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Opioid Abuse & Diversion of Controlled Substances - Grand Jury Report, CPL 190.85(1)(C)

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SUFFOLK COUNTY SUPREME COURT SPECIAL GRAND JURY

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GRAND JURY REPORT, CPL 190.85(1)(C)

PRELIMINARY STATEMENT

The Suffolk County Supreme Court Special Grand Jury, Term 1E, was empanelled on January 4, 2012 by order of the Honorable James C. Hudson to complete an investigation into the diversion and dissemination of controlled substances and issues related thereto.

The Grand Jury heard testimony from 38 witnesses and considered 123 exhibits, many of which consisted of multiple pages.

As a result of this investigation, the following report has been adopted pursuant to New York State Criminal Procedure Law 190.85(1)(c), and is respectfully submitted to the Court.

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FINDINGS OF FACT

I. Introduction

On Father's Day, June 19, 2011, four people were brutally murdered during the armed robbery of a pharmacy in Suffolk County, New York. David Laffer, and his wife, Melinda Brady-Laffer, who were prescription-pill abusers desperately seeking a supply of opioid pain medication, planned a robbery of the Haven Pharmacy in Medford, New York.[1] The callous murders of four unarmed, unsuspecting customers and employees occurred during the commission of this robbery when David Laffer summarily executed them.

Over the past ten years, Suffolk County has experienced a 413% increase in arrests for Driving While Intoxicated where the intoxicant was a prescription controlled substance.[2] (Grand Jury Exhibit 98) In 2011 alone, these arrests accounted for 48% of all Driving While Intoxicated charges.[3] In the same time period, arrests for the sale of controlled substances involving prescription drugs increased 878%. (Grand Jury Exhibit 99) Burglary, robbery, and vehicular crimes involving death or serious physical injury have also risen dramatically during this period.

Against this backdrop are alarming statistics concerning the availability and use of prescription controlled substances, including opioids. The United States accounts for approximately 4.6% of the world's population but consumes 80% of the global opioid supply

[1] Pain medications are generally classified as opiates or opioids. Opiates are derived and manufactured from opium which is the sap from the poppy plant; opioids are manufactured by synthesizing chemicals. Pharmacologically, they have similar effects. For reference, the term "opioid" is used in this report to encompass both opiates and opioid pain medications.

[2] Controlled substances are defined in Article 220 of the New York State Penal Law and Article 33 of the New York State Public Health Law. They are substances whose possession and use are controlled or regulated by law and are listed in Schedules I through V.

[3] The Vehicle & Traffic Law section is technically entitled Driving While Ability Impaired by Drugs, §1192.4

and 99% of its hydrocodone supply.[4] According to the Centers for Disease Control and Prevention (CDC), in 2006, there were over 27,000 unintentional drug overdose deaths in the United States, a rate of approximately 9 for every 100,000 Americans. Approximately 12,000 of those deaths were from the use of opioid analgesics or pain medications. (Grand Jury Exhibit 6) Shockingly, Americans are six times as likely to die from a prescription drug overdose as from a heroin overdose, and twice as likely as from a cocaine overdose. In 2011 in Suffolk County alone, there were 231 overdose deaths from controlled substances. Of those, 174 were from opioid analgesics. (Grand Jury Exhibit 90) In the United States, between 1997 and 2007, sales of hydrocodone increased 280% while sales of oxycodone increased 866%.[5] The United States Department of Justice Drug Enforcement Administration (DEA) reports that between 1996 and 2006, the New York State consumption of hydrocodone increased from approximately 2,000 mgs. per person to 12,000 milligrams per person; oxycodone consumption increased from approximately 1,000 mgs. per person to 16,000 milligrams per person;[6] at the same time, statistics from the Substance Abuse and Mental Health Services Administration (SAMHSA), reveal that treatment admissions for opioid analgesic abuse have risen both nationally and in New York State at rates of greater than 300%. (Grand Jury Exhibit 6) A graphic from the National Vital Statistics System and DEA demonstrates that prescription pain medication sales, overdose deaths, and substance abuse treatment admissions have risen on parallel courses from 1999 through 2010. (Grand

[4] Grand Jury Exhibit 103A – Pain Physician Journal, Effectiveness of Long-Term Opioid Therapy for Chronic Non-Cancer Pain E134, 2011. Hydrocodone is an opioid pain mediation and is a Schedule III controlled substance.
[5] Grand Jury Exhibit 103A – Pain Physician Journal, Effectiveness of Long-Term Opioid Therapy for Chronic Non-Cancer Pain E134, 2011. Oxycodone is an opioid pain medication Schedule II controlled substance. It is a higher Schedule than hydrocodone because it is deemed by the DEA to have a higher risk of addiction . It is twice as potent as morphine – Grand Jury Exhibit 7 at 29.
[6] Mgs. is an abbreviation for the dosing measurement used in prescribing pain medications. It refers to milligrams. Each milligram is 1,000th of an ounce; hence, since there are approximately 28.35 grams to an ounce, there are 28,350 milligrams per ounce.

Jury Exhibit 6) Some controlled substances may be legally manufactured, marketed and prescribed. Hence, it is an inescapable conclusion that their resulting availability, diversion for illegal use, and alarming impact on the community, arose inevitably from a series of avoidable circumstances; these included a disregard for the addiction potential of these substances due to the profit motive of manufacturers and prescribers that, in some instances, led to the intentional misleading of an unsuspecting public. As such, it is incumbent that strong and swift measures must be taken to correct the current system of production and distribution, to enforce and enhance existing legal requirements, and better educate providers and consumers of these dangerous and addictive substances.

A. Background

Pursuant to the Federal Food, Drug, and Cosmetic Act, controlled substances are initially authorized for manufacture, marketing and distribution by the United States Food and Drug Administration (FDA). The FDA must approve the use and labeling of controlled substances. The term "on-label" refers to the use of a substance for the labeled purpose as authorized by the FDA based upon its determination of intended use, safety and efficacy; "off-label" refers to a permissible although unapproved use. (Grand Jury Exhibit 7)[7] The Drug Enforcement Administration (DEA) then regulates their manufacture and distribution within the enforcement structure of the Controlled Substances Act. (Grand Jury Exhibit 118)[8] Included in this is the classification of controlled substances which places them in one of five Schedules based upon medicinal value and potential for abuse. States may adopt the DEA Schedules or create their own more restrictive classifications. Prescribers must obtain a

[7] United States General Accounting Office Report, *Prescription Drugs*, December (2003) 11. "Efficacy" is determined after clinical trials lasting 12 weeks.
[8] The Controlled Substances Act of 1970 succeeded the Harrison Narcotics Tax Act of 1914.

specific license number from DEA to issue prescriptions for controlled substances.[9] However, with few exceptions, no specialized training or certification is required to obtain such a license.[10] Although physicians and other prescribers must appropriately treat pain, they are forbidden by law to prescribe opioids merely to maintain the comfort level of an addict. In New York, for example, prescribers may not issue a prescription:

> "…to an addict or habitual user of controlled substances…for the purpose of providing the user with narcotics or other controlled substances sufficient to keep him comfortable by maintaining his customary use…." (Grand Jury Exhibit 35A)[11]

A similar proscription exists under federal law. (Grand Jury Exhibits 84 and 118)[12] States also have the responsibility to license and discipline prescribers and dispensers of controlled substances. In New York, the licensing agency is the Department of Education. Discipline of physicians, physician assistants and special assistants is regulated by the Department of Health's Office of Professional Medical Conduct; all other prescribers are disciplined by the Department of Education's Office of the Disciplines.[13]

B. Scheduling of Controlled Substances

Schedule I controlled substances are classified as patently illegal, have no accepted medicinal value and have the highest potential for abuse. Examples are heroin, lysergic acid diethylamide (LSD) and marijuana. Schedule II substances have medicinal value, may be legally prescribed but have essentially the same high level of abuse potential as Schedule I substances. Prescriptions for Schedule II substances may not have refills. Oxycodone is an

[9] 21 USC 800 et seq; and 21 CFR 1306.03
[10] A special DEA license is required to prescribe controlled substances for the treatment of drug abuse, and requires certain training or medical background.
[11] Part 80: New York State Rules and Regulations on Controlled Substances §80.65
[12] 21 CFR 1306.07 and 21 USC 800 et seq. referred to as the Controlled Substances Act
[13] The other prescribers in New York are Nurse Practitioners, Doctors of Osteopathy, Dentists as DDS or DMD, Optometrists, Podiatrists, and Veterinarians.

example of a Schedule II substance. Schedule III substances also have medicinal value, may be legally prescribed but are deemed to have a lower abuse potential. Refills may be authorized for these substances. Schedule III opioids are combination drugs; hydrocodone, a commonly prescribed opioid for example, is combined with acetaminophen.[14] All opioids in Schedules I, II or III, are for all intents the same. Schedule II and III opioids, because they may be legally prescribed for pain relief, are referred to as opioid analgesics or pain relievers. However, because it has no legal or medicinal value, the illegal opiate derivative, heroin, is not referred to as an analgesic or legitimate pain reliever. Pharmacologically heroin and oxycodone, a Schedule II drug, have similar addiction potentials. (Grand Jury Exhibit 7).[15] Schedules IV and V, contain the remaining controlled substances such as the benzodiazepines.[16]

C. History of Opioid Analgesics

Opioids have been utilized to treat pain for thousands of years and are some of the most commonly prescribed pain medications. (Grand Jury Exhibit 146) In fact, in the early 1900's, heroin was commercially manufactured and marketed for multiple medicinal purposes, and was touted as a safer treatment alternative to existing morphine treatments. Unfortunately, heroin was quickly diverted to non-medicinal usage with the result that the United States experienced its first heroin epidemic. Medical heroin was ultimately removed from the market. In 1970, the Controlled Substances Act was signed into law, the regulation

[14] Acetaminophen is commonly referred to by its brand name, Tylenol. The combination of hydrocodone and acetaminophen is commonly referred to by its brand name, Vicodin.
[15] United States General Accounting Office Report, *Prescription Drugs*, December (2003) 2
[16] Benzodiazepines include sedatives and sleep medications.

of controlled substances was modernized, and the Schedules were enacted. During the 1970's, heroin abuse surged then waned until recently.

Opioid analgesics continued to be available and prescribed for pain relief throughout the twentieth century. Their use remained relatively stable until the latter part of the 1990s. The number of prescriptions for opioids, and thus their availability, drastically increased beginning in 1996 and was the ineluctable result of a series of circumstances. (Grand Jury Exhibit 6) In particular, a change in medical practice converged with developments in the pharmaceutical manufacturing of opioid pain medications causing what the Centers for Disease Control and Prevention (CDC) now describes as an epidemic of opioid addiction. The results of this epidemic have led to the community tragedies described herein.

D. The Evolution of Pain Management

Beginning in 1986, medical pain management and treatment entered a new phase. (Grand Jury Exhibit 7) The United States General Accounting Office Report of 2003 reveals that in 1986 the World Health Organization encouraged physicians to treat cancer patients with opioids for pain.[17] In 1995, national medical advocacy groups expanded this position. Funding for some of these organizations included donations by pharmaceutical manufacturers. (Grand Jury Exhibit 9)[18] The result was a recommendation that pain be considered by medical practitioners the fifth vital sign, joining pulse, blood pressure, core temperature and respiration. Pain was no longer considered a symptom but rather a condition requiring treatment. Consequently, opioids were recommended for treatment of both cancer and noncancer related pain. In 2001, pain standards were instituted by the Joint

[17] United States General Accounting Office Report 7-8
[18] American Pain Foundation 2010 Annual Report

Commission on Accreditation of Healthcare Organizations (JCHAO) "to ensure that patients received appropriate pain treatment." (Grand Jury Exhibit 7)[19] Whereas pain management had been previously focused on the treatment of both acute short-term pain and palliative end of life cancer pain, the horizon was expanded to include chronic noncancer pain. The latter is described in the Code of Federal Regulations as *intractable pain* "…in which no relief or cure is possible or none has been found after reasonable efforts."[20] Despite the availability of objective tests to evaluate medical conditions, injuries and ailments, pain alone is subjectively diagnosed by both patient and prescriber. Classified as a vital sign or indicator of health, pain is now also considered a treatable condition in and of itself.

A medical physician and expert in addiction treatment testified before the Grand Jury that, although there were exceptions in the law, prescribers were traditionally cautioned not to prescribe opioids to an addict. Nevertheless, at the same time as trends in the medical profession were expanding the pool of pain management patients, pharmaceutical manufacturers were aggressively marketing opioid products. Indeed, one manufacturer marketed its opioid analgesic product to prescribers based upon a representation that it was less addictive, and less subject to abuse and diversion. (Grand Jury Exhibit 119) The convergence of these factors became the foundation for the rapid increase in opioid use and abuse. Thus was created the epidemic.

The consequences of these events and circumstances were dramatic. The growth in the manufacture and availability of opioid analgesics parallels the increase in their use, leading to an increase in violent crime, and countless personal tragedies involving abuse, addiction, and death.

[19] United States General Accounting Office Report 8
[20] 21 CFR 1306.07

The tremendous growth in the availability of these analgesics also became a prelude in Suffolk County and elsewhere not only to prescription drug addiction but to the resurrection of heroin abuse. Between 2006 and 2010, heroin arrests rose from 486 to 1315, an increase of approximately 170%. (Grand Jury Exhibit 97) Opiate abusers in Suffolk County fell into a vicious cycle of alternating between expensive opioid analgesic pills and the cheaper heroin creating a large overall class of opiate abusers and addicts.

Because opioid analgesics under Schedules II and III are legally manufactured, regulated and prescribed substances, their illegal distribution, possession, delivery, and use is referred to as diversion. (Grand Jury Exhibit 102)[21] Diversion encompasses activities including theft from manufacturers and dispensaries such as pharmacies,

> …"physician shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, prescription forgery…illegal sales of prescription drugs by physicians, patients, or pharmacists, as well as obtaining controlled substances from Internet pharmacies without a valid prescription.[22]

Testimony and statistical evidence presented to the Grand Jury from DEA, the New York State Department of Health, addiction experts, and pain management professionals indicate that **improper prescribing** accounts for a startling 70-80% of the diversion of opioid analgesics; although as noted by one expert, it begins innocently enough with a simple prescription.[23] Alarmingly, the 2008 Report of Office of National Drug Control Policy states that:

> …teens abuse prescription drugs more than any illicit drug except marijuana…and…responsible parents are in a unique position to reduce teen access because the drugs often are found in the home.[24]

[21] New York State Public Health Law §3302.12
[22] United States General Accounting Office Report 2, footnote 4
[23] DEA delineates authorized prescribers in New York to include Medical Doctors; Doctors of Optometry; Doctors of Osteopathy; Dentists, be they DDS or DMD's; Veterinarians; Podiatrists; Nurse Practitioners; and Physician Assistants.
[24] Grand Jury Exhibit 118 at 529

The improper prescribing of analgesic opioids for treatment is reckless; due to the high potential for abuse and addiction, a patient easily becomes addicted. Diversion also occurs when unused portions of prescriptions are stored and subsequently taken by someone for whom they were not prescribed; unused portions are offered to another for recreational use and abuse, or as a misguided attempt to ease another who suffers perceived pain. With each prescription written, the potential for abuse and addiction is present, with an addiction potential that is pharmacologically identical to heroin but without the social stigma attached to its use.[25]

As previously noted, prescribers must obtain DEA authorization to issue prescriptions for controlled substances. However, there is no prerequisite of specialized training, board certification or continuing medical education required as a prerequisite at the federal or state level. Prescribers are authorized to issue prescriptions for analgesics, having the same addiction potential as heroin, without any specialized training or certification. This is unacceptable. The Grand Jury also received evidence from addiction and pain management experts that the use of opioid analgesics for chronic long-term noncancer pain is medically suspect and its efficacy as a treatment tool under those conditions is not established in the scientific and medical community.[26] In fact, there are studies which indicate that patient functioning is not necessarily increased by the use of opioid therapy and may actually decrease it:

> It is argued that physicians should be encouraged to prescribe opioids because they are indispensable for the treatment of pain and suffering, because uncontrolled pain could have deleterious physical effects, and because persistent pain destroys people's autonomy, dignity, and decision making capacity…It is also recognized that opioid therapy, specifically on a long-term basis for chronic pain, is associated with multiple side effects, drug abuse, and

[25] Grand Jury Exhibit 103A - Pain Physician Journal, Effectiveness of Long-Term Opioid Therapy for Chronic Non-Cancer Pain E135, 2011. In addition to abuse and addiction, other possible side effects of opioid use include hormonal and immune system effects; increased disability, medical costs and subsequent surgery; and increased emergency room visits.

[26] Grand Jury Exhibits 48, 103A-109 inclusive

> addiction. In fact, in Denmark, a country that has a free flow of opioids, the results showed worse pain, higher health care utilization, and lower activity levels in opioid patients, compared with a matched cohort of chronic pain patients not using opioids…[**i]n the United States…it has been reported that as many as 90% of [pain management] patients receive opioids for chronic pain management….However, the claims of undertreatment of pain and the campaign for increased availability of opioids and so-called assessment for proper treatment of pain continue** (emphasis added)**.** [27]

Clearly, undertreatment of pain is not the issue. In fact, as attested to by a high ranking official from the New York State Department of Health, there is no shortage of opioid analgesic pill prescriptions written in Suffolk County. In fact, there are 70% more prescriptions for oxycodone in Suffolk than the average for the State of New York overall. The primary issue then is not access to opioid analgesic medications for treatment; rather it is the improper prescribing of these controlled substances leading to diversion, abuse, and death for users and innocents alike.

The Grand Jury heard testimony and received evidence from all available sources for the purpose of including and evaluating every aspect of the issues. This encompassed representatives from manufacturing and distribution; the medical and pharmacy societies; independent medical and scientific experts; the regulatory and law enforcement communities at the federal, state and local levels including those involved in professional discipline; public health officials at the state and local levels; victims of drug-related crimes; and those addicted to the prescription drugs some of whom were criminal defendants.

[27] Grand Jury Exhibit 103A - Pain Physician Journal, Effectiveness of Long-Term Opioid Therapy for Chronic Non-Cancer Pain E134, 2011

II. Public Health & Safety in Suffolk County

"The Most Cold-Blooded Robbery Homicide in Suffolk County History"[28]

On June 19, 2011, the peaceful calm of a Sunday morning was shattered with the senseless killing of four innocent victims inside the Haven Pharmacy in Medford, Suffolk County, New York. Among the victims were employees Raymond A. Ferguson Jr. and Jennifer Mejia; and customers Bryon Sheffield and Jamie Tacetta. The massacre would quickly draw national attention as the investigation developed. Within days, the Suffolk County Police Department identified and arrested the gunman, David Laffer, and his wife, Melinda Brady-Laffer.

The investigation revealed that David Laffer entered the pharmacy that morning armed with a loaded .45 caliber Springfield handgun secreted in a black backpack, intent on robbing the pharmacy of prescription painkillers. Although Raymond Ferguson immediately complied with his demands, Laffer showed no mercy as he fired at Ferguson and Mejia behind the counter, and gunned down Sheffield and Tacetta, shortly thereafter. Waiting outside in their vehicle was Laffer's wife, Melinda Brady-Laffer. They fled, returning to their Medford home, where they remained until they were arrested.

A search warrant subsequently executed at their residence uncovered a total of 1,117 commercially marked tablets. Laboratory analysis revealed these tablets to be consistent with hydrocodone and acetaminophen, a Schedule III controlled substance commonly referred to as Vicodin.

[28] Chief Trial Prosecutor John Collins, describing the crimes committed by David Laffer and Melinda Brady-Laffer on June 19, 2011 before the Honorable James Hudson, September 8, 2011.

Laffer was indicted on five counts of Murder in the First Degree and four counts of Criminal Use of a Firearm in the First Degree. Melinda Brady-Laffer was indicted on one count of Robbery in the First Degree. Both pled guilty to each and every count of their respective indictments. David Laffer will be in prison for life. [29] Melinda Brady-Laffer will serve a sentence of 25 years followed by 5 years of post-release supervision for her role in the robbery.[30]

In the aftermath of those killings, the residents of Suffolk County were awakened to a new and alarming reality. Until then, the prescription pill epidemic had been receiving increased attention from national, state, and local interest groups; it was now vividly in the forefront of the collective consciousness of the County. There were calls to action at all levels of government with pharmacy safety concerns drawing immediate attention. With a deepening understanding of the impact on the community of opioid addiction, public discourse became an outcry for help. And while community leaders rallied to respond, the epidemic continued to prey on innocent victims.

A. The Impact on Public Health: Overdose Deaths and Substance Abuse

According to data compiled by the CDC and the DEA, as per capita sales of opioid analgesics steadily rose between 1997 and 2007, so did their potency and the rate of unintentional overdose deaths involving these substances.[31] In 2007 there were 27,658 unintentional drug overdose deaths in the United States. This number far exceeds the annual overdose figures during the heroin epidemic of the 1970s and the cocaine epidemic of the 1980s

[29] Laffer was sentenced to the maximum penalty available under the law which included four consecutive sentences of life without parole.
[30] The imposed sentence is the maximum permitted under the law.
[31] In New York State, consumption of oxycodone and hydrocodone shows a similarly sharp rise between 1997 and 2006. Grand Jury Exhibit 6

and 1990s. Beginning in 1996, there has been a dramatic and steady rise in the number of unintentional drug overdose deaths nationally, leaping from a rate of 3 per 100,000 persons in 1996, to 9 per 100,000 persons in 2007. This increase is largely attributable to opioid analgesics. In 2007, opioid analgesics accounted for approximately 12,000 overdose deaths, with cocaine accounting for approximately 6,000, and heroin 2,000. (Grand Jury Exhibit 6)

Suffolk County statistics reflect similar patterns.[32] According to the Suffolk County Medical Examiner's Office, there has been a progressive increase in opioid related deaths in the County. Data was provided that reflected two events: the first, overdose victims whose blood tests revealed the presence of an opioid; the second, were victims for whom the opioid appeared in the cause of death. Between 2004 and 2011, this data reveals the following: there was a 30% rise in the number of victims whose blood contained opioids; oxycodone in particular was present in victims at a rate that was 266% higher by 2011.[33] (Grand Jury Exhibit 89)[34] Alprazolam, which abusers often take in conjunction with an opiate, was present in 45 victims in 2004 and rose to 70 by 2011 for an increase of 56%. (Grand Jury Exhibit 91)[35] It should be noted that the age group of these deaths spans the ages of 21 to 60.

For the same time period, Suffolk County has seen a steady increase in overdose deaths wherein opioids have been listed not merely as present in the blood, but as contributing to the cause of death. The statistics report a 69% increase in such deaths. The deaths involving Alprazolam increased a startling 114% increase.[36]

[32] There are approximately 12,000 deaths in Suffolk County every year, approximately only 4,000 -5,000 of these deaths are reported to the ME. If a death is outside a medical center or a death occurs in a hospital that is determined not to be from natural causes then it goes to the ME's office. All unnatural deaths have to be reported to the Medical Examiner.

[33] Total victims with opioids present rose from 277 to 359. Oxycodone numbers rose from 35 to 128. It should be noted that these deaths do not include those involving heroin.

[34] Oxycodone is a Schedule II controlled substance

[35] Alprazolam is a schedule IV controlled substance commonly known as Xanax

[36] Total deaths rose from 103 to 174 for opioids, and from 21 to 45 for Alprazolam.

While recognizing that historical data is highly instructive, the Medical Examiner's Office emphasized that resources must be directed towards identifying trends and fluctuations in data **before** an event reaches epidemic proportions. Localities, including Suffolk County, must take pre-emptive action. Employing the expertise of an epidemiologist in a Medical Examiner's Office to study data as trends and patterns develop, would be highly beneficial.[37] Currently, Suffolk County does not have an epidemiologist on staff.

According to a report published by the Substance Abuse and Mental Health Services Administration, Office of Applied Studies, substance abuse treatment admissions attributable to opioid analgesics rose dramatically, by more than 300% between 1997 and 2007; they rose from approximately 16,000 nationally in 1997 to 75,000 in 2006. A similarly sharp rise is reflected in data for New York State, with a high of more than 6000 such admissions in 2006. Demographically, those seeking treatment for opioid addiction during this period are largely white (non-Hispanic), with males and females affected similarly. (Grand Jury Exhibit 6)

A Senior Probation Officer in Suffolk County testified before the Grand Jury about the exponential growth of opioid-based addiction in the County. (Grand Jury Exhibit 96) He has more than twenty years of experience in the field of substance abuse treatment through the criminal justice system. His testimony offered a snapshot of treatment admissions in Suffolk County illustrating the impact of opioids as compared to other addictive substances. Between 1996 and 2011, heroin use rose steadily accounting for a 425% increase in the number of participants in the Suffolk County Drug Court Program.[38] During this same period, opioid pill use accounted for an startling **1,136%** increase. To compare, cocaine use resulted in a 29% increase during the same period, but declined of 13% between 1996 and 2001.

[37] An epidemiologist studies data to detect trends for use in disease prevention and control.
[38] This judicially monitored program allows misdemeanor and felony defendants meeting, certain criteria, to receive treatment as an alternative to incarceration.

This expert also presented an alarming statistic from the Office of Applied Studies, Substance Abuse and Mental Health Services Administration Treatment Episode Data Set (TEDS) from 2006. Of the 247,000 heroin-driven referrals to treatment that year, only 14% were referred by the criminal justice system, and 59% were self-referred. Similarly, opioid-driven referrals by the criminal justice system were at 16%, with 51% being self-referrals. The expert testified:

> That is amazing to me, because here is a group of people who suffer because of the consistency of this drug…that tells me that although they didn't get into trouble with the law, that they had to get into treatment, that their lives were spiraling out of control.

In essence, this treatment expert is astounded by the number of people with opioid addiction problems apparently leading otherwise law-abiding lives.

B. General Public Health Concerns in Suffolk County

The New York State Bureau of Narcotic Enforcement (BNE) recently analyzed cash prescriptions in Suffolk County according to both patient home addresses and the dispensing or pharmacy locations where they were filled. Cash-only transactions were evaluated because they are an indication of diversion because the patient does not want his insurance provider to track his activities and risk law enforcement attention. An inordinate distance between the patient address and the dispenser address is also considered a red flag for "doctor shopping" and improper prescribing practices. Although alone it may be innocent, when considered in conjunction with cash transactions it is cause for concern. Suffolk County was almost twice the state average in the number of cash prescriptions for oxycodone and the data revealed three

clusters with abnormally high cash prescription opioid rates: Shirley, Patchogue and Rocky Point.[39] Based upon the BNE analysis, this indicates at least red flags for diversion in these areas.

The Suffolk County Commissioner of Health was highly critical of prescribing practices, emphasizing to the Grand Jury that opioids "make people unable to function…the ability to hold a job, to perform manual duties and to be alert is compromised, potentially."[40] The education and training of medical doctors in the 1970s advocated Tylenol and aspirin as the first line of pain relievers. The protocol was to begin treatment with the least toxic and least addictive medication. But the Grand Jury found that gradually opioids have replaced Tylenol and aspirin in common practice.

Because, over time, "chronic pain" has become a commonly accepted diagnosis and condition, prescribers are fearful of malpractice suits and repercussions from professional organizations for under-treating pain; in turn, they have responded by overprescribing to ensure that the patient is satisfied with their treatment. As a result, prescribers are issuing more prescriptions for opioids and in higher doses.

Overprescribing and overuse of opioids are a serious concern for the Suffolk County Commissioner of Health who testified that better education of prescribers is vital. He believes that the training and education of prescribers must start in medical school; as students progress into their specialties and see patients in hospital and clinical settings difficult decisions must be made, and proper education and training in prescribing controlled substances is essential. Post-graduation and once licensed, practitioners must also be required to receive medical training and

[39] The highest level of prescribing in New York is for hydrocodone in Buffalo.
[40] The Suffolk County Commissioner of Health graduated in 1975 from McMaster University and holds MD, MPH, MBA, & MSW degrees. He has been the Commissioner since April 2010. The Suffolk County Department of Health is a branch of the New York State Department of Health. Each County in NYS has a Department of Health.

education in this area so as to be ever cognizant of the proper prescribing and use of controlled substances. This enables practitioners to exercise their best judgment in prescribing.

Suffolk County Commissioner of Health is taking pro-active steps to educate prescribers in the proper use of controlled substance by providing them with a recently revised informational pamphlet (Grand Jury Exhibit 95). This includes information on the prevention of prescription opioid abuse as well as the proper disposal of unused medications.[41]

The Commissioner also supports the mandatory use of the Prescription Drug Monitoring Program (PDMP) database by all prescribers before issuing a prescription for a controlled substance, as well as E-Prescribing. The PDMP and E-Prescribing are discussed at length later in this report.

C. The Medicine Cabinet

People need to take back the responsibility, that yes you are responsible for you own life, your own world, your own house, your own community.

Experts estimate that 70-80% of diversion starts in the medicine cabinet at home.[42] The legal and commercial manufacturing of controlled substances has created a false sense of security in the patient-consumer public; the falsity is that these medications are not as dangerous and subject to addiction and abuse as illicit Schedule I substances such as heroin - however, they are. Consequently, unused portions of medications are frequently offered to others for recreational use and abuse, or as a misguided attempt to ease the perceived pain of another. At other times, teenagers in particular simply take the unused pills from their parents' medicine

[41] Suffolk County Data is being added along with proper disposal tips to be mailed to all prescribers of controlled substances in Suffolk County.
[42] Federal Substance Abuse and Mental Health Services Administration

cabinets for recreational use; the theft is unnoticed since the legitimate use by the parent/patient has ceased.

The unanimous testimony by experts in all fields is that large unused quantities of controlled substances are carelessly stored in unsecured medicine cabinets in patients' homes. Because of their high potential for addiction, however, these drugs must be secured when in use, and then properly disposed of when no longer legitimately needed for treatment. Disposal effectively means turning over the unused portions of prescriptions to DEA, the New York State Police, or the local police department for ultimate destruction. It is also critical to warn patients of the dangers and risks inherent in the use of opioids and controlled substances to make certain they are properly handled. Indeed, the New York State Education Law requires that every patient receiving a controlled substance prescription must be counseled by the pharmacist, or sign a declination. This rule must be enforced.

Towards this end, "Operation Medicine Cabinet" has been instituted in Suffolk County wherein residents may anonymously bring any medication to a local police precinct with no questions asked. The Suffolk County Commissioner of Health believes that having additional avenues of disposal would be beneficial and he supports the expansion of the disposal of unused prescription medications at pharmacies and prescriber offices with all the appropriate regulatory, safety and precautionary measures in place.[43] He emphasizes that "the more places that are appropriate for people to get rid of these medications and any other medications would be valuable." He further notes that "the easier you can make it for the consumer, the more likely it is for it to be used." The Commissioner also recommends that patients be mandated to return the unused portion of opioid medications before being prescribed any additional amount. For example, if an opioid is prescribed but proves ineffective, a new prescription may not be

[43] DEA authorization must be obtained as well.

dispensed unless the unused portion of the initial drug is returned to the dispenser. This prevents stockpiling in the "medicine cabinet," and eliminates a major source of diversion.

The Drug Enforcement Administration (DEA), for example, is having its fourth "take back" program in April 2012 to allow the return of prescription drugs to them.[44] The Pharmacists Society of the State of New York (PSSNY) supports a regulatory change authorizing "take-back" programs at the pharmacy level with appropriate security measures in place.

The Director of the New York State Bureau of Narcotic Enforcement (BNE) echoed sentiments of the Office of National Drug Control Policy in its report that diversion of prescription drugs often begins in "our medicine cabinets." Specifically, he referred to children who take unused medications from the home:

> Getting the drugs out of our home is a big deal. Two out of three times you will be your kids own drug dealer by going to your medicine cabinet to get the drugs.

He referred to a statistic from SAMHSA providing estimates that 70%-80% of diversion is coming from this source.[45] Public education is therefore vital. Simply stated, these controlled substances should not be in the family medicine cabinet. Keeping prescription drugs out of medicine cabinets requires prescribers to understand and employ proper pain management. As the Director commented, thirty-day supplies of opioids for root canals are unnecessary. To better educate physicians, BNE recommends mandatory continuing medical education concerning the

[44] The DEA has hosted take-back programs which have yielded 978,000 pounds of all prescription pills, including controlled substances. To put this in perspective, there are approximately 25 capsules/tablets per ounce amounting then to a take-back of almost 400,000,000 pills.
[45] Federal Substance Abuse and Mental Health Services Administration

dangers of prescribing opioids.[46] This requirement is supported by the pharmaceutical manufacturing industry.

Experts unanimously agreed with the Suffolk County Health Commissioner who supports a warning label on prescription bottles regarding the risk of addiction, as well as the consequences of mixed usage with alcohol and other drugs, and the impairment of driving skills.

D. Individual Accounts

As outlined earlier in this report, Suffolk County has experienced a substantial increase in drug-related crimes. Among them are Aggravated Vehicular Homicide, Vehicular Manslaughter, Driving While Ability Impaired by the Combined Influence of Drugs; and, Reckless Driving. These crimes occur after motor vehicle operators have consumed a variety of controlled substances including prescription tranquilizers, sedatives, and opioid analgesics. Crime scene evidence in many of these cases reveals prescription pill bottles strewn about the interiors of these motor vehicles.

Recent criminal investigations confirm that there is no shortage of prescription controlled substances for sale on the streets of Suffolk County. A recent case, presented to this Grand Jury, is demonstrative: within a two-month period, an undercover officer purchased 30 mg oxycodone pills from a dealer on 6 separate occasions totaling 215 pills for a combined price of $4,600. One purchase alone yielded 150 pills and a Class A-2 felony charge.[47] The following accounts presented to the Grand Jury further illustrate the negative impact this epidemic is having on the public health and safety of residents of the Suffolk County.

[46] BNE is sending all licensed practitioners in the New York City Department of Health Prescribing Guidelines, an eight page document (Grand Jury Exhibit 95).
[47] Class A-II felony is punishable by three to ten years for a first time felony offender.

Defendant A testified that five years ago, when told by a "friend" to just take "it", he did. That was the "first time I got high off anything" but not the last. "It" turned out to be a 10mg Vicodin pill. *Defendant A* liked the high and started "getting into them," and would seek out individuals to supply him with the pills. Soon *Defendant A* developed an addiction using Vicodin for two years, twelve pills a day, costing $120 daily.[48] At that point, he continued daily usage out of fear of becoming sick with withdrawal symptoms if he stopped. These symptoms included cold sweats, leg twitches, and diarrhea. This lifestyle ultimately prevented the defendant from continuing in college:

> The addiction got so bad I couldn't go to class, couldn't get out of bed, I was very depressed. It was awful. It ruined everything in my life.

When asked to explain what was happening while lying in bed with the knowledge that his supply of pills was gone, the defendant testified:

> When you don't have a pill and you are addicted, it just feels, it feels worse than death, not that I know how death feels like, but I have a lot to live for, I was never suicidal or anything. …When you're talking withdrawals, it's just this feeling like you can't get out of bed, you can't even get up and go to the bathroom, let alone do anything else. You are just worrying about everything in the world, like when you are getting your next pill, you have this crazy anxiety of everything on your mind but nothing at all. It's very overwhelming and it's just unbearable.

At this point in the addiction, opioid use is not about getting "high"' anymore:

> If you just find the next pill, not to get high anymore, just to feel okay, to function, to get up, to do anything, to be normal.

Defendant A explained that Vicodin was his drug of choice; however, in the spring of 2011, the defendant could not find a source. He began purchasing and using 30mg oxycodone pills.

[48] *Defendant A* would take three or four Vicodin pills at a time, three or four times a day over two years. These were 10 milligram Vicodin with a street value of $1 per milligram.

> I never took Oxycodone, I always took the Vicodin. Just a psychological thing, even though they are the same exact kind of pills it's like I knew I had to take Vicodin, but these worked too.

The defendant ingested 2-3 oxycodone 30mg pills several times a day. Each oxycodone pill cost $30 dollars, so the "*habit just got more money, more, money." Defendant A* finally sought help in the summer of 2011.

Despite hitting rock-bottom, requesting the help of family, attending an out-patient program, and being prescribed Suboxone[49], the defendant could not shake his oxycodone addiction, which led to an arrest in the fall of 2011.

> I knew (sic) wouldn't get high because I was on Suboxone, I still bought and took Oxycodone knowing it would not do anything, just a big psychological problem. It's hard to overcome.

After a second arrest a few months later, the defendant has been sober: "*It's now 51 days since my last pill."*

Defendant B resides in Suffolk County, and is a New York State licensed Adult Nurse Practitioner, wife and mother. At the time of her arrest for three counts of Criminal Possession of a Forged Prescription in the 1st degree, she was employed by a local hospital. The charges involved the forgery of prescriptions for opioid pain medications. Although her case is still pending, *Defendant B* voluntarily testified during this proceeding and related her story of opioid diversion and addiction, and how it damaged her life, her family, and her career.

Upon reflection, *Defendant B* recognizes that she made a series of bad decisions indicative of the aberrant behavior commonly associated with addiction.[50] The most tragic was

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[49] A brand name for buprenorphine, a Schedule III controlled substance. Suboxone is used to treat opioid addiction as is Methadone.

[50] Though not excusing legal culpability, one expert who testified before this Grand Jury indicated that opioid use affects the orbital frontal cortex of the brain, which is the decision-making center; continued use can cause impairment of judgment and greater harm.

an attempted suicide, which resulted in a short stay at a local psychiatric hospital and detoxification unit.

Her opioid use began approximately five years ago with a lawfully issued prescription for 5 mgs of Percocet.[51] Post-child birth muscle spasms, along with emotional and physical stress, prompted a visit to her primary care physician for diagnosis and treatment. Initially he prescribed physical therapy, chiropractic care, and non-narcotic medication to provide pain relief. When these methods offered minimal results, and she proved to be intolerant of the commonly prescribed Soma[52], she began an extended course of opioid treatment therapy. At no time in her medical exam or self-reporting did she indicate there was a family history of opioid addiction:[53]

> Originally, I would just start at night…and then the pain was so significant I would have to take it during the day. Three times a day maybe. But unfortunately I would need more and more just to get relief.

Within two months of ingesting her first Percocet, she recognized that a tolerance had developed. She continued receiving chiropractic care and physical therapy but still felt pain. Six months into treatment, her primary care physician referred *Defendant B* to a pain management specialist. The specialist recommended a course of treatment that included lidocaine injections 1-2 times each week, and 10 milligrams of Norco[54] 3-4 times a day. Her use quickly escalated to 6-7 times a day. At this time she recognized the signs of drug dependency:

> ….I started to realize I could not be without it when I tried to stop, like if there was a day that went by, I would have withdrawal symptoms. And it scared me to death. And I also realized I was taking it sometimes when I was not in a

[51] Schedule II controlled substance containing oxycodone
[52] Schedule III controlled substance and muscle relaxer
[53] According to other expert testimony before this Grand Jury, reporting such information would not necessarily inhibit a practitioner from prescribing opioids.
[54] Schedule III controlled substance containing hydrocodone.

> significant amount of pain, where probably other alternatives would have worked, but I found myself taking them anyway.

She called her pain management specialist who recommended a long-acting morphine. Instead, with the help of a family member also employed in the medical field, she visited another physician who diagnosed her as an addict and put her on a course of treatment using Suboxone.[55] Approximately 4-6 months after starting Suboxone, she experienced a decrease in pain symptoms. Within months she was able to start a new job, but soon after learned that she was pregnant.[56] Her physician advised her to either switch to Subutex or stop the Suboxone therapy completely.[57] Instead, fearful of experiencing the pain of withdrawal, she decided to return to illegally obtained oxycodone which she continued using in slowly decreasing amounts until approximately three weeks before she delivered her child.[58] *Defendant B* started taking approximately ten 15 mg tablets of oxycodone daily and weaned herself down to no pills shortly before giving birth.[59]

In an ironic twist, after giving birth to a healthy child, her physician prescribed opioids post-delivery, first through an intravenous tube, then orally. She was given a prescription for 5 mg oxycodone tablets to be taken as needed, not to exceed one every four hours. Although she filled the prescription and began taking it as directed, within two days she increased her intake in excess of the prescribed dose. When she quickly ran out of her lawfully prescribed supply, she used her own DEA license to write unlawful prescriptions to feed her own addiction. It is illegal

[55] As noted throughout this report, Suboxone is commonly prescribed during the course of addiction therapy because it prevents opioid withdrawal symptoms. A prescriber must possess a special DEA certification to prescribe Suboxone.
[56] Although her new employer conducted a drug test, she did not indicate at the time that she was on Suboxone, and this drug would not present in commonly used tests.
[57] She explained that Suboxone is a pregnancy category "C" drug which means there are not enough scientific studies to indicate whether it can be safely taken during pregnancy.
[58] She explained that Oxycodone is a pregnancy category "B" drug which she indicated is "the safest you can get."
[59] She explained that she did experience common symptoms of withdrawal at this time.

in New York State for a prescriber to issue to herself, so she engaged in a criminal scheme of fraud and deceit, using the names of family members to acquire the pills.

> …I already have a prescription pad with the hospital name on it, and a stamper with my license (DEA) number….so basically I would just write the prescription under somebody else's name and then I would bring it to the pharmacy and fill it.[60]

This continued for approximately one year, until her husband found her stash of pills. Though he had been aware of her past addiction, she testified that he did not know that she returned to opioids after the birth of their child. Combined with what she explained as pre-existing depression, this revelation triggered extreme despair and an attempted suicide. *"Basically I felt like I just wanted to die,"* she said.

During her one-week stay at a psychiatric hospital she was treated with methadone, a commonly prescribed treatment for drug abusers.[61] Upon her release, she was prescribed Lexapro for depression. Within two weeks, she voluntarily surrendered her DEA license, thereby no longer having privileges to lawfully prescribe controlled substances. Yet, despite the now obvious harm done to her life, she soon wrote another unlawful prescription for opioids. She took the prescription to one of the very same pharmacies she had used on many prior occasions; and it was filled, despite having surrendered her DEA privileges weeks earlier. The regulatory system clearly had its faults:

> At first I thought that I would go there and they would tell me I'm sorry we cannot fill this prescription, you do not have a DEA number. But for me, again, I made so many, series of, bad decisions, that I just felt like my life was in ruins, I'll just try….knowing that the ramifications would be really bad….and surprisingly enough, my number was still in the system….it was still there….nothing in the computer system saying that my DEA number was voluntarily surrendered. So they filled it.

[60] This is a reference to the federal requirements for prescribing controlled substances under 21 USC 800 et seq and 21 CFR 1306.
[61] Schedule II controlled substance

Approximately two weeks later she returned to the same pharmacy with another unlawful opioid prescription. This time she was told that a DEA representative had been there and advised the pharmacist that her number had been surrendered and she no longer had privileges. The pharmacist kept this prescription and days later she was under arrest.

Defendant B went on to describe that within a two year period, she filled unlawfully issued-prescriptions at four different pharmacies. She explained that "95% of the time" she went to the same pharmacy, sometimes close in time, always issued the prescription with a family member as a patient; her name was listed as prescriber, they knew who she was, and for two years no one ever came to pick up a filled prescription besides her. **"And no one ever said a word….I don't know if they trusted me or just didn't care."**

As she reflects on her experience, this professional provides additional insight into the problem. For example, she believes that dependency and addiction are interchangeable. Though often used to distinguish certain behaviors, in her experience they are effectively the same thing. She also related that when she was taking opioids, if she were without them for an extended time, she felt more intense pain than if she had never taken them.[62]

Defendant C is currently an inmate in the Suffolk County Jail. He started smoking marijuana at age 16 while in high school. A year later, he dropped out of high school and his drug abuse escalated to include prescription opioids, which at first he would purchase from friends, and soon thereafter obtained through physicians' prescriptions.[63] It started with Vicodin and Percocet, and then he switched to oxycodone and Roxicodone.[64] At the time, he could purchase a Vicodin pill for $3 on the street, Percocet was $5, Roxicodone cost $8, and

[62] This symptom is defined as hyperalgesia, whereby patients experience worse pain sensation than they previously experienced (discussed elsewhere in this report). It is a condition recognized by medical experts as a side effect of continued opioid use.
[63] Defendant C believes that his actions were obvious to the prescribing doctors.
[64] Roxicodone is a brand name of oxycodone.

oxycodone was about $25. Despite learning a trade and initially supporting his drug use with the money he earned legitimately, the lure of fast money and a drug dealer's lifestyle took hold;[65] this young adult's life has come to an inevitable ending with a long period of incarceration and an extensive criminal history which includes violent felony convictions. Along the way, however, he gained an insider's look at the world of opioid diversion and abuse and shared this information with the Grand Jury.

Defendant C explains that he was initially exposed to opioids as a teenager, following dental surgery, when he was prescribed Vicodin for pain. He liked the way it felt. When his first drug of choice, marijuana, no longer satisfied him, he went out on the street and illegally purchased opioids to support his growing habit:

> After taking Vicodin for so long, it does nothing. It doesn't affect you at all. So we, I had to move up the ladder, which eventually went up to heroin."[66]

As previously noted in the report, heroin is pharmacologically similar to the opioid pain prescription medications; however, given its high level of addiction potential and lack of medicinal value, it is a Schedule I controlled substance and patently illegal.[67]

It is easy to identify sources of supply according to *Defendant C*:

> If you put the word out there, you know, you can call one friend, listen, I need whatever[68] ….you get a call back in ten minutes.

Roughly six months after receiving that first prescription from his dentist, *Defendant C* was operating an illicit opioid distribution business that extended well beyond his immediate circle of friends. He explains:

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[65] Defendant C explains that getting involved was "as easy as tying your shoe."
[66] At the height of his opiate abuse, *Defendant C* reports his tolerance escalated so that he was ingesting thirty 80 mg oxycodone tablets daily, in crushed powder form.
[67] As previously explained, opiates are derived naturally from the poppy plant; opioids are semi-synthetic creations with the same effect. Heroin is an opiate, but the term opioid has been used for consistency throughout this report.
[68] "Whatever" refers to Vicodin, Percocet, OxyContin, and Roxicodone, "any of those drugs."

> What happens is your name gets out there. And then it's, listen, I have a friend, can you sell him any one of those drugs. Now you have that guy. Now say that guy tells somebody else, you meet them. Now you have that guy. And it just branches off from there.

In his first year of selling, *Defendant C* generated approximately $75,000 in profits. He continues, "it just grew bigger from there," and he adapted to the needs of the market he served by securing and selling more potent drugs such as oxycodone and Roxicodone, which he purchased for $8 a pill and sold for between $12 and $15. While *Defendant C* had a ready source of supply, the desire to expand his illicit network prompted visits to physicians for unnecessary prescriptions to supplement his supply, which were easy to obtain.[69] At the height of his illicit enterprise, *Defendant C* was selling an oxycodone tablet for $50. His profit skyrocketed and continued for several years; he then expanded his trade to include heroin when market demand shifted to that illegal substance. When asked what caused him to stop, *Defendant C* bluntly replied, "A SWAT team kicking in my front door."

E. Public Education and Awareness

> ***…teens abuse prescription drugs more than any illicit drug except marijuana…and…responsible parents are in a unique position to reduce teen access because the drugs often are found in the home.***[70]

"Public awareness and public education is crucial in this war," and is of primary importance as a preventive measure addressing the issue of diversion. Educating children and teenagers in particular on the dangers of prescription controlled substances is essential in attempting to address the issue of diversion. There is inadequate attention given to this component of diversion prevention and it must be addressed not just through the schools but

[69] *Defendant C* recalls purchasing in excess of 1,000 pills per week at this time.
[70] 2008 Report of Office of National Drug Control Policy, Grand Jury Exhibit 118 at 529

through public awareness in general. Witnesses urge New York State to actively promote this goal through public service announcements and school district programs.[71]

Given his recent experience working at a university health center, *Pharmacist A* is keenly aware of issues that impact the 18-21 year old population, particularly relating to both the legitimate and illicit uses of controlled substances. He is frustrated by limitations on his ability to help students whom he reasonably suspects may be dealing with addiction issues. Under Federal privacy laws, young adults, aged 18-21, can be prescribed opioids and psychotropic medications or stimulants without a parent's knowledge.[72] *Pharmacist A* believes that the law should be amended to allow for parental notification when a controlled substance prescription is issued to anyone under the age of 21.

More complete and effective education for patients about the warning signs of addiction is imperative.[73] Witnesses, including *Pharmacist A*, related a familiar scenario involving a patient who was issued a prescription for opioids after surgery; despite taking the prescription as authorized by the prescriber, after seven to ten days the patient was addicted. *Pharmacist A* reiterated the statistic that globally 99% of all hydrocodone and 80% of all opioids are consumed in the United States. "I mean, are we in that much pain?" he commented ruefully.

Patients must be educated as to the proper use, expected side effects, and the proper disposal of controlled substances. One simple measure to to accomplish this goal is to place a warning label on each opioid prescription bottle alerting patients that "**this drug may be addictive.**" This can easily be accomplished by placing a warning label on the prescription

[71] *Don't Get Me Started*, for example, is a program based in Ohio which includes five videos and is appropriate for middle school and high school students

[72] Though not the specific subject of this report, *Pharmacist A* and other witnesses alerted the Special Grand Jury to the widespread use among young adults of other controlled substances such as Adderall and Ritalin.

[73] A "bag stuffer" or pamphlet, for instance, may be included with a patient's prescription informing them of the signs of addiction, to speak with their health care provider, and provide contact numbers for assistance.

bottle. The Suffolk County Commissioner of Health told the Grand Jury that it is within his power to institute this label warning as a local law, which can be then adopted at the state and national level.[74]

III. DIVERSION AND THE REGULATORY SCHEME

The heroin, crack and cocaine epidemics were minor compared to now.

Federal and State governments share regulatory responsibility for the legitimate medical availability of controlled substances. This includes safeguards to prevent diversion and abuse. The Grand Jury heard testimony from an individual whose extensive career has been devoted to the investigation of drug diversion. Currently he is a Medical Fraud Investigator for a non-profit insurance administrator managing Medicaid benefits in New York State. Previously, he was an investigator with the New York State Attorney General's Office Medicaid Fraud Control Unit and assisted in its Pharmaceutical Drug Crime Unit; prior to that, he was an investigator with the Bureau of Narcotic Enforcement. He is also a certified pharmacy technician. His career focuses on opioid diversion and he is responsible for hundreds of arrests in this area. In his testimony before the Grand Jury, he emphasized that the current opioid epidemic is the most significant he has ever seen.

This witness agrees that "the medicine cabinet" at home is the single largest source of diverted controlled substances. He testified about various other forms of diversion that he has investigated including "doctor shopping" which occurs when a person spends the bulk of his life going from physician to physician, pharmacy to pharmacy, amassing huge quantities of

[74] A federal or state law can supersede a local law, however no such regulation is in place at the federal or local level. Previously, Suffolk County passed a local law on cold medications containing Ephedrine which thereafter became a statewide and national law.

controlled substances. "Doctor Shoppers" usually have Medicaid or some other insurance plan, and to circumvent detection they use their plan once a month and pay for the remainder of the pharmacy and physician visits with cash. Another form of diversion is prescription forgery, which is committed through stolen prescription paper, or altered prescriptions. [75] Medical identity theft is prevalent as well. A common scheme involves people "renting" Medicaid cards from other recipients, paying $10 or $20 for the day, and using the card to fill a prescription.

Medical professionals find themselves involved in fraud and diversion. This witness testified that prescribers often prescribe improperly or engage in fraudulent billing practices. Pharmacy fraud occurs when payment is sought for drugs that are never dispensed. Sophisticated schemes involve collusion between and among the patient, practitioner and the pharmacy. One example is a "pill mill." Typically a "pill mill" operates as a pain management practice, but it can be any physician prescribing for addicts or dealers. Word and reputation spreads quickly in the addict community. Lines form outside of the physician's office early in the morning; sometimes patients camp out in the parking lot. Patients are observed going in and coming out of the office in ten minutes or less; clearly not having a medical visit, they are just getting prescriptions. In his investigative experience, in a "pill mill" operation, a physician essentially knows that a patient is not legitimate but he will test him to be sure that he is not an undercover officer. The physician will ask questions and then offer the patient a drug that is weaker than the patient requests or the physician suggests a non-controlled pain reliever such as a Motrin-type drug. The physician assesses the patient's reactions to the questions or the admonishments about addiction. Once confident that the patient is not an undercover officer, the physician will start issuing prescriptions to the patient for whatever he wants. It is implied, if not

[75] NYS law requires prescriptions be issued on state-issued paper provided free of charge to prescribers.

actually spoken, that the patient is an addict. The patient often tells the physician which drug he wants, rather than wait for the physician to tell him what he needs.

To address and prevent fraud and diversion, the witness recommends that the New York State Bureau of Narcotic Enforcement (BNE) have enhanced abilities to investigate diversion and fraud, particularly in the proactive use of the PDMP and its immense data.[76] Most importantly, software upgrades would allow the flagging and investigation of improper prescribing practices as well as of "doctor shoppers." Greater collaboration between BNE investigators and outside law enforcement agencies is also recommended, accompanied by the latter's greater access to the PDMP data.

He urges the amendment of New York State Penal Law §220.65; this statute criminalizes the sale of a prescription for a controlled substance when the prescriber fails to act in "good faith".[77] The current language makes investigations of fraudulent prescribers difficult because fraudulent prescribers can attempt to shield themselves from criminal liability by trying to elicit from a patient some kind of need for the drug. In fact, physicians issuing baseless prescriptions encourage patients to articulate some kind of pain, however fictional it may be. A typical exchange based on years' of experience as an investigator working in an undercover capacity is related here:

> You can't just go in and say, Doc, give me a prescription for OxyContin or Percocet. Well, what do you need it for? I just need it. Tell me what's wrong. And you go back and forth on the conversation. Look, you have to tell me something. I was, alright, I was in a bad car accident in 2009 and I have a bad back. And if you were a fly watching, you would say that conversation was not

[76] New York State maintains a database commonly referred to as the Prescription Drug Monitoring Program or PDMP. It is discussed in greater detail later in this section.

[77] NYS Penal Law §220.65 reads, in part, "for the purposes of this section, a person sells a prescription for a controlled substance unlawfully when he does so other than in good faith, in the course of his professional practice." This crime is a class C felony.

> really legitimate. But he's putting this in the chart. That chart eventually becomes evidence, or he would just put his own language in the chart, regardless of what you said.

In this exchange, it is clear that the patient does not have a medical need but that the physician has encouraged him to state one. For appearance sake, the physician could claim that he acted in "good faith" when in fact he had not. In order to enable prosecutors to effectively use this statute, "good faith" must be more clearly defined by law.

A. **The Food and Drug Administration**

The FDA approves controlled substances for marketing, while DEA establishes and administers the regulatory scheme. States have the option of imposing additional regulations and are also responsible for the licensing and disciplining of prescribers and dispensers.

Under the Food Drug & Cosmetic Act, the FDA is responsible for ensuring that drugs are safe and effective before being available in the marketplace. (Grand Jury Exhibit 7) [78] The FDA reviews scientific and clinical data and makes a determination based on the intended use and effectiveness of the drug, as well as its risks and benefits. For every prescription medication, the FDA approves its label which is referred to as an "FDA label" or "package insert." This label or insert contains information about intended use, dosage, side effects and other related details. The FDA continues its mission by monitoring drugs for safety after granting approval for marketing. Once approved, the FDA regulates the advertising and promotion of prescription drugs. Marketing must be truthful, balanced, and accurate.[79] Under the FD&C Act, labeling includes

[78] United States General Accounting Office Report, *Prescription Drugs*, December (2003)
[79] FDA regulations require that promotional labeling and advertisements be submitted to the FDA at the time of initial dissemination (for labeling) and initial publication(for advertisements)

"all labels and other written printed or graphic matter accompanying an article." (Grand Jury Exhibit7)[80]

The Controlled Substances Act requires that the FDA notify DEA when it reviews a new drug application for a substance that has the potential for abuse.[81] A medical and scientific assessment is performed, and, if approved, the FDA recommends that an initial Schedule level be assigned by DEA to a new controlled substance.[82] The FDA also approves a label designed for the prescriber that contains information about the substance: it highlights correct dosing, possible side effects, and risks. The most important information on the label is the "indication" for appropriate prescribing and use of the drug.[83] Issuing a prescription for a substance in accordance with the "indication" is an "on-label" use; prescribers are, however, permitted to prescribe for a condition that is not indicated on the label, which is referred to as "off –label prescribing."[84]

A medical expert specializing in addiction treatment testified before the Grand Jury that FDA labeling of opioids is misleading. The labels currently indicate that opioids are properly prescribed and used in the treatment of "moderate to severe pain." This clearly implies to prescribers that opioids are safe, for example, in the treatment of chronic back pain yet there is no evidence supporting that position. The expert believes that the labels for all opioids must be more specific and should read for "short term use to treat acute pain" and "to ease suffering at the end of life." In other words, the indication should be for either short-term acute pain or for palliative care only; it should explicitly exclude chronic non-cancer pain. Prescribers would still

[80] United States General Accounting Office Report, *Prescription Drugs*, December (2003) 11
[81] Abuse potential means that the substance has a stimulant, depressant or hallucinogenic effect on the central nervous system.
[82] United States General Accounting Office Report, *Prescription Drugs*, December (2003)
[83] The indication exists for every prescription medication.
[84] Off-label prescribing may be appropriate. An example is the use of the prescription drug Trazadone, labeled as an anti-depressant but is prescribed off-label as a sleep medication.

have the option of "off-label" prescribing of opioids for chronic pain. However, pharmaceutical manufacturers would not be permitted to advertise them as such. In his expert opinion, "this I think would bring the epidemic under control." The net effect would be a significant reduction in the prescribing of opioids and therefore a concomitant reduction in their manufacturing. With a reduced supply, a decrease in diversion follows.

B. **Drug Enforcement Administration**

> ***The biggest problem in diversion is physicians that write for people that they should not be writing for, and on occasion, when it happens, pharmacies that should not be filling the prescription.***[85]

A Diversion Manager of DEA in New York testified before the Grand Jury. DEA is the primary agency responsible for enforcing the Controlled Substance Act (CSA) of 1970. (Grand Jury Exhibit 7)[86] This involves civil and administrative regulation in addition to criminal enforcement. All parties authorized to manufacture, distribute, possess, prescribe and dispense controlled substances are identified by DEA as registrants.[87] DEA reports that nationwide there are over one million registrants.[88]

After a controlled substance is authorized for marketing by the FDA, DEA determines into which Schedule it will be classified. (Grand Jury Exhibit 118)[89] With limited exceptions

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[85] The Diversion Program Manager, Drug Enforcement Administration, describing the diversion of controlled substances. The Diversion Program Manager has been in this position since 2008. She has been with the DEA since 1980 in the capacity of investigator, supervisor and section chief.

[86] The Controlled Substances Act of 1970 serves as the foundation for the Federal Government's authority over controlled substances. This Act consolidated over fifty laws regulating the manufacturing, distributing, importing and exporting and dispensing of controlled substances. It created a closed system that allows DEA to determine who should be registered to handle controlled substances

[87] *Class A* registrants include doctors and pharmacies. *Class B* registrants include manufacturers, distributors, importers, exporters, narcotic treatment programs, researchers and on occasion analytical labs. These are onsite investigations and are conducted every three years, depending on the timing of the audits.

[88] This increase is due in part to the licensing of Physician Assistants and Nurse practitioners.

[89] Scheduling is determined by the substance's medicinal value and potential for abuse

for research, Schedule I controlled substances may not be manufactured and distributed.[90] For the remaining Schedules II-V, regulation is initiated by DEA with the establishment of raw material quotas; this defines how much material is available for the manufacturing of these drugs.[91] DEA may increase the amount allocated from year to year if a greater need for the active ingredient of a particular controlled substance is presented. Automated Record-keeping Consolidated Ordering System (ARCOS) information must be submitted by all manufacturers and distributors.[92] Further, the CSA establishes which security measures must be utilized by the registrant based on the substances handled.[93] Recordkeeping requirements are included in the Controlled Substance Act.[94] "Cyclic Investigations" are conducted of Class B registrants.[95] In addition, manufacturers and distributors must have "suspicious ordering" systems in place to monitor the purchasers of controlled substances. If there is a rapid increase in purchasing, manufacturers are under a duty to inquire; based on that inquiry, the manufacturer or distributor must determine whether or not they should continue selling to this customer. If the registrant decides to no longer sell to a particular customer, such must be reported to DEA. DEA is responsible for ensuring that controlled substances are properly handled and dispensed by the

[90]Schedule I substances are deemed to have no accepted medicinal value and to have a high potential for abuse. These include Lysergic acid diethylamide (LSD), heroin and marijuana

[91] Manufacturers must provide DEA with information as to the substances they intend to manufacture and their prospective quantities, as well as prospective purchasers of their substances. DEA then determines whether the amount of raw material requested is adequate and consistent with the manufacturer's proposal.

[92] ARCOS –Automated Recordkeeping Consolidated Ordering System which provides DEA with information on inventories that the manufacturers have on hand. It also indicates the distributors' sales and purchases throughout the year. The manufacturers and distributors must report to DEA on a monthly or quarterly basis as to whom they are selling.

[93] For illustration purposes, manufacturers have vaults with electronic monitoring devices that allow DEA to determine whether a break-in occurred or if an unauthorized person attempted to enter. Additionally, for example, Schedule III –IV substances are required to be stored in a cage meeting certain requirements to safeguard the controlled substances.

[94] Recordkeeping requirements include Registrants maintaining an inventory of the controlled substances on hand as well as the controlled substances that are being dispensed. For registrants such as pharmacies, doctors or hospitals, or in the case of distributors, records of amounts sold must be kept. Records must also be maintained that indicate which controlled substances were destroyed for accountability purposes. Theft and robbery of controlled substances must also be reported to DEA.

[95]These are onsite investigations and are conducted every three years, depending on the timing of the audits.

registrants that are entrusted to handle them.[96] Once manufactured and distributed in accordance with the CSA, controlled substances are available for prescribing and dispensing.

DEA is observing physicians that are writing inappropriately, not for a legitimate medical reason. "As many physicians as we take down, I see more just coming up." For instance, prescribers with a lawful practice have a number of patients for whom they inappropriately issue prescriptions for controlled substances. The "pill mill" prescriber described earlier in this report. has few patients, if any, with legitimate medical needs. This "pill mill prescriber" issues prescriptions for controlled substances to anyone. DEA distinguishes between this class of "pill mill" diversion and "doctor shopping", the latter described as:

> you could have a physician that is a good doctor, and he's got this person in front of him who actually has a medical condition, and you are believing that person to be who they say they are, and that they have this condition, and you are the only physician they are seeing, and you are being duped because he went to somebody else two days ago. So the doctor shopping doesn't always mean the physician is bad. It just means you have an individual that is using a medical condition to gather as much of a controlled substance as they possibly can.

DEA may revoke a prescriber's registration or license for several reasons: the registrant knowingly provides false information in a new application or renewal application; or the registrant is convicted of a felony regarding controlled substances in a federal or state jurisdiction. DEA has the authority to initiate a public interest revocation[97]:

> If I had an existing DEA number and I was prescribing to such an extent that people were dying because I was writing so many bad scripts and people were overdosing and causing all kinds of havoc that could be grounds for a public interest revocation. It shows that I am not responsible and I should not have that DEA number. And that is grounds for us to take action against that registrant.[98]

[96] Registrants include manufacturers, distributors, importers, exporters, analytical laboratories, researchers, narcotic treatment programs, hospitals, teaching institutions, practitioners, and pharmacies.
[97] Public Interest Revocation is an Immediate Suspension Order
[98] Grand Jury Exhibit 79

It is unclear whether DEA notifies the New York State Office of Professional Medical Conduct (OPMC) of a registration revocation. However, to effectively discipline practitioners, monitor their activities, and protect the public health, OPMC must be notified by DEA of a revocation from a physician, physician assistant or specialist assistant. OPMC, does on the other hand, notify DEA by mail of every public action it takes.

Grand Jury testimony reveals that the New York State Bureau of Narcotic Enforcement (BNE) conducts a daily internet search of a DEA-encrypted file that accesses the DEA list of authorized prescribers. However, BNE has signed an agreement with DEA that prohibits the sharing of the status of a prescriber's DEA license with any other agency. BNE compares this list with New York's 96,0000 current prescribers.[99] In addition, BNE is in daily contact with OPMC and is notified of discipline imposed by OPMC.[100] The physician's authorization to order new prescription pads is revoked when BNE is advised of a revocation.

C. **Federal Regulation of Manufacturing & Distribution: an Illustration**

To illustrate how DEA regulations apply to manufacturing and distribution, the Grand Jury heard testimony from a representative of a leading manufacturer of generic pharmaceuticals.[101]

This company, like others, assigns the function of DEA compliance and security to trained personnel who are responsible for oversight, implementation, reporting and enhancement

[99] Not all changes in the database are based upon a license suspension or revocation. Some registrants retire, surrender licenses, or change locations – all of which are noted in the DEA file.
[100] Since Pharmacists do not have access they would not necessarily know if a license has been suspended
[101] Generic pharmaceuticals are the bio-equivalent of a brand name drug, typically containing the same efficacy, the same strength, and most of the same ingredients.

in this area. Their efforts have resulted in an extremely low percentage of product loss for this company which appears consistent throughout the industry.

DEA establishes security regulations for the manufacture of controlled substances. For example, pursuant to DEA regulations, Schedule II controlled substances awaiting distribution must be stored in a vault; Schedule III controlled substances must be stored in a cage. Exceeding these requirements involves a combination of state-of-the-art technology and security personnel. The path of the product within the facility is monitored by camera and security guards. Product is never handled by less than two people and one of the two must be a supervisor. The product travels in a cage, even if it is moving 15 feet down a hallway. Drums are always sealed with metal seals, and each seal is documented. Boxes are barcoded.

The vault is about the size of a modest house without any interior walls, and is DEA approved. Combination locks, computerized access control, enhanced alarm systems, and video monitoring provide enhanced security. A sophisticated video monitoring system also ensures against diversion by employees; one facility may use more than 100 cameras. Every door leading to a production room requires computerized access control to enter. Security guards are stationed at the factory entrance and employees are checked each time they enter or exit. During breaks, access to the production line is prohibited. This witness related only one instance of employee theft during his long tenure with the company. Furthermore, to ensure the safety of the facility as well as the citizens in neighboring communities, this company has recently welcomed local law enforcement to tour its facility, evaluate its security measures, and make recommendations for enhanced systems. Two recommendations have since been implemented, and another is still under review. To minimize the potential for loss and diversion during the distribution phase, this company only distributes its controlled substances directly from the

manufacturing sites. This limits the amount of road time the product must travel, thereby lowering the risk of hijacking, their greatest concern. As the witness told the Grand Jury "When it's under our roof, we have total control over it. Once it leaves our property, it's in a tin can, basically, in a truck, and just driving along the road. That's what keeps me up at night."

Measures are taken to avoid hijackings including: using two drivers so a truck is never left vacant, and ensuring a truck will be driven nonstop except for fueling and food; the company secures photo identification in advance for each driver; new technology devices, such as Lojacks, are placed in product skids so they can be tracked in transit across the country.

Product waste in the manufacture of controlled substances must also be tracked and disposed of pursuant to DEA regulations. For example, certain machines produce waste during normal operation; the compression machine used to change the product from powder to tablets runs for 30 seconds and spills 10,000 tablets that will go to waste when the machine is being calibrated. That waste is then stored in a company vault awaiting secure destruction:

> We ask permission from the DEA to destroy it. We actually invite them to come along with us. If they don't come along with us, we hire an armed security guard. We witness the destruction. I along with two other people and the armed officer will actually sit in a crane and watch the product be picked up and dropped into a boiler, and we stay there until it all actually gets burned and we can sign off and say the product has been destroyed.

Compliance with DEA reporting regulations is a critical tool for preventing loss and monitoring production. Essentially, there is a DEA-approved form used to record every transaction involving a controlled substance. The company submits this ARCOS data quarterly.[102] ARCOS accounts for all of the company's transactions including purchases, sales, theft or a loss in transit,

[102]Automated Recordkeeping Consolidated Ordering System which provides DEA with information on inventories that the manufacturers have on hand. It also indicates the distributors' sales and purchases throughout the year. The manufacturers and distributors must report to DEA on a monthly or quarterly basis as to whom they are selling.

returns from customers, and destructions. At year end, a complete reconciliation of these transactions is provided with a complete accounting for "almost every single gram, and we deal with hundreds, actually millions of grams." Every manufacturer must renew its DEA registration annually.

According to this manufacturer, a major focus of the DEA in the past few years is SOM – Suspicious Order Monitoring, which monitors buying patterns:

> We are, as a distributor and manufacturer, responsible for our entire downstream. We have to know who we sell to, who they sell to, basically until it gets to the end user. There are many ways to monitor that. But we have a system that checks for spikes in order patterns, changes in order patterns. If a customer orders way more this week than they did last week, we have to call them out and get a reason. If the reason is not good, we actually report the order to the DEA. We also have to know our customer. We have to visit them and make sure they are compliant, they are doing the right thing, they are doing the same thing we are doing, they check who they sell to. It's just a lot at stake.

Illustrating the strict compliance required by DEA, the witness referenced a large pharmaceutical manufacturer based in Florida recently closed by DEA for distributing to 4 pharmacies that were supplying illegal pain clinics; that was from a total of 2,400 pharmacies properly supplied by the manufacturer.

To help control the flow of controlled substances in the marketplace, DEA also regulates manufacturing production quotas. The United Nations World Health Organization (WHO) sets the global limits of raw materials; DEA then oversees distribution of raw material in the United States. For example, a manufacturer will forecast its annual production needs, and DEA in turn approves an amount that balances the needs of the marketplace with the overall supply of raw ingredients. A company may estimate a need for 1,500 kilograms, and DEA approves 1,200. Purchasing of that raw material is then monitored and reported to the DEA. A company cannot

exceed its quota, although it may request waivers from the DEA to do so, which may or not be approved.

Applying this regulatory scheme to opioids, specifically two of the more commonly prescribed over the past ten years, this witness referenced the **Aggregate Production Quota History for Selected Controlled Substances** (Grand Jury Exhibit 68) as contained in the DEA Diversion Control Program website:

> It's a list of quotas for raw material provided by the UN from 2002 to 2012. For hydrocodone, the DEA issued 25,000 kilos of hydrocodone in 2002. In 2012, they issued 59,000 kilos. To give you a basic idea, to make a batch of a million tablets or, a million tablets of ten milligram product of hydrocodone, you need ten kilos. And they are issuing 59,000 kilos. That is a significant increase over a ten year period. Just because I don't think pain has increased that much. The quota for oxycodone tripled during this same time frame – from 34,482 kilos in 2002, to 98,000 kilos in 2012. I believe it's a significant increase.

Hence, between 2002 and 2012, DEA approved significant increases in the supply of raw materials; in the case of hydrocodone the supply more than doubled, and it almost tripled for oxycodone. This clearly reflects the perceived need generated by various interest groups: those who promoted pain as a vital sign, the manufacturers who aggressively marketed the opioids, the pain management societies funded in large measure by the manufacturers, and the prescribers issuing the prescriptions.

In addition to federal regulation, in New York State, the Bureau of Narcotic Enforcement within the Department of Health has the primary responsibility for managing the flow of controlled substances; it maintains a staff of investigators, though reductions in force have occurred during the past ten years.

D. State Regulation: New York State Bureau of Narcotic Enforcement

All prescribers of controlled substances must have a license from DEA.[103] In New York, the prescriber must also be licensed by the State through the Department of Education. Controlled substances may only be dispensed upon the issuance of a lawful prescription.[104] The New York State Board of Regents and the New York State Education Department oversee the preparation, licensure, and practice of the professions.[105] This includes all prescribers and dispensers of controlled substances.

The New York State Bureau of Narcotic Enforcement (BNE) is responsible for protecting the public health by combating the illegal use and trafficking of prescription controlled substances. BNE is a unit within the New York State Department of Health and is comprised of a Director, seventeen investigators, four pharmacists, and support staff. (Grand Jury Exhibit 101)[106]

BNE is primarily responsible for administering the New York Central Registry, the official Prescription Drug Monitoring Program (PDMP).[107] All New York State prescriptions must be issued on watermark serialized paper that is supplied by New York State.[108] BNE monitors these prescriptions once they are dispensed. Dispensers are required to report them to BNE by the 15th day of the month following their dispensing. Hence, there may be as long as a

[103] In New York, eligible practitioners for a DEA number include medical doctors, doctors of optometry, osteopathy, dentists (DDS or DMD), veterinarians, podiatrists, nurse practitioners and physician assistants. The DEA number is always secondary. You must have the state authority to prescribe in order to obtain a DEA number.
[104] 21 USC 829 et seq. Limited exceptions are noted in the statute.
[105] Currently the Office of Professions regulates forty-eight professions.
[106] The current Director of BNE was appointed by Governor Cuomo in November 2011.
[107] New York State Public Health Law §3322 describes the record keeping requirements.
[108] NYS Prescription paper is paid for through a special allocation from the State Insurance Fund, and provided to practitioners free of charge. In 2011, NYS prescribers issued 164 million prescriptions. These figures include controlled and non-controlled substances.

45-day lag between the dispensing of a controlled substance and its reporting in the PDMP.[109] This lag in reporting diminishes the value of the data from both a law enforcement and public health perspective. Absent any further modifications to the PDMP, BNE supports a mandate requiring that dispensers report prescriptions to them within 24 hours.

BNE is currently restricted in its ability to pursue diversion cases and to assist other law enforcement agencies by New York State Public Health (PHL) § 3371 which limits the disclosure of patient confidential information.[110] PHL§3371 only allows information sharing with certain limited enumerated parties.[111] Conspicuously absent from this list of authorized recipients are law enforcement agencies. With a staff of only 17 investigators for the entire state, clearly BNE has inadequate staffing to investigate diversion cases statewide. BNE must have the ability to proactively refer suspected criminal conduct, including patient identifying information, to local law enforcement. Currently, such agencies must initiate the process with a judicial subpoena or court order in a criminal case based on information they independently obtain. This presents a Catch-22 situation: BNE, charged with the safeguarding of public health and the prevention of diversion, may have information indicating ongoing criminal conduct in Suffolk County; however, the PHL constrains BNE from notifying local law enforcement of this specific information. BNE cannot, of its own volition, share the names of people committing criminal conduct absent a subpoena. BNE is given the power of information gathering but is unrealistically constrained in its use to effectively protect the public. To correct this errant system and to effectively combat the pill mill epidemic, PHL §3371 must be amended to allow BNE to proactively share information with local law enforcement. This would have the added

[109] Based upon a standard 30-day month, if a prescription is dispensed on the 1st of the month but not reported until the 15th of the next month, 45 days would have elapsed from the time of dispensing until reporting to BNE.
[110] Grand Jury Exhibit 102
[111] The enumerated exemptions include: Office of Professional Medical Conduct (OPMC), DEA, and the Office of Medicaid Inspector General of NYS (OMIG).

benefit of allowing BNE to more effectively utilize its investigators to regulate other matters within its jurisdiction.

To further assist BNE in combatting diversion, dispensers must have access to the PDMP database; currently they report information but cannot access it themselves. With this modification, before they dispense a controlled substance, all dispensers must be mandated to check the database for "physician shopping" patient information[112] Along with this, PHL §3371 must be amended to allow Medical Examiners access to the PDMP database. Such information would assist in determining more precisely the cause of death, and be valuable as a local public health resource.

BNE and DEA both support changing the law, rules and regulations to mandate that prescribers access the PDMP prior to issuing a prescription for a controlled substance. Accessing of the database is currently done on a voluntary basis. However, of the 96,000 registered prescribers in New York State, remarkably only 2,400 in a two-year period have ever used this free database. Further, the information available must be complete and current. Today, if a prescriber searches the database for patient X, he will only see the prescription history of X if he filled at least two prescriptions from two different physicians at two different pharmacies. BNE proposals would lower the threshold to ensure that **any** patient who received a prescription appears in the database. To facilitate the use of the database by prescribers, BNE recommends that a prescriber be permitted to designate a licensed professional within his office to access the database.[113] This also requires an amendment to PHL §3371.

[112] Denominated as Controlled Substance Information

[113] If the prescriber is going to see, for example, thirty people in his office the next day, he can have the registered designee in his office run all thirty patients the night before, and place the information in the files.

Two years ago, PHL §3371 (a) was enacted enabling BNE to share the PDMP database with other states; however New York has not yet done so.[114] The implementation of this provision is essential since criminal diverters of controlled substances frequently cross state lines to fill their prescriptions. To be effective, BNE must be interconnected with the other states to combat this situation.

With respect to pharmacies, the BNE Director testified about thefts by unlicensed and unregistered pharmacy assistants or staff that have access to medications. In New York, every pharmacist may operate his pharmacy with up to two non-licensed persons commonly referred to as pharmacy assistants, who perform the non-judgmental tasks such as counting tablets, pouring solutions, billing, cashier duties, etc. This allows the pharmacists to perform collaborative drug therapy management, work more closely with prescribers, counsel patients, and provide flu shots. More than forty states officially recognize this role. Assistants are a valuable resource; however, they have access to controlled substances and, as such, must also be monitored to prevent diversion.[115] Currently, if an assistant is fired from one pharmacy for theft or diversion, there is no registry record for a subsequent pharmacist-employer to access. A diverter may then be employed unwittingly by the new pharmacy. BNE recommends that pharmacy assistants be licensed or at least registered through the State Education Department so that documented addicts or thieves are prevented from employment in pharmacies.[116] Experts in other fields echoed their support for such an initiative.

[114] Article 3371(a) Interconnectivity/Interoperability

[115] A recent study indicated that approximately 80% of pharmacy diversion in Texas was due to diversion by technicians.

[116] The New York State Board of Pharmacy estimates that there are 30,000 to 60,000 assistants who would come under the Board's authority. However, the Executive Director believes it is necessary to at least require their registration.

E. State Regulation: New York State Office of Professional Medical Conduct

The Office of Professional Misconduct (OPMC) within the New York State Department of Health investigates complaints against physicians, physician assistants, and specialist assistants (See Grand Jury Exhibit 80-81).[117] OPMC's statutory authority is governed by the New York State Education Law (Grand Jury Exhibits 72, 73, 74).[118] The Assistant Director of Investigations for the Office of Professional Medical Conduct (OPMC) within the New York State Department of Health testified before the Grand Jury. A twenty-year veteran with the Albany Police Department, retiring at the rank of Assistant Chief, she explained that OPMC investigates allegations of misconduct by physicians, physician assistants and special assistants. The procedures followed by OPMC are governed by the New York State Public Health Law. (Grand Jury Exhibits 69, 70, 71)[119] In summary, the Department of Education licenses these practitioners, and the Department of Health disciplines physicians, physician assistants and special assistants. An application from a physician, physician assistant or specialist assistant to restore a license is done through the Department of Education, not the Department of Health, the disciplinary agency.

Under §230 of the NYS Public Health Law, every complaint that is filed with OPMC must be examined.[120] A determination is made thereafter as to whether there is also a potential violation of §6530 of the Educational Law which defines professional misconduct. (Grand Jury

[117] OPMC monitors practitioners who are subject to Orders of the State Board of Professional Medical Conduct.
[118] New York State Education Law Sections 6530, 6531, & 6532 address professional medical misconduct.
[119] New York State Public Health Law Section 230.
[120] Anyone can file a complaint; it is initially directed to the Central Intake Unit, Troy New York. The Central Intake Unit is comprised of Nurse and Lay Investigators. The complaint is reviewed to see if it encompasses Physicians, Physician Assistants and Special Assistants.

Exhibit 72) If these two criteria are met then a determination is made to open the investigation in either the Central or a Regional Office.[121] Investigations are also prioritized.[122]

Once a case is opened, the assigned investigator takes the necessary steps to evaluate the complaint.[123] Medical records are reviewed by a certified physician on the OPMC board.[124] If the reviewing physician determines that the standard of care is met then the case is closed.[125] If the conclusion is that the standard of care was not met, then OPMC would call the physician for an interview.[126] If further proceedings are necessary, an independent medical expert must review the case pursuant to §230 of the Public Health Law (Grand Jury Exhibits 69-71). If the allegations are substantiated, the next step is to present the case to an investigation committee.[127] If the investigation committee concurs with the initial recommendation, the case will move forward, to an administrative warning, the comprehensive medical review, or the hearing process.[128] If the investigative committee does not concur, OPMC closes the case outright or it

[121] OPMC has three metropolitan offices; Central Islip, New Rochelle, New York City as well as Central offices in Buffalo, Rochester, Syracuse, and Capital District Office. The determination is based on whether or not the investigator in central intake feels there is a potential for conducting site visits, for doing in-person interviews and whether or not hat h subject physician has an open case.

[122] Cases are prioritized by either A, B or C. "A" is the most egregious or the one that would represent the most potential patient harm, and would be given the most attention. "B" would be the average case, one in which more information is needed in order to make a determination as to whether it was an appropriate case for a hearing or may in fact be a closure. "C" would be the lowest level case, one which would likely not be opened.

[123] The investigator would make contact with the complainant, order medical records, and interview others with knowledge of the complaint.

[124] The Physician on the board makes a determination as to whether or not the minimal community standard of care has been met. The Physicians that sit on the board have various specialties in the Medical Profession and cases that fit a particular specialty are reviewed by that Physician.

[125] Administratively no further action is taken. The complainant would be notified by letter that the case has been closed with no further action. The subject physician would also be notified that their case is being closed without any further action.

[126] This interview is voluntary. The physician cannot be compelled to participate in the interview.

[127] If there is a potential hearing case, then it needs to be presented to an investigation committee. The investigation committee is a panel of three members of the Board of Professional Medical Conduct (two physicians and one layperson). The panel will determine whether they concur with the initial findings or if no further action is warranted. The further action that would be taken would be a referral for a hearing or an administrative warning or a comprehensive medical review which is defined in Article 230 PHL.

[128] An administrative warning is given in instances of minor and technical violations that do not rise to the level of misconduct. They are non-public. Since it is non-public the complainant will only be told that the case was closed without any further action. If the case gets voted to a hearing, OPMC would set consent parameters which are similar to a plea bargain agreement. If there is no consent then the case would be scheduled for a hearing.

may be sent for further investigation.[129] OPMC statistics indicate an increase in improper prescribing complaints over the last few years (Grand Jury Exhibit 78). OPMC does not have the authority to automatically suspend a high priority complaint. In order to properly protect the public, this option must be available to OPMC.[130]

Under present leadership, OPMC and BNE confer regularly on cases, although it is not structurally mandated. Both agencies are pursuing formal protocols for information sharing within the Office of Health Systems Management. (Grand Jury Exhibit 81)[131] Increased cooperation between these offices is critical to fight opioid abuse, addiction, and diversion.

F. ELECTRONIC PRESCRIBING (E-PRESCRIBING)

E-Prescribing is a secure way of writing prescriptions and making sure they end up in the right hands."[132]

Electronic Prescribing (E-Prescribing) is authorized by DEA and is voluntarily used in New York for non-controlled substances. Although not currently in place, E-Prescribing of controlled substances would be a substantial step towards tighter regulation of controlled substances, and would greatly reduce the opportunity for diversion. The Grand Jury heard testimony from individuals at all levels including manufacturing, prescribing, and dispensing in support of E-Prescribing.

At present, prescriptions for controlled substances in New York are written on paper forms. These are subject to theft and forgery, and are a primary source of diversion. Many

[129] The investigative committee may feel there are other avenues that need to be investigated.
[130] A Class A or B complaint. OPMC currently has the authority to limit a physician, physician assistant and special assistant's license.
[131] OPMC and BNE can develop something within the office of Health Systems Management (Grand Jury Exhibit 81)
[132] Testimony of the NYS Director of BNE

current proposals to address diversion are predicated on this manual prescription-issuing process; however, a system mandating E-Prescribing eliminates the circulation of these written forms and would essentially eliminate prescription forms as a source of diversion.

DEA has approved the federal standards and protocols to ensure security for the E-Prescribing of controlled substances (Grand Jury Exhibit 83). As testified to by the Chief Executive Officer of the Pharmacists Society of the State of New York (PSSNY) in support of E-Prescribing. The idea is to:

> stop making it profitable for prescribers to just write for anybody that walks through their door…ninety-nine percent of the diversion of these scripts and stealing of these scripts would be stopped.

To implement E-Prescribing, New York must either adopt the DEA protocols or modify them in accordance with DEA regulation. Pharmacist representatives and the Division of Legal Affairs within BNE are working on DEA-compliant regulations to institute E-Prescribing.[133] E-Prescribing verifies the authenticity of the prescription. Under DEA protocols, prescribers must be fingerprinted and digitally sign each prescription.[134] A designated person in the prescriber's office may write the prescription but the prescriber must sign the prescription himself, using authenticating factors. The prescription is then digitally sent to the pharmacy, which must utilize certified security measures.[135] Optimally, E-Prescribing will be integrated with electronic health records so prescribers can access health records and prescription information in one system. PSSNY contrasts this proposal with the current one put forth by the New York State Attorney General referred to as I-Stop. I-Stop does not integrate database systems together. Rather, it creates an additional database terminal that prescribers and dispensers must utilize to access

[133] Walgreens has software utilized in other states that is the gold standard for E-prescribing.
[134] DEA requires two of the three authenticating factors: something you know, something you have, something you are.
[135] The security uses Public Key Infrastructure (PKI) or a computerized encryption method to guarantee privacy.

prescription histories. PSSNY believes that greater efficiency and effectiveness would be achieved by utilizing an integrated system that included E-Prescribing and the use of one computer terminal to access all information.[136]

The New York State Board of Pharmacy was an early advocate of E-prescribing and supports a mandate that requires, with limited exceptions, all prescribers to electronically prescribe controlled substances,[137] According to the Executive Director, the benefits are many. Among them are enhanced safety, eliminating the black market for stolen New York State official prescription paper, and eliminating forged prescriptions. Blank prescriptions have been stolen by the tens of thousands in New York City and are being forged.[138] PSSNY indicates that prescribers call regularly to report stolen prescription pads. The Board of Pharmacy recommends that New York State coordinate with the already-approved DEA regulations and approve E-prescribing regulations as soon as possible.[139]

The software utilized and approved by DEA for E-prescribing would connect to the current list of DEA Registrants; this ensures that a prescriber would not be able to submit an E-Prescription unless his registration numbers were current. New York must also exercise its authority under Article 3371(a) of the New York State Public Health Law which allows for interstate interconnectivity/interoperability. This would connect New York prescription records with other states to prevent diversion activities that cross state lines.

[136] The proposed I-Stop program in New York will create burdens on the prescribers and pharmacies to utilize a third terminal because there is no provision for it to be incorporated into any current system.
[137] A task force formed in 1997 anticipated completion in 2002, but national events interceded.
[138] Law enforcement information indicates that blank prescriptions have a street value of $100-$300 each
[139] This process also requires that prescriber and pharmacist software be validated to meet the standards of the DEA and New York State. Virginia, California and Florida are currently running test programs.

IV. Medical Practice and Pain Management

A. Controlled Substances Licensing

DEA and federal law establish who may lawfully prescribe controlled substances as well as the registration requirements for obtaining such authorization[140]. In New York, prescribers permitted to seek authorization are medical doctors, doctors of osteopathy, dentists, veterinarians, podiatrists, optometrists, nurse practitioners and physician assistants. Individuals seeking long-term pain relief are often directed to practitioners who specialize in pain management. To obtain a DEA license, a New York practitioner must prove authorization to prescribe controlled substances under New York law, and either registration with DEA or proof of an exemption therefrom. As noted in this report, New York does not require specialized training, certification, or continuing medical education for its prescribers in the proper use of opioid therapy. There is no such requirement at the federal state level either.

B. Medical Practice

The Grand Jury received testimony and evidence from a practicing nurse practitioner who possesses a doctorate degree in Nursing, specializing in pain management. The witness was the Chairperson of the Graduate Nursing Studies Department at a Long Island medical center, a board member of a recognized nursing society for pain management, and a member of the Ethics Committee of another such society. As with other recognized specialists in the field, this witness has been a speaker at non-accredited industry seminars on the use of drug therapies for pain management, receiving payment either directly from a pharmaceutical manufacturer or through a third-party educational sponsor, as is common in the field. Additionally, the witness co-authored a publication for practitioners of pain management. (Grand Jury Exhibit 47)

[140] 21 USC 800 et seq; 21 CFR 1306.03

This pain management practice includes two medical doctors, one who is board certified in neurology and the other in pain management. The practice consists almost exclusively of chronic non-cancer pain patients. As with many pain management practices, it was explained to the Grand Jury that most of chronic non-cancer type pain patients suffer from muscular skeletal pain, with lower back pain being the most common complaint. The practice does include other patients with diabetic neuropathy, headaches, neck pain, and a variety of other types of pain. The witness was uncomfortable with the recent attention drawn to pain management practices and the growing perception that such practices do nothing more than prescribe opioids. According to her testimony, patients come to the practice seeking pain relief when other non-opioid methods such as non-steroidal anti-inflammatory drugs, Tylenol, or epidural steroid injections have failed. Non-specialists are often reluctant to prescribe opioids since doing so requires vigilance in patient monitoring. As a result, it has become a specialty practice that has grown significantly in the past two decades.[141]

Almost all of her patients are referrals, typically from primary care physicians. Patients are frequently referred to a pain management clinic when their pain relief is otherwise inadequate.[142] According to this witness, it is very common in a pain management practice to treat patients with opioid analgesics.

In the witness' practice, as well as others with which the witness is familiar, Schedule II and Schedule III drugs are prescribed most often.[143] In fact, the witness testified that 99.9% of her patients treated for pain have been on opioid therapy for more than 30 days. Every patient

[141] Grand Jury Testimony, January 31, 2012, Page 34, 35.
[142] A typical first visit would include an assessment and physical examination by the attending physician in the practice, obtaining a complete history, and a review of prior records provided by the patient including x-rays, MRI results and other such tests if available. The referring physician may be contacted when the records are inadequate. If the decision to treat the patient is to include opioid analgesics, prior to writing the first prescription, a screening urine analysis would be taken.
[143] Among those noted by the witness are Oxycodone, OxyContin, Vicodin, Percocet, Morphine, Fentanyl, and Dilaudid.

considered for opioid treatment must complete an opioid risk tool, which is comprised of fifteen questions designed to illicit indicators for potential drug abuse. This self-reporting screening tool may impact the manner in which the patient is treated, but will not necessarily cause the prescriber to choose non-opioid therapy alternatives. Instead, more frequent appointments and urine screenings are the likely response to patients assessed at a high level of risk for abuse.[144] An "opioid agreement" is another tool commonly employed, which when used as intended, allows prescribers to have a discussion with the patient, outlining potential side effects associated with the medication, and reviewing terms such as dependence and abuse. The witness testified that New York State's Prescription Drug Monitoring Program (PDMP) is sometimes checked to verify that a patient is not seeking drugs from another prescriber. Such techniques are commonly referred to as Risk Evaluation and Mitigation Strategies, and are more frequently employed by opioid prescribers than other practitioners since the FDA recently indicated that it was pursuing a mandate for such use.

Addressing the abuse potential of opioid analgesics, the pain management specialist referred to the introduction of a time-release form of oxycodone, a Schedule II controlled substance. This time-released form of oxycodone is manufactured to provide up to twelve hours of relief from a single tablet. At the time of its introduction, the other primary long-acting opioid on the market was morphine-based. The witness repeatedly emphasized that when this new oxycodone formulation was first introduced "it was very well marketed" and said marketing was highly influential with "many, many" practitioners, physicians and nurse practitioners in the field.[145] The manufacturer claimed it had created a low risk opioid analgesic that could provide

[144] Screenings which identify potential abuse trigger further consultation with the patient, referral to an addictionologist, a weaning-off period for opioid treatment, and the introduction of non-opioid treatment therapies such as physical therapy and non-controlled drugs.
[145] United States General Accounting Office Report, *Prescription Drugs*, December (2003) 8-28,

long-acting pain relief that was less addictive and less subject to abuse. Sales of the product grew rapidly.[146] Indeed, approximately 40% of the patients in the witness' practice who receive opioid analgesics are prescribed this oxycodone formulation, typically an average dose of 80 milligrams three times per day. Of that 40%, some patients are prescribed the drug for many years.[147] In the opinion of this witness, pain management experts treat chronic pain as a disease that has biological and psychological components, as well as social effects.[148] Proper treatment, therefore, ideally includes medication to address the biological aspect, and self-help interventions to address the psychological and social aspects of the disease.[149] In the experience and opinion of the witness, opioid therapy is more readily reimbursable by insurance for long-term treatment than other treatment modalities. She believes that to effectively treat such patients, opioid therapy is a necessity.

Nevertheless, despite the widespread use of opioids for the treatment of chronic non-cancer pain, there is considerable expert opinion that opioids have not been proven safe and effective for chronic pain; at a minimum, the data does not exist to support such use.[150] For example, the timeframe of the clinical trials relied upon by the FDA when approving their manufacture is only 12 weeks in duration. Although these trials may show modest pain relief over that period of time, there is no data to indicate that pain relief effectively continues after longer use. Medical experts have reason to believe that pain relief may actually decrease over

[146] Grand Jury Exhibit 103A – Pain Physician Journal, Effectiveness of Long-Term Opioid Therapy for Chronic Non-Cancer Pain E134, 2011

[147] As noted earlier, this is practice is predominantly for chronic non-cancer pain; 99.9% of its patients receive opioid therapy for some period of time. Hence, 40% of the total practice involves the prescribing of time-released oxycodone.

[148] A representative of a major pharmaceutical manufacturer of opioid medications testified that e does not believe pain to be a disease, but rather is a symptom only.

[149] An example might include coping skills therapy, or continued use of exercises learned during physical therapy after the normal course of treatment, payable by insurance, has expired.

[150] Grand Jury Exhibit 103A

time, due to tolerance; there is also evidence that patient functioning declines with long-term use of opioids.

The Executive Director of the New York State Board of Pharmacy agrees with other pharmacists and medical experts that opioid analgesics may be appropriate therapy for some patients. In fact, early in his career he and a colleague operated a specialty satellite pharmacy in the cancer clinic at Albany Medical Center Hospital, with a mission to reduce pain and other side effects from chemotherapy. This sensitized him to the need to treat patients experiencing chronic pain. However, he disagrees with those organizations and prescribers who offer support for a more liberal practice of prescribing controlled substances, opioids in particular. Rather, he believes that

> the evidence is clear that what we are seeing in these numbers is not *(pause)*, proper prescribing is not a defense for what we're seeing. The numbers are just too staggeringly high. There is not that much chronic pain.

The Executive Director refutes the position of those in the medical industry who argue that physicians are in fact under-prescribing opioid analgesics. To assist in correcting this, the Executive Director is supported by others including a medical physician specializing in addiction treatment, a research scientist in the field, and other pharmacists, in recommending a change by the FDA in the labeling of these substances. Specifically, they argue that the "on-label" use of all opioid analgesics must be carefully restricted to instances of acute pain, palliative care and end-of-life care situations. This change does not prohibit a prescriber from alternate "off-label" prescribing for the management of moderate to severe pain over extended period of time,

including chronic non-cancer pain. The hope is that it may induce more cautious prescribing practices.[151]

Moreover, there is a relatively new concept in the study of pain management referred to as opioid-induced hyperalgesia, a term used to describe the body's response to increased doses of opioid analgesics. Raising the dose of medication may actually cause an increased sensory response in the body perpetuating the pain. Increased doses may actually cause greater pain. The nurse practitioner witness before the Grand Jury reports that some of her patients have experienced hyperalgesia.

It is obvious despite the disgraceful history of careless marketing of opioids, the collaborative relationship between manufacturers and practitioners continues to thrive. The Grand Jury was presented with testimony and evidence about pain organizations whose stated purpose is to "serve people affected by pain." In 2010, nine of the top ten donors for one such organization were manufacturers of pharmaceuticals and medical products. (Grand Jury Exhibit 9) Donations that year ranged from $50,000 to more than $1 million. The nurse practitioner who testified she has at times participated in industry-funded educational programs, described the relationship between manufacturer and practitioner as complex. She agreed that while it is incumbent on the practitioners to learn about new medicines that are available, each practitioner has to be "very, very careful" about the influence of marketing on prescribing practices.

Unfortunately, not all prescribers are as vigilant. Opioid addiction breeds deceptive behavior by patients to secure more and more pills. The medical community, unwittingly or otherwise, appears to be complicit in feeding an addiction. *Defendant C* provides insight into this when describing his own actions. At the height of his addiction, he was ingesting 30

[151] These experts also urge the FDA not to approve an opioid currently in clinical trials which is pure hydrocodone in a time-released form.

oxycodone or 80 Roxicodone daily depending on availability.[152] What he could not obtain from physicians, he would purchase on the street. He had regular monthly visits with two different physicians. He believes his addiction and diversion practices were "obvious to a duck." He did not hide anything. He would go to his appointments wearing expensive jewelry, driving luxury vehicles, and high on prescription opioids. When asked if the physicians knew he was addicted, abusing or diverting, *Defendant C* explains, "You got to know. You got to know." Ignoring obvious evidence of addiction, was a violation of the New York State Public Health Law §3372 which states that:

> It shall be the duty of every attending practitioner to report promptly to the commissioner, or his duly designated agent, the name and, if possible, the address of, and such other data as may be required by the commissioner with respect to, any person under treatment if he finds that such person is an addict or a habitual user of any narcotic drug.

Nevertheless, over a period of more than five years, *Defendant C* never encountered resistance from any of the physicians he visited. He described that the first visit to each physician was standard in that forms were completed, and insurance coverage was documented as well as the purpose of the visit. Typically on the first visit most addicts will state that they suffered a back injury, *Defendant C* explains that it is also common to tell the physician that you were previously prescribed the drug you are currently seeking. During the initial visit with one particular physician, *Defendant C* indicated that he had lifted weights and heard a pop, his back was injured, and he had pain down his leg. The physician asked him to bend down and touch his toes. No further examination took place and the physician issued him a prescription for an opioid. After the initial visit, *Defendant C* had regular appointments every 3-4 weeks, but he did not see the physician each time. He merely made the appointment explaining to the receptionist that he was still in pain. When he appeared for the appointment, he spoke with the receptionist

[152] Roxicodone is one manufacturer's name for oxycodone

who would have his prescription waiting at the desk. He paid her the co-payment and left with the prescription. Every 3-4 visits he would see the physician. *Defendant C* had a similar routine with another physician during this same timeframe, although in this instance he did see the physician during each visit. The physician readily prescribed what *Defendant C* needed. He advised neither physician that he was receiving prescriptions from the other.

V. The Pharmacist Perspective

A. Introduction

Pharmacist A has been a registered pharmacist since 1984, and is currently the Supervising Pharmacist at the Student Health Center of a major New York university. He previously owned two different pharmacies in Suffolk County and was the victim of an armed robbery in each. During each robbery, a controlled substance was stolen from his pharmacy. In November of 1986, two armed defendants entered his Centereach pharmacy seeking Dilaudid, a prescription opioid painkiller. Bystanders were ordered to the ground, *Pharmacist A* retrieved the demanded drugs. The defendants fled and hours later were apprehended, asleep at the wheel of their vehicle on Middle Country Road, an apparent result of ingesting the stolen Dilaudid.

In August of 2000, in the afternoon hours, *Pharmacist A* again encountered the criminal side of addiction when an agitated male jumped over the counter of his Setauket pharmacy, brandished what appeared to be a gun, shouted at the pharmacist and his two female employees to get on the floor, and directed him to put the drugs in a bag:

> He had what appeared to be a gun….put it to my chest and said 'put the shit in the bag….don't look at me….get down on the floor,'…he kept yelling 'put the shit in the bag.'

This time the defendant stole Valium, a Schedule IV controlled substance. The defendant fled, but after alerting others to call 911, *Pharmacist A* pursued the defendant and observed him driving away. Suffolk County police apprehended the defendant 15 minutes later about one and a half miles away. The defendant, identified as James McGoey, was convicted and sentenced to a term of state prison. After the second robbery, *Pharmacist A* sold the pharmacy and went to work at the university.

The pharmacist told the Grand Jury about many sleepless nights since he was robbed. His feelings were compounded after another armed robbery at Charlie's Pharmacy in Seaford, Nassau County, New York. Now released from prison, James McGoey entered Charlie's Pharmacy in December of 2011to forcibly steal prescription opioid medications. During the chaos that ensued, John Capano, an off-duty agent of the Bureau of Alcohol, Tobacco & Firearms, was shot and killed. Reflecting on this tragedy, *Pharmacist A* is haunted by his own experiences.

Pharmacist B testified before the Grand Jury about the criminal activity that she knows is associated with prescription controlled substances. In addition to owning a pharmacy, *Pharmacist B* is the President of the Long Island Pharmacist Society (LIPS). Increased prescribing and increased availability of controlled substances has resulted in an increase in pharmacy burglaries. *Pharmacist B* was victimized twice within a two month period when large amounts of opioids were stolen in one burglary, and benzodiazepines were stolen in the second. She testified that the criminal impact of this problem "has made all of us in the profession a little more fearful of going to work." Some pharmacies now hire guards for their entrance ways or are installing buzzers to allow access into the pharmacy.

The Executive Director of the New York State Board of Pharmacy testified before the Grand Jury.[153] He is a licensed pharmacist, holds a Bachelor's Degree from the Albany College of Pharmacy, and a Masters of Health Sciences and Administration from Union College. He has spent thirty years in the profession. Prior to receiving his current appointment, he was the Supervisor of Pharmacy Practice and Registration in the Office of the Board of Pharmacy. He testified that the current epidemic of prescription controlled substance abuse is the worst ever experienced in this country, as evidenced, in part, by the extreme rise in opioid analgesic treatment admissions. (Grand Jury Exhibit 6)[154] He points to a confluence of factors contributing to this problem which include the availability of opioids from both legal and illegal sources; misperceptions of potential harm due to the lawful commercial manufacturing of these drugs; Internet distribution practices; overprescribing; and inappropriate prescribing of controlled substances. The Chief Executive Officer of the Pharmacists Society of the State of New York (PSSNY) agrees that diversion comes from a variety of different causes and methods. He also notes that twenty-seven million prescriptions are written yearly and seventy four thousand are dispensed daily. These statistics represent all prescriptions, not just opioids. However, the high-volume figures highlight the need for an effective database that monitors prescriptions.

In response to the concerns of pharmacists, a Task Force was set up by PSSNY which includes member of the New York State Senate and Assembly, the Attorney General, Physicians and Pharmacists to address this multi-faceted problem. The Task Force is seeking to address

[153] The New York State Board of Pharmacy regulates the pharmacy profession within the State Education Department. The Board is comprised of pharmacy professionals and lay members, each appointed for five-year terms and representing diverse segments of the profession including hospitals, nursing homes, community pharmacies and academia. It provides the Board of Regents and Commissioner of Education with guidance and advisory opinions on professional practice, education, experience and licensure issues. This includes commentary on proposed legislation and new standards of education. There are approximately 27 Professional Boards in New York State which regulate professions such as architecture, engineering, dentistry, midwifery, etc. al.

[154] SAMHSA 2009 Report

issues including excessive prescribing; the failure of prescribers and patients to be cognizant of the powerful and potentially addictive nature of controlled substances; proper monitoring of patients receiving controlled substances; proper dispensing; reforms of the New York State Central Registry commonly referred to as the Prescription Drug Monitoring Program (PDMP); education and public awareness.

B. Legal Obligations and Continuing Education

Pursuant to Part 80.65 of the Rules and Regulations on Controlled Substances in New York State:

> "A prescription, in order to be effective in legalizing the possession of controlled substances, shall be issued for legitimate medical purposes only. The responsibility for the proper prescribing and dispensing of controlled substances shall be on the physician, dentist, podiatrist, veterinarian or other authorized practitioner, but **a corresponding liability shall rest with the pharmacist who fills the prescription**. **An order purporting to be a prescription, issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with narcotics or other controlled substances sufficient to keep him comfortable by maintaining his customary use, is not a prescription** (emphasis added) within the meaning of subdivision 30 of section 3302 of the Public Health Law, and the person knowingly filling such an order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances (Grand Jury Exhibit 35A).[155]

To fulfill this obligation, pharmacists receive more training with reference to the composition, use, and effects of controlled substances than does any other profession. The New York State Board of Pharmacy selects the Professional Examination each pharmacist must pass to practice

[155] Federal law also imposes a corollary responsibility on pharmacists to ensure that a prescription is issued for a valid purpose. 21 CFR 1306.07 and 21 USC 800 et seq. referred to as the Controlled Substances Act.

in the State, and issues licenses and administers professional compliance matters.[156] Continuing professional education for pharmacists is mandatory in New York State. [157] This is not the case for most physicians and others who prescribe. Prescribers, in particular, are not required to have mandatory continuing education concerning the proper use and prescribing of controlled substances. A medical doctor specializing in addiction testified that

> Physicians that are prescribing these opiates have been out of school for decades and have not been educated on how powerful they are because these drugs are more recent. They can't just be prescribing these like it's candy, because it's not.

One measure to ensure that prescribers fully understand the nature of the controlled substances they prescribe, their proper and lawful applications, and further train them to identify and distinguish drug-seeking behavior, is linking mandatory education to DEA registration. To receive or maintain a DEA license to prescribe controlled substances, a prescriber must be required to show proof of continuing education in the field. This suggestion was supported by witnesses from the medical, pharmacy and regulatory communities. This approach guarantees that educational resources are focused on addressing the current epidemic. Physicians in pain management settings must be educated and updated on evidence-based treatments for pain, such as non-steroid anti-inflammatories and physical therapy, which may provide better results with fewer side effects than opioids.

[156] Since 2004, the requirements for becoming a pharmacist are a minimum of six years education; two years of pre-professional study and four years of professional study which includes one year of clinical rotations. Upon successful completion, the candidate receives a Doctor of Pharmacy degree and must then pass the North American Pharmacist Licensure Examination (NAPLEX) and the NYS Multistate Pharmacy Jurisprudence Exam and Practical Exam. Approximately 1,100 licenses were issued in 2011 in NYS.

[157] Forty-five hours of continuing education is required of pharmacists every three years to keep their license. Pharmacists also complete two hours a year on patient safety which includes fraud, waste and abuse. It is even being suggested that Pharmacists are mandated to have two to three hours of controlled substance training every three-year cycle period.

C. Prescription Drug Monitoring Program (PDMP)

The PDMP is officially designated as the Central Registry but is commonly referred to nationwide as a Prescription Drug Monitoring Program (PDMP). Pharmacists and their professional boards and societies provided information and perspective for increasing the effectiveness of this system to the Grand Jury. In New York State, every prescription for a controlled substance contains a serialized code. Pharmacists in New York State have an obligation to send all controlled substance prescriptions to BNE. Reporting must be done by the 15th day of the month following the filling of the prescription.[158] BNE does not report back to the pharmacist about the submitted prescriptions, nor does the pharmacist have access to the PDMP database itself. When attempting to comply with the legal and ethical obligations under Part 80.65, the pharmacist is denied access to a patient's prescription history.[159] Clearly, this impedes the effective fulfilling of that obligation.

To further assist pharmacists in fulfilling their obligations, experts recommended to the Grand Jury that prescribers place an indication of the drug's medical purpose on every prescription.[160] This information would assist in preventing medical errors and, in the instance of controlled substances, place the onus on the prescriber to more diligently diagnose the patient and determine a proper course of treatment.

[158] Under current regulations then, this could amount to a 45-day delay in reporting a prescription issued on the 1st day of one month to the 15th day of the following month.
[159] Part 80.65 of the New York State Rules & Regulations of Controlled Substances prohibits prescribers and dispensers from issuing controlled substances to an addict for the sole purpose of maintaining his comfort and customary use.
[160] PSSNY believes this is a necessary patient safety issue in that approximately handwritten errors made by the prescriber frequently occur.

VI. SCIENTIFIC AND MEDICAL RESEARCH

I have chronic pain…I take Tylenol

A. Declaration of an Opioid Epidemic: Centers for Disease Control

The CDC studied overdoses from prescription pain relievers in the United States from 1999 through 2008.[161] Its findings are both cause for alarm and a call to action. Prescription drug overdoses in the United States have reached epidemic proportions. During the ten year period studied, drug overdose deaths were a close second to the number of deaths from motor vehicle accidents. Opioid pain relievers accounted for more overdose deaths than heroin and cocaine combined. (Grand Jury Exhibit 6) When questioned in the Grand Jury regarding the abuse potential of Vicodin, a DEA representative stated that hydrocodone products were the number one abused drugs in the United States until 2010 when oxycodone exceeded it.[162]

B. Addiction Research

Everyone who dies from an opioid overdose, suffocates.

Understanding why opioid analgesics, and the resulting addiction, have plagued so many Americans requires an understanding of how these drugs function. The Grand Jury heard testimony from a leading scientist in the field of substance abuse and addiction who utilizes brain imaging in his research. This expert holds an MD and PhD from the University of Iowa and completed a post-doctoral fellowship in the Neurology Department at Stony Brook University

[161] "Vital Signs: Overdoses of Prescription Pain Relievers --- United States, 1999—2008" *http://www.cdc.gov/mmwr*

[162] Vicodin is a combination of hydrocodone and acetaminophen. Because of the combination, it is a Schedule III controlled substance. Hydrocodone and oxycodone alone are Schedule II controlled substances. DEA may change scheduling classifications of controlled substances.

Hospital. For more than 23 years he practiced as a research scientist at the Brookhaven National Lab Imaging Center specializing in imaging in the field of substance abuse. He is now with the Feinstein Institute at North Shore/LIJ University Hospital, while also serving as a full-time professor with Hofstra University's newly opened medical school.[163] He has published more than 150 peer review publications, 17 book chapters, and approximately 260 abstracts; the expert also volunteers his time providing educational presentations on substance abuse prevention to schools throughout the tri-state area.

This expert has spent the majority of his career studying and refining his research using an imaging technique known as Positron Emission Technology (PET Scan).[164] Unlike the more familiar imaging techniques including CAT Scans, X-rays, or MRIs, a PET Scan visualizes *function*, which is how an organ or body part lives; the other imaging methods visualize *anatomy*, which is how it looks. This difference is critical in the study of the human brain and its interaction with various controlled substances. Every disease starts with a change in body function as opposed to a change in anatomy. This includes drug addiction. As the disease progresses, anatomy changes which can be seen using CAT Scans, X-rays, or MRIs. But these scans are not useful until a disease progresses to a point where a change in appearance can be seen. In contrast, PET scan imaging and detection reveal functional changes which occur at a much earlier stage of the disease.

Unlike every other organ in your body, the brain uses glucose (sugar) for energy. To conduct a PET scan, radiopharmaceutical molecules containing glucose are injected in the

[163] While at Brookhaven Labs, with rare exception, the majority of his work was funded by the US Department of Energy. The National Institute of Health funds the majority of his work at Feinstein.
[164] PET Scans are the number one test for cancer today. Hundreds are currently in use throughout the world, as compared to just four in the mid-1980s.

patient, much as thallium is injected for the purpose of cardiac stress tests.[165] As the brain needs sugar for energy, it absorbs it, and the radioactive-labeled portion is tracked. The patient is injected; waits 30 minutes for the body to absorb the molecule, and a scan lasting 8 minutes is performed. Images of brain function are then captured using the rainbow color scale.[166] Therefore, when viewing a PET scan image of the brain, the color red will indicate areas where the brain is very active, descending to the color blue, reflecting no activity.

When viewing PET scan images of the brain it is important to remember that age matters. Unlike CAT Scans or MRIs which will present identical images of the human brain in an infant, six-year old, or sixty year old, a PET scan will display a different image for each stage; age causes the brain to function differently at different ages; and again, it is function that is imaged through a PET scan.

Whether it is caffeine, the number one drug of abuse, or methamphetamine, one of the most addictive drugs known, all drugs elevate brain dopamine; the degree of elevation and the manner in which a drug elevates dopamine indicates the addictive power of a drug.[167] Natural rewards, such as a good grade on a test, enjoying a movie, or your team winning a championship, elevate dopamine levels 10-15%. Drugs such as methamphetamine will elevate it between 500,000 and 600,000%.

According to this expert, the epidemiology or study of substance abuse reveals it to be an adolescent disease. Accepted medical and scientific understanding is this: most illicit drug use begins by the age of 21. Thereafter, the likelihood diminishes dramatically. This is because adolescents have the highest levels of brain dopamine. Higher levels of dopamine increase the

[165] Specifically, F18. fludeoxyglucose
[166] The rainbow color scale includes red, orange, yellow, green, blue, indigo and violet, in consecutive order.
[167] Dopamine is the primary neuron responsible for movement. It allows us to feel good.

likelihood of novelty or thrill seeking behavior, such as substance abuse. PET scan measurements and studies of dopamine levels have revealed that generally by the age of 21, dopamine levels decrease naturally. This explains why people in their 20s and 30s tend not to become substance abusers, and bolsters the recommendations of experts and this Grand Jury for greater education concerning substance abuse particularly among the young.

Despite the statistical data, however, drug abuse and addiction have risen for those in their 20s and older. Based upon the decreased dopamine levels and concomitantly reduced likelihood of thrill-seeking or risky behavior, this age bracket should not be at risk for abuse; however, they are, and prescription opioids are a major cause of their addiction and abuse. (Grand Jury Exhibit 6)[168] Not suspecting that a commercially manufactured, government regulated, and lawfully prescribed medication may cause addiction, these patients unwittingly have fallen victim to the disease. For a large number of these addicts, the result is the previously described cycle of opioid and heroin use.

Scientific studies reveal that drug use is encoded or associated with the environment within which it is used by the abuser. Hence, the primary cause of relapse is an environmental trigger. When the trigger is present, PET scan images reveal activation in the portion of the brain responsible for craving, reward, and motivation. This may be in response to a song that was heard while smoking marijuana, or even walking by a familiar street corner where drugs were purchased. Therefore, the PET scan is a powerful tool because behaviors can be triggered and resulting brain activity visualized.

[168] The 2004 data from SAMHSA indicates that opiate abuse is highest between the ages of 20 & 50.

Throughout his career, this expert has used the PET scan technology to study the impact of various substances on brain functioning – everything from caffeine, alcohol and nicotine, to marijuana, cocaine, and opioids. Looking back over a 30 year career in medical science, this expert observes:

> I have never seen as big an increase in the use of opiates over any other drug. In the 80s cocaine was big; in the 90s we had club drugs; we had GHB, we had Ecstasy. Now here we are in 2012 and opiates are everywhere. And opiates are particularly dangerous for a number of reasons. And I think most of us probably know why. They are so prevalent. We have people writing scripts.

Research identifies opioids and methamphetamine as having the highest addictive liability. Every prescribed opioid operates within your system by metabolizing or converting into morphine; and it is the morphine that instructs the brain to manage pain. In the manufacture of currently marketed opioids, drug companies encapsulate the morphine by attaching different molecules to it, so it takes longer for the morphine to get into your brain; the body must process those molecules first.

Studies have shown that one of the particularly unique effects of opioids is their impact on the orbital frontal cortex (OFC) of the brain. The orbital frontal cortex is that part of your brain that activates what is called a go/no-go decision. For example, the traffic light turns red, you stop. It turns green, you go. That is the result of the OFC functioning properly. It is instructing you when to do something and when not to do something. With the ingestion of opioids, users start to lose the function of their OFC.[169] As this function decreases, users will literally lose their ability to say no. This manifests itself in very real and sometimes tragic ways:

> You know it's wrong, you wouldn't do it. But if you have no OFC you don't have a go/no-go response…..that is why you can take an opiate user and say, look, if you take that next dose, you'll go into respiratory arrest

[169] PET scan images from various published studies were presented.

> and die. They don't hesitate. They take the next dose because they lose their OFC. It's very unique to opiate abusers….and it does appear very rapidly in opiate abusers.

Even a single dose of an opioid will start to alter impulse control. This is evident in an increasingly prevalent situation referred to as "buzz driving" by this expert. The expert provides examples, such as the inability to stop at a red light or the decision to just go through it; or whether or not to go around the railroad crossing gate. Therefore, "opioid-buzz driving" is extremely dangerous because of the risks taken by such drivers. To combat the problem, this expert supports an amendment to the NYS Vehicle and Traffic Law which broadens the list of controlled substances included in prosecutions for operating a motor vehicle while ability is impaired by drugs under §1192.4. This would include those designated by either the federal or state Schedules.[170]

Another effect on the brain of opioid abuse is the appearance of large white lesions referred to as leuco encephalo, or white matter lesions. This is very unique to opioids and similar in appearance to the lesions often present in multiple sclerosis patients. Because of this similarity, patients are often misdiagnosed. When the lesions appear around the brain stem, which controls breathing, the results can be deadly. The reticular activity system (RAS) in the middle of the brain stem controls spontaneous breathing. In effect, it takes over our spontaneous breathing when sleeping by communicating with our lungs. Opioid abuse causes leuco encephalopathy to develop around the brain stem, meaning that the RAS no longer communicates with the lungs, breathing stops, and death ensues. Simply put, everyone who dies from an overdose of opioids, suffocates.

[170] For example, Soma is now a Schedule IV controlled substance under federal law but is not yet scheduled under the New York State Public Health Law.

It is important to note that in the presence of pain, opioids bind to the open pain receptors in the brain. But if those receptors are not open, as would be the case for a recreational user/abuser, the opioid circulates and causes the white matter lesions. The same is true for the effect on the orbital frontal cortex – in the presence of actual pain you will not experience a decrease in OFC functioning. But if you continue to take opioids in the absence of pain, changes occur.

Perhaps one of the most useful applications of the PET scan in the context of opioid prescribing, though not currently employed as such, is its ability to image the presence of pain or lack thereof. Pain opens receptors in the brain, thus imaging the location of the pain. It also monitors images of pain as it dissipates. The scan captures and monitors even moderate chronic pain, such as that caused by the common slipped disc or shoulder injury. For example, a PET scan will capture pain that, in layman's terms, comes and goes. In this expert's opinion, such a patient is not a candidate for opioids. Because of its unique ability to diagnose and monitor the treatment of pain, this expert supports instituting a protocol mandating the use of PET Scan technology to properly test and treat pain management patients before controlled substances are prescribed, certainly for long-term noncancer-related pain therapy.[171] Pharmacists and medical experts suggest that all patients receiving prescription opioids in chronic pain settings should, at a minimum, submit to regular blood testing to determine whether proper therapeutic levels of the prescribed opioid are present. Urine testing, which is currently used by some prescribers, provides limited information to the prescribing physician.

[171]The FDA is now requiring pharmaceutical manufacturers to include PET Scanner testing in all new drug approval applications. The test is also commonly used today for cancer detection and epilepsy. However, most insurance companies today will not cover the cost of a PET scan for the treatment of pain.

Experts also suggested "drug holidays" as a component of treatment modalities to the Grand Jury. Opioid patients being treated for moderate to severe pain cease taking the medication for 24 hours; or for at least a minimum of one dose. The treating physicians can then image the brain using a PET scan. If, after missing a dose the pain returns, it will be reflected in the scan and prescription therapy can resume; otherwise, it should cease.

According to the research expert, a single dose of an opioid may cause addiction. Pre-clinical studies demonstrate this finding.[172] In large numbers, substance abusers report that, unlike other addictive substances such as nicotine, alcohol or cocaine, one dose of an opioid began the addiction.

Addiction involves not only how high dopamine levels rise, but also how quickly they do so. In light of this, pharmaceutical companies have developed extended release tablets that lower the rate of transmission of morphine to the brain. While this reduces addictive liability, it does not eliminate the possibility of addiction developing over time with continued use.

Poly-drug abuse, the use of multiple drugs, is prevalent today particularly among the teenage population, and the risks are significant. When a person ingests multiple addictive substances, brain dopamine levels increase in a synergistic, rather than an additive, manner.[173] For example, a shot of alcohol may increase brain dopamine levels 200%; a hit of marijuana may increase levels 300%. But if ingested at the same time, dopamine levels will increase 5,000% not 500%. In this example, alcohol opens the blood brain barrier which normally functions to prohibit toxic substances in the body from entering the brain. By ingesting marijuana along with

[172] Pre-clinical studies use animals for testing.
[173] Additive means that the combination is equal to the sum effect of using multiple drugs. Synergy, however, refers to a combined effect that is greater than merely additive.

alcohol, the effect allows a higher level of the active ingredient in marijuana to enter the brain and the effects will last longer.

This synergistic danger dovetails with earlier testimony in the Grand Jury from an experienced diversion investigator. One of his recommendations included the addition of Soma as a scheduled controlled substance in New York State, because it is frequently abused and commonly diverted.[174] When taken with an opioid, Soma enhances the effect of the "high" by metabolizing into a drug similar to a benzodiazepine. "Almost every addict I have seen that is addicted to opiates is also taking Soma." Similarly, Ultram and Tramadol are highly abused and should be scheduled since, when combined with opioids, they also produce that enhanced effect.

There is virtually no disagreement in the medical community that addiction is a disease of the brain. Problems arise in diagnosis and treatment, however, because of the notion that addiction is a moral failing, rather than a disease. It is this misperception that causes many who develop the disease to experience shame and embarrassment, often leading to aberrant behavior in an attempt to hide the addiction. Certainly while we are each accountable for our own actions, experts agree that addiction alters brain function in such a way that proper decision-making is impeded.

The Grand Jury heard testimony from addiction treatment experts. One such expert is a physician who received his medical degree from Temple University in Philadelphia, and completed his residency in psychiatry at Mount Sinai Hospital in New York City. Thereafter, he had a Congressional Fellowship in Health Policy in the United States Senate. He then completed a Public Psychiatry Fellowship at Columbia University. Subsequently, he was the Medical

[174] Soma, a commonly prescribed muscle relaxant, is a Schedule IV controlled substance in the **federa**l statutory scheme but not currently under the New York State Public Health Law.

Director of Special Projects at the New York City Department of Health and Mental Hygiene, initially working with the Department to reduce the number of people dying of drug overdoses. He is currently Chair of the Department of Psychiatry at Maimonides Medical Center in Brooklyn where much of his work is focused on providing mental health treatment for the local community, where he remains very involved in studying the prescription pain pill problem. He recently founded an organization called Physicians for Responsible Opioid Prescribing and serves as its President. He has published several articles on the topic of opioid prescribing, most recently "Long-term Opioid Therapy Reconsidered" which was published in the Annals of Internal Medicine in September 2011; the article is a critique of the manner in which physicians are treating pain with narcotic pain medication.[175]

In addition to supporting E-Prescribing, to address the public health crisis of prescription pill abuse, this expert recommended the following: first, the FDA must provide appropriate regulation of pharmaceutical products. Specifically he recommends that the FDA change the labeling of opioids to exclude their use for moderate to severe non-cancer pain, and limit indications to acute pain and palliative care settings, which accurately reflects the current available clinical evidence on the products. Proper labeling would lead to "primary prevention", the creation of fewer addicts by more careful prescribing. Because of their abuse potential, this expert advocates the rescheduling of hydrocodone and acetaminophen combinations such as Vicodin to Schedule II drugs, from Schedule III. This expert strenuously argues that the FDA must not approve the hydrocodone-based extended release product containing ten times the strength of Vicodin, without acetaminophen.[176] He believes it is unnecessary and dangerous. The OPMC must also revise its informational packets for physicians and patients which continue

[175] Grand Jury Exhibit 108.
[176] This drug is currently in Stage III clinical trials.

to promote opioids as non-addictive and monitor prescribers and patients who exceed the appropriate limited use of opiates. All practitioners must be mandated to utilize the PDMP prior to issuing an opioid prescription. Pharmacists should have access to the data and the New York State must use the data to link patients to treatment. This expert also supports "secondary prevention" described as the funding of additional treatment programs for those who become addicted. Stricter federal control over and limitation of the supply of raw materials for the production of opioids is also necessary and, to avoid conflict of interest, pharmaceutical manufacturers should not be permitted to play any role in the education of prescribers. Conflict of interest disclosures inadequate to distinguish between information that is marketing-driven and material that is evidence-based. This expert emphasizes that "doctors need to be prescribing based on good medical evidence, not advertising." And finally, he recommends that government officials should be prohibited from acquiring positions with pharmaceutical companies upon retirement or separation from government service.

Based upon this research, one expert reiterates the critical need to better educate prescribers, medical students, parents, teachers and adolescents about the effect of opioids, prescribing protocols, and abuse prevention. He too supports placing a warning label on all opioid prescriptions indicating that the substance is addictive. In the face of today's opioid epidemic, he supports limiting the supply of opioids by limiting their application in chronic pain settings. To achieve this, he believes it would be reasonable for the FDA to modify its on-label designation for opioids, making chronic pain treatment an off-label use. Such labeling may help limit the prescribing of opioids to those truly needing them. This position is supported by the recently formed independent Physicians for Responsible Opioid Prescribing, as well as other experts in the field, advocating cautious, evidence-based opioid prescribing. Evidence exists

globally that prescription opioids are associated with many long term adverse consequences. Among these are illicit drug use, increased disability, higher medical costs, subsequent surgery and lifetime substance use disorders. (Grand Jury Exhibit 103A) Currently, most opioids prescribed contain an FDA-approved on-label indication that the drug may be appropriately prescribed for "moderate to severe" pain. In increasing numbers, experts agree that the FDA needs to exercise its existing authority and modify the on-label indication for opioids, accurately reflecting existing research – or lack thereof. There are no studies demonstrating that prescribing opioids for long-term chronic pain is safe and effective.

Specifically, based on available research, the indications for opioids should be limited to "for short-term use to treat acute pain" and "to ease suffering at the end of life" or "palliative care." Indications must specifically ***exclude*** chronic noncancer pain. As it currently reads, and as widely promoted by opioid manufacturers, the indication of opioids for "moderate to severe pain" implies to physicians that it is safe and effective for treatment of a condition like chronic back pain, but the Grand Jury finds no evidence to support that position.

As with all FDA-approved drugs, this proposed "on-label" modification would not alter a practitioner's authority to prescribe opioids for "off-label" uses, including, when appropriate, certain limited chronic pain settings. It would, however, prevent a manufacturer from advertising its opioid analgesic product as appropriate for the treatment of chronic pain, thereby reducing the supply of opioid analgesics in the marketplace.

Medical experts and pharmacists also expressed concerns over patients who are prescribed opioids for pain management while awaiting surgery and suffered "accidental addiction" which was illustrated as follows: an insurance company delays hip replacement

surgery for eighteen months to three years for a patient; the patient nonetheless receives opioids to manage the pain, and the insurer covers the prescriptions during this extended time. However, the patient becomes addicted during the waiting period. It was suggested that the insurer should cover the cost of addiction recovery as well.

C. Addiction Treatment Experts

The Grand Jury heard testimony and received evidence from experts in the field of addiction including treating physicians, public health practitioners, and an addiction counselor. An expert in addiction treatment from Maimonides Medical Center advised the Grand Jury that a standard opioid prescription allowing for dosage at 3-4 times a day for two weeks can make a patient physically dependent. Addiction my soon follow if it has not already developed. Withdrawal can cause panic attacks and anxiety. Functioning declines with long-term use and typically dosage requirements increase simply to stabilize the user. For the unwitting or unscrupulous prescriber, this makes for a permanent patient and income source; opioid addiction does not go away.

As did other witnesses before the Grand Jury, addiction experts attribute much of the cause for the opioid epidemic to a change in physician prescribing practices, largely influenced by the marketing efforts of manufacturers and industry-supported advocacy groups. After conducting focus groups with members of the medical community prior to the launch of one such product, the manufacturer recognized the need to redefine the consumer value of its product. The industry promoted pain as "the fifth vital sign" and emphasized that opioids should be prescribed to treat chronic pain without fear of addiction. The Joint Commission for Hospital Accreditation later adopted this philosophy. Corporate dollars helped fund the formation of pain

patient organizations to help carry this message. Indeed, one organization urged state licensing Boards to advise doctors that, if they did not change their prescribing patterns, they would be sanctioned.

Addiction experts agree that compounding the problem is the labeling permitted by the Food and Drug Administration, specifically that opioids are appropriate for treating moderate to severe pain. The consensus, however, among these experts is that no data currently supports this representation. Addiction experts advocate for a change indicating use for acute pain and palliative care only.

In 2009, the FDA proposed regulatory changes to address abuses related to the extended release forms of opioids. These new regulations would have required that every practitioner take a class on the appropriate use of the drug and also mandated patient registries to monitor usage patterns. The pharmaceutical industry, however, quickly rallied its resources and successfully lobbied the FDA to eliminate any initiatives that may have led to less prescribing of the opioids.

D. Position of the Medical Professions

In stark contrast to this evidence is the position adopted by representatives of the medical professions at recent State Senate hearings and other forums in New York.[177] The Grand Jury received testimony from a high-ranking expert who is also a practicing psychiatrist who has worked extensively with drug and alcohol detoxification patients.

[177] These forums include the Attorney General's Office, the Bureau of Narcotic Enforcement, and State Legislators.

This witness testified that, in general, there is a serious opioid abuse problem that must be addressed quickly because "the longer we take, the more lives we are losing." But he expressed the need for caution to allow for the exercise of proper medical judgment:

> while we certainly need to address this and work on limiting abuse and diversion of these medications, we don't want to be so heavy handed that we limit access to medically needed care for patients with acute pain from recent illness, or chronic pain from long-term injury or illness, or people even needing addiction treatment themselves where sometimes a controlled substance is used early on in that treatment to get someone stabilized and they are detoxed off the meds of abuse.

Given this reasonable concern for treating patients, the witness was asked, as a practitioner, to define pain. He replied, "I guess that is difficult to define. That's one of the problems is how we define it and how each person experiences it." He was then asked if he were familiar with the Code of Federal Regulations (CFR) which permits the prescribing of opioid analgesics for the treatment of "intractable pain." (Grand Jury Exhibit 84)[178] He was not. Indeed, this representative testified that it can be very difficult for a physician to assess the nature of the pain and make an accurate determination as to whether or not opioid therapy is appropriate. The tools or methods employed to assess a patient's condition do not always yield instructive results. For example, a person may have a herniated disc that appears on an MRI, yet based on its location, that person may not be in pain. So the image itself does not necessarily answer the question of whether or not the patient needs pain medication. Therefore, "it's always a judgment call on the part of the physician."

The Grand Jury finds that this inability to define pain raises a troubling issue at the crux of this universally acknowledged epidemic. Pain is promoted as a vital sign and a treatable

[178] 21 CFR 1306.07(c) states that: "This section is not intended to impose any limitations on a physician…to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts."

condition; manufacturing and prescribing of opioids for pain management have skyrocketed as has addiction; and yet there is apparently no commonly accepted professional understanding or definition of pain, the very condition that is to be treated with these medications. In essence, this highly addictive class of drugs has been readily prescribed for a condition that is poorly understood by practitioners. The explosion of opioid treatment for a poorly defined medical condition lies with pharmaceutical companies whose aggressive marketing of these drugs has persuaded practitioners of their value.

Many of the publicly discussed solutions are met by the medical profession with tepid support at best, particularly those requiring physicians to adapt to new regulations, modify their treatment protocols, or invest financial resources. Individual practitioners support the mandatory use of the PDMP and E-Prescribing. However, the representative of the medical profession who testified before the Grand Jury opposes any mandates on prescribers, including the required use of the PDMP and E-prescribing; he indicated that they place unwanted administrative burdens and costs on prescribers. He also opposes the concept of requiring Board Certification in Pain Management for prescribers who treat chronic pain patients, calling such a proposal overreaching. Instead, this medical professional prefers voluntary cooperation, improvements to the current PDMP, and improved law enforcement efforts to combat the "abuse and diversion" of controlled substances. This medical representative has warned the State Senate during recent hearings not to "overcorrect the problem." When asked how the State could possibly "overcorrect" a public health epidemic, the expert told the Grand Jury the following: physicians are informed that pain is actually under-medicated or under-treated; but they are unnecessarily afraid of overprescribing, or prescribing to someone who may not really need that medication. To support the claim that pain is under-treated, he specifically referenced a recent report

published by the Institute of Medicine (IOM) which declared that patient pain needs are not being met.[179] The report appeared to indicate that more than 100 million adult Americans are currently in chronic pain. The IOM conclusion was accepted without challenge by the witness.

Not all experts agree with this conclusion. As one medical expert in addiction treatment explained to the Grand Jury, 100 million Americans with chronic pain would mean that more than one-third of the entire population in the United States is in need of pain treatment. While acknowledging some truth to the figure, he explained that it was derived from a study of the frequency of chronic pain complaints. The IOM looked at the reported percentage of the population in pain and extrapolated what many perceive to be an alarming number, declaring that 100 million adult Americans are in chronic pain.[180] The pharmaceutical industry and advocacy organizations have since relied on this figure to argue that over 100 million adult Americans have the *disease* of chronic pain, and will be disabled by it unless they get treatment. Clearly such a figure expands and enhances the marketability of prescription opioids, thus further increasing profits.

Up until very recently, medical school students were taught that pain was a symptom, a clue to an underlying medical problem. Today, students are taught to think about pain, particularly chronic pain, as a disease in itself. So, for example, the patient who complains of pain, saying 'I have had pain in my back for three months,' will likely be diagnosed with the disease of chronic pain. Many experts believe this is the root of the problem; instead of teaching the physician to explore why the patient has pain and discover its underlying cause, the pain itself is the disease, and it can be treated by simply prescribing an opioid.

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[179] The Institute of Medicine receives funding from a variety of sources, including pharmaceutical manufacturers, including those manufacturing and marketing opioid analgesics. It describes itself as an independent, nonprofit organization that works outside of the government to provide "unbiased and authoritative" advice to decision makers and the public. .

[180] In fact, he recommended a combination of Tylenol and Advil as an effective non-narcotic pain reliever.

Experts also take issue with statements such as one currently published on a website for the White House Office of National Drug Control Policy: "When taken as directed for legitimate medical purposes, prescription drugs are safe and effective. However, they are just as dangerous and deadly as illegal drugs when used for non-medical reasons." Policy makers have mistakenly promoted the position that opioids are not dangerous and addictive for patients who take them as prescribed. As one expert emphasized:

> These are dangerous medications. Sometimes it's appropriate to prescribe them and to do so carefully. But they are dangerous even when taken as prescribed. And to imply as that statement did, that they are safe and effective, maybe safe and effective used short-term for acute pain, maybe safe and effective if someone is at the end of life and you don't have to worry about addiction. But not safe and effective to put somebody on this medicine long-term for a backache.

The inevitable danger is that more people will be harmed than helped; more people will be exposed to the lifetime disease of addiction than will be properly treated for pain. Indeed, a representative of a major pharmaceutical manufacturer was asked by the Grand Jury about the risk of addiction from one of its opioid products. He candidly answered: "No one really knows."

The Grand Jury heard testimony from a representative of a major pharmaceutical company that manufactures prescription opioid medications; the representative is also a physician and dentist, and he has practiced anesthesiology and psychiatry. The manufacturer has been cited twice by the FDA for using potentially false or misleading medical journal advertisements for one of its opioid products. In fact this major pharmaceutical manufacturer entered into a settlement of a criminal action with the Federal Government for one count of felony misbranding of its product.[181] The manufacturer now has a Compliance Officer for internal control purposes; its product has been reformulated; it provides funding for professional

[181] Grand Jury Exhibits 113 & 119

educational materials, and funds law enforcement efforts to combat diversion. When questioned about the IOM report, he stated that, in reality, there were surveys revealing that only 5%-10% of the population actually suffers from chronic pain. Even using the 10% figure would yield a patient population of approximately 30 million; this is a far cry from the extrapolated figure of 100 million. He testified that the IOM provides no information on the severity of the chronic pain and he believes there is really no accurate accounting of it. Based upon his medical experience and position at the manufacturer, the representative was questioned by the Grand Jury as to his personal experience with prescription opioids. He responded as follows:

> I have chronic pain, I'm pushing 60. I don't take opioids. I take Tylenol, [and] exercise to try to stay limber…I'm one of those people who don't like the feeling of opioids…I get queasy.

Some in the medical profession have relied on the concept of "pseudoaddiction" to justify their prescribing practices. In the late 1980s, a physician, who is now employed by a leading manufacturer of opioid analgesics, coined the term pseudoaddiction in a published paper describing a young African-American male who was hospitalized with leukemia and was experiencing severe pain. The patient was asking for more pain medicine; the nurses did not recognize that his pain was legitimate and thought that he was merely an addict. The term "pseudoaddiction" was then used to describe a person who was perceived as addicted because he was asking for more medicine; in fact, he was in actual pain from his disease. Though appropriate in that case, and perhaps others where a patient is suffering with a serious illness and experiencing extreme pain, the term has since been distorted and abused in its application. Unfortunately, the concept has been used to encourage physicians to prescribe opioids under inappropriate circumstances, for instance: a patient presents in your office two weeks ahead of schedule saying "I ran out of my medicine," or demands more medicine, and even though the

physician has every reason to believe that the patient may have an addiction, the problem is not the patient; rather, you must treat the pain and prescribe additional medicine. The natural consequence is that if the physician gives the patient as many prescription opioids as they could possibly want, they stop coming in early. So the message has been that if a patient looks as if they are addicted, then you should give them more medicine. "That's a very dangerous thing to teach physicians," according to the addiction expert.

Ironically, during the opioid epidemic of the early 1900s, Congress passed the Harrison Act, succeeded in 1970 by the Controlled Substances Act, which specifically prohibits physicians from prescribing narcotics to a patient they know to be addicted. Conveniently, the concept of pseudoaddiction, as it is now improperly interpreted, allows a physician to circumvent that prohibition and sustains the market for the pharmaceutical manufacturers.

VII. CONCLUSIONS

Hell is full of good intentions[182]

The Grand Jury makes the following conclusions based upon the stated findings of fact:

In 1986, the World Health Organization promulgated a global philosophy that argued cancer-related pain was being inadequately treated. In the United Sates, interest and advocacy groups and official agencies expanded that worthy declaration to include all pain. With the support and encouragement of pharmaceutical manufacturers of opioid pain medications, pain became a vital sign and by many, a disease, which demanded treatment. Manufacturers seized

[182] Saint Bernard of Clairvaux (1091-1153)

the initiative and developed more potent, longer-acting, opioids. Federal regulators approved these formulations and their early advertising. The medical and prescribing professions resisted at first; they were aware of the highly addictive nature of the opioids. However, manufacturers persisted with extremely effective and misleading marketing campaigns that promoted these formulations as safer and less subject to abuse than earlier versions. The professions relinquished their collective best judgment and accepted the advertising as true. This led to vastly increased production, prescribing, and availability of opioids. The professions readily prescribed them to unsuspecting patients as safer and less subject to addiction, misleading patients into believing the claims. This was easy, the pills are not manufactured illegally in an unknown locale; they are not supplied by or purchased from an anonymous drug dealer on a street corner. Opioids are commercially manufactured under a highly regulated structure and are quality-controlled to ensure their safety. Nothing could have been more wrong. The epidemic of opioid abuse was under way. Once dependent upon or addicted to opioids, users began alternating their use with the cheaper and even more dangerous derivative, heroin. A new generation of heroin addicts was born. And countless tragedies resulted: addiction, loss of life, broken families, and a rise in violent crime have all followed the increased availability of these drugs.

The illegal use of otherwise legally prescribed controlled substances is referred to as diversion. It presents in many forms: “pill mills”, “doctor shopping”, over-prescribing and improper or ill-advised prescribing, prescription forgery, burglary and robbery. The largest source of diverted drugs is the “medicine cabinet” at home where they are carelessly stored often after being prescribed for temporary acute pain. But those substances do not reach the home but for the initial prescription.

The Grand Jury finds that law enforcement and regulatory agencies are awash in the consequences of a river of controlled substances. Statutes and regulations that were designed primarily for patently illegal Schedule I drugs are inadequate to address this problem. Staffing and training of these agencies, as well as of the treatment facilities necessary for this new and enlarged generation of abusers, is also lacking.

The Grand Jury concludes that statutory and regulatory changes are required at the federal, state and local levels. Enforcement of these changes is essential. Federal regulators must be more vigilant and persistent in evaluating the claims and marketing of controlled substances; federal and state regulation of manufacturers and prescribers must be enhanced and implemented; prescribers must be certified and trained specifically in this area to ensure proper prescribing practices; criminal and regulatory decrees must be updated to adequately enforce the lawful distribution and prevent the unlawful diversion of controlled substances; and better education for the consuming public, particularly the young, must be in place. The current epidemic and crisis occurred under the watch of regulators operating in a system they believed was capable of the task. It is incumbent that the system be corrected.

VII. RECOMMENDATIONS

To address division and its effects on the public health and safety of Suffolk County, the Grand Jury submits recommendations for changes in the New York State Penal Law, Vehicle & Traffic Law, Public Health Law, and regulatory changes at the federal, state and local levels. Of necessity, the recommendations begin with modifications to the FDA process of authorizing prescription opioids for manufacturing, marketing, and labeling. At the state level, the mandate

of E-Prescribing must be enacted; all other methods of regulating written prescriptions, although helpful, will fall short of their purpose in preventing diversion.

Based upon the stated findings of fact and all of the evidence heretofore had before this Grand Jury, and in order to protect the public from continued harm arising from the diversion of controlled substances; to improve statutory and regulatory provisions to prevent diversion and aid in the proper management of controlled substances; to hold accountable those whose actions are responsible for or contributing to diversion; and to assist in the prosecution of individuals and institutions responsible for or contributing to diversion; NOW THEREFORE, by the authority vested in this Grand Jury by the Criminal Procedure Law §190.85(1)(c), the following executive, legislative, and administrative actions are recommended in the public interest:

Legislative

I. The New York State Penal Law Article 220 must be amended to define the term "practitioner" as it is defined in the Public Health Law §3302(29). The Penal Law and the Public Health Law both regulate practitioners; there should be no discrepancy or ambiguity in their definition or applicability.

II. The New York State Penal Law Article 220 must be amended to define more explicitly the term "good faith." This will properly and clearly define the bounds of lawful practice as well as aid law enforcement in pursuing misconduct.

III. Currently, the New York State Penal Law crime of Criminal Sale of a Prescription for a Controlled Substance is a class C felony under §220.65. To more effectively investigate and prosecute practitioners who are acting outside of accepted lawful medical practice, the Grand Jury recommends the creation of two crimes in its place. The first is Criminal

Sale of a Prescription for a Controlled Substance in the second degree, a class B felony under Penal Law §220.64. This would retain the same language and definitions as the current §220.65. The second is Criminal Sale of a Prescription for a Controlled Substance in the first degree, wherein the prescription is for a Schedule II controlled substance, a class A-II felony. Under appropriate circumstances, this also allows for the prosecution of individuals for the class B felony of Conspiracy in the second degree when distributing Schedule II controlled substance prescriptions.

IV. The New York State Penal Law Article 220 must be amended to include a new section, §220.66 Criminal Sale of a Controlled Substance by a Practitioner or Pharmacist, a class B felony. Designation of a separate felony sale charge for professionals, as opposed to an amendment of Penal Law §220.39, emphasizes the significance of the epidemic and the responsibility of the professionals prescribing and dispensing the scheduled controlled substances.

V. The Grand Jury recommends that the New York State Legislature pass and the Governor sign the currently pending legislative proposals for revising Article 178 of the New York State Penal Law, and creating Articles 179 and 219. These are contained in legislation denoted as A7251-C and S5260-C. These provisions enhance current laws combatting diversion and also include provisions that address the possession of non-controlled substances prescription medications and devices. A copy of the proposals is annexed to the **Recommendations**.

VI. The Grand Jury recommends that New York State Penal Law Article 460, Enterprise Corruption, be amended to include the proposed crimes of Criminal Sale of a Prescription for a Controlled Substance in the first and second degrees, and Criminal Sale of a

Controlled Substance by a Practitioner or Pharmacist. These crimes address the prosecution of "pill mill" prescribers. The amendment of Enterprise Corruption to include these crimes is necessary to effectively prosecute those prescribers and their accomplices who are part of a larger organization.

VII. The Grand Jury recommends that New York State Criminal Procedure Law §700.05, Eavesdropping definitions and terms, be amended to include the proposed crimes of Criminal Sale of a Prescription for a Controlled Substance in the first and second degrees, and Criminal Sale of a Controlled Substance by a Practitioner or Pharmacist. Conspiracy and Enterprise Corruption cases are frequently investigated and prosecuted by utilizing electronic surveillance. Article 700 of the Criminal Procedure Law specifies which crimes are designated offenses and may be the subject of an eavesdropping warrant. The current crime of Criminal Sale of a Prescription for a Controlled Substance is not a designated offense. Upon creation of the proposed crimes, the Criminal Procedure Law must be amended to coincide with the amended Penal Law crimes.

VIII. New York State Public Health Law §3345, *Possession of controlled substances by ultimate users original (sic) container*, must be made a crime under the Penal Law and designated as a class A misdemeanor. This law punishes individuals who possess controlled substances in anything other than the original prescription bottle. People who have illegally obtained prescription medications for use or resale often carry them in unmarked containers. The law does not punish possession in a container if it is in an appropriate amount for current use, typically stored in a daily dose container.

IX. New York State Public Health Law §3397, *Fraud and Deceit*, must be made a class E felony under the Penal Law. The legislation is designed to prevent "doctor shopping" and should be prosecuted criminally.

X. §1192 of the New York State Vehicle and Traffic Law must be amended to include the definition of "drug" as any controlled substance included in the New York State Public Health Law or the federal Schedules as promulgated by DEA. There are occasions when DEA has added a substance to the Schedules but New York has not yet done so. This will ensure enhanced prosecution of "drugged drivers" under §1192-4.

XI. §1192 of the New York State Vehicle and Traffic Law must be amended to include mandatory blood testing for the operator of a motor vehicle involved in an accident resulting in death or serious physical injury, without the necessity of obtaining a search warrant or the consent of the operator.

XII. §3306 of the New York State Public Health Law containing the Schedules of controlled substances should be amended to reclassify hydrocodone as a Schedule II substance. Based upon the addictive nature of the drug, it should be classified in the same manner as oxycodone.

XIII. §3371 of the New York State Public Health Law should be amended to permit disclosure of information by BNE if it is reasonably apparent that criminal conduct has or is occurring. This includes active referral of information to law enforcement and Medical Examiners. The Grand Jury has found that BNE is restricted in its ability to prosecute "doctor shoppers" or criminal prescribers by the current limitations of the statute.

XIV. §3371-a of the New York State Public Health Law permits New York to share prescription monitoring data with other states (PDMP data). The Grand Jury finds that

New York State must participate in such an interoperability program for diversion efforts to be successful.

Administrative

XV. The Grand Jury recommends that the FDA amend the labeling of all opioids. Specifically, the indication for "moderate to severe pain" must be removed and the label should clearly state that use of opioids for chronic pain management - other than palliative care situations - is an off-label use. This warning may give prescribers pause before advising patients to take them and encourage more careful consideration of alternative treatment methods.

XVI. The addictive quality of opioids is well known but not fully understood; in fact, the Grand Jury finds that the addiction risk of a currently popular opioid is unknown. Therefore, the Grand Jury recommends that the FDA not authorize the manufacturing and marketing of newer formulations until further study is completed into addiction risks.

XVII. Part 80: Rules and Regulations on Controlled Substances in New York State must be amended to mandate Electronic Prescribing for Controlled Substances (E-Prescribing). This will eliminate paper prescriptions and force prescribers to utilize the PDMP. It inhibits "doctor shopping" and holds prescribers accountable through the unique log-in required to access the system.

XVIII. To further accountability, Part 80: Rules and Regulations on Controlled Substances in New York State must allow the dispensers of controlled substances, pharmacists, immediate access to the information in the PDMP.

XIX. In the alternative, if E-Prescribing is not authorized, Part 80: Rules and Regulations on Controlled Substances in New York State must be amended to mandate that all dispensers must enter prescription data into the PDMP within 24 hours of dispensing; currently the entry of this information can be delayed up to as much as 45 days after dispensing. Information must be current to be effective.

XX. In the alternative, if E-Prescribing is not authorized, Part 80: Rules and Regulations on Controlled Substances in New York State must be amended to mandate that all prescribers access the PDMP database before issuing prescriptions for a controlled substance. A verifying identifying number, generated by the PDMP, must be included on the written prescription.

XXI. The PDMP must provide access to the entire prescription history of patients and be accessible to all prescribers and dispensers. Currently, prescribers may view the history when a patient sees 2 or more prescribers, for 2 or more prescriptions, and fills them at 2 or more pharmacies. To properly prescribe any drug, prescribers and dispensers must have full knowledge of prescription medications in a patient's history.

XXII. To facilitate the use of the PDMP, prescribers must be permitted to designate a registered staff member to access the database. The Grand Jury finds that one drawback to the current voluntary system is the lack of time available to prescribers. This will obviate that issue.

XXIII. In conjunction with Recommendation XII, the New York State PDMP must be linked to a Department of Justice approved/sponsored interoperability system to connect with an interstate PDMP database. This is essential to effectively monitor "doctor shopping" and the illegal trafficking in fraudulent prescriptions.

XXIV. The New York State PDMP must include the current licensing status of prescribers; specifically, whether DEA authorization to issue prescriptions for controlled substances has been suspended or revoked, or whether a New York State Department of Education license to practice has been suspended/revoked.

XXV. All prescriptions, including those issued if E-Prescribing is mandated, must include a diagnostic code. This will add clarity for the dispenser when advising a patient and contribute to public health.

XXVI. Private pharmaceutical manufacturers must subsidize the recommended changes to and maintenance of the PDMP. Manufacturers provide the supply of controlled substances, pay to market them, and reap enormous profits. It is therefore reasonable to require that, as a cost of doing business in New York, manufacturers subsidize the implementation and operation of the PDMP here. There is precedent for this in Florida. Manufacturers must also contribute to a research fund for addiction evaluation and treatment.

XXVII. Following the recommendation for private funding of the PDMP, the Grand Jury recommends that the Penal Law be amended to include a surcharge upon conviction of a practitioner or pharmacist for an Article 220 offense.

XXVIII. Absent E-Prescribing, dispensers must photograph the presenter of a prescription for a controlled substance when the prescription is uttered. Patient identification is currently required but not everyone has a photo i.d. Funding can be sought through manufacturers/distributers to bridge this gap.

XXIX. Prescription bottles must contain a stark warning label admonishing users that *controlled substances may cause addiction*. Part of the improper use and diversion of controlled substances is due to inadequate consumer/patient knowledge of the dangers associated

with the use of these substances. Prescription bottles are currently labeled to reflect certain information; adding a label such as this should not incur additional cost or burden.

XXX. To further the goal of greater consumer/patient education, dispensers must provide an insert when dispensing controlled substances that advises the patient of the potential dangers of use including death, overdose, and addiction.

XXXI. Since most diversion begins with a prescription for an addictive substance, prescribers must be better educated and continually trained in this area. Medical Education (CME) for prescribers of all controlled substances, opioids in particular, must be mandated. DEA currently requires training/certification for Suboxone prescribing yet there is no CME/training/certification required to prescribe addictive substances in general.

XXXII. Article 21 of the Code of Federal Regulations requires prescribers to obtain a DEA license number which authorizes them to prescribe controlled substances. If CME is not required by New York, the Grand Jury recommends that DEA amend Article 21 to require periodic training and certification for all licensed prescribers.

XXXIII. To further educate prescribers, the Grand Jury recommends that New York State adopt and promulgate the New York City Department of Health guidelines concerning the misuse of opioid therapy.

XXXIV. To assist prescribers in educating their consumer/patients, written and co-signed Informed Consent documents must be executed when prescribing controlled substances. The Department of Education must mandate that prescribers of controlled substances explain to the consumer/patient the risks and benefits of the medication. The Informed Consent must include the risks of addiction, overdose, and death. Further, patients must

disclose to the physician any prior prescriptions and the name(s) of the prescriber(s). This includes a proviso that the age of consent is 21 or over.

XXXV. Teenagers are highly susceptible to drug abuse and addiction. In an effort to remedy this, the Department of Education must include prescription controlled substance abuse and addiction education and information in the middle and high schools. These should be coordinated with law enforcement to facilitate the return and destruction of unused prescription medications of any kind.

XXXVI. Increased access and funding for treatment facilities is essential. The manufacturing and prescribing of controlled substances has greatly increased the number of citizens suffering from substance abuse and addiction. Many of these were unwitting while others were the result of diversion.

XXXVII. The Grand Jury recommends that Suffolk County employ an epidemiologist in the Office of the Medical Examiner. Resources must be directed to identify trends and fluctuations in data before any public health event reaches epidemic proportions.

Administrative

State and local agencies affected by the changes implied in the legislative measures and the regulatory changes noted herein should be given the necessary authority to adopt administrative rules and regulations necessary for the effective implementation and execution of these recommendations.

Executive

The Governor of the State of New York should introduce legislation consistent with the legislative and regulatory recommendations in this report, or, in the alternative, he should support legislation introduced by others. The Governor should commit appropriate budgetary resources necessary to implement the legislative and regulatory recommendations including appropriating additional resources to law enforcement.