> Similarly, the National Association of Attorneys General reported a recent survey of 1,400 New York physicians, in which 30 to 40 percent said that fear of regulators has influenced their prescribing practices.<sup>75</sup>

Experts express concern that, as a result, fewer and fewer pain specialists and other doctors will be willing to run the risk of investigation, and patients will face increasing difficulties finding doctors who will treat their pain. As the Executive Director of the American Pain Foundation describes it, "[Pain patients] have gone to every physician within hundreds of miles and can't get someone to prescribe to them.<sup>76</sup>

Consequently, any regulatory, law enforcement, or public education efforts to reduce prescription drug abuse must be assessed for their potential impact on patient misconceptions and the apprehension of medical professionals. An important public

<sup>71</sup>"Why Is the DEA Hounding This Doctor?" *Time Magazine* (July 18, 2005).

<sup>72</sup>David E. Weissman et al., "Wisconsin Physicians' Knowledge and Attitudes about Opioid Analgesic Regulations," *Wisconsin Medical Journal* 90 (1991): 671.

<sup>73</sup>Schmidt, *supra*, n. 67 at 554.

<sup>74</sup>Michael Potter *et al.*, "Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians n the UCSF/Stanford Collaborative Research Network," *Journal of Family Practice* (2001): 148.

<sup>75</sup>National Association of Attorneys General, *Improving End-of-Life Care: The Role of Attorneys General* 28 (2003).

<sup>76</sup>"Why Is the DEA Hounding This Doctor?" *Time Magazine*, *supra*, n. 71.

policy goal is to reduce, not contribute to, these problems.

#### III. RECOMMENDATIONS FOR COMBATING AND PREVENTING PRESCRIPTION DRUG ABUSE AND DIVERSION

The growing prevalence and impact of prescription drug abuse call for increased efforts to combat and prevent it. Yet this campaign must be waged without deterring or compromising effective pain management and quality health care. We must take a carefully balanced approach to protect ourselves against the dangers of abuse while ensuring that patients have access to the benefits of pharmaceutical therapy. An intervention should be designed so that it is "most supportive of, and least disruptive to, [legitimate] medical and pharmacy practice."<sup>77</sup>

These two goals need not be mutually exclusive. If we can work together to create a collaborative environment among law enforcement and regulatory authorities and medical and pharmaceutical professionals, we can pursue both goals synergistically. As recognized in a joint statement of the DEA and scores of health organizations, "both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse . . . the roles of both . . . in maintaining this essential balance between patient care and diversion prevention are critical."<sup>78</sup>

Our approach to combating prescription drug abuse should focus on two fronts. First, we should enhance the tools available for both law enforcement and health care professionals to identify and prevent pharmaceutical abuse and diversion without compromising access to optimal drug therapy and health care. Second, we should increase public outreach and education efforts to make everyone more aware of the growing prevalence and dangers of prescription drug abuse. Specifically, we should pursue the following steps:

#### MARYLAND SHOULD DESIGN AND IMPLEMENT AN ELECTRONIC PRESCRIPTION MONITORING PROGRAM.

We need a better means of deterring drug abusers and diverters from exploiting

<sup>&</sup>lt;sup>77</sup>David E. Joranson, Grant M. Carrow, Karen M. Ryan, et al., "Pain Management and Prescription Monitoring," *Journal of Pain and Symptom Management* 23 (2002): 231, 237.

<sup>&</sup>lt;sup>78</sup>"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," a Joint Statement from 21 Health Organizations and the Drug Enforcement Administration (October 21, 2001), *available at* <u>http://www.medsch.wisc.edu/painpolicy/dea01.htm.</u>

the system. We have already described an environment in which those seeking drugs for nonmedical purposes can take advantage of the lack of integration to acquire from different physicians and pharmacies quantities of drugs that no responsible single doctor or pharmacist would knowingly allow.<sup>79</sup> Likewise, a small minority of health and pharmaceutical professionals also misuse the system. While a mechanism for tracking and identifying these fraudulent activities would not address all prescription drug abuse and diversion, of course, it could be of substantial benefit to both health care professionals and law enforcement in their efforts to combat the problem.

The Maryland State Advisory Council on Pain Management, in its *Final Report to the General Assembly September 2004,* recognized that "[m]onitoring of prescription practices can be a valuable tool in detecting fraud and other criminal conduct."<sup>80</sup> It observed that while "the great majority of health care professionals comply with the laws on controlled substances, law enforcement cannot ignore the minority who do not."<sup>81</sup> At the same time, the Advisory Council cited substantial concern about "the potential burdens and chilling effect of ill-designed prescription monitoring programs," and recommended that any program Maryland adopted "should be designed to protect legitimate prescribing and dispensing while assuring patient privacy."<sup>82</sup>

The National Association of Attorneys General has also called for states to develop prescription monitoring programs and other strategies to combat the "tragic and vexing problem" of prescription drug abuse. Like the Maryland State Advisory Council, it has underscored the importance of doing so in a "balanced" manner, with attention to the "potential impact on the legitimate use of prescription drugs," and the need to ensure "appropriate confidentiality and access controls."<sup>83</sup>

Adhering to the guidelines set forth by the Advisory Council and the National Association of Attorneys General, Maryland should establish a carefully designed prescription monitoring program ("PMP") which is both safe and effective. To achieve this balance, we must tread carefully, making sure that all relevant expertise be

<sup>79</sup>Brushwood, *supra*, n. 43 at 42.

<sup>80</sup>*Final Report to the General Assembly, September 2004*, Maryland State Advisory Council on Pain Management, at 23.

 $^{81}$ *Id*.

<sup>82</sup>*Id.*, Recommendation 30, at 24.

<sup>83</sup>National Association of Attorneys General, 2002 Resolution: "Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications;" and 2003 Resolution: "Encouraging States to Continue To Develop Balanced Strategies to Combat the Problem of Prescription Drug Abuse and Diversion." included in the design process. Maryland's PMP must avoid unintended consequences like invasion of patient privacy or interference with the medically appropriate use of pharmaceuticals for effective pain management and quality health care. To be effective, it must actually reduce the abuse and diversion of prescription drugs and improve legitimate drug therapy for patients. As recognized by the FSMB, the PMP must further "the dual obligation of government to develop a system that prevents abuse, trafficking and diversion of controlled substances while ensuring their availability for legitimate medical purposes."<sup>84</sup>

#### 1. Description of Other States' Prescription Monitoring Programs

Twenty-one states have some version of a prescription monitoring program, and several others have programs in the pipeline. Although most now operate with an electronic transfer of data to a centralized source and share some other core elements, the overall approach and specifics of the programs vary. For example, some are administered by the state health department, while others are run by a law enforcement entity. Some cover all controlled substances, while others are limited to Schedule II or III drugs. The kind of information and timing of reporting also differ.

Variations in the design and implementation of PMPs reflect the states' differing views of what they are attempting to accomplish. Some programs are developed primarily as an intervention and treatment tool for medical professionals. The primary goal of others is to assist law enforcement in combating diversion. Ideally a program can accomplish both purposes, depending upon the details of how the program is designed. For example, what categories of professionals should have access to the data, in what form and under what circumstances? Does the state want the program's function to be limited to helping law enforcement advance investigations which are based initially on information obtained from sources other than PMP data? Does the state want the program data used to help identify potential diversion in the first instance? Should physicians also have access to PMP data to assist them in making decisions about optimal pharmaceutical care and in identifying patients who may need addiction treatment? How can these goals be reconciled with patients' interests in privacy and confidentiality, and what kinds of protections must be put in place to ensure privacy to the greatest extent possible? Different states have answered these questions in different ways, reflecting the particular goals of their respective programs.

#### 2. Essential Elements of a PMP in Maryland

Maryland should consider the experience of other states in fashioning a PMP which balances carefully the multiple goals and interests at issue here. The program should support the legitimate medical use of controlled substances and should facilitate

<sup>&</sup>lt;sup>84</sup>"Development of the Model Policy for the Use of Controlled Substances for the Treatment of Pain," *supra*, n. 65; *see also*, Brushwood, *supra*, n. 43 at 41.

the identification and treatment of individuals addicted to prescription drugs. It should also help identify and prevent drug diversion and assist law enforcement's efforts to combat it. It can also help inform health care professionals and the public of trends in the use and abuse of prescription drugs. At the same time, it must protect patient privacy and confidentiality.

To these ends, the following issues must be weighed carefully in designing Maryland's program, and the enabling legislation should establish a multi-disciplinary board of pain management and other health care professionals, regulatory and law enforcement authorities, and patients' rights advocates to advise in the development and operation of the program:

- a. Which agency should administer the program, and what kind of review board should analyze the data?
- b. Which substances should be included in the program?
- c. What information should be reported? What codes and other patient confidentiality safeguards should be put in place?
- d. Who should be authorized to obtain access to the data, for what purposes, and what protections from liability should attach to those with access to the data?
- e. Under what circumstances should the administering agency notify law enforcement of suspicious activity?
- f. What penalties should be imposed for violations in the reporting, disclosure, and use of the data?
- 3. Evaluation of the PMP

Finally, Maryland's PMP should contain a strong and effective evaluation component. Evidence suggests that PMPs are extremely helpful both to law enforcement in identifying potential diversion and shortening the duration of complex investigations, and to practitioners in making difficult decisions about whether patients have legitimate need for controlled substances or instead need treatment for addiction. For example, Kentucky's PMP has reduced the average time to complete pharmaceutical drug investigations from 156 to 16 days. Nevada's PMP has resulted in a 46% reduction in the estimated number of pharmaceutical dosage units distributed to suspected abusers.<sup>85</sup> One physician in Utah wrote that "this service has been the single best tool that physicians and nurses in emergency departments and doctors'

<sup>&</sup>lt;sup>85</sup>*Pharmaceuticals Drug Threat Assessment, supra,* n. 44 at 4.

offices have ever had to help us determine which patients have legitimate medical needs for these medications, and which ones are in fact substance abusers needing referral to treatment programs.<sup>86</sup> Law enforcement agencies around the country credit PMPs for increasing their success and saving substantial resources in breaking up major pharmaceutical diversion rings.<sup>87</sup> Yet we do not yet have the benefit of rigorous, controlled studies of electronic PMPs' efficacy and safety. Thus, Maryland should conduct its own assessment of how effectively its PMP achieves its goals.

#### MARYLAND SHOULD STRENGTHEN ITS LAWS WHICH PROHIBIT OBTAINING PRESCRIPTION DRUGS WITH INTENT TO DISTRIBUTE THEM FOR NON-MEDICAL PURPOSES.

Maryland's laws addressing the possession of prescription drugs for non-medical purposes through prescription fraud, theft and doctor-shopping are generally adequate, although some consolidation, clarification, and filling in gaps may be in order. The laws which address fraudulently obtaining controlled dangerous substances and other prescription medications *with intent to distribute them,* however, need to be strengthened. Most are currently a misdemeanor only. Both state and federal law enforcement officials, as well as health care professionals, cite this as a major problem. These criminal activities should be felonies, with up to five years imprisonment and appropriate fines. Mandatory minimum sentences for repeat offenders with escalating fines should also be considered.

#### MARYLAND SHOULD REDUCE THE DIVERSION OF PRESCRIPTION DRUG RETAIL INVENTORY BY ENACTING LEGISLATION TO REGULATE UNLICENSED PHARMACY TECHNICIANS.

Unlicensed pharmacy personnel, commonly known as pharmacy technicians, perform integral parts of the process of dispensing medications. In some cases they may carry out the entire dispensing process (*e.g.*, prescription data input, drug selection, drug count or measurement, and labeling) before a pharmacist performs the final check. Currently, there are no prerequisites to becoming a pharmacist technician other than those instituted by a particular employer.

Other states have enacted licensing laws to enhance oversight of pharmacy technicians. Because there are virtually no educational or training requirements for these technicians and yet they have easy access to controlled dangerous substances, the positions can be enticing to those who wish to divert drugs for illicit purposes.

<sup>&</sup>lt;sup>86</sup>A Closer Look at State Prescription Monitoring Programs, supra, n. 32 at 1.

<sup>&</sup>lt;sup>87</sup>*Id*.

Pharmacy technicians may also increase their capacity for such diversion by "job hopping." Since Maryland does not have a mechanism for tracking pharmacy technicians, this avenue of drug diversion generally goes undetected.

Maryland should, therefore, close this gap in the State's oversight of pharmaceutical distribution by passing a law authorizing the Maryland Board of Pharmacy to regulate unlicensed pharmacy personnel.

#### MARYLAND SHOULD WORK CLOSELY WITH THE DRUG ENFORCEMENT ADMINISTRATION TO INCREASE COORDINATION AMONG FEDERAL, STATE, AND LOCAL LAW ENFORCEMENT AGENCIES TO COMBAT DRUG DIVERSION, AND TO DEVELOP AND PROVIDE TRAINING PROTOCOLS FOR INVESTIGATING AND PREVENTING PRESCRIPTION DRUG ABUSE AND DIVERSION.

As with virtually all law enforcement efforts, better coordination and communication among different agencies enhance effectiveness. Such efforts have already begun; the Washington/Baltimore High-Intensity Drug Trafficking Area has created a diversion task force, and HIDTA has already assisted local law enforcement with major prescription drug diversion cases.<sup>88</sup> We should continue and build upon this kind of coordination and cooperation.

In addition, we must ensure that law enforcement officials are properly trained for this highly sensitive, specialized kind of investigation and prevention effort. Training must emphasize the need for law enforcement to understand not only prescription drug abuse and diversion patterns, but also the complexities of effective pain management. As the Director of the Pain & Policy Studies Group expressed it in a letter to the DEA, the appropriate balance between effective pain management and preventing drug diversion "can be accomplished only when health professionals who treat pain also understand and avoid knowingly contributing to diversion, and when law enforcement and regulators who deal with diversion also understand and do not interfere in pain management."<sup>89</sup> Thus, law enforcement training in combating prescription drug abuse and diversion must reflect these dual goals.

<sup>&</sup>lt;sup>88</sup>See, Office of National Drug Policy, Washington/Baltimore HIDTA, supra, n. 40.

<sup>&</sup>lt;sup>89</sup>Letter to DEA Deputy Administrator Leonhart from David Joranson, Director of the Pain & Policy Studies Group, WHO Collaborating Center for Policy and Communications in Cancer Care, March 11, 2005, commenting on Docket No. DEA-261, *Dispensing of Controlled Substances for the Treatment of Pain*.

#### MARYLAND SHOULD LAUNCH A PUBLIC OUTREACH AND EDUCATION CAMPAIGN TO MAKE PEOPLE MORE AWARE OF THE DANGERS AND SIGNS OF PRESCRIPTION DRUG ABUSE, THE GROWING RISK OF THE INTERNET AS A PIPELINE FOR PHARMACEUTICALS, AND THE STEPS THEY SHOULD TAKE TO PROTECT THEMSELVES AND THEIR CHILDREN.

Public education campaigns can take many forms, depending upon resources and other factors. Some suggestions to consider:

- 1. **Children and teens:** We could communicate the dangers and signs of prescription drug abuse to children and teens by: 1) including it in school substance abuse prevention programs, *e.g.*, the D.A.R.E. program, health classes with drug education components; 2) enlisting MedChi, The Maryland State Medical Society; the state chapter of the American Academy of Pediatricians; and other organizations to encourage pediatricians to talk to parents and teens about it; and 3) promoting greater awareness among parents about the problem and the need to talk to their children through organizations such as the PTA and community associations.
- 2. **Parents and other adults:** We should educate parents and adults who may be vulnerable themselves about the growing prevalence, the dangers, the warning signs, and the need to take steps to protect themselves and their children from abuse. Educations efforts could include, *e.g.*, articles in PTA and other school newsletters, public service announcements, warnings in materials given out with prescriptions, *etc.*

#### MARYLAND SHOULD DEVELOP INFORMATION AND TRAINING FOR PHARMACISTS AND PHYSICIANS REGARDING HOW TO DETECT AND PREVENT DOCTOR SHOPPING AND THE USE OF FRAUDULENT PRESCRIPTIONS.

Healthcare professionals have recognized their critical role in identifying and preventing prescription drug abuse. In their statement issued jointly with the DEA, over 40 of the nation's healthcare organizations underscored the importance of both healthcare and law enforcement professionals becoming "more aware of both the use and abuse of pain medications."<sup>90</sup> Thus, we should develop information and training for both physicians and pharmacists about how to detect and prevent prescription drug abuse and diversion without compromising effective pain management.

<sup>&</sup>lt;sup>90</sup>"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," *supra*, n. 78.

#### MARYLAND SHOULD ENCOURAGE FEDERAL EFFORTS TO REGULATE THE ONLINE PHARMACEUTICAL INDUSTRY, AND SHOULD TAKE ALL MEASURES POSSIBLE TO EDUCATE PEOPLE ABOUT THE DANGERS OF THE CURRENT, ALMOST COMPLETELY UNFETTERED ACCESS TO CONTROLLED DANGEROUS SUBSTANCES AND OTHER PRESCRIPTION DRUGS OVER THE INTERNET.

Because the Internet is fast becoming a major source of pharmaceutical diversion, any effort to combat prescription drug abuse must address this significant means of access. The federal government imposes virtually no regulation on Internet pharmacies, not even a requirement to disclose their owners, locations, doctors, affiliated pharmacies or telephone numbers. States' regulations vary, but obtaining a license to do business as an online pharmacy is relatively easy. In Maryland, anyone shipping drugs into Maryland must obtain a non-resident pharmacy permit. The only requirements for obtaining such a permit, however, are that the pharmacy must comply with Maryland's patient confidentiality laws, must have a toll-free number, and must be open for business a minimum of 40 hours and 6 days a week. Otherwise, it need simply assert its compliance with the laws and regulations of its home state.<sup>91</sup>

This lack of meaningful state and federal regulation has created the freewheeling environment which makes possible the current, almost completely unfettered online access to controlled dangerous substances and other prescription drugs. This dangerous phenomenon must be reined in.

First, we must encourage the federal government to begin regulating the online distribution of prescription drugs. Because the technology of the Internet renders it possible for pharmacies located anywhere, including overseas, to do business in any and every state, only the federal government can impose meaningful regulation on this burgeoning industry.

Second, we should encourage the medical community to do what it can to stop the dispensing of powerful drugs without meaningful medical oversight. An option to consider would be establishing a standard of care regarding the type of consultation necessary for prescribing certain drugs. For example, the standard of care could require that prescriptions for controlled dangerous substances contain a physician's certification that he has conducted, at some point, a face-to-face consultation with the patient. This would curtail the ability of "one-stop shopping" online pharmacies to dispense drugs without requiring bonafide prescriptions by hiring doctors to write the prescriptions based only on "online consultations." Currently, many sell drugs to anyone who can answer on online questionnaire, such as children posing as adults, people who are diverting narcotics onto the black market, or people suffering from addictions. Such a standard of care would, at least, limit these pharmacies' ability to

<sup>&</sup>lt;sup>91</sup>Health Occupations Article, Annotated Code of Maryland §12-403(f).

hire doctors to write such bogus prescriptions.

Finally, because meaningful regulation will not happen overnight and will never prevent these abuses completely, we must educate people more effectively about the risks associated with the growing Internet trade in pharmaceuticals. People must understand the grave danger of obtaining powerful medicines without the meaningful oversight of a doctor who is actually treating them. They must also take steps to protect their children and adolescents. That children have such unregulated access to dangerous narcotics and other drugs is unacceptable. Its potential for tragic outcomes is simply too great.