



MICHAEL CUSICK
Assemblyman 63RD District

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February 16, 2012

Statement of New York State Assemblyman Michael J. Cusick (D-Staten Island) to the New York City Council Subcommittee on Drug Abuse

Ladies and Gentlemen,

Thank you for having me here today to speak on such an important topic for our state. As you are well aware, New York is experiencing an alarming increase in the abuse of prescription drugs. The abuse statistics are staggering, particularly in my hometown of Staten Island, which, sadly, may well be considered "ground zero" for controlled substance abuse in the State. In New York City, oxycodone prescriptions rose 66 percent from 2007 to 2009, with a great number of those prescriptions filled in Staten Island.

Currently, New York State operates a limited prescription monitoring program that does not utilize real time technology. "I-STOP" will allow physicians and pharmacists to track potential abuses, treat addiction, and stop those who enable and profit off of the illegitimate use of prescribed drugs. This will virtually eliminate Doctor shopping, slash Medicaid prescription fraud, and curb abuse.

The information gap between doctors and pharmacists allows addicts and abusers to slip through our regulatory cracks. I am the sponsor of a number of pieces of legislation that would aim at preventing this problem including A3806 which gives pharmacists access to the current program and A3807 which would establish a new prescriptions drug monitoring program requiring medical professionals and pharmacists to track controlled substances.

I am also the sponsor of the I-STOP legislation in the Assembly, which establishes a real time controlled substance reporting system. This system will better coordinate health care services so that patients receive the medication they need, while addicts and those who profit off of abuse receive the treatment they deserve.

The Drug Enforcement Administration has found that more than 7 million Americans admit to abusing prescription drugs. Further, the DEA has concluded that prescription drugs have surpassed marijuana as the number one gateway drug for first-time drug abusers in the United States. And, emergency room visits for reactions to opioid painkillers, like oxycodone, have more than doubled from 2004 (144,600) to 2008 (305,900).

I commend the New York City Council for introducing resolution T2012-4291 and look forward to the passage of the "I-STOP" legislation in Albany.



The New York Academy of Medicine

At the heart of urban health since 1847

**Testimony of Dr. Ruth Finkelstein, ScD
Senior Vice President for Policy & Planning
The New York Academy of Medicine**

***New York City Council Hearing on Internet System for Tracking Over-Prescribing Act
(A.8320/S.5720)***

***February 16, 2012
New York City***

Thank you for the opportunity to discuss the proposed bill in the New York State legislature, A8320/S5720, relating to the Internet System for Tracking Over-Prescribing Act, and the growing problem of prescription drug-related harms in New York City and State. On behalf of The New York Academy of Medicine, we appreciate the City Council's interest in this issue and are particularly pleased that you have chosen a hearing to discuss I-STOP and prescription use, misuse and abuse. The Academy is the leading independent organization dedicated to enhancing urban health globally. For over 160 years, we have been at the heart of urban health. Through policy leadership, innovative research, evaluation, and a comprehensive program of education, training and community engagement, The Academy takes on the urban health challenges that the world is facing with more than 5.1 billion people living in cities by the year 2030. Drawing on the expertise of more than 2,000 full-time professional staff and elected fellows from across the health professions, NYAM will play a critical role in transforming the health of cities.

New York and the U.S. are facing a critical public health issue. Over the past decade, we have seen a dramatic rise in morbidity and mortality from prescription drug use, both legitimate and illegitimate. Nationally, between 2004 and 2009, all drug-related visits (illicit and prescription) to the emergency department increased by more than 80%. Nearly 4.6 million emergency room visits in the U.S are related to drugs, of which over 3.3 million have involved pharmaceuticals¹. Deaths from drug overdose now outnumber those from traffic fatalities.² Similar trends are seen here in NYC. For example, opioid analgesic-related emergency department visits in NYC have more than doubled since 2004.³ In 2009, 25% of all overdose deaths in New York City involved a prescription opioid and one third involved a benzodiazepine.^{3, 4} Much of the attention surrounding this increase in

morbidity and mortality from prescription drugs has focused on the illegal diversion of medications, but a closer look at the data suggests the problem is far more complex. Today, I want to briefly delineate several different kinds of problems that appear to be driving the dramatic increase in medication-related emergency visits and suggest that prescription monitoring programs can only address a small part of the crisis. I also want to urge you to balance the need to prevent prescription-related injury and death with the imperative to insure all New Yorkers have access to needed medications.

The first distinction it is important to make is that the sharp increase in drug-related emergency visits has been driven by both medical and non-medical use of prescription drugs. Consider this - nationally, almost half of the drug-related ED visits were for prescriptions that were used 'as prescribed'¹, and in New York City 39% of all drug related emergency room visits involved people taking their medications as prescribed⁵. This indicates that patients experienced adverse drug reactions from prescription drugs, over-the-counter medicine, or dietary supplements that they took in compliance with provider or medication instructions. This is not a problem of diversion, but a problem of inadequate patient and provider education and communication, and/or problems in coordination of care among providers. Prescription drug monitoring programs, which have been used largely as a tool to identify diversion and misuse, do not necessarily capture and address this significant proportion of individuals with legitimate medical needs who are being prescribed drugs by their providers and taking them in good faith. While a prescription monitoring program may be able to identify some patients' medication history or instances of over-prescribing, it does not provide sufficient context regarding the patients' medical needs and history or adequate guidance to the provider in deciding appropriate care. Therefore, our solutions must insure that providers have a thorough understanding of their patients' medical history, other conditions and providers, and legitimate need for medications, while simultaneously mitigating the risk of adverse drug reactions. Such a solution incorporates strategies to improve physician and patient education, particularly with regards to drug safety, best prescribing practices, and best treatment practices for special patient populations; coordination of care, especially for patients with multiple needs and providers; access to electronic medical records (across providers); and access to Naloxone – a proven safe, life saving prescription drug that prevents death in the event of an overdose.

While a significant proportion of drug-related emergency visits involved people taking medications as prescribed, we must also address the rising number of emergency visits involving deadly combinations of prescription and illicit drugs. Nationally, emergency department visits involving the use of prescription drugs and

illicit drugs in combination rose 97% between 2004 and 2009 – the use of prescription drugs, illicit drugs and alcohol together rose 76%¹. In New York City, 5% or over 6,000 drug-related emergency visits involved mixing illicit and prescription medications - almost half of which involved alcohol as well⁵. Unfortunately, prescription drug monitoring programs do not identify the use of or patient's addiction to illegal drugs or alcohol. The persistent prevalence of harm relating to illegal drug use, whether alone or in combination with prescription drugs, has to be addressed. Strategies include improving physician screening, treatment and referral of addiction, insuring access to drug treatment for people who need it, and increasing access to Naloxone. In New York, the New York State Department of Health Overdose Prevention Program has already shown the benefits of improving access to Naloxone for people who have a history of illicit drug use through documented overdose reversals and the decline in unintentional poisoning deaths from illegal drugs^{4, 6}. This life-saving medication needs to become even more widely available through expansion of the NYS Overdose Prevention Program and by encouraging the distribution of Naloxone by opioid prescribers, pharmacists and emergency rooms.

Finally, we must address the emergency room visits that specifically involve prescription misuse, which includes non-compliant use and/or the use of diverted drugs. Nationally, approximately 24% of all drug-related ED visits involved the misuse of prescription medications¹; in New York City, the percentage was 17% of all drug-related ED visits and approximately 30% of ED visits for drug abuse or misuse⁵. Prescription drug monitoring programs may assist in identifying this kind of prescription misuse through the detection of "doctor shopping" and concurrent prescribing from other providers. However, nationally representative studies have shown that nearly 71% of people aged 12 years and older who have used opioid analgesics for nonmedical purposes got them for free or buying them from family or friends. Moreover, in 80% of cases where opioid analgesics were obtained for free, the friend or relative had received the drugs from just one doctor.⁷ This kind of sharing or buying between friends and family of medications obtained through a single doctor is not likely to be identified through a prescription drug monitoring program.

Taken together, the data we have suggest that morbidity and mortality associated with prescription medications come from different kinds of use requiring different kinds of policy responses. At best, prescription monitoring systems can address only one small part of the issue at hand. We must weigh also the potential benefit of a prescription monitoring program against its potential harm, such as deterring doctors from prescribing needed medications in the best interests of their patients. In addition, at a time when health information technology is rapidly growing both in utility and reach, we have an opportunity to go beyond "real

time” monitoring to use health information technology to improve care coordination and quality. Ultimately, a patient’s prescription history is only one component of their medical history. Considering the expense of this new system, we believe that it would be better to invest in increasing the capacity of our health information systems so that they can: a) develop algorithms to detect and flag potential prescribing errors and facilitate appropriate responses; b) expand access, utilization and interoperability of electronic health records for use by patients, providers, and pharmacists; and c) facilitate the adoption of e-prescribing by providers. An issue as complex as prescription medication use requires an investment in a multi-purpose system with multiple benefits.

Finally, as I hope the above discussion has made clear, no monitoring program, however well-designed, can alone address the multifaceted problem of prescription drug use. Although we sincerely applaud efforts by our government leaders to invest in this critical issue, we urge you to make investments wisely and develop systems that will be effective in addressing the underlying causes of this complex problem. We must take a step back, clearly define the different kinds of issues at play, and design a comprehensive approach to address them. As described above, an effective strategy to decrease and prevent misuse will include provider and pharmacy education as well as consumer education, increased access to Naloxone, improved coordination of care between providers, and incentives to support the interoperability of electronic medical records. Therefore, one of the more immediate investments we recommend is in physician training, including education on the benefits of broader Naloxone prescribing, and a pilot program to increase Naloxone availability through pharmacies. And as previously mentioned, building the capacity and functionality of our health information system as a whole is critical. There is no easy fix. But working together we can develop a comprehensive approach that reduces the harm from prescription medications, while insuring that every New Yorker has access to the medications he or she needs.

For more information please contact Ruth Finkelstein, ScD at (212)822-7266 or

RFinkelstein@nyam.org

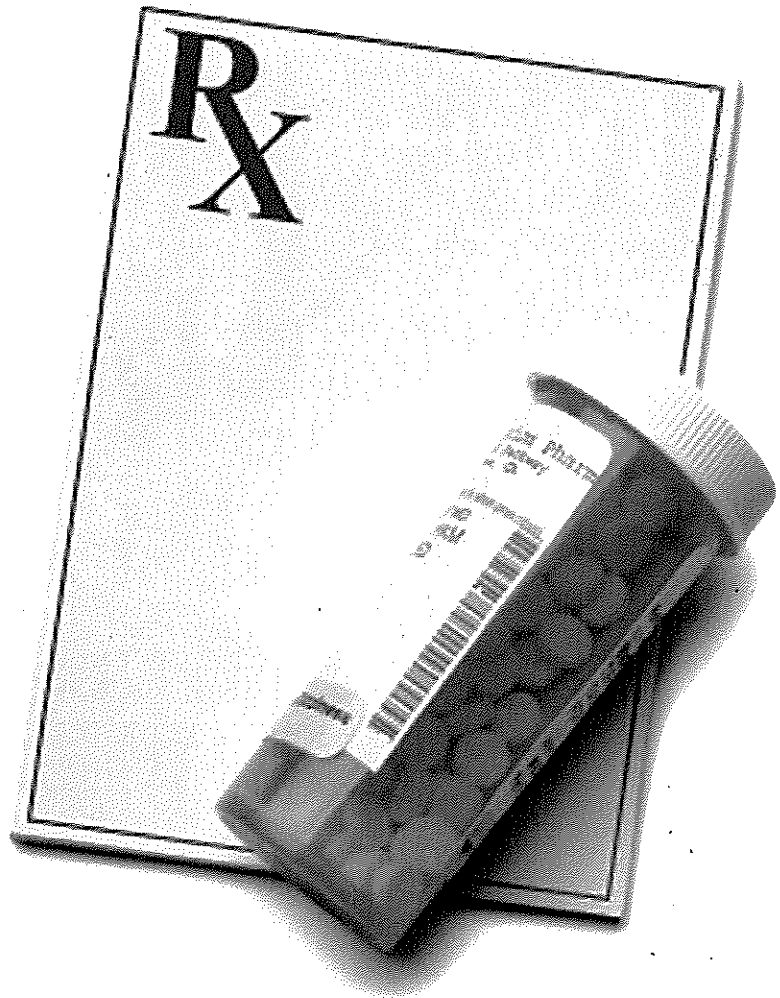
1. Substance Abuse and Mental Health Services Administration. *Drug abuse warning network, 2009: national estimates of drug-related emergency department visits*. HHS Publication No. (SMA) 11-4659, DAWN Series D-35. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011.
2. Miniño AM, Murphy SL, Xu J, Kochanek KD. Deaths: Final data for 2008. *National Vital Statistics Reports*. Center for Disease Control and Prevention. December 7, 2011;59(10).
3. Paone D, O’Brien DB, Shah S, Heller D. Opioid analgesics in New York City: Misuse, morbidity and mortality update. *New York City Department of Health and Mental Hygiene; Epi Data Brief*. 2011;3:1-2.
4. O’Brien DB, Paone D, Shah S, Heller D. Drugs in New York City: Misuse, morbidity and mortality update. *Epi Data Brief* 2011 August;10:1-2.
5. Substance Abuse and Mental Health Services Administration. *Metro brief: Drug-related emergency department visits in metropolitan areas – New York City*. Center for Behavioral Health Statistics and Quality, 2011.

6. Piper TM, Stancliff S, Rudenstine S, Sherman S, Nandi V, Clear A, Galea S. Evaluation of a naloxone distribution and administration program in New York City. *Subst use Misuse* 2008;43(7):858-70.
7. Substance Abuse and Mental Health Services Administration. *Results from the 2010 national survey on drug use and health: Summary of national findings*. Rockville, MD : NSDUH Series H-41, HHS Publication No. (SMA) 11-4658, 2011.

New York State Office of the Attorney General

INTERNET SYSTEM for
TRACKING OVER-PRESCRIBING (I-STOP)

A Proposal Addressing New York's
Prescription Drug Abuse and Drug Diversion Epidemic



The following report describes the background and rationale for New York Attorney General Eric T. Schneiderman's proposal to address the prescription drug crisis through a modernization of the state's Prescription Monitoring Program.

The Internet System for Tracking Over-Prescribing (I-STOP) Act

Executive Summary

Prescription drug diversion involves channeling legitimately produced controlled substances from their lawful purpose into illicit drug traffic. Abuse of diverted drugs comprises the nation's fastest growing drug problem, and in recent years has reached epidemic proportions. It affects every sector of society, straining our healthcare and criminal justice systems, and endangering the future of our younger generations.

Painkiller overdoses nationwide killed nearly 15,000 people in 2008. In New York, the number of prescriptions for *all* narcotic painkillers has increased from 16.6 million in 2007 to nearly 22.5 million in 2010 - prescriptions for hydrocodone have increased 16.7 percent, while those for oxycodone have increased an astonishing 82 percent. In New York City, the rate of prescription pain medication misuse among those age 12 or older increased by 40 percent from 2002 to 2009, with nearly 900,000 oxycodone prescriptions and more than 825,000 hydrocodone prescriptions filled in 2009. The roots of the problem are two-fold. First, a lack of education and communication between practitioners significantly increases the likelihood of over-prescribing and dangerous drug interaction. Second, access to an ever-increasing supply of prescription narcotics, through legal or illegal means, has grown four-fold in the past decade.

Virtually all observers of prescription drug diversion agree that expanding the use of Prescription Monitoring Programs (PMPs), and enhancing the quality and availability of the data they collect, are essential to the solution. The federal Governmental Accountability Office (GAO), the Centers for Disease Control and Prevention (CDC), the insurance industry, the White House, and independent researchers all point to such an expansion as a key part of the solution to prescription drug fraud, abuse and diversion.

While New York's PMP collects critical data on prescription drugs dispensed by pharmacists, the current system is outdated with regard to how and when data is collected, who has access to it, and how it is used.

New York State Attorney General Eric T. Schneiderman has introduced a program bill in the State Legislature that would exponentially enhance the effectiveness of New York's existing PMP to increase detection of prescription fraud and drug diversion. A.8320 (Cusick)/S.5720 (Lanza) would enact the *Internet System for Tracking Over-Prescribing (I-STOP) Act*, to establish an on-line, real-time, controlled substance reporting system that requires prescribers and pharmacists to search for and report certain data at the time a controlled substance prescription is issued, and at the time such substance is dispensed. The legislation would:

- require the Department of Health to establish and maintain an on-line, real-time controlled substance reporting system to track the prescription and dispensing of controlled substances;
- require practitioners to review a patient's controlled substance prescription history on the system prior to prescribing;
- require practitioners or their agents to report a prescription for such controlled substances to the system at the time of issuance;
- require pharmacists to review the system to confirm the person presenting such a prescription possesses a legitimate prescription prior to dispensing such substance;
- require pharmacists or their agents to report dispensation of such prescriptions at the time the drug is dispensed.

I-STOP will vastly enhance the effectiveness of the present system. Its goal is to enable doctors and pharmacists to provide prescription pain medications, and other controlled substances, to patients who truly need them. At the same time, it will arm them with the necessary data to detect potentially dangerous drug interactions, identify patterns of abuse by patients, doctors and pharmacists, help those who suffer from crippling addictions and prevent potential addiction before it starts.

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Part 1 — THE PRESCRIPTION DRUG ABUSE & DIVERSION EPIDEMIC

A. The Drug Use and Diversion Crisis

The combined problems of prescription drug abuse and diversion affect every sector of society, strain our healthcare and criminal justice systems, and endanger the futures of young people. They constitute the nation's fastest-growing drug problem, and have been classified as an epidemic by the Centers for Disease Control and Prevention (CDC).

The extent and speed of its growth is alarming. In the decade from 1995 to 2005, the number of Americans abusing controlled prescription drugs jumped from 6.2 to 15.2 million, with some drugs seeing over a five-fold increase in sales from 1997 to 2005. Among patients suffering with chronic pain and receiving opioids,¹ an estimated 1 in 5 abuses prescription controlled substances.² According to a recent Quest Diagnostics Drug Testing Report of more than 5.5 million urine drug tests, opiate-positive test results in the general U.S. workforce climbed 40 percent from 2005 to 2009.³ And while Americans constitute only 4 percent of the world's population, they now consume 80 percent of the global supply of opioids, and 99 percent of the global supply of hydrocodone.⁴

The 2009 National Survey on Drug Use and Health (NSDUH) reveals that the problem is growing increasingly acute. Some specific findings of the Survey include:

- The proportion of all substance abuse treatment admissions reporting painkiller abuse increased more than four-fold between 1998 and 2008, from 2.2 percent to 9.8 percent;
- Emergency department visits involving misuse or abuse of pharmaceuticals increased 98.4 percent between 2004 and 2009 throughout the country;
- From 2002 to 2009, there was an increase among young adults aged 18 to 25 in the rate of current nonmedical use of prescription-type drugs (from 5.5 to 6.3 percent), driven primarily by an increase in painkiller misuse (from 4.1 to 4.8 percent). Interestingly, the survey showed decreases in the use of cocaine (from 2.0 to 1.4 percent) and methamphetamine (from 0.6 to 0.2 percent), indicating that prescription drug abuse in the early part of the 21st century may be displacing more "traditional" recreational drugs.

The Survey also found that most illicit drug users were employed - of the 19.3 million current illicit drug users aged 18 or older in 2009, 12.9 million (66.6 percent) were employed either full or part time. The number of unemployed illicit drug users increased from 1.3 million in 2007 to 1.8 million in 2008 and 2.5 million in 2009, primarily because of an overall increase in the number of unemployed persons.⁵

¹ 'Opiates' are drugs that are derived from the Opium poppy plant. 'Opioids' are compounds that bind opioid receptors in the brain, producing effects characteristic of naturally occurring opiates.

² Manchikanti, L. "National Drug Control Policy and Prescription Drug Abuse." *Pain Physician Journal*. 2007; 10:399-424. Available at <http://www.painphysicianjournal.com/2007/may/2007;10;399-424.pdf>.

³ Cohen, J.R. "The health crises of chronic pain and prescription drug misuse." *Medical Laboratory Observer*. 9/1/2011. Available at <http://web.ebscohost.com.dbgateway.nysed.gov/ehost/pdfviewer/pdfviewer?vid=3&hid=122&sid=6e43f0ff-58aa-4b6e-af63-161107cf2ef6percent40sessionmgr112>

⁴ *Supra*. Note 2

⁵ U.S. Department of Health and Human Services. *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings*. September, 2010. Available at <http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf>.

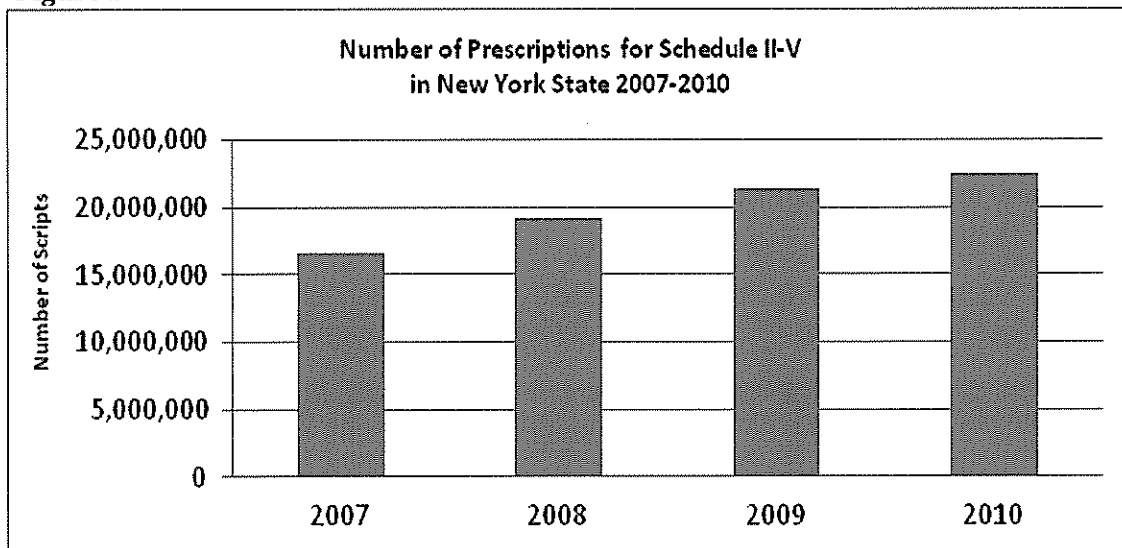
The Societal Manifestations of Prescription Drug Addiction

The prescription drug addiction epidemic exhibits all the societal manifestations of any drug addiction, including accidental overdose, violence, and its transmission from mothers to newborn babies. While it is difficult to isolate its specific fiscal impact from that of all substance abuse, because the prescription drug abuse epidemic is such a rapidly growing problem, its implications can be intuitively extrapolated from aggregate data.

1) Accidental Overdose

In its most recent study of prescription drug abuse and diversion, the CDC found prescription painkiller overdoses killed nearly 15,000 people in the U.S. in 2008, and that enough were prescribed in the United States in 2010 to medicate every American adult around-the-clock for a month.⁶ In New York, the number of prescriptions for *all* narcotic painkillers has increased from 16.6 million in 2007 to nearly 22.5 million prescriptions in 2010 (Figure 1).⁷

Figure 1



Data Source: NYS DOH, Bureau of Narcotics Enforcement

Nationally, the treatment admission rate for opiates other than heroin increased from 10 admissions per thousand to 53 per thousand - an increase of 430 percent - from 1999 to 2009. New York is higher than the national average for the time period - 450 percent -⁸ ranking the state 11th in the nation for admissions to chemical dependence programs for abuse of opioids other than heroin.⁹ Since 2007, when the state Bureau of Narcotic Enforcement (BNE) started collecting data on all narcotic prescriptions dispensed in the state (see below), prescriptions for hydrocodone have increased 16.7 percent, while those for oxycodone have increased an astonishing 82 percent (Figure 2).

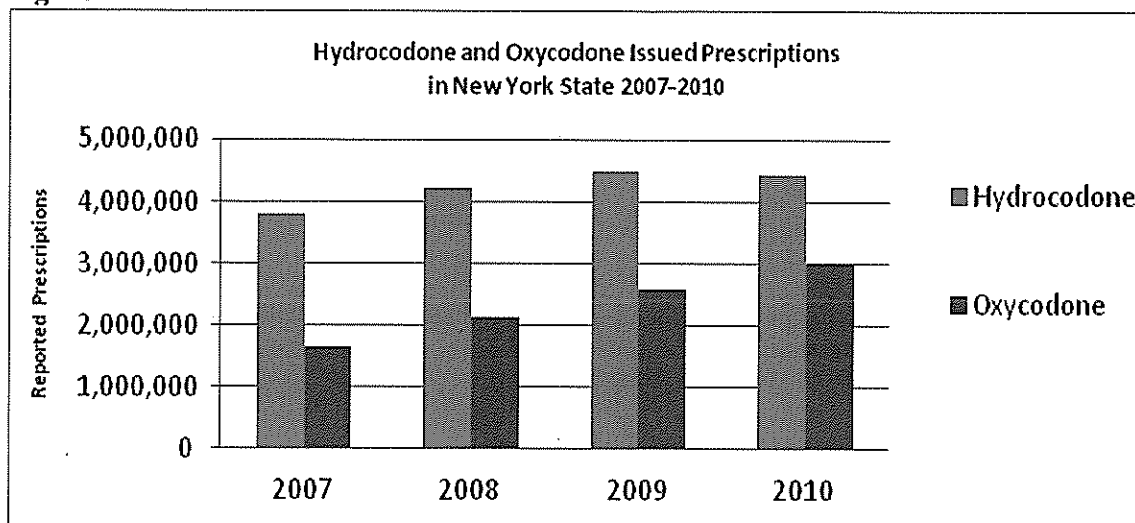
⁶ Centers for Disease Control and Prevention (CDC). *Prescription Painkiller Overdoses in the US*. "Prescription painkillers" refers to opioid or narcotic pain relievers, including drugs such as Vicodin (hydrocodone), OxyContin (oxycodone), Opana (oxymorphone), and methadone. Available at <http://www.cdc.gov/VitalSigns/PainkillerOverdoses/index.html>

⁷ NYS Department of Health, Bureau of Narcotics Enforcement.

⁸ Department of Health and Human Services, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (SAMHSA). *Treatment Episode Data Set (TEDS) 1999-2009*, p. 77. Available at <http://www.dasis.samhsa.gov/teds09/teds2k9nweb.pdf>.

⁹ National Survey on Drug Use and Health (NSDUH). Available at <http://oas.samhsa.gov/nsduhLatest.htm>.

Figure 2



Data Source: NYS DOH, Bureau of Narcotics Enforcement

In the spring of 2011, the *Buffalo News* published a series of stories about the impact of prescription drug abuse and misuse throughout New York, and particularly in the western part of the state. Heart-wrenching stories of individual and family tragedy,¹⁰ unintentional over-prescription of controlled substances, and shocking cases of intentional abuse of medical authority depict an environment of "unchartered seas."¹¹ The series found that doctor shopping, the use of multiple painkiller prescriptions and easy access to opioids have created a perfect storm, not only in the western part of the state, but throughout New York.¹²

In the North Country, prescription narcotics have displayed an alarming increase in the percentage of non-crisis admissions for substance abuse, eclipsing cocaine and heroin in Clinton and Franklin Counties, and surpassing even marijuana in St. Lawrence County. Prescriptions for hydrocodone and oxycodone have increased significantly in the region as well. From 2008 to 2010, Clinton County saw an increase of 18 percent and 28 percent for each substance, respectively. During the same period, St. Lawrence County saw increases of 32 percent for each substance, and Franklin County saw increases of 48 percent for hydrocodone and 49 percent for oxycodone.¹³

The implications of this increased use are compelling. The Village of Massena, St. Lawrence County, provides a case in point. In the first three weeks of November 2011, the community of about 10,000 saw three prescription drug suicides. From 1993 to 2010, the village police department investigated 18 suicides - eight of which have taken place since 2007.¹⁴

¹⁰ Michel, L., and Schulman, S. "A Journey to disaster." *Buffalo News* 4/27/2011. Available at www.buffalonews.com/city/special-reports/article372060.ece.

¹¹ Fairbanks, P. "Defense points to 'unchartered seas' in Falls doctor's painkiller case." *Buffalo News* 9/21/2011. Available at www.buffalonews.com/city/police-courts/courts/article565059.ece.

¹² *Supra*. Notes 10, 11. See also Davis, H.L. "Study finds multiple painkiller prescriptions." *Buffalo News* 4/5/2011. Available at www.buffalonews.com/city/special-reports/rx-for-danger/article385481.ece.

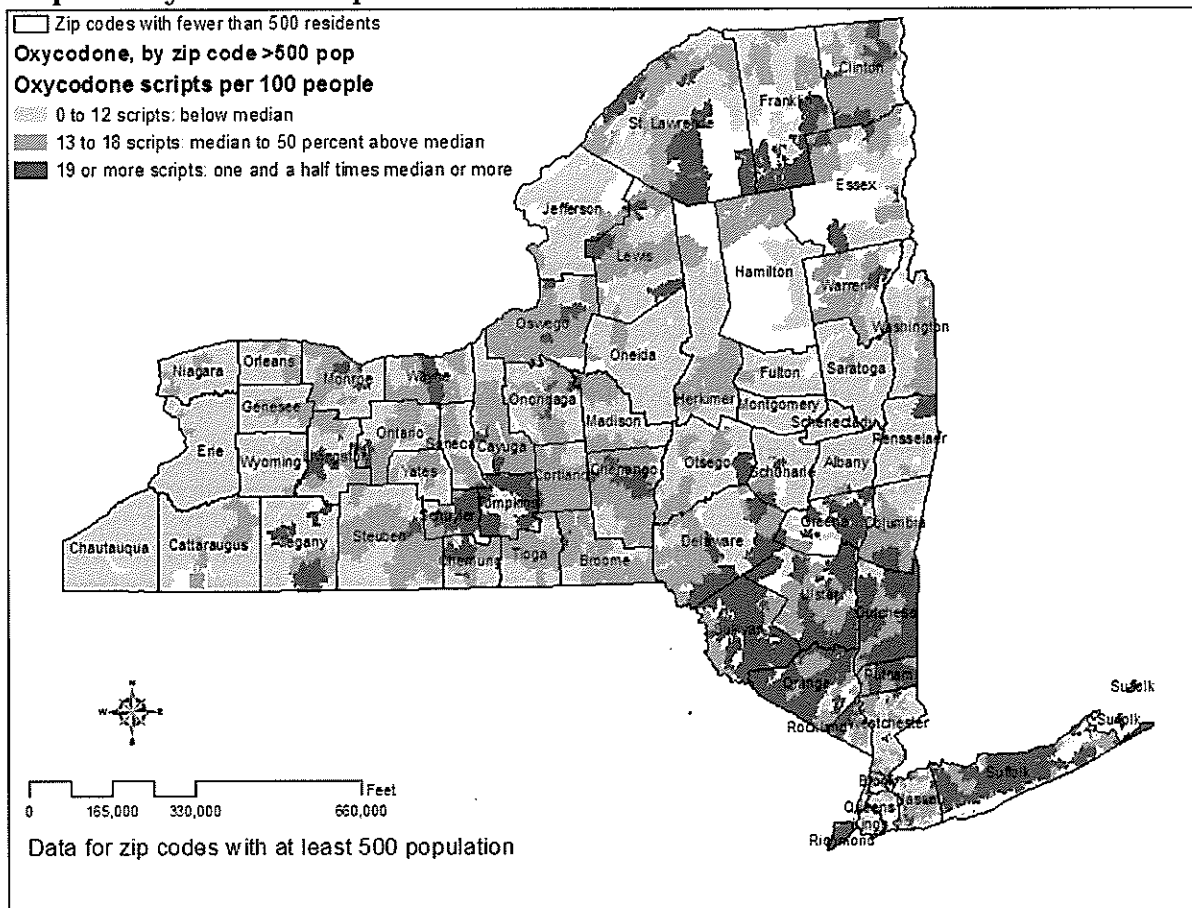
¹³ "Selected Data on Prescription Drug Abuse in the NY/NJ HIDTA Region." Office of National Drug Control Policy, the White House, using data from the New York State Office of Alcohol and Substance Abuse Services (OASAS) and the NYS Department of Health's Bureau of Narcotics Enforcement (BNE).

¹⁴ Martin, R. "Prescription drug crime on the rise." (Potsdam-Massena) *Daily Courier-Observer*. 11/23/2011. Available at www.watertowndailytimes.com/article/20111123/DC001/311239981.

On Long Island, both crisis and non-crisis admissions to drug treatment that involve cocaine and opiates other than heroin have increased at alarming rates. In Nassau and Suffolk Counties, admissions increased 57 percent and 40 percent, respectively, for crisis admissions from 2007 to 2010. Non-crisis admissions are even more shocking – such admissions increased almost 70 percent in Nassau County, and nearly 80 percent in Suffolk County over the same time period. Since 2006, oxycodone has contributed to more deaths than any other prescription opioid in Nassau County, and the prescriptions for the drug increased 42 percent from 2008 to 2010. Suffolk County saw prescriptions for oxycodone increase 23 percent during the period.¹⁵

Maps 1 and 2 depict the geographic distribution of the two drugs. Hydrocodone use appears concentrated in the western and central parts of the state, while oxycodone use is prevalent in the south eastern part of the state and Long Island.

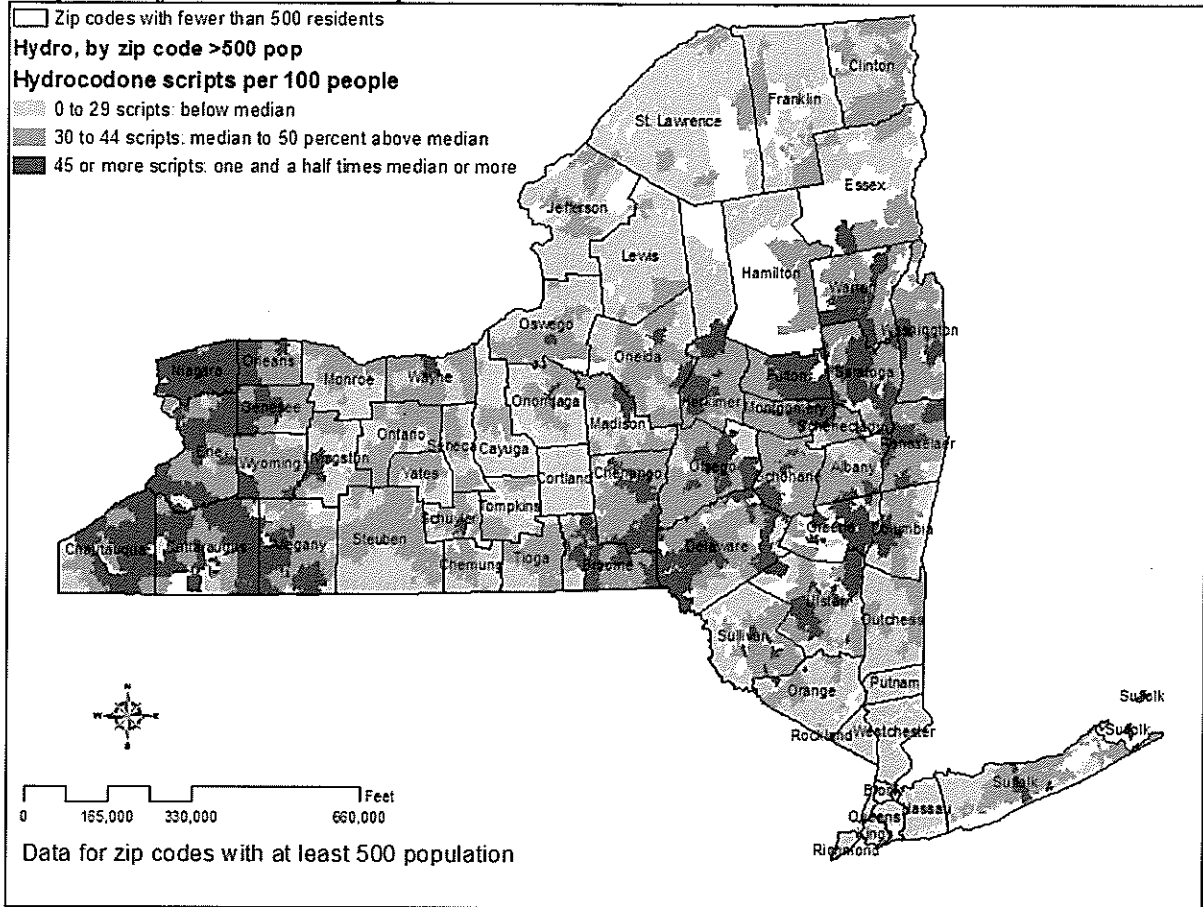
Map 1 – Oxycodone Scripts in New York State



Source: *Buffalo News*

¹⁵ *Supra*. Note 13.

Map 2 – Hydrocodone Scripts in New York State¹⁶



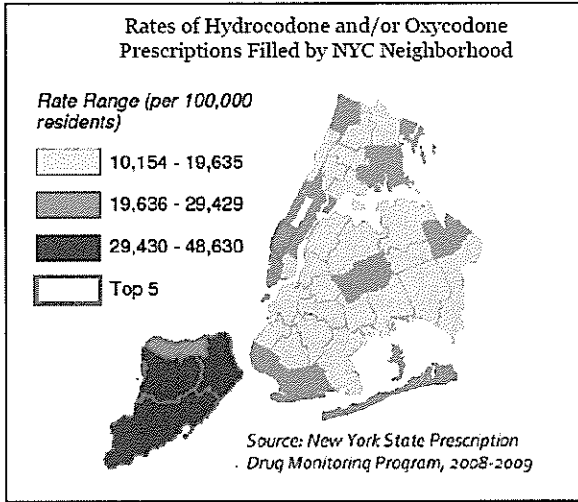
Source: *Buffalo News*

The situation is similar in New York City. In a report released in May of 2011, the New York City Department of Health and Mental Hygiene found that the rate of prescription pain medication misuse by New York City residents who are 12 or older has increased by 40 percent from 2002 to 2009. Oxycodone and hydrocodone were the most commonly prescribed opioid analgesics in 2008-2009, with nearly 900,000 oxycodone prescriptions and more than 825,000 hydrocodone prescriptions filled in 2009. The highest rates of prescriptions filled per 100,000 residents were in high- and medium-income neighborhoods – of the five neighborhoods with the highest fill rate, four were in Staten Island. Maps 3 and 4 illustrate this overlap.¹⁷

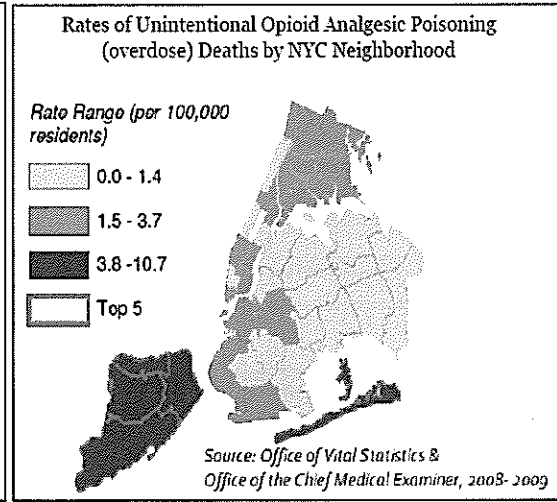
¹⁶ Maps 1 and 2 are reproduced from original graphics created by the Buffalo News. The map was originally published by BuffaloNews.com on March 28, 2011 as part of a Special Report entitled, "RX for Danger." Available at: <http://www.buffalonews.com/incoming/article368405.ece/BINARY/Oxycodone+Map>, and <http://www.buffalonews.com/incoming/article368343.ece/BINARY/Hydrocodone+Map>, respectively.

¹⁷ New York City Department of Health and Mental Hygiene. "Opioid Analgesics in New York City: Misuse, Morbidity and Mortality Update." Available at <http://home2.nyc.gov/html/doh/downloads/pdf/epi/epi-data-brief.pdf>.

Map 3

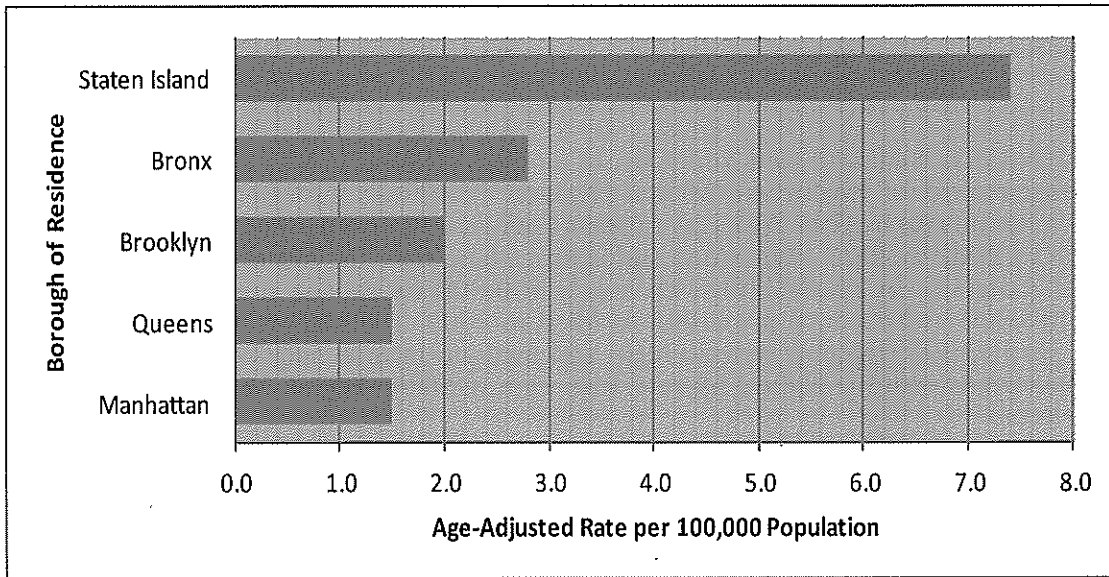


Map 4



In 2008-2009, 4 percent of City residents (263,000 people) said they had misused prescription painkillers.¹⁸ Such misuse is tragically reflected in the unintentional opioid analgesic poisoning death rate, which increased by 20 percent between 2005 and 2009 from 2.0 to 2.4 per 100,000 residents, while the heroin poisoning death rate decreased by 24 percent. Nowhere is this trend more alarming than on Staten Island, where the rate increased by 147 percent from 3 per 100,000 in 2005 to 7.4 per 100,000 in 2009 – more than double that of any other borough (Figure 3).

Figure 3 - Opioid Analgesic Poisoning Deaths by Borough (2009)¹⁹



¹⁸ Ibid.

¹⁹ Mortality data result from an in-depth review by the Health Department's Bureau of Alcohol and Drug Use Prevention, Care and Treatment (BADUPCT), Bureau of Vital Statistics and the Office of the Chief Medical Examiner records for 2005-2009. Data is available at <http://www.nyc.gov/html/doh/downloads/pdf/epi/datatable3.pdf>.

2) Addiction Related Violence

As with many drugs, the manifestations of addiction can turn tragically violent. On Father's Day of 2011, David Laffer walked into a small Suffolk County pharmacy, intending to rob the store to feed his addiction to prescription painkillers. Laffer killed two employees and two customers before stuffing his backpack full of prescription narcotics and running to a get-away car driven by his wife, Melinda Brady. It was later revealed that in the days before the shooting, Laffer had filled six prescriptions for more than 400 pills from five different doctors. As often as 11 times a month, the couple had visited medical professionals, who prescribed 11,881 pills beginning in June 2007. More than a third of that total - 4,251 pills - was obtained in the first six months of this year. Laffer was sentenced in early November to consecutive life prison terms after pleading guilty to four counts of murder; Brady received 25 years after pleading guilty to robbery charges.²⁰

On New Year's Eve, John Capano, an agent with the federal Bureau of Alcohol, Tobacco and Firearms, was mistakenly killed by a retired police lieutenant outside a pharmacy in Seaford in Nassau County. Capano, who was picking up cancer medication for his father, tried to thwart a cash-and-drug robbery attempt by James McGoey, who had recently been released from prison, where he served time for prior robbery convictions - some of them involving pharmacies.²¹

In New York City, the increase in numbers of prescriptions strongly correlates with the increase in prescription drug crime. In 2007, 6 percent of the Special Narcotics Prosecutor's (SNP) caseload was comprised of prescription drug-related arrests. By 2010, that percentage had more than doubled to nearly 15 percent. The SNP has also noted that violence is becoming more commonly associated with the black market prescription drug trade, as prescription drug investigations have involved robberies, gun seizures and, in some cases, even seizures of small arsenals.²²

The North Country Village of Massena has seen a 160 percent increase in violent crimes over the past 15 years - from 273 offenses in 1995-96 to 582 in 2003-04 to 711 in 2009-10. Authorities attribute the rise in armed robberies, aggravated assaults and burglaries to prescription drug abuse and addiction. Users are smoking, snorting and injecting the pills in an effort to sustain the high, and are more prone to violence than cocaine addicts because the withdrawal is so painful. Village police are even aware of addicts assaulting drug dealers to get pills.²³

"We've seen an escalation of violent assaults... people sticking guns in the faces of working people and threatening their lives. Defendants are admitting to us that they are addicted to painkillers and are stealing to sustain their habits."

***Joseph W. Brown, Massena
Village Police Investigator***

²⁰ Associated Press. "NY killer legally got 12,000 pain pills from docs." 11/18/2011. Available at <http://online.wsj.com/article/AP291d30e080fa47b2ac686964f720410a.html>

²¹ Kleinfeld, N.R. "Behind the Counter, an Acute Anxiety." *New York Times*. Available at <http://www.nytimes.com/2012/01/09/nyregion/anxious-days-for-long-island-pharmacies.html>

²² Office of the Special Narcotics Prosecutor for the City of New York, *2010 Annual Report*. Available at <http://www.nysenate.gov/files/Roundtable-Materials-3.pdf>

²³ Martin, R.R. "Prescription Drug Crime on the Rise." (Potsdam and Massena) *Daily Courier and Observer*. 11/23/2011. Available at www.watertowndailytimes.com/article/20111123/DC001/311239981.

3) *Transmission of Addiction to Newborns*

Like drug addiction epidemics of the past - cocaine in the 1980s and crack in the 1990s - health care professionals across the nation are witnessing explosive growth in the number of prescription drug-addicted mothers giving birth to babies hooked on powerful prescription narcotics. Though precise national statistics are not available, the number of babies diagnosed with newborn withdrawal syndrome - known as Neonatal Abstinence Syndrome (NAS) - more than doubled to almost 12,000 between 2003 and 2008.²⁴

States with the worst problems have only begun to collect data, but scattered reports indicate that the number of addicted newborns has perhaps more than tripled over the past decade. In Florida, which has been ravaged by the illicit prescription drug trade, the number of babies suffering from NAS soared from 354 in 2006 to 1,374 in 2010, according to the Florida Agency for Health Care Administration.²⁵ Actual numbers may be much higher than reported, because many pregnant women are neither tested for drug use, nor admit to using drugs during pregnancy.²⁶ In Maine, which has also been plagued by prescription drug abuse, the number of newborns treated or watched for NAS at the state's two largest hospitals climbed to 276 in 2010 from about 70 in 2005.²⁷ In Ohio, some hospitals have seen more than a four-fold increase in the NAS cases, resulting in longer hospital stays for the affected babies and higher public health care costs.²⁸

New York State has not been spared the increases in neonatal abstinence syndrome. At the Catholic Health System in Buffalo, which operates New York State's largest methadone clinic outside of New York City, physicians used to see one to three babies a month with symptoms of withdrawal from narcotic pain pills. Now, the number approaches 10 a month, and the number of cases has grown enough that the hospital network is reorganizing services to standardize the care of addicted mothers-to-be and their newborns.²⁹

4) *The Fiscal Consequences of Substance Abuse*

In terms of fiscal costs, the numbers are staggering. In May of 2009, the National Center on Addiction and Substance Abuse (CASA) released a report that analyzed the fiscal impact of substance abuse - including the growing problem of prescription drug abuse and addiction - on federal, state and local budgets. CASA measured the impact of the problem on all public programs, from education to health to the criminal justice system, and found that in 2005, federal, state and local government spending as a result of substance abuse and addiction was at least \$467.7 billion - \$238.2 billion at the federal level; \$135.8 billion at the state level; and \$93.8 billion at the local level. The total of \$467.7 billion constituted 10.7 percent of the entire \$4.4 trillion contained in federal, state and local budgets.

²⁴ Colon, D. "Number of Newborns Addicted to Painkillers Rising." National Public Radio. Available at <http://www.npr.org/2011/02/16/133805289/number-of-newborns-addicted-to-painkillers-rising>

²⁵ Leger, D.L. "Doctors see surge in newborns hooked on mothers' pain pills." USA Today. 11/13/2011. Available at <http://yourlife.usatoday.com/parenting-family/babies/story/2011-11-13/Doctors-see-surge-in-newborns-hooked-on-mothers-pain-pills/51186076/1>.

²⁶ Training Presentation by the Office of the Attorney General, State of Florida. Prescription Drug Abuse: Florida's Health Crisis. Available at <http://leonrdmc.org/docs/pdf/Aronberg%20Rx%20Drug%20Abuse%20Training.pdf>

²⁷ Goodnough, A., and Zezima, K. "Newly Born, and Withdrawing From Painkillers." New York Times. 4/9/2011. Available at <http://www.nytimes.com/2011/04/10/us/10babies.html?pagewanted=all>

²⁸ Larsen, D. "Prescription drug abuse nation's fastest-growing drug problem." *Dayton Daily News*. 12/7/2011. Available at <http://www.daytondailynews.com/news/dayton-news/more-babies-born-addicted-to-opiates-1295255.html>.

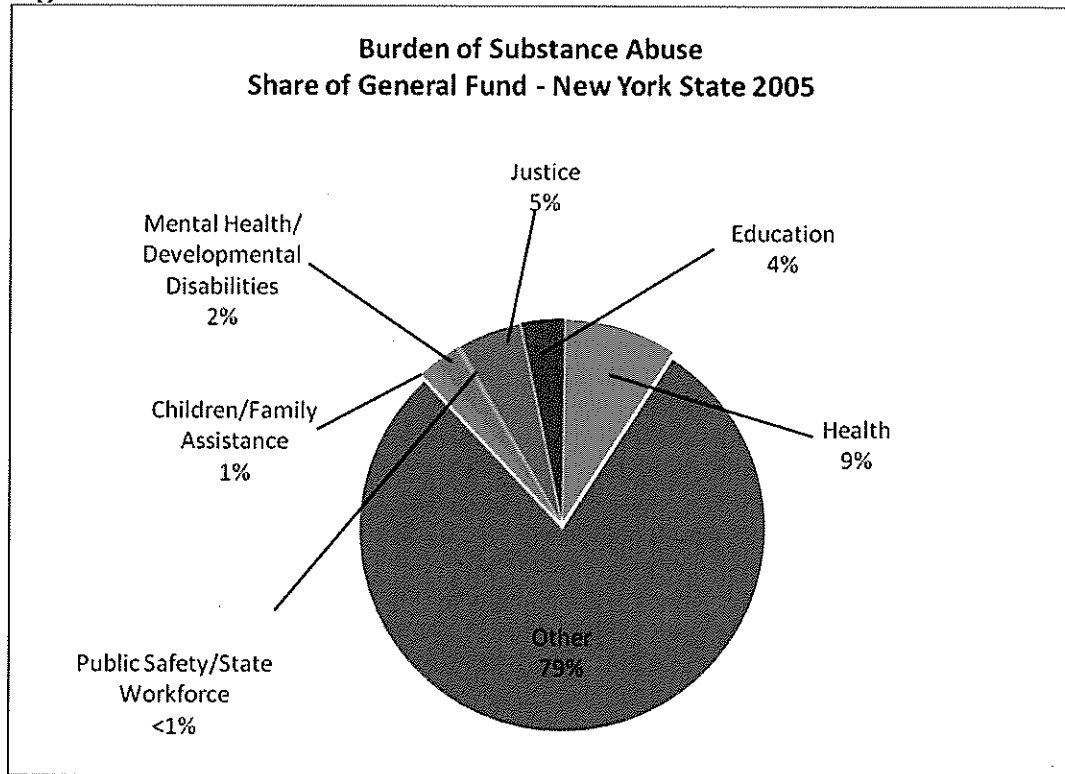
²⁹ Davis, H.L. "Treating the tiniest addicts: Mothers' pill abuse leads to newborns' exposure." Buffalo News. 6/1/2011. Available at <http://www.buffalonews.com/city/article439798.ece>

CASA also found that these massive expenditures were grossly skewed toward dealing with the consequences of substance addiction rather than prevention and treatment. For every dollar federal and state governments spent on the latter, they spent \$59.83 on public programs shoveling up the wreckage left by substance addiction, despite a substantial and growing body of scientific evidence confirming the efficacy of science-based interventions and treatment and their cost-saving potential.³⁰

In New York, spending on prevention, treatment and research constituted only 2.14 cents of every dollar that was spent on the burden that substance abuse and addiction placed on all impacted public programs.³¹ The state ranked third among all states in 2005, with regard to this burden – 21.1 percent of the General Fund (\$13.132 billion), which translates into \$680.19 per capita - ranking New York eighth in the nation (Appendix B).³²

It is not possible to filter prescription drug abuse from the broader category of substance abuse in CASA's data. It is logical to assume, however, that because diversion and abuse of prescription drugs has been increasing at an accelerated rate over the last five years, the problem is consuming an ever-larger piece of the budgetary pie. Figure 4 illustrates the composition of that pie in 2005.

Figure 5



Data Source: CASA

³⁰ National Center on Addiction and Substance Abuse (CASA). *Shoveling Up II: The Impact of Substance Abuse on Federal, State and Local Budgets*. CASA has not updated the 2009 report, nor does it have specific data broken out.

³¹ *Ibid.* p. 4.

³² *Ibid.*, Table 1 is reproduced from p.119.

B. Underlying the Prescription Drug Abuse Epidemic

There are two essential and related elements to the prescription drug abuse epidemic – the lack of training and communication among health care professionals, and the easy access, legal or otherwise, for abusers to prescription narcotics.

1) *Absence of Health Care Practitioner Training and Communication*

One primary underlying cause for the increases in diversion, addiction, and accidental deaths attributed to controlled substance prescriptions may be traced back to the lack of training and communication among health care practitioners who prescribe controlled substance prescriptions. To be sure, there are many medical professionals who possess the proper education and training to appreciate the potency and potential danger of addiction opioids present. However, a large number of physicians, such as the general practitioner or internist, may unintentionally prescribe controlled substances at higher dosage or quantity than required. Additionally, many physicians have not been specifically trained in identifying the warning signs that a patient is engaged in fraud or "doctor shopping" for the purpose of abusing prescription drugs.

Without this much-needed education, it is no surprise that the CDC found the quantity of controlled substance prescriptions sold to pharmacies, hospitals, and doctors' offices was 4 times larger in 2010 than in 1999.³³ One of the effects of overprescribing controlled substances is the unintentional stockpiling of painkillers in America's medicine cabinets.

For example, in Western New York, nine "prescriptions drop-offs," whereby households can dispose of unwanted and unnecessary drugs, were conducted over two years between October 2008 and November 2010. In total, these drop-offs yielded 652 *pounds* of controlled substances, comprised of 124,050 doses of narcotics, including 48,883 doses of hydrocodone, 16,393 doses of oxycodone, and 2,287 doses of fentanyl.³⁴

More troubling than the lack of physician training is the lack of communication between doctors treating the same patient when it comes to prescribing medication. Currently, New York practitioners rely largely on in-office patient reporting. But for whatever reason, some patients do not or will not fully disclose all medical treatment he or she is receiving, and data that can be gleaned by doctors from the current PMP is severely limited (see below). This, too often results in the overprescribing of medications. It can also result in unintentional dangerous drug interactions with tragic consequences.

In 2009, Michael David Israel, who suffered from Crohn's Disease, was prescribed Lortab (hydrocodone) by one physician to deal with disease-related pain. The following year, he was prescribed Cymbalta and Xanax – both of which can interact dangerously with hydrocodone – by another physician for depression brought on by his condition. By the spring of 2011, his addiction to the pain medication became evident to his parents, and they admitted Michael to a detoxification center, from which he was discharged after a week to deal with the ad-

³³ Centers for Disease Control (CDC). "Prescription Painkiller Overdoses in the US." Available at <http://www.cdc.gov/VitalSigns/PainkillerOverdoses/index.html>

³⁴ Michel, L. and Shulman, S. "A journey to disaster." *Buffalo News*. March 20, 2011. Available at www.buffalonews.co/city/special-reports/article372060.ece. A similar National Prescription Drug Take-Back event, the third sponsored by the DEA, collected 188.5 tons of unused prescription drugs from 5,327 take back sites across all 50 states on a single day. Press Release available at justice.gov/dea/pubs/pressrel/pr110311.html.

diction on an out-patient basis, with little success. By June, Michael tried to be readmitted to the center, and was told there were no beds. Seeing no alternative to the pain and addiction, Michael, age 20, went to the bedroom of his parents' home, pulled out his shot gun and took his own life.³⁵

Similarly, Dr. Andrew Kolodny, Chair of the Department of Psychiatry at Maimonides Medical Center, noted that when his staff investigated the deaths of several patients, they were found to have been prescribed benzodiazepines for anxiety by staff psychiatrists. Unbeknownst to these psychiatrists, the patients were also taking opioids prescribed by other physicians outside the clinic.³⁶ In either of these cases, and many like them, it is possible that tragedy could have been averted if all practitioners had access to a central data repository from which patient's entire prescription history could be consulted.

"What should be [available] is that a physician can look up any patient, any time and get any information on controlled substances that have been prescribed as recent and far back as the database goes, even if it's one prescription."

***Dr. Frank Dowling, before the
NYS Senate Drug Diversion
Roundtable***

2) Easy Access to Prescription Narcotics for Abusers

Another major cause is access to the ever-increasing supply of controlled narcotics by non-legitimate means. In addition to the unintentional over-prescription described above, other avenues of access range from the crooked doctor, to the street-level drug dealer, to fraudulent prescriptions. Indeed, as shown below, a single crooked doctor can result in hundreds of thousands of doses of controlled substances on the street, and reports of prescription pad thefts indicate millions of such doses.

Crooked Doctor: In April of 2006, Dr. Apryl Mamzette McNeil, MD of New York City pled guilty in federal court to one count of conspiracy to distribute Schedule III and IV controlled substances and one count of conspiracy to launder money.³⁷ Between November 2003 and May 2004, McNeil authorized at least 220,090 dosage units of Schedule III controlled substances and 15,510 dosage units of Schedule IV controlled substances over the internet. The prescriptions were not issued for a legitimate medical purpose and not in the usual course of a practitioner's professional practice.³⁸

The Street-Level Dealer: After pleading guilty to felony drug-possession and conspiracy charges, a Staten Island man was

Easy Access

- A NYC doctor pled guilty in 2006 to authorizing at least 235,600 dosage units of Schedule III and Schedule IV narcotics for non-medical purposes.***
- In 2011, a Staten Island man pled guilty to distributing 42,775 oxycodone pills from his ice-cream truck.***
- In western NY, a voluntary collection of unused and unwanted prescription narcotics yielded 652 pounds of pills over two years.***

³⁵ Recounted by the parents of Michael David Israel.

³⁶ Testimony before Senator Hannon's Roundtable, August 31, 2011.

³⁷ Controlled substance schedules are defined under Title 21 of the U.S. Code - The Controlled Substances Act. Schedule definitions can be found in Appendix D.

³⁸ US Drug Enforcement Administration. Cases Against Doctors. Available at http://www.deadiversion.usdoj.gov/crim_admin_actions/doctors_criminal_cases.pdf

sentenced in October of 2011 to 3 1/2 years in prison. Louis Scala operated a Lickety Split ice-cream truck that served the South Shore, and was part of a group that distributed some 42,755 oxycodone pills across the borough in 2009 and 2010. Customers knew where and when to wait for the truck to arrive. Supply was maintained by recruiting 28 "runners," many of whom were addicts desperate for cash, to fill forged prescriptions on forms that a co-conspirator stole from the doctor's office she managed.³⁹

Fraudulent Prescriptions: Stolen prescription pads are big business for prescription drug dealers. Recently, a Monroe County drug ring was caught with purloined pads, but not before 40,000 prescriptions had been written under one doctor's name without the doctor's knowledge.⁴⁰

In the spring of 2011, *Newsday* reported that as many as 1.4 *million* scripts had been stolen since 2008 from several different hospitals within the New York City Health and Hospital Corporation, the city's public hospital system. Most of the fake scripts were written for oxycodone.⁴¹ In the fall of the same year, DOH confirmed that another 14,000 blank prescriptions were missing from Westchester County's Mount Vernon Hospital.⁴²

³⁹Donnelly, F. "Staten Island man admits selling prescription drugs from ice cream truck." Available at http://www.silive.com/southshore/index.ssf/2011/08/staten_island_man_admits_selli.html

⁴⁰ Crowley, CF. "Taking pulse of Medicaid costs." *Times Union* (Albany). October 26, 2011.

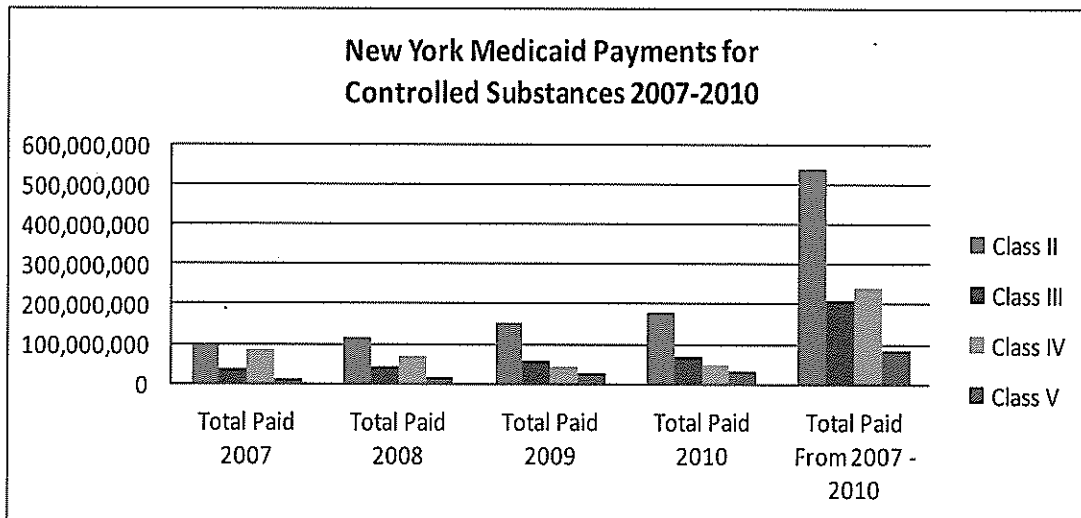
⁴¹ Lewis, R. and Van Sant, W. "Up to 1.4 million stolen Rx forms." *Newsday*. October 22, 2011. Available at <http://www.newsday.com/news/region-state/ny-up-to-1-4m-prescription-forms-stolen-1.3265916>.

⁴² Lewis, R. and Van Sant, W. "State: More hospital prescription forms missing." *Newsday*. 11/10/2011.

C. The Prescription Drug Abuse Crisis and New York's Medicaid Problem

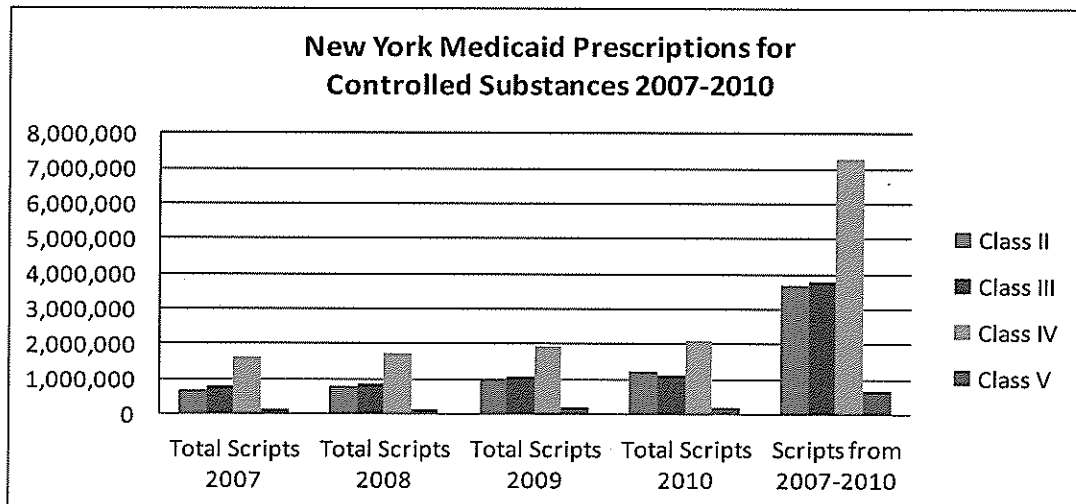
The New York State Medicaid program spent over \$1 billion on controlled substance prescriptions over the past four years. This cumulative figure does not, however, reflect a stable annual rate of \$250 million per year, but rather an alarming trend, manifested by a 38.4 percent increase from 2007 to 2010 (Figure 5).⁴³

Figure 5



The increase in Medicaid payments is due to the increase in prescriptions written for controlled substances during this time frame. From 2007 to 2010, the number of scripts for Schedules II through IV drugs paid by Medicaid increased from 3,126,268 to 4,611,002, or 47.5 percent (Figure 6).

Figure 6



⁴³ Data from the Attorney General's Medicaid Fraud Control Unit.

The underlying elements of the epidemic cited above are reflected in the Medicaid program as well. While there are no actual numbers that demonstrate how much prescription drug fraud/diversion costs Medicaid (and New York taxpayers) annually, a very small increase in prevention recoveries could amount to tens of millions of dollars in savings every year. Indeed, New York State's Medicaid Fraud Control Unit estimates that the cases the unit prosecutes for fraudulent prescriptions average a \$1 million loss *per case*. Several prominent cases involving doctors who are no better than drug dealers, and others who entered a downward, out-of-control spiral, support the MFCU's estimates:

Case 1 - Drug Dealing Doctor: In a sting operation conducted by government agents posing as Medicaid patients, Dr. Abdolhosein Baghai-Kermani, a licensed psychiatrist in New York, knowingly sold prescriptions for controlled substances. Upon arrival at the Baghai-Kermani's office, the "patients" would register with a receptionist, provide a photo ID, a Medicaid card and \$80 to \$90 in cash. The doctor would conduct a brief five- to ten-minute "session," then give the patient a prescription for the agreed upon controlled substance. Baghai-Kermani sold prescriptions for Valium on six occasions, Ativan on three occasions, and a prescription for Xanax once to agents, where no medical necessity for these prescriptions existed. MFCU estimated that over the course of 18 months, Baghai-Kermani pocketed \$1,200,000 in cash by selling over 13,000 prescriptions.

- ***NYS Medicaid spent over \$1 billion on controlled substance prescriptions over the past four years.***
- ***Medicaid fraud cases prosecuted by New York's Medicaid Fraud Control Unit (MFCU) average a \$1 million loss to the state's taxpayers per case.***

Case 2 - Out-of-Control Doctor: In 2002, Dr. David Roemer engaged in a conspiracy to possess and sell narcotic/controlled substance/non-controlled substance prescription medications. Roemer wrote prescriptions that were not medically necessary to Medicaid patients, charging \$100 cash for each. A group of patients recruited, and even drove, other patients to Roemer's High Falls office to receive the prescriptions. Roemer and 39 other defendants were indicted for Criminal Controlled Substance in the First Degree and other criminal charges. Roemer pled guilty and received a jail sentence as well as other defendants, patients-drivers-recruiters.

Roemer is a classic example of a physician who went out of control. In 2000, he wrote a weekly average of one controlled substance prescription, and a weekly average of 19 controlled substance prescriptions the following year. By 2002, that weekly average had increased to 71 controlled substance prescriptions for Medicaid recipients, and by the third quarter of that year, he prescribed Xanax, oxycodone, and Klonopin more than 79 percent of the time for Medicaid recipients. Of those prescriptions, 159 were made out to Medicaid recipients who resided at a drug rehabilitation treatment house in the Bronx. While Roemer was not enrolled as a provider in the Medicaid program, and his act-

- ***Over one 18-month period, a licensed psychiatrist in New York sold over 13,000 prescriptions for controlled substances, pocketing \$1.2 million in cash.***
- ***A Long Island physician went from writing only 18 prescriptions for controlled substances over a ten-year period to issuing 380 scripts over three months, and billing Medicaid \$940,000.***
- ***Over two years, a High Falls physician went from writing one controlled substance prescription per week to writing an average of 71.***

ivities "flew under the radar," Medicaid (and ultimately New York taxpayers) reimbursed for the drugs that he prescribed.

Case 3 - Out-of-Control Doctor: In 2007, Dr. Michael Chait of Amagansett, Long Island, was charged for writing hundreds of illegal prescriptions for patients from New York City.

Chait's "patients" would drive from the Bronx and Manhattan to his practice far out on the Long Island shore, where they paid him for controlled substance prescriptions. While they were frequently filled at pharmacies that could be mapped out along exits on the Long Island Expressway, one pharmacy accounted for 86 percent of the filled prescriptions, even though it, and the patients' residences, were literally hours away from Chait's practice. Another example of an "out of control" doctor, Chait went from prescribing controlled substances only 18 times in ten years to issuing over 380 scripts in three months, for drugs that cost Medicaid and other insurers over \$940,000. Chait was convicted in 2009 and sentenced to three years in prison followed, by five years of post-release supervision.

Case 4 - Counterfeit Prescriptions: Between 2009 and 2011, Suzanne Benizio of the Bronx created more than 250 forged prescriptions for OxyContin and Roxicodone, written on prescription paper stolen from doctors and hospitals in the New York City area. Benizio arranged for the counterfeit scripts to be filled at pharmacies in 20 counties across the state through a group of co-conspirators that presented misappropriated Medicaid cards to the pharmacies.

MFCU estimates Benizio's operation resulted in the diversion of \$200,000 in controlled substances. At the time of her arrest in March of 2011, she possessed enough prescription paper to create an additional 1,500 prescriptions, and a special printer needed to process the thermal prescription paper the state uses for the official prescription pads it distributes to practitioners.⁴⁴

⁴⁴ Associated Press. "Bronx Woman Pleads Guilty To Forging Painkiller Prescriptions." Available at <http://newyork.cbslocal.com/tag/prison/feed/>.

Part 2 — “I-STOP” — A SOLUTION FOR NEW YORK

A. National Consensus on Prescription Monitoring Programs

Virtually all observers of prescription drug diversion agree that expanding the use of PMPs, and enhancing the quality and availability of the data they collect, is part of the solution. The federal Governmental Accountability Office, which has produced several reports over the years in response to Congressional requests, the insurance industry, the White House, and independent researchers have all pointed to such expansion as part of the solution to prescription drug fraud and diversion. And among the recommendations in its 2011 Prescription Drug Abuse Prevention Plan, the White House Office of National Drug Control Policy (ONDCP) calls for better monitoring through implementation of PMPs in every state to reduce “doctor shopping” and diversion, and enhance PMPs to make sure they can share data across states and are used by health-care providers.⁴⁵

“State prescription monitoring programs (PMPs) are among the most effective ways to detect and prevent diversion—if funded adequately and used properly... [yet] only half of states have PMPs. States that do have PMPs vary widely in the kind and amount of data collected, who can access the data, and how well the data can be mined for suspicious patterns.”

White House Office of National Drug Control Policy

In its most recent findings, the CDC has recommended that states improve prescription drug monitoring programs and use them, Medicaid, and workers' compensation data to identify improper prescribing of painkillers.⁴⁶

B. New York's Current Prescription Monitoring Program

The New York PMP collects data on all Schedule II, III, IV, and V controlled substance prescriptions dispensed in New York State. Every pharmacy licensed by New York State to dispense a controlled substance is required to transmit certain patient, doctor and drug information for every controlled substance prescription that is dispensed at such state-licensed pharmacy. Those pharmacy transmissions are required to be sent to the Bureau of Narcotic Enforcement (BNE), within the State Department of Health (DOH) by the 15th day of the following month. *Critically, New York's current PMP does not require physicians to report the prescriptions that they issue in any manner whatsoever.*

The BNE oversees the PMP, and collects and analyzes the data on all Schedule II, III, IV, and V controlled substance prescriptions dispensed in the state to identify persons who may exhibit behavior that suggests potential controlled substance prescription abuse and/or diversion. BNE may share a patient's controlled substance prescription information with other state agencies, including the professional boards of pharmacy and medicine and the Office of the Medicaid Inspector General (OMIG), as well as those health care practitioners who treat such patient. The agency may not disclose any data from the PMP to law enforcement agencies without subpoena or court order.

⁴⁵ White House Office of National Drug Control Policy. Available at <http://www.whitehouse.gov/ondcp/prescription-drug-abuse>

⁴⁶ Centers for Disease Control (CDC). “Prescription Painkiller Overdoses in the US.”

The BNE began the program in 1973, limiting data collection to Schedule II controlled substances, expanded it to include benzodiazepines in 1989, and *all* controlled substance prescriptions in 2007. Under the current program, a practitioner must maintain a record of every controlled substance prescription written for a patient and such patient's record must contain sufficient information to justify a diagnosis that warrants a controlled substance prescription. Data collected from the dispensing pharmacy include:

- Pharmacy identification;
- Patient information, including name, address, date of birth and gender;
- Prescription information, including number, date written and dispensed, drug type and quantity, and refill information;
- Practitioner information, including DEA number and NPIU number (if available); and
- The unique Official NYS Prescription serial number (see below).

Unfortunately, few health care practitioners have used the current PMP system to access to their patients' controlled substance prescription history. Although a recent change allows doctors to check the data, they are not required to do so. The system will therefore fail to prevent dealers, crooked doctors, and addicts from obtaining or diverting prescription drugs. Furthermore, a practitioner may only be informed of a patient's documented controlled substance prescription history if such practitioner has signed up to receive information from BNE, the patient has been prescribed a controlled substance by two or more practitioners, *and* the patient has had those prescriptions filled by two or more pharmacies within a month.

In trying to detect over-prescription at Maimonides Medical Center, Dr. Andrew Kolodny found New York's PMP system to be severely limited:

"...if the patient is getting all their medications from one pharmacy, you get no information back; or if they're going to different pharmacies but getting all their prescriptions from the same doctor, you get no information back. So, in effect, the system that we have was useless for our purposes.

Dr. Andrew Kolodny

Pharmacists also have a responsibility to see that controlled substances are dispensed for legitimate medical use, and are required by law to report any suspected diversion to the BNE. They are, however, currently prohibited from accessing a customer's controlled substance prescription history on the PMP. Such limitations have not gone unnoticed by pharmacists and other interested parties, and the BNE is currently working to improve information access and program effectiveness. At a New York State Senate Roundtable discussion in August of 2011, Dr. Andrew Kolodny of Maimonides Medical Center notes that:

"... we've got terrific data in New York State – probably better than any place else in the country, but we're not using it... we need to allow the providers to utilize the prescription data that's available. Right now the system we've got does not work for clinical practice. New York State allows a physician to go on the database to find individuals who meet the definition of a doctor shopper, but if you want to see if a

patient is already on an opioid... you get no data back unless the patient fits the definition of a doctor shopper."⁴⁷

Other observations and recommendations for the existing PMP that emerged from the Senate Roundtable and subsequent interviews by OAG staff with practitioners include:

- *Lack of User-Friendliness*: the website is difficult to find; only the practitioner is permitted access; there is no singular patient identifier, making it very easy to "fake out the system."
- *Time Consuming*: the lack of user-friendliness makes the current system too time-consuming for a physician to use. A misspelling or typo on a birth date can slow down the process, which averages three to four minutes. In a busy office, this poses significant doctor-patient time constraints.
- *Limited Data Access*: under the current access protocol, a patient's data is only available to an inquiring physician if the patient meets the following criteria, which flags them as a possible abuser/diverter: the filling of two or more prescriptions for controlled substances from two or more physicians at two or more pharmacies. If a patient does not fit this profile, the physician will get no information back, even though the patient might have a substantial controlled substance use history.
- *Limited Information*: the information provided when all these criteria are met only goes back a few months, and is likely to be as much as a month behind, due to the 45-day reporting requirement for pharmacies. In addition, known abusers are not always in the database.
- *Monthly Statement*: To detect stolen prescriptions, physicians should be able to get a monthly statement of their prescription activity to make sure the record matches their actual history. If a prescription appears that the physician didn't write, it would be a forged prescription. Such procedure would also detect changed prescriptions.⁴⁸

But the true Achilles heel of the current PMP is that doctors are not required to provide any data to the system whatsoever. There simply is no tracking of prescriptions issued. Accordingly, when a doctor writes a prescription for a controlled substance (e.g. Oxycontin), he or she has no knowledge that the patient may have received one, two, three, or even a dozen scripts for the same or similar medication from multiple doctors over a short period.

In addition, the system does nothing to prevent drug abusers or criminal drug gangs from getting narcotics with stolen or forged prescription pads. Section 3338 of the NYS Public Health Law requires the DOH to prepare and issue prescription blanks, with unique serial numbers, to all practitioners authorized to write such prescriptions, as well as to institutional dispensers. With the exception of emergency and oral prescriptions, which can be prescribed for only up to five days, all controlled substance prescription and dispensation may be done only via an Official NYS Prescription, an electronic prescription or out-of-state prescription.

⁴⁷ Andrew Kolodny, M.D., Chairman of the Department of Psychiatry, Maimonides Medical Center, member of Physicians for Responsible Opioid Prescribing, NY Society of Addiction Medicine.

⁴⁸ Ibid.

It is this written "script" that gives legitimacy to the entire prescription transaction, whether the "patient" is doctor shopping or the prescribing practitioner is no better than a drug dealer with a medical license. A stolen script pad empowers the thief with a pass to obtain any kind of prescription drug, as we have seen in just two recent cases of prescription fraud cited above. The BNE estimates that the street value of blank Electronic Medical Record (EMR) forms ranges from \$100 to \$300 per form. The street value of a single 30 mg tablet of Oxycontin is between \$25 and \$35;⁴⁹ and a single 80 mg Oxycontin can bring as much as \$70 per pill on the street. A prescription for 30 can bring over \$2,000 to the dealer.⁵⁰

"While New York's PMP collects substantial data from pharmacists, it is lacking a verification mechanism to ensure that the script the pharmacist fills is authentic. The true Achilles heel of our current system is the possibility of stolen prescription pads."

Assemblyman Michael Cusick

Cost of the Current System

The Department of Health does not use an outside vendor in any aspect of the current data gathering process, and has done all data collection and technical work in-house. The total cost of the PMP for the current fiscal year is \$16.4 million, which is significantly more than the cost of other state programs examined by staff (see below).

A direct total cost comparison would be, however, misleading. While New York does not contract for data collection, standardization and maintenance, it does contract for other services, including the printing and distribution of all Official NYS Prescription pads. In SFY 2011-12, this cost was \$11.66 million, or more than 71 percent of the entire program cost.⁵¹ This is a cost that no other state incurs, without which New York's program cost would currently be \$4.74 million – the cost of personnel (\$2,186,000) and other contractual services.

Other contractual services include a Program Help Desk, manned by three contract staff for a total cost of \$225,000; a program hotline (\$5,000); postage (\$10,000); cell phones (\$6,000); vehicle maintenance (\$20,000); and miscellaneous contractual services (\$74,000). Supplies (\$220,000), travel (\$100,000), equipment (\$200,000), fringe benefits (\$1,059,000) and indirect cost (\$635,000) round out non-personal program expenses for a total of \$14,214,000.

The Department of Health is also reported to have contracted with a software company to track Medicaid expenses in real time. The *Albany Times Union* reports that DOH has recently contracted with Salient Management Services to track Medicaid's \$52 billion annual budget, 4.7 million recipients and 60,000 health care providers, at a cost of \$1.4 million over three years.⁵²

⁴⁹ DOH internal memorandum "Diversion and Counterfeit New York State Official Prescription Forms."

⁵⁰ Herbeck, D. "New breed of drug dealer." *Buffalo News*. March 21, 2011.

⁵¹ All current program cost figures provided by the NYS DOH.

⁵² Crowley, CF. "Taking pulse of Medicaid costs." *Albany Times Union*. 10/26/2011. Available at <http://www.timesunion.com/local/article/Taking-pulse-of-Medicaid-costs-2236429.php>. The cost of this contract could not be readily verified at the time of this writing.

C. Proposal — The Internet System for Tracking Over-Prescribing (I-STOP)

Essential Elements of the I-STOP Proposal

New York State Attorney General Eric T. Schneiderman has introduced a program bill that would exponentially enhance the effectiveness of New York's existing PMP to increase detection of prescription diversion, doctor shopping and pill mills A.8320 (Cusick)/S.5720 (Lanza) would enact the *Internet System for Tracking Over-Prescribing* (I-STOP) Act, to establish an on-line, real-time controlled substance reporting system that requires practitioners and pharmacists to search for and report certain data at the time a schedule II, III, IV, or V controlled substance prescription is issued and at the time such substance is dispensed (Appendix C). The legislation amends the State's Public Health Law to:

- Require the Department of Health to establish and maintain an on-line, real-time controlled substance reporting system to track the prescription and dispensing of controlled substances;
- Require practitioners to review a patient's controlled substance prescription history on the system prior to prescribing;
- Require practitioners or their agents to report a prescription for such controlled substances to the system at the time of issuance;
- Require pharmacists to review the system to confirm the person presenting such a prescription possesses a legitimate prescription prior to dispensing such substance;
- Require pharmacists or their agents to report dispensation of such prescriptions at the time the drug is dispensed.

To ensure privacy, I-STOP prohibits the disclosure of viewing of all statutorily-required data collected on the system by a practitioner, pharmacist or the Commissioner of Health, unless authorized by law, and imposes new civil penalties for violations. It also provides for immunity for public officers acting in good faith and civil penalties for those persons who knowingly violate privacy provisions in the Public Health Law. It also creates a specific new crime penalizing anyone who accesses the data in violation of the law. To keep users current with system capabilities and proper usage, the bill requires continuing education programs to practitioners, pharmacists and law enforcement.

I-STOP will be fundamentally more effective in reducing the abuse of prescription drugs than the present system. It will arm physicians and pharmacists with the necessary data to protect those who suffer from crippling addictions, while ensuring they can provide prescription pain medications, and other controlled substances, to patients who truly need them.

In addition, I-STOP will render *useless* to the drug addict or drug gang stolen or forged prescription pads. If there's no record in the database to match the paper script, a pharmacist cannot fill the prescription. This is another improvement over the present practices, which doesn't include data from the physician to verify paper prescriptions.

I-STOP also recognizes that not every physician in the state has Internet access, and directs the Commissioner of Health to promulgate rules and regulations to create alternate methods of reporting for those practitioners who do not have access to broadband Internet (described more fully below).

Finally, the I-STOP legislation prohibits the Commissioner from imposing a fee or tax on a practitioner or pharmacist to pay for the system.

Table 1 - Current NYS PMP vs. I-STOP

	Practitioner Reviewing ⁵³	Practitioner Reporting	Pharmacist Reviewing	Pharmacist Reporting
Current PMP	Optional; access to information restricted	None	None	Mandatory reporting of controlled substances at least once every 45 days
I-STOP	Mandated review of patient history prior to prescribing	Report issuing prescription at time of issuance	Access to system and reviewing is mandated	Mandatory reporting of controlled substances as they are dispensed

Benefits of Critical I-STOP Requirements

- Enhanced prevention of “doctor shopping.”

“Doctor shopping” refers to the practice of a drug-seeking “patient” requesting prescriptions from multiple physicians, often simultaneously, without informing the physician they have done so. This practice is usually for the purpose of obtaining medically-unnecessary prescription drugs for use and/or re-sale.

By mandating that doctors report their prescriptions in “real time”, I-STOP enables subsequent doctors to detect that they are issuing a script to a person who has recently obtained one from another source. And while perhaps a second doctor can be duped into giving an abuser a wholly duplicative prescription (a patient can always claim the script was lost), the information is likely to stop the cycle, as a subsequent doctor and a pharmacist will both see the pending prescription and can make responsible inquiries to the original prescriber.

- Enhanced prosecutions and increased deterrence of crooked “drug-dealing” doctors.

Currently it is nearly impossible to prosecute “drug dealing” doctors or crooked doctor cases without extraordinary deployment of traditional law enforcement methods (“Crooked Doctor” is a phrase to describe doctors who do little more than sell prescriptions, rather than treat patients’ health needs). In essence, the practice of crooked doctors intentionally dealing in prescription drugs approaches the “perfect crime,” because everyone involved is covered by the paperwork. The “patient” has the script, issued by a licensed physician, and presents to the pharmacist for dispensing. Furthermore, only the worst cases of a crooked doctor are generally susceptible to prosecutions. This is because the defense of the accused practitioners in such cases is that the “patients” lied about their symptoms and that the defendant doctor was merely duped - the process allows the practitioner to hide behind a façade of plausible deniability. It is a very effective defense, as juries tend not to believe addicts over practitioners.

I-STOP grants the ability to break this criminal chain. By mandating that doctors review a patient’s prescription history — and enabling and requiring both doctors and pharmacists to create a “real time” history of that patient — I-STOP *eliminates* the crooked doctors’ defense.

⁵³ Neither I-STOP nor the current pharmacist reporting system covers the in-house dispensing of drugs in emergency rooms or by practitioners.

A doctor cannot escape conviction by claiming to have been lied to by an addict when the patients' accurate and real time history is accessible, and the doctor is required to check it.

- Prevention of dealers and addicts from using stolen or forged prescriptions to obtain drugs.

The pass-key to a prescription drug in our society is the prescription itself, which is presumptively valid when presented to a pharmacist. This is particularly true in New York State, under the current Official NYS Prescription process, by which it constitutes what is essentially the legal "currency," upon which the prescription transaction system is based. As seen above, one of the most destructive ways around any controls over the obtaining of prescription drugs is when addicts and dealers steal prescription pads or forge prescriptions or — more likely — re-write the numbers on the prescriptions to increase the amount of drugs dispensed.

Last spring, Newsday reported on a BNE internal memo revealing as many as 1.4 million scripts had been stolen since 2008 from several New York City hospitals.

"That much paper getting out into the community... it's akin to letting the most virulent virus you can find loose in New York State and not telling anyone."

***Jeff Reynolds, LI Council
on Alcoholism and Drug
Dependence***

By mandating that practitioners create an electronic record of the issuance of a prescription *and* that pharmacists check to see if the prescription handed to them matches that record, I-STOP will make it nearly impossible for forgers or those with stolen pads to use those scripts to obtain drugs.

- Enhanced communication, early prescription drug abuse detection and prevention.

We should not think of I-STOP only as a law enforcement tool. I-STOP will also be a *diagnostic* tool. The very same enhanced communication aspect that will increase the ability to detect fraud and doctor shopping will also provide practitioners with the means to confirm a patients' controlled substance history electronically. This will not only enable them to better identify addicts, but will also help them evaluate a patient's prescription drug history as part of determining the proper treatment for that patient.

The same components that make I-STOP an effective law enforcement tool also make it an effective prevention tool. I-STOP will help shift the public policy focus of prescription drug abuse from reaction to its consequences to pro-active prevention.

In addition, I-STOP will be an important back-stop to alerting a practitioner about dangerous mixing of prescription drugs should a patient fail (or be unable) to accurately describe his or her own prescription drug history.

In short, I-STOP's provisions significantly enhance the possibility for early prescription drug abuse detection, and therefore early and less costly intervention. In this regard, I-STOP is a win-win proposition that will save lives and money by shifting the public policy focus of prescription drug abuse and addiction from reaction to its consequences to the proactive prevention of such abuse in the first place.

Table 2 - Benefits of Critical 'I-STOP' Provisions

		I-STOP Provision Necessary to Address Diversion Problem					
		Practitioner Reviewing	Practitioner Reporting	"Real Time" aspect of practitioner reviewing & reporting	Pharmacist Reviewing	Pharmacist Reporting	"Real Time" aspect of pharmacist reviewing & reporting
Prescription Drug Abuse & Diversion Problems	Enhanced prevention of doctor Shopping	☒	☒	☒			
	Enhanced prosecutions & increased deterrence of "drug dealer" doctors	☒	☒	☒		☒	reporting only
	Necessary to prevent dealers and addicts from using stolen prescriptions to obtain drugs		☒	☒	☒		reviewing only
	Necessary to prevent dealers and addicts from using forged prescriptions to obtain drugs		☒	☒	☒		reviewing only
	Helping doctors better judge whether prescriptions are medically necessary	☒	☒	reviewing only	☒	☒	

D. Cost Estimates of the I-STOP Proposal

The question of system cost was determined after consulting with four different sources:

- 1) OAG Tech Staff Analysis: OAG Information Technology Staff performed its own cost estimate of the I-STOP proposal.
(Cost Estimate: \$6.5 million)
- 2) MFCU Tech Staff Analysis: Working separately from their OAG counterparts, the Attorney General's Medicaid Fraud Control Unit performed its own cost estimate of the I-STOP proposal.
(Cost Estimate: \$5 million)

Overall, as described in detail below, OAG has concluded after a detailed review of these sources that I-STOP will require an initial investment of no more than \$10 million.

- 3) OAG Private Vendor Outreach: OAG staff made inquiries of several private vendors that have experience in establishing similar systems in other states. Two vendors responded to this inquiry in time to be incorporated into this report.
(Cost Estimate: \$7.5 million)
- 4) Other State Comparisons: OAG also looked at other states that have implemented real-time reporting for pharmacists (none require such reporting of doctors). California and Oklahoma were the states chosen for these inquiries, because they have both recently initiated real-time, or near real-time pharmacist reporting systems. PMP costs in those states are derived from conversation with respective state officials.
(Cost Estimate: \$350,000)

Overall, as described in detail below, OAG has concluded after a detailed review of these sources that I-STOP should require an initial investment of no more than \$10 million, and that the costs associated of running the I-STOP program do not require any significant amount funds above that the New York currently allocates to run the current PMP program.

1) I-STOP Cost Analysis from OAG Tech Staff

Given the myriad of hardware, software, programming languages, and network infrastructure solutions available there are a large number of possible designs for such a system.

The following outlines *possible design approaches*, each varying in complexity, cost, and usability. Three possible system designs were identified – (1) Basic Web Application, (2) Systems Integrated Web Application, and (3) Provider-Integrated and Provider-Built Application (below). Each application incurs costs in hardware, software and development.

Design Approach #1 - Basic Web Application

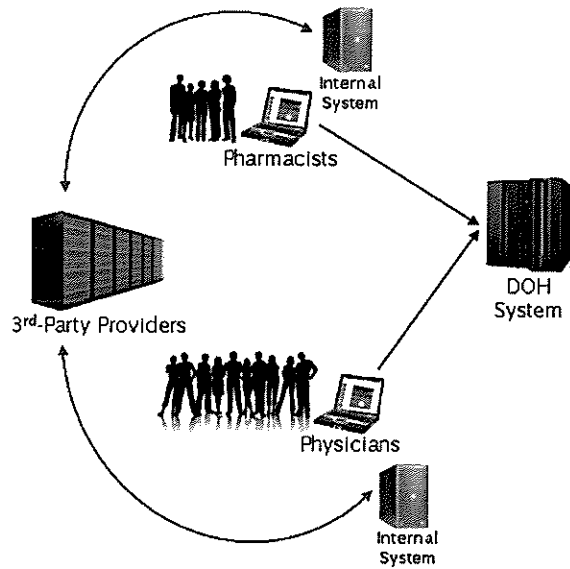
It will essentially be a database-driven, web application to allow physicians and pharmacists to track prescriptions of controlled substances.

It is assumed that physicians and pharmacists already have some access to each other and/or 3rd-party providers, but this design requires no interaction with these disparate systems.

Highlights:

- A basic web application, as it is proposed, would be the most straightforward development effort and potentially the least expensive.
- Essentially, physicians and pharmacists will individually logon, query, and enter information on scripts for patients.
- Since so many individuals (100,000+) will require access - account setup, verification, and maintenance represent a large factor component of the costs.
- Depending on the age of equipment the system may encounter significant numbers of older browser versions without the necessary capabilities required.
- This system would require a database table of drugs to ensure accuracy. The source of this data for importation and updating is unknown.

- This system might require duplicate data entry on the part of physicians and pharmacists since they require access to their regular electronic medical record (EMR) systems and there might be no inherent integration with the I-STOP system.
- Since real-time transactions are a requirement, some form of redundancy and high availability will be required to ensure system availability, increasing the cost of this option significantly.

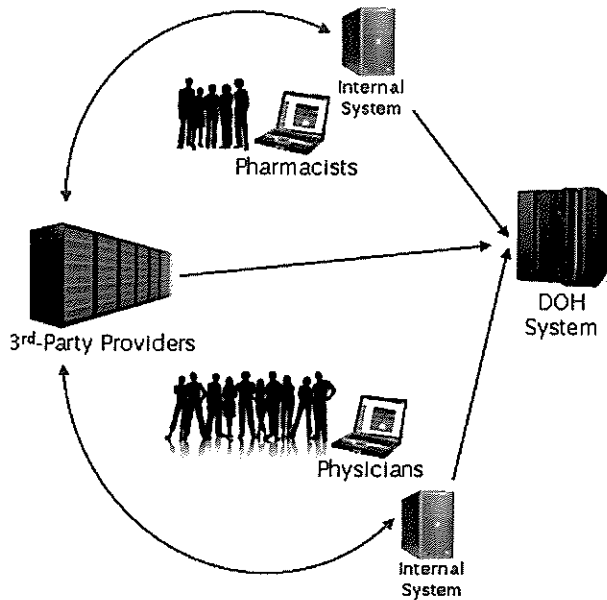


Design Approach #2 - Systems-Integrated Web Application

The basic functionality from the perspective of physicians and pharmacists will be the same, but user authentication and potentially data input could come from their own internal or 3rd-party providers. This design assumes physicians and pharmacists already have some internal and/or 3rd-party provider systems.

Highlights:

- User authentication is off-loaded to their internal or provider systems, significantly decreasing account maintenance. This is referred to as a "federated security model".
- While decreasing individual account maintenance, having to interface with so many external systems increases the application complexity and potentially cost, though some of the burden may be assumed/transferred to those responsible for those external systems.
- By interfacing with their systems, it has the potential to reduce or eliminate redundant data entry.

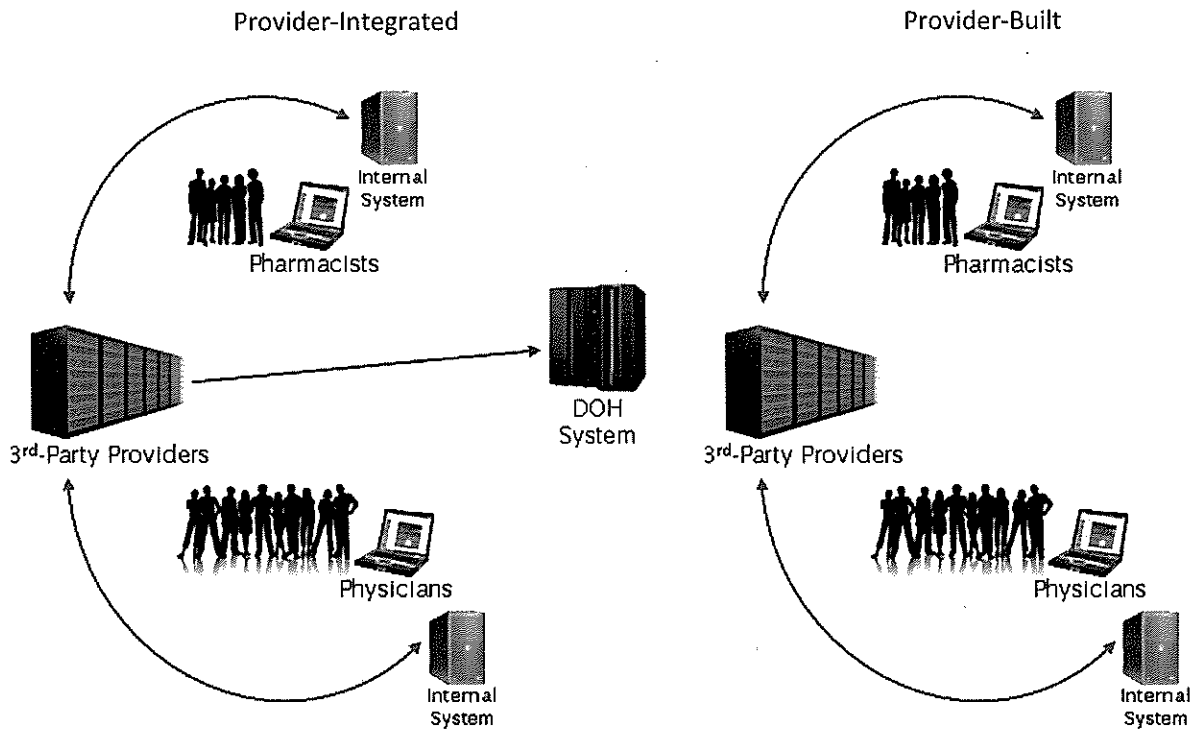


Design Approach #3 - Provider-Integrated and Provider-Built Web Application

If a significantly large number of physicians and pharmacists utilize a small number of 3rd party providers already, then integration with a handful of systems would greatly simplify the system over the previous (Systems-Integrated) design.

Additionally, if these providers are already processing scripts in real-time electronically for physicians and pharmacists now, then by modifying current legislation to allow these provid-

ers to also process controlled substance prescriptions could negate the need for this system altogether.



Basis for Cost Estimations of Each Approach: Cost estimates were developed using available hardware pricing and development costs of initiatives of similar size, though in the case of the Systems-Integrated Design the complexity of integrating with so many disparate systems is a reasonable estimate. In the case of the Provider-Built Design, the costs could conceivably be zero. Research has shown that the company SureScripts already seems to provide the necessary integration and services between physicians and pharmacists and has recently been approved to handle controlled substances.⁵⁴

Any cost estimate must include the following considerations:

- **Hardware:** Estimates will vary depending on the DOH environment and whether high availability (HA) is required, which would seem to be the case here. Hardware HA usually means duplicative servers and storage configured for business continuity (BC) to allow fail-over in the event of a disruption of services. Network load-balancers may be required to distribute network traffic/load across multiple servers as will SSL accelerators used to offload from servers the process of encrypting/decrypting web traffic to/from physicians and pharmacists.
- **Software:** Costs will also vary depending on the database used, the type of application server facilitating the application, sever operating systems, annual maintenance, and so on. There may be

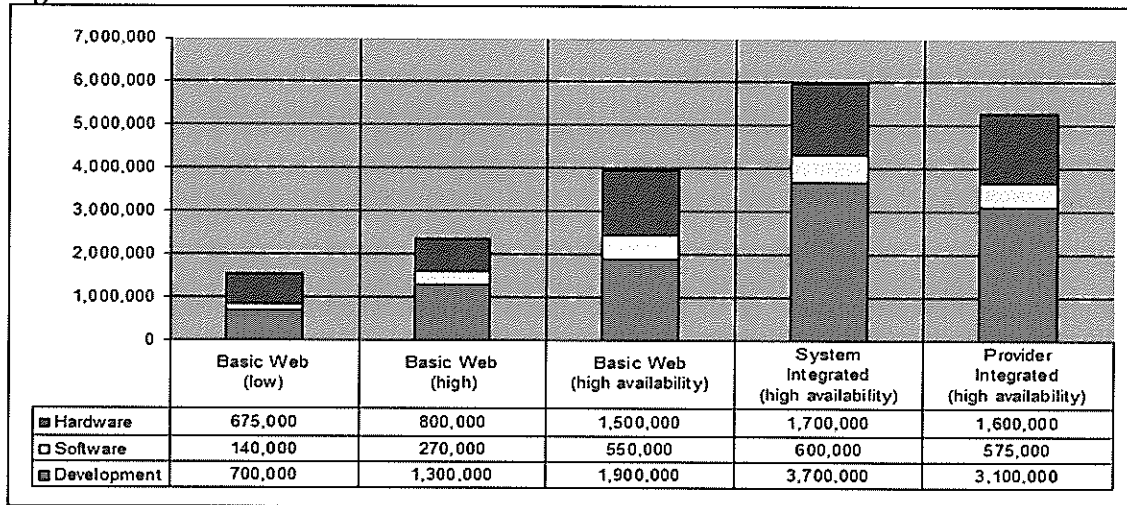
⁵⁴ "Surescripts Announces Network Upgrade for E-Prescribing of Controlled Substances." Press release available at <http://www.surescripts.com/news-and-events/press-releases/2011/september/sept12-eps.aspx>. Staff has consulted with Surescripts representatives, and requested a cost estimate for I-STOP. While Surescripts agreed to provide such an estimate, it was not completed at the time of this writing. The Attorney General will make that estimate available as soon as it is received. At this time, it is unknown whether either of these designs can be implemented without more research.

software components of HA that may be required and if servers are virtualized, then there would be added costs for that software and maintenance.

- *Application Development:* Developing the actual applications are where estimates will vary the greatest and is dependent on the rates of the project managers, business analysts, programmers and the scope/complexity of the project. In addition, it must be determined whether to import historical data, which could add considerable cost to the project.
- *Administrative:* Additionally, there may be costs that are not strictly technical in nature, such as an administrative process to set up, verify, and maintain accounts for physicians and pharmacists (This is not reflected in the costs below, but was reflected in the \$10 million cost estimate of the entire system).

Figure 7 breaks down estimated costs for each of the three applications. In addition, it provides three possible variants of Application I (Basic Web Design): "Low", "High" and "High Availability", with cost estimates or each, in reference to system data storage and availability.

Figure 7



"Low" would be adequate for limited data entry, storage and access – essentially rudimentary patient data entered by both the practitioner and the pharmacist. "High" includes more servers and greater storage capacity. "High Availability" includes redundancies that ensure access for review and reporting at any time.

Development costs are reasonable estimates for staff augmentation through an outside vendor. However, they could increase significantly – even double - if an outside firm were to contract for the complete development solution.

Annual system maintenance can be estimated at 20 percent of initial hardware/software costs. This results in an annual cost range of \$163,000 to \$460,000, depending of the application chosen. Of course, these costs will be offset by the costs currently borne by the State to maintain the current PMP system.

2) I-STOP Cost Analysis from the OAG Medicaid Fraud Control Unit

As with the Attorney General's IT staff, initial estimates arrived at by MFCU IT staff are based on imperfect information, such as current Health Department capabilities. Based upon conversations with DOH, nationally recognized vendors, vendors partners, white papers, and consultants, MFCU IT staff estimate that the initial startup costs for a project of this type for items including hardware, software, licensing, design, development, disaster recovery, should not exceed \$5 million dollar range.

Recurring expenses could range from 10 to 25 percent of the original cost depending on various factors and requirements that have yet to be defined. Staff bases this estimate on a number of factors, some that are readily definable, such as hardware and licensing costs for the required servers, disk storage, and infrastructure improvements, to lesser known (and probably more costly) factors that impact the existing system applications utilized by both prescribers and drug dispensers.

Other considerations could be the costs of owning versus not owning the equipment, or leaving the hosting of the data facility to an experienced private sector identity.⁵⁵ Generally, hardware and equipment would range from 500,000 to 1,500,000 depending on various configurations and requirements.

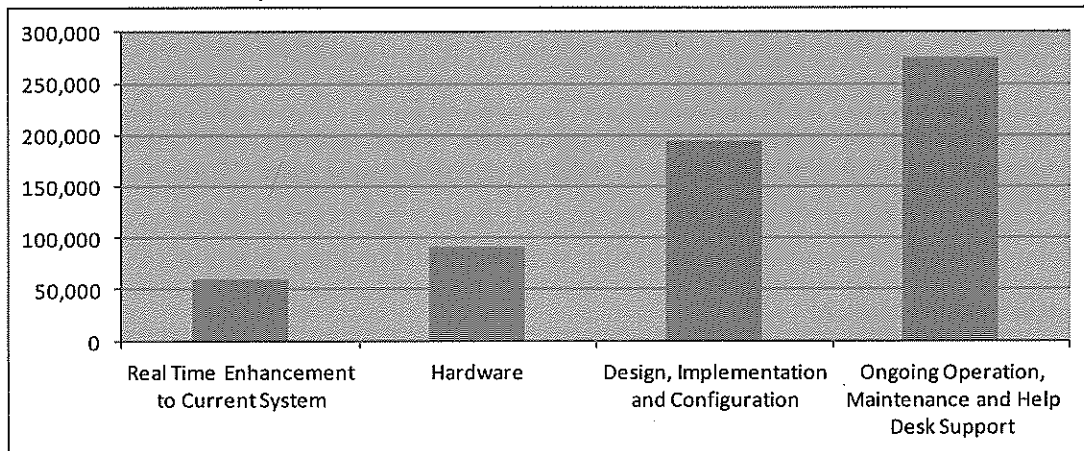
The remaining costs would be associated with the development of software applications or systems to receive, retrieve, manage and integrate existing systems into a new highly performing automated system to facilitate the access, security, input, delivery, reporting, and exchange of data. These costs are probably one and one half to two times the hardware acquisition costs, again subject to any number of factors that could affect development, performance, access, and participation by both prescribers and dispensers.

3) Vendor Estimates

Staff requested I-STOP cost estimates from three different vendors. The first was made of Health Information Designs (HID), which has won PMP competitive bids in 15 states. Estimated pricing from HID included enhancements to the current system to include real-time access for practitioners and pharmacists, design, configuration and implementation of the enhancements over a 6-month time period, and ongoing maintenance and technical help desk operational support (Vendor Estimate Figure 1).

Start-up costs, including the annual operational costs in the first year, would be \$619,300. Annual operational costs thereafter would be \$275,000 – similar to operational costs for both the Oklahoma PMP and California’s CURES (see below).⁵⁶ Of course, these costs will be offset by any such costs currently borne by the State to maintain the current PMP system.

Vendor Estimate Figure 1

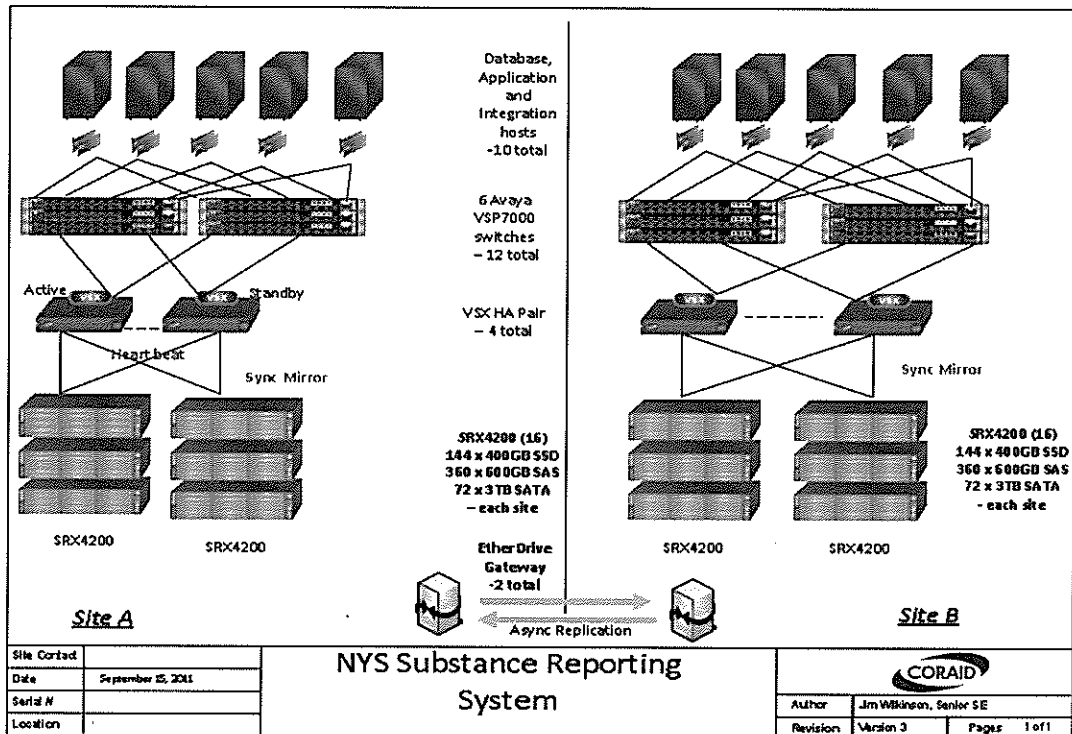


⁵⁵ The variations and complexities that must be considered in all phases of the development of the system cannot be thoroughly reviewed and enumerated without weeks of discussions to fully define the business requirements of the users or the complexities involved in assuring seamless data integration from various existing prescriber and dispensing applications for such a system.

⁵⁶ This estimate was provided in response to a telephone interview with Susan Cotton, HID’s Director of Business Development, with subsequently submitted in writing to OAG staff.

A second request, referred to above, was to Surescripts, which operates the nation's largest health information network, and was not received by the time of this writing. Finally, MFCU IT staff consulted with Coraid, a technology manufacturing company that designs and manufactures a full line of computer data storage products branded under EtherDrive storage. Coraid counts General Electric, Harvard University, Lockheed Martin and the United States Marine Corps among its clients. The company also currently works with the Medicaid Fraud Control Unit. Coraid responded to MFCU's non-formal Request for Information (RFI) with a detailed analysis of cost (Appendix C), given what information staff could make available, and subject to limitations cited above, with a basic conceptual system design (below).

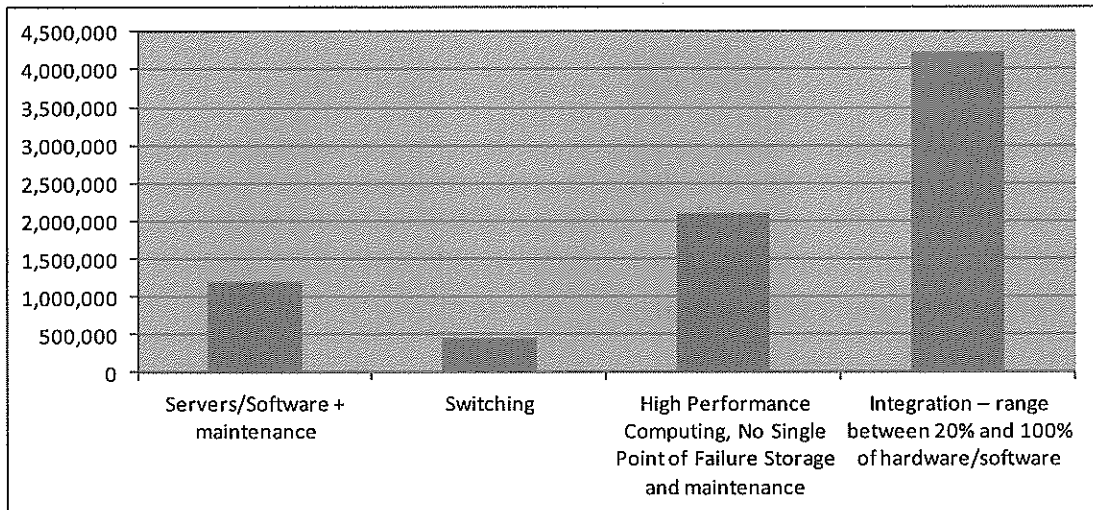
Coraid Conceptual System Design



Initial start-up costs for hardware and software are estimated at \$3,744,773. This cost does not include system integration, by which all components of the system will communicate with each other. This cost is difficult to estimate with current information – on the low end, it could be a relatively small additional cost on top of the start-up cost; on the high end, it could be as much as 100 percent of the start-up cost, or an additional \$3.7 million, though it would be non-recurring. Assuming the lowest-cost for integration is 20 percent of hardware and software costs, and the highest-cost would double hardware and software costs, the start-up scenario runs \$4.5 million to \$7.5 million (Vendor Estimate Figure 2).⁵⁷

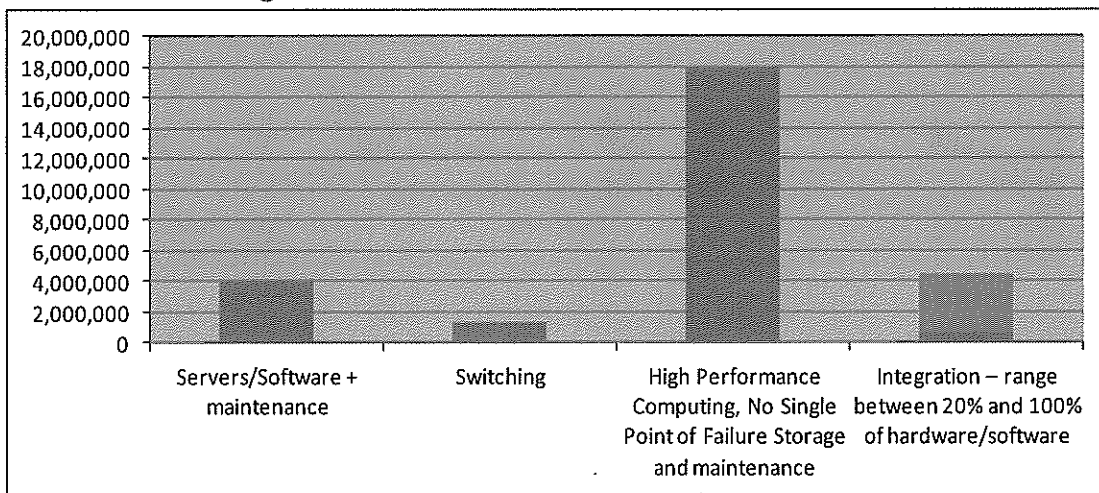
⁵⁷ Full Coraid Estimate is available at the Office of the Attorney General.

Vendor Estimate Figure 2



Over ten years, Coraid estimates total costs of \$23,326,440, not including the cost of integration. Using the same estimate range for integration costs, the total over the next decade ranges from \$24 million to \$27 million (Vendor Estimate Figure 3) with an annualized cost range of \$2.4 million to \$2.7 million. This includes estimates for adjustments made over time, such as data growth, maintenance, and a technology “refresh” after the fourth year.

Vendor Estimate Figure 3



4) Other States

The cost of implementing and operating a PMP varies from state to state. Average cost for implementation is approximately \$350,000, while annual operating costs have been estimated to range from \$100,000 to \$1 million. Many factors contribute to this variation, including: the population of the state, program differences, the number of drugs being monitored, the number of practitioners and pharmacies, the number of staff, and whether the state has enlisted the services of an outside vendor.⁵⁸

⁵⁸ Institute for Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Kentucky. *Review of Prescription Drug Monitoring Programs in the United States*. Kentucky All Schedule Prescription Electronic Reporting Program

OAG Staff made inquiries to two states that have implemented real-time or near-real-time pharmacist reporting, California and Oklahoma.

California: California's PMP was originally established in 1939. The Controlled Substance Utilization Review and Evaluation System (CURES) was automated in 1997 and enhanced again in 2009. According to the System Manager, the initial upgrade in 1997 was done at a cost of \$1 million, which included the purchase of additional servers and consultative services. The 2009 enhancement, which gave physicians access to the data and required real-time reporting of dispensed controlled substances by pharmacists (and physicians and dentists who dispense such substances directly to the patient) currently costs about \$296,000 a year to operate and maintain.⁵⁹

- ***The initial 1997 upgrade for CURES costs approximately \$1 million for additional servers and consultative services.***
- ***CURES currently costs approximately \$296,000 each year to operate and maintain.***
- ***The annual cost for Oklahoma's real-time PMP is about \$300,000.***

Physician enrollment is voluntary, with about 8,000 of the state's 165,000 licensed physicians, and all of the state's 3,600 pharmacists are now participating. The program is gaining in popularity; prior to the 2009 enhancement, it averaged about 65,000 inquiries each year. Since October of 2009, the system has responded to over 1 million inquiries.

Oklahoma: The Oklahoma PMP is housed with the state's Office of the Bureau of Narcotics (OBN), an independent agency with a very small staff. It was created through the Oklahoma Anti-Drug Diversion Act, which requires all dispensers of Schedule II, III, IV, and V controlled substances to submit prescription dispensing information to the OBN within 24 hours of dispensing a scheduled narcotic.⁶⁰ The program requires dispensers (mainly pharmacies) to report electronically every 5 minutes.⁶¹ Although there are no waivers, mail order pharmacies are given up to seven days to report all controlled substance prescriptions after such prescriptions are filled.⁶²

Oklahoma officials do not view compliance as a problem: by this past September, one-third of all pharmacies were already reporting in real time. And while pharmacists are required to report dispensed narcotics to the system, they are not required to review the PMP database prior to dispensing.⁶³

Physicians are not required to report to the system, and consultation of the PMP database, which holds reliable data back to 2006, is on a voluntary basis. Physicians can acquire an account for themselves and a sub-account for staff.

The system provides secure system access to other interested parties, including regulatory and law enforcement agencies, district attorneys and the Attorney General's Office. Other agencies must make an official request for access based on appropriate use (e.g. the Highway Patrol was denied access because it did not make an effective "appropriate use" argument).

(KASPER) Evaluation Team. Report cites GAO 02-634: *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*. GAO, May 2002, available at <http://www.gao.gov/new.items/d02634.pdf>.

⁵⁹ Conversations with John Masoney, Director of CURES, and Kathy Ellis, CURES System Manager. September 8, 2011.

⁶⁰ 63 O.S. Section: 2-309

⁶¹ Beginning on January 1, 2012, all dispensers must report the dispensing of scheduled narcotics within 5 minutes of being delivered to the customer. See the Oklahoma PMP website at http://www.ok.gov/obn/dd/Prescription_Monitoring_Program/

⁶² This exception was a last-minute amendment to the legislation as it worked its way through the State Legislature.

⁶³ OAG staff contacted Don Vogt, Director of the Oklahoma PMP, on September 8, 2011. Information otherwise unattributed regarding the Oklahoma program derives from that conversation.

Oklahoma has 15,000 practitioners, of which OBN estimates only 50 percent write more than 10 scripts per month for controlled substances. 60 percent of those who do write 10 or more scripts per month have already applied for access. They are generally excited about the program, as indicated by the number of physician queries, which had increased this year from 30,000 to 45,000 per month.

Oklahoma's approximate \$300,000 cost is financed through a biannual licensing fee on practitioners.

E. Consideration of NYS Practitioners without Internet Access

Some practitioners in New York do not access the Internet either because (a) they are among the few that work in an area of the state without broadband access,⁶⁴ or because (b) they have decided that such access is not necessary for their practice. The Attorney General's legislation addresses the problem by explicitly giving the Department of Health the ability to provide waivers from the system and to designate other means — presumably by fax or telephone — that certain practitioners may access and utilize I-STOP. The Department of Health could also potentially allow practitioners to opt-out of the system if they do not wish to prescribe schedule II-V controlled substances, or if they only rarely prescribe a very small number of such substances.

⁶⁴ Two reasonable estimates can be made as to the number of practitioners who cannot obtain broadband Internet access by virtue of their location in the state. These estimates can be obtained by using NYS Department of Education (SED) data of licensed practitioners in the state or by using data from the Broadband Mapping Project. By the former approach, 94.5 percent of all NY licensed physicians are in counties that are close to 100 percent covered by broadband access. This estimate in all probability is low, because it eliminates the entire practitioner population of the state's most rural 35 counties (Appendix A – Licensed Physicians in New York State). Under the Broadband Mapping Project, the New York State Office of Cyber Security (OCS) estimates that broadband access reaches 99 percent of the state's population, in one form or another. In a population of nearly 20 million, this means that almost 200,000 New Yorkers do not have such access, and that population is geographically dispersed in pockets throughout the state. Data available at <http://www.broadbandmap.ny.gov/content/compare-areas.html>.

Appendix A: Practitioners in New York State

Licensed Physicians in New York State⁶⁵

County	Number		County	Number		County	Number	
	Full	3-yr		Full	3-yr		Full	3-yr
Albany	1,501	6	Jefferson	211	14	Saratoga	448	3
Allegany	38	0	Kings	4,852	82	Schenectady	418	3
Bronx	1,833	61	Lewis	28	0	Schoharie	19	0
Broome	593	4	Livingston	71	0	Schuyler	25	0
Cattaraugus	104	5	Madison	103	0	Seneca	15	0
Cayuga	101	0	Monroe	2,943	51	Steuben	173	3
Chautauqua	170	9	Montgomery	78	1	St. Lawrence	163	8
Chemung	260	3	Nassau	8,500	16	Suffolk	4,868	6
Chenango	65	0	New York	16,505	187	Sullivan	90	5
Clinton	208	0	Niagara	268	3	Tioga	42	0
Columbia	122	0	Oneida	539	7	Tompkins	239	4
Cortland	64	0	Onondaga	1,741	36	Ulster	328	1
Delaware	38	0	Ontario	281	0	Warren	254	1
Dutchess	869	1	Orange	866	15	Washington	36	0
Erie	2,909	79	Orleans	30	0	Wayne	79	0
Essex	38	1	Oswego	95	3	Westchester	6,204	53
Franklin	101	2	Otsego	302	1	Wyoming	36	0
Fulton	67	1	Putnam	246	0	Yates	29	0
Genesee	68	0	Queens	4,614	58	NYS TOTAL	67,920	754
Greene	46	0	Rensselaer	291	1	OTHER US	17,089	118
Hamilton	2	0	Richmond	1,410	18	NON-US	253	15
Herkimer	46	0	Rockland	1,239	2	TOTAL	85,262	887

⁶⁵ <http://www.op.nysed.gov/prof/med/medcounts.htm>

Licensed Physician Assistants in New York State

County	Number	County	Number	County	Number
Albany	174	Jefferson	60	Saratoga	139
Allegany	16	Kings	833	Schenectady	83
Bronx	217	Lewis	4	Schoharie	7
Broome	73	Livingston	28	Schuyler	4
Cattaraugus	23	Madison	36	Seneca	7
Cayuga	13	Monroe	461	Steuben	29
Chautauqua	39	Montgomery	16	St. Lawrence	39
Chemung	32	Nassau	1097	Suffolk	894
Chenango	15	New York	540	Sullivan	16
Clinton	31	Niagara	58	Tioga	16
Columbia	35	Oneida	69	Tompkins	29
Cortland	15	Onondaga	287	Ulster	59
Delaware	13	Ontario	57	Warren	70
Dutchess	121	Orange	107	Washington	17
Erie	501	Orleans	3	Wayne	36
Essex	29	Oswego	23	Westchester	349
Franklin	21	Otsego	55	Wyoming	15
Fulton	19	Putnam	37	Yates	4
Genesee	18	Queens	938	NYS TOTAL	8,496
Greene	15	Rensselaer	69	OTHER US	1,702
Hamilton	4	Richmond	339	NON-US	12
Herkimer	18	Rockland	124	TOTAL	10,210

Appendix B

New York

Summary of State Spending on Substance Abuse and Addiction (2005)

	State Spend- ing by Cate- gory (\$000)	Spending Related to Substance Abuse			
		Amount (\$000)	%	% of State Budget	Per Capita
Burden Spending		13,131,778.1		21.1	680.2
Justice	3,759,218.1	3,102,669.0		5.0	160.7
Adult Corrections	2,770,658.0	2,284,269.2	82.0		
Juvenile Justice	245,338.7	198,867.8	81.1		
Judiciary	743,221.4	619,532.1	83.4		
Education (Elementary/Secondary)	16,547,015.0	2,155,491.1	13.0	3.5	111.7
Health	19,057,416.8	5,581,196.0	29.3	9.0	289.1
Child/Family Assistance	2,382,629.1	897,594.5		1.4	46.5
Child Welfare	880,150.5	667,824.4	75.9		
Income Assistance	1,502,478.6	229,770.2	15.3		
Mental Health/Developmental Disabilities	3,336,415.9	1,247,211.8		2.0	64.6
Mental Health	1,891,654.7	1,102,607.8	58.3		
Developmental Disabilities	1,444,761.2	144,604.0	10.0		
Public Safety	484,778.0	94,166.1	9.4	0.2	4.9
State Workforce	13,231,000.0	53,449.4	0.4	0.1	2.8
Regulation/Compliance	21,720.0	21,720.0	100.0		1.1
Licensing and Control	14,720.0	14,720.0			
Collection of Taxes	7,000.0	7,000.0			
Prevention, Treatment and Research	287,641.0	287,641.0	100.0	0.5	14.9
Prevention	49,577.0	49,577.0			
Treatment	283,063.9	283,063.9			
Research	N/A	N/A			
Total		13,441,139.0		21.6	692.6

Appendix C

Editorials and Op-eds

Upgrade tracking of prescriptions

Newsday

July 12, 2011

The point of having classifications of controlled substances in the United States is controlling them. That must be done better with opiates like the ones David Laffer allegedly stole during a robbery and multiple murders in a pharmacy last month.

Prescription drug abuse is on the rise, leading to more pharmacy robberies, and the main substances involved are oxycodone and hydrocodone. These drugs are necessary for many people. They're being prescribed more and more, and this may in some cases reflect physicians who seem unaware how easy it is to become addicted, and need to be more careful with their pads. It is also, though, just the reality of an aging population that requires more pain management.

Prescription medication dispensing needs to be tightly overseen. A recent bill proposed by New York Attorney General Eric Schneiderman would establish a database to enable pharmacies to see when customers are getting drugs from multiple locations, or prescribed by multiple doctors, and whether prescriptions that patients bring in have been legally issued. This would help considerably.

And the federal government needs to crack down on Internet pharmacies that are selling these drugs with or without prescriptions.

But just as important may be increasing the awareness of parents and grandparents that for some kids, the medicine cabinet has become the new liquor cabinet, and they're sampling.

Attorney general: Program would reduce prescription drug abuse, get addicts much-needed help

The Journal News

July 10, 2011

By Eric T. Schneiderman

Drug abuse is not typically associated with pharmacies, doctors' offices or the home medicine cabinet. But the fact is, New York has a dangerous and growing prescription drug problem that has redefined our sense of addiction, rightly demanding the attention of our communities and law enforcement officials.

The numbers indicate nothing short of an epidemic. Between 2007 and 2010, the rates of admission to treatment programs for prescription drug abuse increased by 45 percent. At the same time, more prescriptions were filled - in Westchester County, the number of oxycodone prescriptions grew by 31 percent from 2008 to 2010, while zolpidem (Ambien[Oxae]) grew by 25 percent.

The data reflect national trends showing prescription drug abuse as the country's second most prevalent illegal drug problem. Ending it will require us to stop prescription drugs from falling into the wrong hands.

In response, I have proposed new legislation called the "Internet System for Tracking Over-Prescribing Act," or "I-STOP," a program which connects doctors and pharmacists to a real time, online database to track the prescription and dispensing of frequently abused drugs.

We know that most prescription drug addicts and dealers rely on licensed doctors and pharmacists to

access substances like oxycodone, Vicodin and Xanax. I-STOP provides our medical professionals with the information they need to prescribe medications to patients who truly need them, and prevent those same substances from falling into the wrong hands.

Doctors and pharmacists who act in good faith will have better tools to treat their patients. If a patient complains of severe pain and asks for a prescription, the provider will immediately be able to see if that same patient already has multiple outstanding prescriptions for painkillers. In that case, the doctor could not only decline to write a new prescription, but also have a conversation with their patient about whether they are at risk for drug abuse, and recommend treatment options.

If a doctor or pharmacist sees a disturbing pattern in prescriptions that have been written or filled by other providers they could also report their concerns to state health authorities.

For the small number of bad actors who fuel prescription drug abuse by selling drugs to anyone who asks for them, or simply turning a blind eye to obvious signs of abuse, this law will give them fewer places to hide. In the past, unscrupulous providers could hide behind their patients by claiming that a patient didn't report their history. Under I-STOP, providers will be required to check the patient's prescription history, so they won't be able to plead ignorance if they willfully overlook evidence of abuse.

I-STOP would be a vast improvement over the present system. Current practice requires pharmacies to report sales of controlled substances, but only several weeks after the event and not in coordination with the doctors who make the prescriptions. A recent change allows doctors to check the data, but they are not required to, allowing addicts and dealers to slip through the cracks.

I-STOP will also invalidate the use of stolen prescription pads because if there's no record in the database to match the paper script, a pharmacist will not be able to fill the prescription. This is another improvement over the present practices, which doesn't include data from the physician to verify paper prescriptions.

We want doctors and pharmacists to be able to provide prescription pain medications and other controlled substances, to patients who truly need them. To do so, they must be armed with the necessary data so that we can protect those who suffer from crippling addictions. The time to act is now; we can't afford to lose another life.

The writer is the Attorney General of New York.

Track the abusers; State database would help in struggle against illicit use of prescription drugs

Buffalo News

July 2, 2011

Attorney General Eric T. Schneiderman has stepped up to bring the authority of the state into the burgeoning social-medical-criminal crisis of prescription drug abuse. The new attorney general, responding in part to a Buffalo News series on the problem, "Rx for Danger," is proposing a tracking system that he believes could be a model for the rest of the nation. The nation needs it, as does Western New York.

The problem is urgent and hasn't received the attention it demands. As reported in The News series in March, more people die in Erie County from using prescription opiates than cocaine and heroin combined. Nationally, accidental drug deaths involving prescription opioids more than tripled from 4,000 in 1999 to 13,800 in 2006. The causes range from inadvertent addictions to doctors providing drugs to dealers for money.

The series found that addicts and dealers often get the drugs from friends and family members, but also steal them from pharmacies or persuade doctors to write prescriptions for which the patients have no medical need.

The Schneiderman bill would provide doctors and pharmacists with real-time information to avert

overprescribing and doctor-shopping by patients. The measure would require health care professionals and pharmacists to report to the state when certain controlled substances are prescribed and dispensed.

It's a common-sense measure that treats the problem on the front end, by helping to prevent crimes from being committed and addictions from being created or nourished. More may be needed on the back end to punish and, thus, to deter doctors and patients from gaming the system, but Schneiderman's bill fills a critical need.

This is, by and large, an issue for the states, and Schneiderman's bill would put New York in the forefront in seeking strategies to cope with a new and difficult problem. Albany should take it up as promptly as it can.

That's not to say Washington plays no role in combating this problem. Sen. Charles E. Schumer, D-N.Y., has announced that he is co-sponsoring legislation that would require doctors to receive specialized training before prescribing opioid narcotics. The goal of that legislation is to help doctors better identify patients vulnerable to addiction. In addition, Washington can function as a funding source and clearing house for states seeking to deal with this problem.

Addiction is fierce. It resists taming as it ruins lives, families, friendships and careers. It takes a toll on the economy. This expanding problem must be confronted quickly and firmly, punishing those who abuse the system and helping those who are in the deadly grip of addiction.

HEADS UP: Control drugs, prevent suicides

Newsday

June 17, 2011

A disturbing study released on Thursday by the federal Substance Abuse and Mental Health Services Administration finds drug-related suicide attempts by men ages 21 to 34 increased 55 percent from 2005 to 2009. This rapid rate of growth calls for an urgent response. New York Attorney General Eric Schneiderman has introduced a bill to allow doctors and pharmacists to monitor drug prescriptions in real time. Should this become law, doctors will be able to avoid prescribing drugs to patients who have already been given the medication. The federal study cited prescription drugs as part of the problem, and in the fight against drug-related suicide, restricting access is the most important step. Though a new prescription-drug law would be a key step in preventing suicides, it is the first of many that are needed. This is a crisis that needs a response.

Appendix D

Definition of Controlled Substance Schedules⁶⁶

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations, 21 C.F.R. Sections 1308.11 through 1308.15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Some examples of controlled substances in each schedule are outlined below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use.

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Some examples of substances listed in schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("ecstasy").

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

⁶⁶ Reproduced from U.S. Department of Justice, Drug Enforcement Administration. Available at <http://www.deadiversion.usdoj.gov/schedules/index.html#define>

Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction.

Examples of schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in schedule III.

An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®).

Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®).

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I represent: _____

Address: _____

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Address: 1216 5th Avenue