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White Paper on

Intractable Pain Treatment Act

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Origins of the Intractable Pain Treatment Act

It is difficult to document the exact history of all the circumstances that lead to Tennessee's General Assembly taking up the cause of patients suffering with severe, chronic and intractable pain. An audio recording of the debate from the Assembly reveals approximately 20 minutes of debate before the passage of the act.[5] Some of the debate included comments that other states had adopted similar legislation and it was time that Tennessee follow suit. There were also statements of the need for doctors to freely prescribe opiates to patients that were in need of pain relief for end-of-life care. The comments indicate that physicians were fearful of censure if they prescribed the amount of opiates needed for successful pain relief. It was assumed that doctors were under-prescribing pain medication to patients who were in need.

The Intractable Pain Treatment Act (IPTA) of 2001 includes 11 declarations from the General Assembly. [1] The first declaration within the IPTA is that the state has the right and duty to control the illegal use of opiate drugs. This declaration indicates that the Act was being enacted to enhance the control of illegal opiate drug use in some manner. The second statement, "Inadequate treatment of acute and chronic pain originating from cancer or non-cancerous conditions is a significant health problem accommodates the fears expressed of doctors' treatment end-of-life patients and the fear of physician censure. The third and fourth statements, "For some patients, pain management is the single most important treatment a physician can provide" and "A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain" indicate the urgency that the assembly felt to provide freedom for doctors' fears of censure and increase access to appropriate pain relief for Tennesseans. The fifth declaration was submitted at a much more naïve time for Tennessee; "In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe." While the statement is generally truthful, Tennessee has seen increases in the consequences of opiate use since the passage of the bills.

Highlights of the IPTA/Pain Patient Bill of Rights

The Intractable Pain Treatment Act recognized the complexity of treating patients with chronic, severe and intractable pain. [1] It identified the need to utilize a team of clinicians to address the associated physical, psychological, social, and vocational issues. The act allows a physician to determine that an opiate medication is not the most appropriate modality for pain relief, but also requires that this same physician to inform the patient that that there are physicians whose primary practices are the treatment of severe chronic intractable pain with methods

that include the use of opiates. The law includes its own "loophole" to allow for patients seeking opiates to legally receive a prescription for a medication that may not be considered as the best form of treatment for them. Section 8, C contains an interesting provision for the use of a "dangerous drug or a controlled substance" to treat patients that are:

1. A current drug abuser;
2. Not currently abusing drugs but have a history of drug abuse; or
3. Lives in an environment that poses a risk for drug misuse or diversion of the drug to illegitimate use.[1]

The Act included provisions of protection of the patient to ensure the use of prescribed "dangerous drug or a controlled substance" was used for the intended purposes. The law specifies that each prescribing physician will document drug name, dosage and method of taking the drug, number of dose units prescribed and the frequency of prescribing and dispensing of the drug. There are two other specific provisions that are particularly designed to protect patients: an understanding between the physician/patient about the prescribed treatment and a requirement for the physician to consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate. [1]

The Pain Patient's Bill of Rights, Section 5 of the Intractable Pain Treatment Act – Chapter 327, indicates that patients have the right to reject or request the use of any or all modalities in order to relieve his or her severe chronic intractable pain. [1] These patients may choose opiate medications before attempting other modalities of pain relief. The requirement for a physician who does not believe opiates are the best course of pain relief is repeated by stating the physician must inform their patient that there are physicians whose primary practices are the treatment of severe chronic intractable pain with methods that include the use of opiates.

Developments to Supplement the Intractable Pain Treatment Act

Since the implementation of the IPTA, Tennessee has initiated many efforts to combat the increased use of opiates. Multiple state agencies utilizing a myriad of strategies have committed state and federal resources to this cause. The following strategies outline some of the larger efforts associated with Tennessee's attempts to help citizens with opiate dependency issues.

In 2002, Tennessee enacted the Controlled Substance Monitoring Act and established a statewide database to monitor the dispensing of Schedule II, III, VI and V controlled substances. Data collection actually began for dispensers on December 1, 2006.[4] The Prescription Safety Act of 2012 enhanced the capabilities of the system and made stricter requirements for its use. It is commonly referred to as the Controlled Substance Monitoring Database (CSMD). By 2012, the

Tennessee Department of Health identified the Act as "representing a significant effort by the General Assembly to address the problem of prescription drug abuse."[4]

In 2013, Department of Health's Commissioner John Dreyzehner required that all babies born with the diagnoses of Neonatal Abstinence Syndrome (NAS) be reported in the state's surveillance system as a Reportable Diseases and Event.[6] It was the first time that a non-communicable disease was added to this list. NAS diagnosed babies have experienced drug exposure from opiate or narcotic drugs such as heroin, codeine, oxycodone, methadone or buprenorphine while in utero. Commissioner Dreyzehner's letter to Tennessee's hospitals (hospitals were tasked with the requirement to report NAS) cites a ten-fold rise in the incidence of babies born with Neonatal Abstinence Syndrome in Tennessee (during the same time period, the nation has experienced a 3 fold increase).[7] This rise is paralleled by an increase in the prescription and use of narcotic pain medications across Tennessee. He further outlines other compelling reasons for the issuance of the unprecedented guidelines to report this non-communicable disease:

> "Infants with Neonatal Abstinence Syndrome may experience serious neurologic, gastrointestinal and respiratory symptoms and are more likely to have difficulty with weight gain. Tennessee estimates suggest that the care of these infants may exceed $40,000 throughout the first year of life, compared with costs closer to $4,300 for an otherwise healthy infant born at a normal birth weight. As you know, these blameless infants born dependent on addictive drugs face a tragically painful beginning and an uncertain future. NAS also places a tremendous burden on the hospitals that provide care for these infants and the insurance payors who cover the costs of such hospitalizations, as well as the primary care providers who provide ongoing care in these often heart-wrenching cases. Costs to Medicaid (TennCare) alone exceeded $22 million in 2010. Additionally, the associated social circumstances place tremendous strains on the child welfare and human services systems.
>
> The human costs of NAS are not inconsequential. These babies are often born into difficult social circumstances and can present challenges for new parents who are trying to welcome such a distressed baby while often simultaneously working through their own distress. The social circumstances for many of these families are not optimal, and families as well as providers may worry about the long-term consequences of both the prenatal exposure and postnatal social milieu." [7]

The surveillance system data from December 2013 indicate that 19.3 percent of mothers that birthed NAS diagnosed babies reported receiving their prescriptions as part of supervised pain therapy. Another 39.9 percent reported using a prescription substance for which they did not have a prescription.[8]

In 2012, Governor Haslam initiated a sub-cabinet workgroup focused on NAS. It consists of the Commissioners of Department of Health, Department of Mental Health and Substance Abuse Services, Department of Children's Services, Department of Safety, Department of Human Services and representatives from the Bureau of TennCare, Finance and Administration and the Children's Cabinet. The group continues to meet discussing and implementing strategies to lessen prescription drug abuse – including opiates.

Senator Ken Yager and Representative Bill Dunn's "Safe Harbor Act" became law in June 2013. The law allowed pregnant women referred for drug abuse or drug dependence treatment at any treatment facility that receives public funding would be a priority user of available treatment. It provided these further protections:

> "If during prenatal care, the attending obstetrical provider determines by the 20th week of pregnancy that the patient has used prescription drugs which may place the fetus in jeopardy, and drug abuse or drug dependence treatment is indicated, then the provider must encourage counseling, drug abuse or drug dependence treatment and other assistance to the patient. If the patient initiates drug abuse treatment or drug dependence treatment based upon a clinical assessment prior to her next regularly-scheduled prenatal visit and maintains compliance with such treatment based on a clinical assessment as well as prenatal care throughout the remaining term of the pregnancy, then the department of children's services may not file any petition to terminate the mother's parental rights or otherwise seek protection of the newborn solely because of the patient's use of prescription drugs for non-medical purposes during the term of her pregnancy." [9]

The Tennessee Bureau of Investigation's Medicaid Fraud Control Unit was created in 1984 with a 12-person staff. During recent years, the staff has grown to over 36 to assist with the increased need for investigations. Many of the investigations are the result of the rise prescription drug use. The Office of Investigator General also investigates the fraudulent misuse of Tennessee's Medicaid program, TennCare, in obtaining opiate drugs. The Inspector General maintains a "TennCare Fraud Most Wanted" site.

The Current Epidemic

The Tennessee Department of Mental Health and Substance Abuse Services released a report during the summer of 2014 that included Governor Haslam's strategy to address the current prescription drug abuse epidemic. The report was produced in collaboration with Tennessee's Departments of Health, Children's Services, Safety and Homeland Security and Corrections as well as the Tennessee Bureau of Investigation, Bureau of TennCare and U.S. Department of Justice Drug Enforcement Agency. The report outlines the current epidemic with the following points:

- More Seeking Treatment: In 2012, prescription opioids became the primary substance of abuse for people in TDMHSAS-funded treatment, overtaking alcohol for the first time. [10]
- Non-Medical Reasons: Almost five percent of Tennesseans have used pain relievers in the past year for non-medical purposes. [10]
- Younger Tennesseans: Young Tennesseans (18- to 25-year-olds) are using prescription opioids at a 30 percent higher rate than the national average.
- More Prescriptions Being Dispensed: There were 25 percent more controlled substances dispensed in Tennessee in 2012 than in 2010. [10]
- Doctor Shopping: In March 2013, more than 2,000 people received prescriptions for opioids or benzodiazepines from four or more prescribers. [10]
- Prescribing Practices: As of August 1, 2013, 25 physicians had been prosecuted for overprescribing during 2013. [10]
- Sources of Prescription Drugs: More than 70 percent of people who use prescription drugs for non-medical reasons got them from a friend or relative. [10]
- Healthcare Costs: The number of emergency department visits for prescription drug poisoning has increased by approximately 40 percent from 2005 to 2010. [10]
- Overdose Deaths: There has been a 220 percent increase in the number of drug overdose deaths

since 1999, growing from 342 in 1999 to 1,094 in 2012. [10]

- Criminal Justice System Involvement: Drug-related crimes against property, people, and society have increased by 33 percent from 2005 to 2012. [10]
- Lost Productivity: The cost of lost productivity due to prescription drug abuse in Tennessee was $142.9 million in 2008; adjusted for 2013 inflation, that is $155.2 million. [10]
- Children in State Custody: About 50 percent of the youth taken into Department of Children's Services custody resulted from parental drug use. [10]
- Neonatal Abstinence Syndrome: Over the past decade, we have seen a nearly ten-fold rise in the incidence of babies born with Neonatal Abstinence Syndrome in Tennessee. [10]
- Treatment Costs: It is estimated that the cost of providing state-funded treatment services to individuals that abuse prescription drugs and live below the poverty level would cost $27,933,600.[10]

In 2010, the number of prescriptions provided to Tennesseans represented fifty-one pills of hydrocodone for EVERY Tennessean above the age of 12, twenty-two pills of alprazolam for EVERY Tennessean above the age of 12 and twenty-one pills of oxycodone for EVERY Tennessean above the age of 12.[11]

The Need for Policy Reform

The repeal of the Intractable Pain Treatment Act would remove the ability of Tennessee citizens to self-determine that their legitimate health conditions required opiates for pain relief in order to easily receive a prescription from their medical provider. It would also help to eliminate those with illegitimate health conditions from easily obtaining opiate drugs. A repeal of this act will put the doctors back in a position to provide medical opinions on pain treatment and take it from the hands of patients. Repealing this law would help alleviate the unintended consequences of the proliferation in the number of opiate prescriptions and subsequent addiction of many Tennesseans. The Prescription for Success report estimates that 69,100 Tennesseans are addicted to opiates and are in need of treatment. Another 151,900 Tennesseans are estimated to be in a risky prescription opiate use category and in need of early intervention. These two categories represent 4.56 percent of the population of Tennessee.[10]

The General Assembly provided 11 declarations in the Intractable Pain Treatment Act of 2001 that warrant being revisited. "The state has a right and duty to control the illegal use of opiate drugs." The illegal use of opiate drugs has increased in the time since the passage of this law. Rather than curbing the illegal use, it has grown. "Inadequate treatment of acute and chronic pain originating from cancer or non-cancerous conditions is a significant health problem." **Opiate prescriptions for cancer conditions (as well as other end-of-life conditions) resulting in hospice care is currently not a consideration for inclusion in the reporting requirement of the CSMD.** [12] "A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain." Since the implementation of this act, pain management clinics have proliferated. Tennessee Department of Health's certified pain management clinics registry indicates that there are 303 clinics throughout the state.[13] There is no geographical area of the state where clinics do not exist. Also, since 2001, new pain management drugs have been released. Other modalities of pain relief have become popular with many chronic pain sufferers such as yoga, general physical fitness, nutrition, acupuncture, chiropractic care and other modalities. "In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe." While this statement is generally true, Tennessee has experienced an increase in overdose deaths, addiction and incidences of NAS/Drug Exposed Infants. A repeal of this act

will assist in the reduction of overdose deaths, incidences of opiate addiction and drug dependency in infants that are born to mothers using opiate prescription medication.

Finally, the discussion for the need of the Intractable Pain Treatment Act included a discussion of the fear of doctors regarding censure for the appropriate prescribing of opiates. It appears that this fear has been alleviated. The pendulum has swung to the other end where now the Department of Health has issued letters to top prescribers of opiates requesting their justification in their prescribing patterns. The Prescription for Success report states that "the perceived under-prescribing or prescribing opioids less frequently than appropriate by Tennessee physicians in 2001 has now been replaced by overprescribing or prescribing opioids excessively or unnecessarily. While opioids should no longer be considered first-line treatment of chronic pain, they do continue to be prescribed at very high rates in Tennessee. As of August 1, 2013, 25 physicians had been prosecuted for overprescribing during 2013.[10]

The CSMD's functionality was updated to include individual patient's milligram morphine equivalents (MME). [14] MME is an industry recognized standard that allows medical practitioners to identify individual dosages of opiates as equivalent doses of morphine – much like a calorie can be used to understand the energy available in different types of food. Data from the CSMD can now follow patients who are prescribed MME's that make them extremely risky for overdose or diversion of their opiates. Repeal of the IPTA will reduce overprescribing opiates and eliminating them as first line treatment of chronic pain.

A repeal of this magnitude will generate a public discussion of this problem and likely result in increased awareness. It will provide an opportunity for increased education on alternative modalities for pain relief, dangers of addiction to opiates and dangers associated with opiates during pregnancy.

Glossary

***CSMD*:** Controlled Substance Monitoring Database of Tennessee.

***Intractable pain*:** a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

***Neonatal Abstinence Syndrome*:** a condition in which a baby has withdrawal symptoms after being exposed to certain substances. Many times, the baby is exposed when the mother uses substances such as medications or illicit drugs during pregnancy and after the baby is born (and separated from the mother's body), the baby goes through withdrawal because it is no longer receiving the substances. Less commonly, very sick babies may receive medications after birth to help control pain or agitation, and once those medications are stopped, the baby may go through withdrawal.[15]

***Opioid*:** opioids include illegal drugs such as heroine, as well as prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone (Oxycontin, Percodan, Percocet), hydrocodone (Vicodin, Lortab, Norco), fentanyl (Duragesic, Fentora), hydromorphone (Dilaudid, Exalgo), and buprenorphine (Subutex, Suboxone).

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References

[1] Herron, Senator Roy and Maddox, Representative Mark. (2001, June 21). Intractable Pain Treatment Act. *Public Acts, 2001, Chapter 327 Audio Recording of the General Welfare, Health and Human Resources Senate Committee*. Nashville, TN, USA: LexisNexis.

[2] Leonard J. Paulozzi, M. C. (2011, November 1). Vital Signs: Overdoses of Prescription Opioid Pain Relievers . *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report*, p. 4.

[3] Varney, E. Douglas, Commissioner. (2012). *Governors Public Safety Forum, Governors Public Safety*

Action Plan with a Concentration on: Prescription Drug Abuse. Nashville: Tennessee Department of Mental Health and Substance Abuse Services Research Team.

[4] Health, Tennnessee Department of. (2012, May 9). *Controlled Substance Monitoring Database (CSMD) and Prescription Safety Act Frequently Asked Questions*. Retrieved November 3, 2014, from Tennessee Department of Health Controlled Substance Monitoring Database Program: http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

[5] Herron, Roy and Maddox, Mark. (2001, May 21). *Acts and Resolutions*. Retrieved November 3, 2014, from Tennessee Secretary of State: http://www.tn.gov/sos/acts/102/pub/pc0327.pdf

[6] Health, Tennnessee Department of. (2012, November 28). *Neonatal Abstinence Syndrome—Reportable Disease*. Retrieved November 3, 2014, from Neonatal Abstinence Syndrome (NAS): http://health.state.tn.us/MCH/PDFs/NAS/NAS_Reporting_FAQ.pdf

[7] Dreyzehner, Commissioner John. (2012, November 29). *DreyzehnerLetterNASReportable*. Retrieved November 1, 2014, from Neonatal Abstinence Syndrome (NAS): https://health.state.tn.us/MCH/PDFs/NAS/DreyzehnerLetterNASReportable_112912.pdf

[8] Warren, Dr. Michael D. (2013, December). *Drug Dependent Newborns (Neonatal Abstinence Syndrome) December Update (Data through 12/28/2013)*. Retrieved November 3, 2014, from NAS Update Archive: http://health.state.tn.us/MCH/PDFs/NAS/NAS_Update_1213.pdf

[9] Yager, Ken and Dunn, Bill. (2013, May 22). *Senate Bill 459.* Retrieved November 3, 2014, from TN Capitol: http://www.capitol.tn.gov/Bills/108/Bill/SB0459.pdf

[10] Tennessee Department of Mental Health and Substance Abuse Services. (2014, August). *Prescription for Success.* Retrieved November 3, 2014, from Tennessee Department of Mental Health and Substance Abuse Services: http://www.tn.gov/mental/prescriptionforsuccess/Prescription percent20for percent20Success percent20Summary.pdf

[11] Tennessee Department of Health Safety Subcabinet Workgroup. (2012). *Prescription Drug Abuse in Tennessee.* Retrieved November 3, 2014, from Tennessee Department of Mental Health and Substance Abuse Service: http://tn.gov/mental/policy/persc_drug_docs/Prescription percent20Drug percent20Use percent20in percent20TN_2 percent203 percent202012_R2.pdf

[12] Tennessee Board of Pharmacy. (2014, March). *Rules of The Tennessee Board of Pharmacy Chapter 1140-11 Controlled Substance Monitoring Database.* Retrieved November 3, 2014, from Tennessee Secretary of State: http://www.state.tn.us/sos/rules/1140/1140-11.20140316.pdf

[13] Tennessee Department of Health. (2014). *Department of Health Licensed Facilities.* Retrieved November 3, 2014, from Health Care Facilities: http://health.state.tn.us/HCF/Facilities_Listings/CurrentResults.asp

[14] Tennessee Board of Pharmacy Staff. (2014). *Controlled Substance Monitoring Database 2014 Report to the 108th General Assembly.* Nashville: State of Tennessee.

[15] Tennessee Department of Health. (2014). *Maternal and Child Health/Neonatal Abstinence Syndrome*. Retrieved November 3, 2014, from Tennessee Department of Health: http://health.state.tn.us/MCH/NAS/