

PREVENTING NEONATAL ABSTINENCE SYNDROME WITHIN THE OPIOID EPIDEMIC: A UNIFORM FACILITATIVE POLICY

JEREMIAH A. HO* AND ALEXANDER O. ROVZAR**

ABSTRACT

The United States is currently in the midst of an opioid epidemic that has hit states in southern New England particularly hard—with Massachusetts as one primary example. One of the many unfortunate consequences of the epidemic is a dramatic upsurge in cases of opioid use disorder by pregnant women, often resulting in children born with neonatal abstinence syndrome. Neonatal abstinence syndrome is a clinical syndrome that occurs when a newborn suffers withdrawal symptoms as a consequence of abrupt discontinuation of prenatal substance exposure. The expenses of treating, monitoring, and rehabilitating these chemically-dependent newborns are predominantly shouldered by state taxpayers and are extremely costly, with a mean cost per stay exceeding \$90,000 for pharmacologically-treated cases.

This Article illustrates a policy, grounded in facilitative principles, designed to reduce the rate of neonatal abstinence syndrome in the Commonwealth of Massachusetts. Early identification of opioid misuse during pregnancy is the threshold requirement of the proposed solution’s success. Another key component of the policy necessitates implementation of a standardized protocol to be adhered to uniformly throughout public hospitals statewide. The Article concludes by reemphasizing the importance of acting promptly and assertively to protect society’s most vulnerable members from the opioid epidemic.

TABLE OF CONTENTS

I.	INTRODUCTION	302	R
II.	NEONATAL ABSTINENCE SYNDROME	306	R
	A. <i>Symptoms in Newborns</i>	306	R
	B. <i>Historical Emergence</i>	307	R
	C. <i>Contemporary Societal Costs</i>	309	R
III.	THE BEGINNINGS OF OPIOID MISUSE TREATMENT	310	R
	A. <i>Methadone – Lesser of Two Evils</i>	312	R
	B. <i>Buprenorphine – A Step in the Right Direction</i>	313	R
IV.	A FORMULA FOR DISASTER – OXYCONTIN AND LIBERAL PRESCRIPTIONS	314	R

* Assistant Professor of Law, University of Massachusetts School of Law. I would like to thank my co-author for this collaboration. Also, much thanks to the *UMass Law Review* and my colleagues at the University of Massachusetts School of Law: Emma Wood, Erica Souza, Margaret Drew, Jim Freeley, and Eric Mitnick.

** Associate, Sarrouf Law LLP. The author would like to thank Jim Freeley for valuable commentaries and edits on an earlier draft. For inspiration and support, particularly during the beginning phases of this project, the author thanks his wife, Nichole Alexis.

V. FEDERAL AND STATE REFORMATIVE ACTION	317	R
A. <i>Federal Reformative Measures</i>	318	R
B. <i>Aggressive Steps Forward in Massachusetts</i>	320	R
VI. FACILITATIVE RENOVATIONS – A PREVENTATIVE SYSTEM TO SUPPRESS NEONATAL ABSTINENCE SYNDROME	323	R
A. <i>Mandatory Reporting Insufficient</i>	326	R
B. <i>Proposal for Reform – Facilitative Prevention through Aggressive Identification</i>	327	R
VII. CONCLUSION	332	R

I. INTRODUCTION

*The threat of narcotics . . . properly frightens many Americans. It comes quietly into homes and destroys children, it moves into neighborhoods and breaks the fiber of community which makes neighbors. It is a problem which demands compassion, and not simply condemnation . . . We must try to better understand the confusion and disillusion and despair that bring people . . . to the use of narcotics and dangerous drugs.*¹

To baby boomers, it may seem surreal that nearly fifty years have passed since President Nixon declared war on drugs, identifying drug abuse (hereinafter referred to as “substance use disorder” and/or “substance misuse”)² in America as “public enemy number one.”³ On a similar note, and perhaps etched in the early memories of those who came of age in the 1980s, President and Mrs. Reagan addressed the nation in 1986, calling for a “national crusade” against the “cancer of drugs.”⁴ Today, the perpetual war on illegal substances rages on, with rates of misuse continuing to soar and overdoses reaching all-time highs.⁵

¹ See Richard Nixon, *Special Message to the Congress on Drug Abuse Prevention and Control*, THE AMERICAN PRESIDENCY PROJECT (June 17, 1971), <http://www.presidency.ucsb.edu/ws/?pid=3048> [https://perma.cc/P27X-WJ7T].

² As part of an initiative to reduce stigma and support treatment for substance use disorders, the American Medical Association, the American Society of Addiction Medicine, and other professional associations have urged the adoption of clinical, non-stigmatizing language in connection with communications relative to substance misuse. See, e.g., OFFICE OF NAT’L DRUG CONTROL POL’Y, CHANGING THE LANGUAGE OF ADDICTION (Oct. 4, 2016), <https://www.whitehouse.gov/ondcp/changing-the-language-draft> [https://perma.cc/R7HF-XND4].

³ Richard Nixon, *Remarks about an Intensified Program for Drug Abuse Prevention and Control*, THE AMERICAN PRESIDENCY PROJECT (June 17, 1971), <http://www.presidency.ucsb.edu/ws/?pid=3047> [https://perma.cc/XVN6-HN8N].

⁴ Gerald M. Boyd, *Reagans Advocate ‘Crusade’ on Drugs*, N.Y. TIMES (Sept. 15, 1986), <http://www.nytimes.com/1986/09/15/us/reagans-advocate-crusade-on-drugs.html> [https://perma.cc/6PHW-5NSS].

⁵ An estimated 24.6 million Americans 12 years or older (9.4 percent of the population) are living with substance dependence as of 2013. See SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., Pub. No. 14-4863, NAT’L SURV. ON DRUG USE & HEALTH 3 (2014); see also Nadia Kounang, *Drug Overdose Deaths Reach All-*

Perhaps more alarming than the high number of Americans living with substance use disorders is the phenomenal convergence of two major forces—potent heroin and liberally prescribed pain medication. Each complements the other in forming a multi-dimensional enemy, more threatening than any that the Nixon or Reagan administration could have imagined. As opioid misuse reaches catastrophic levels, federal and state governments must do battle on two separate fronts by encouraging safer prescription practices in the health care profession and stopping the flood of pure and deadly heroin heading towards our most afflicted areas.⁶ Consequently, our nation is in the midst of a perfect storm,⁷ and the war envisioned by the Nixon and Reagan administrations has evolved into a plague—a problem that has become known as America's opioid epidemic.⁸

On March 27, 2014, during his final year as governor of Massachusetts, Deval Patrick declared a public health emergency in the Commonwealth in response to the growing opioid epidemic.⁹ The governor instructed the Massachusetts Department of Public Health (“DPH”) to implement a strategy to combat overdoses, to stem the tide of the opioid epidemic, to guide misusers toward recovery, and to devise a long-term solution to substantially reduce opioid misuse in Massachusetts.¹⁰ In accordance with Governor Patrick's order, DPH created an Opioid Task Force, which was given a sixty-day window to explore the heart of the issue and to provide DPH with recommendations to contain the epidemic.¹¹ The Task Force highlighted as a paramount concern the urgent necessity to regulate opioid prescribing prac-

time High, CNN.COM (Dec. 18, 2015), <http://www.cnn.com/2015/12/18/health/drug-overdose-deaths-2014/> [https://perma.cc/3WXZ-8B5S].

⁶ See Daniel J. McGraw, *How Big Pharma Gave America Its Heroin Problem*, PACIFIC STANDARD (Nov. 30, 2015), <http://www.psmag.com/health-and-behavior/how-big-pharma-gave-america-its-heroin-problem> [https://perma.cc/77F9-SEMY] (“What followed was not all that surprising. Many grew addicted to the opioids, and when the prescriptions ran out, they turned to heroin because of its availability and relatively low cost. The Mexican drug cartels saw this trend and promptly began growing their opium plants, which they consciously made purer and less expensive. And those cartels targeted the suburbs, where those introductory OxyContin prescriptions were being filled—and where the money was.”).

⁷ A perfect storm occurs when a critical or disastrous situation is created by a powerful concurrence of factors. *Perfect Storm*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/perfect%20storm> [https://perma.cc/Q2AK-5VMX] (last visited Feb. 1, 2016).

⁸ Daniel Sosin, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, CTNS. FOR DISEASE CONTROL & PREVENTION (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm> [https://perma.cc/VJS2-BBYT].

⁹ In 2014, there were an estimated 1,256 opioid-related deaths in Massachusetts. This figure is nearly four times the 338 opioid-related deaths recorded in the year 2000. MA DEP'T PUB. HEALTH, DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS (Aug. 2015), <http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/county-level-mpmp/data-brief-aug-2015-overdose-county.pdf> [https://perma.cc/A2RW-EF5K].

¹⁰ MA DEP'T OF PUB. HEALTH, FINDINGS OF THE OPIOID TASK FORCE AND DEP'T OF PUB. HEALTH RECOMMENDATIONS ON PRIORITIES FOR INVESTMENTS IN PREVENTION, INTERVENTION, TREATMENT AND RECOVERY 1 (June 10, 2014), <http://www.mass.gov/eohhs/docs/dph/substance-abuse/opioid/report-of-the-opioid-task-force-6-10-14.pdf> [https://perma.cc/7FP5-V65P].

¹¹ *Id.* at 4.

tices.¹² The Task Force also listed crucial steps toward combating the problem,¹³ including increased education on the dangers of opioid use,¹⁴ centralized treatment resources improving accessibility,¹⁵ and a statewide expansion of recovery services.¹⁶

Governor Patrick's term ended on January 8, 2015.¹⁷ His successor, current Massachusetts Governor Charlie Baker, immediately made the opioid crisis a focal point of his administration, revealing new plans to curb the epidemic's momentum shortly after his inauguration.¹⁸ In February of 2015, Governor Baker announced that Massachusetts Health and Human Services Secretary Marylou Sudders and Attorney General Maura Healey would lead a panel charged with actively collaborating with substance use disorder experts, prescribers, and members of the community to devise "specific, targeted and tangible recommendations to increase public awareness about [opioids] and reduce the rate of addiction."¹⁹ Three months later, the panel presented the Governor with a detailed report, containing sixty-five steps to eradicate the deadly opioid epidemic.²⁰ Unfortunately, as Massachusetts residents continue to succumb to opioid use disorder at notable rates,²¹ the multi-faceted plan will not be implemented as quickly as devised, further delaying its impact.²²

¹² *Id.* at 11–12.

¹³ *Id.* at 17.

¹⁴ *Id.* at 9.

¹⁵ *Id.* at 12–13.

¹⁶ *Id.* at 15–17.

¹⁷ See Michael Levenson, 'Lone Walk' Leads Deval Patrick Back to Private Life, *Bos. GLOBE* (Jan. 7, 2015), <https://www.bostonglobe.com/news/politics/2015/01/07/patrick/A2kpDxeZDjSkyNeM8JM0fK/story.html> [https://perma.cc/NJX5-R4RZ].

¹⁸ See Felice J. Freyer, *Governor Announces New Panel on Opioids*, *Bos. GLOBE* (Feb. 19, 2015), <https://www.bostonglobe.com/metro/2015/02/19/governor-charlie-baker-establishes-panel-address-opioid-crisis/WSp7DYr9q52OZSvhZaumM/story.html> [https://perma.cc/FNH7-ESZ3] (reporting on Governor Baker's appointment of a sixteen-member working group to hold public meetings, assess resources devoted to the problem, and provide a specific plan to tackle the epidemic by May 2015).

¹⁹ *MA Governor Baker Announces Initial Steps to Combat Opioid Addiction Crisis*, *WORKCOMPWIRE.COM* (Feb. 26, 2015), <http://www.workcompwire.com/2015/02/ma-governor-baker-announces-initial-steps-to-combat-opioid-addiction-crisis/> [https://perma.cc/C3WB-3NQ2].

²⁰ MA DEP'T PUB. HEALTH, *RECOMMENDATIONS OF THE GOVERNOR'S OPIOID WORKING GROUP 2* (June 11, 2015).

²¹ In 2014, the estimated rate of unintentional opioid-related overdose deaths, which includes deaths related to heroin, reached levels previously unseen. DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9. The estimated rate of 18.6 deaths per 100,000 residents for 2014 is the highest ever for unintentional opioid overdoses and represents a 251% increase from the rate of 5.3 deaths per 100,000 residents in 2000. *Id.*

²² The findings by the panel include short and long term action items to be implemented between now and the next three years, some requiring legislative action and funding, while others will be achieved through partnerships with private industry and federal leaders. See PRESS RELEASE, THE OFFICIAL WEBSITE OF THE GOVERNOR OF MA, *Governor Baker Releases Opioid Working Group Recommendations* (June 22, 2015), <http://www.mass.gov/governor/press-office/press-releases/fy2015/governor-releases-opioid-working-group-recommendations.html> [https://perma.cc/RF6X-W7K5].

The magnitude of the opioid crisis has reached epidemic proportions.²³ As illustrated by the findings of the Task Force during the Patrick administration and the recent formulation of Governor Baker's sixty-five step plan, the issue presents many challenges, each requiring substantial reform.²⁴ This Article highlights the dramatic rise in reported cases of neonatal abstinence syndrome (NAS)²⁵ and considers potential ways forward for reform. Part II of the Article briefly defines NAS, traces its historical co-existence with opioid misuse, and emphasizes the gravity of social and economic burdens posed by the spike in NAS rates—a troubling consequence of the ongoing opioid epidemic. Part III acknowledges the successes of the two opioid agonist²⁶ medications generally approved to treat opioid dependence during pregnancy, while exposing the unfortunate reality that these medications also contribute to increased incidence of NAS. Part IV discusses OxyContin and its role in the opioid epidemic and the resulting elevation in NAS rates. Part V summarizes recent and ongoing efforts to contain the epidemic on federal and state levels, and suggests that the current state of affairs in the Commonwealth requires immediate and aggressive legislative action. Finally, Part VI illustrates a facilitative policy—one that assumes government and pregnant misusers share an interest in promoting fetal health—that is designed to reduce rates of NAS. The system's success relies on early identification of opioid misuse during pregnancy, as well as adherence to a standardized protocol implemented uniformly throughout public hospitals in Massachusetts. The Article concludes by reemphasizing the importance of acting promptly and aggressively in order to protect society's most vulnerable members from this deadly epidemic.

²³ See DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9.

²⁴ See RECOMMENDATIONS OF THE GOVERNOR'S OPIOID WORKING GROUP, *supra* note 20, at 2 (recommending bold new strategies and strong partnerships among medical community, law enforcement, the judiciary, insurers, providers, health and human services agencies, elected officials and the public); see also *Governor Baker Releases Opioid Working Group Recommendations*, *supra* note 22 (“The solution requires a strong public health approach focusing on prevention, intervention, treatment and recovery.”).

²⁵ See Michael Levenson, *More Than 1,700 Born in Mass. with Drug Issues in 2014*, BOS. GLOBE (Mar. 20, 2015), <https://www.bostonglobe.com/metro/2015/03/19/with-scourge-opiates-more-babies-mass-born-with-addiction/bz75a0bf5zmxDogZFuAuQO/story.html> [<https://perma.cc/ANM6-PFQA>] (reporting that more than 1,700 infants born in 2014 were exposed to drugs and that Boston Medical Center treats triple the number of substance-exposed infants as it did five to ten years ago).

²⁶ An agonist is a chemical substance (i.e., a drug) capable of combining with a receptor on a cell and initiating the same reaction or activity typically produced by the binding of an endogenous substance. *Agonist*, MEDLINE PLUS ONLINE DICTIONARY, <http://c.merriam-webster.com/medlineplus/agonist> [<https://perma.cc/C472-QFGM>] (last visited Feb. 1, 2016).

II. NEONATAL ABSTINENCE SYNDROME

A. Symptoms in Newborns

Months before her birth on April 11, 2011, Mya Barry was in grave danger.²⁷ Shortly after Mya's pregnant mother, a daily heroin user, had given birth to Mya, the opioid-dependent infant went into withdrawal.²⁸ Mya spent six weeks in the hospital while doctors treated her with a morphine-based weaning protocol to ease her sickness and pain while she detoxified from opioids.²⁹ After her hospital stay, Mya was released to her family.³⁰ Within five months, local police officers found Mya, cold and blue, lying on her grandmother's living room floor.³¹ Mya died from ingesting her mother's heroin-tainted breast milk.³² Mya Barry is one of thousands who have fallen victim to the deadly epidemic—tragically contributing another notch to its belt.³³

Although the heroin that passed in utero was not the direct cause of Mya Barry's death, such prenatal drug exposure, the result of which is extreme discomfort to the newborn, has become increasingly common as the opioid epidemic continues its merciless sweep.³⁴ The condition, known as neonatal abstinence syndrome (NAS), increased five-fold nationwide between 2000 and 2012.³⁵ In Massachusetts, where the opioid epidemic has hit especially hard, data and reports suggest that the rate of opioid-dependent newborns is two to three times the national average.³⁶ Although more prevalent today, the social concern is by no means a new phenomenon, as NAS has paralleled trends of opioid use dating back to the mid-nineteenth century.³⁷

NAS is a clinical syndrome that occurs when a newborn suffers withdrawal symptoms as a consequence of an abrupt discontinuation of exposure

²⁷ See Jennifer McKim & Michael Bottari, *Cases of newborns with addictions soaring*, BOS. GLOBE (Mar. 30, 2014), <https://www.bostonglobe.com/metro/2014/03/29/explosion-drug-exposed-infants-reveals-weakness-massachusetts-child-protection/0ZhSZUhIBbn0jVElOBgIsJ/story.html> [https://perma.cc/2KCH-VMSZ].

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9.

³⁴ See Levenson, *supra* note 25.

³⁵ See Gary Peltz & Kanwaljeet J. S. Anand, *Long-Acting Opioids for Treating Neonatal Abstinence Syndrome: A High Price for a Short Stay?*, 314 J. AM. MED. ASS'N 2023, 2023 (2015).

³⁶ See Felice J. Freyer, *Hospitals Adapt as Opioid Epidemic Hits Infant Victims*, BOS. GLOBE (June 28, 2015), <https://www.bostonglobe.com/metro/2015/06/27/rise-drug-dependent-babies-challenges-doctors-families-social-services/wUDg5j1UIInpDckTX6c5XEP/story.html> [https://perma.cc/3BDE-X4G9].

³⁷ See *infra* notes 47–62 and accompanying text (explaining historical records of NAS in America).

to addictive substances.³⁸ Common symptoms of NAS are tremors, high-pitched cries, sneezing, vomiting, diarrhea, sweating, and fever.³⁹ The medical field recognizes two types of NAS: (1) NAS resulting from prenatal exposure to addictive substances in utero, and (2) NAS due to postnatal discontinuation of opioid painkillers.⁴⁰ The recent surge in NAS diagnoses in newborns is attributable to maternal opioid dependence.⁴¹ Such prenatal exposure is the focus of this Article.

B. Historical Emergence

During the Civil War, morphine was plentifully dispensed to sick and wounded soldiers, leaving many dependent on opioids.⁴² Hence, this first major wave of opioid misuse appropriately earned itself the sobriquet “the soldier’s disease.”⁴³ Living up to its reputation as a disease that does not discriminate,⁴⁴ substance use disorder likewise skyrocketed among American women due to the widespread availability of opioids, which were openly sold in drug stores without the need for a prescription.⁴⁵ In fact, by the beginning of the twentieth century, due in large part to the liberal prescription of opioids to treat pain and discomfort, opioid misusers who were female likely outnumbered male counterparts.⁴⁶

One year after heroin was first synthesized in 1875 and was advertised as a “non-addictive” alternative to morphine, a doctor anonymously re-

³⁸ See Kimberly G. Lee, *Neonatal Abstinence Syndrome*, MEDLINEPLUS MED. ENCYC., <https://www.nlm.nih.gov/medlineplus/ency/article/007313.htm> [<https://perma.cc/84J8-HX28>] (last updated Nov. 14, 2013).

³⁹ Walter K. Kraft & John N. van den Anker, *Pharmacologic Management of the Opioid Neonatal Abstinence Syndrome*, 59 PEDIATRIC CLINICS N. AM. 1147, 1148 (2012).

⁴⁰ Ashraf H. Hamdan, *Neonatal Abstinence Syndrome*, MEDSCAPE REFERENCE: DRUGS, DISEASES & PROCEDURES, <http://emedicine.medscape.com/article/978763-overview#a4> [<https://perma.cc/Z255-FUM3>] (last updated Nov. 27, 2016).

⁴¹ See Levenson, *supra* note 25.

⁴² See Walter Ling & Peggy Compton, *Recent Advances in the Treatment of Opiate Addiction*, 5 CLINICAL NEUROSCIENCE RESEARCH 161 (2005), http://www.csam-asam.org/sites/default/files/pdf/misc/Ling_-_recent_.pdf [<https://perma.cc/LUA6-XAG5>].

⁴³ See *id.*

⁴⁴ See NARCOTICS ANONYMOUS WORLD SERVS. INC., NARCOTICS ANONYMOUS xviii (6th ed. 2008) (“Addiction is a disease that does not discriminate”); see also *Regardless of Age . . .*, 18 NA WAY MAG. 1, 1 (2001) (“[A]ddiction does not discriminate or attack one branch of the population over another.”).

⁴⁵ See Stephen R. Kandall, *Women and Addiction in the United States—1850 to 1920*, DRUG ADDICTION RESEARCH AND THE HEALTH OF WOMEN 33, 35–36 (C.L. Wetherington & A.B. Roman eds., 1998) http://archives.drugabuse.gov/pdf/DARHW/033-052_Kandall.pdf [<https://perma.cc/A776-ZEVM>].

⁴⁶ See *id.* Despite many epidemiologic limitations, an 1878 study found that women made up 56 percent of 630 opium users, and 66 percent of morphine users identified in the state of Michigan. *Id.* The same study revealed that the majority of misusers in 88 of the 96 towns that reported substance use disorder were women. *Id.* This study, and others like it, indicate that approximately 100,000 of the estimated 150,000–200,000 Americans with substance use disorder in the late 19th century were women. *Id.*

ported the first case of congenital morphinism⁴⁷—a complex disorder later retitled NAS.⁴⁸ A number of similar cases followed in the remaining years of the nineteenth century, most of which resulted in newborn fatalities.⁴⁹ In April 1903, the first successful treatment of a NAS case was recorded in the *Journal of American Medicine*.⁵⁰ The journal article describes a baby, born to a morphine-dependent mother, who appeared normal at birth, but began crying incessantly on the second day.⁵¹ To ease the infant's discomfort, the doctor administered small doses of morphine every other day, alleviating the newborn's withdrawal symptoms.⁵² This seminal case represents the first reported successful pharmacological treatment of congenital morphism.⁵³

Cases of NAS were reported sporadically through the early 1900s, culminating in an extensive 1934 review of the disorder that cited fifty-three U.S. cases.⁵⁴ Shortly thereafter, *Diseases of the Newborn*, a textbook on pediatrics published in 1937, officially recognized congenital morphism as a cause of convulsions in newborns.⁵⁵ Pharmacological treatment, primarily through doctor-administered morphine, continued to serve as the primary means of weaning dependent infants off opioids.⁵⁶ A particularly severe case, reported in 1941, deviated from the standard morphine-based treatment.⁵⁷ In this case, a newborn plagued by withdrawal symptoms from the mother's misuse of heroin was sedated with phenobarbital.⁵⁸ Almost immediately, the vomiting and diarrhea subsided and the newborn began to gain weight.⁵⁹ The baby underwent regular phenobarbital treatment for eight weeks before the dosage was tapered and eventually stopped.⁶⁰ Subsequent observations conducted over the next year indicated normal childhood development.⁶¹ From this point, phenobarbital sedation became a recognized ther-

⁴⁷ Meyer A. Perlstein, *Congenital Morphinism: A Rare Cause of Convulsions in the Newborn*, 135 J. AM. MED. ASS'N 633, 633 (1947).

⁴⁸ Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134 PEDIATRICS e547, e548 (2014).

⁴⁹ See Perlstein, *supra* note 47, at 633 (reporting 12 infants born to drug addicted mothers in 1892, nine of whom died).

⁵⁰ *Id.*

⁵¹ *See id.*

⁵² *See id.*

⁵³ See Kocherlakota, *supra* note 48, at e548.

⁵⁴ See Perlstein, *supra* note 47, at 633 (citing 50 cases of congenital morphinism in German journals and 53 in American literature).

⁵⁵ *See id.* In his 1937 textbook on pediatrics, *Diseases of the Newborn*, Tow describes thirteen cases of infants born into opiate withdrawal, six of which died in spite of treatment. See generally ABRAHAM TOW, DISEASES OF THE NEWBORN 395 (1937).

⁵⁶ See Perlstein, *supra* note 47, at 633.

⁵⁷ *See id.*

⁵⁸ The newborn vomited excessively and suffered from diarrhea, tremors, and occasional seizures—all common symptoms of NAS. *See id.*

⁵⁹ *See id.*

⁶⁰ *See id.*

⁶¹ *See id.*

R

R

R

R

apeutic agent for NAS, often accompanying full agonists such as morphine or methadone.⁶²

C. Contemporary Societal Costs

Until recently, the societal and economic damage caused by NAS has been difficult to accurately assess due in part to limited self-reporting of substance misuse and underreporting by national and state surveyors.⁶³ However, a combination of forces over the years, most notably the increase in overall opioid use disorder rates in connection with the ongoing crisis, has uncovered an alarmingly high number of NAS cases, forcing federal and state agencies to take note.⁶⁴ The wide assortment and availability of substances such as methadone, buprenorphine, prescription opioid analgesics, anti-depressants, and anxiolytics have increased the complexity and prevalence of NAS.⁶⁵ With these new medications in play, and a full-blown epidemic of prescription pill and heroin misuse sweeping across the nation, the number of newborns requiring hospitalization and treatment for opioid withdrawal is unprecedented.⁶⁶

Aside from the clear public health issues that arise from the soaring number of babies born substance-dependent, expenses for hospital stays and treatment associated with NAS are predominantly shouldered by state taxpayers and have reached extraordinary levels.⁶⁷ An estimated 13,500 babies are born substance-dependent in the United States each year due to in utero

⁶² See *id.*; see also Kocherlakota, *supra* note 48, at e554.

⁶³ See Kraft & van den Anker, *supra* note 39, at 1148.

⁶⁴ See Sosin, *supra* note 8 (noting a quadrupling of opioid pain reliever overdoses between 1999 and 2010, the CDC declared the problem of prescription drug abuse a public health epidemic); MA DEP'T PUB. HEALTH, DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9; see also Freyer, *Hospitals Adapt as Opioid Epidemic Hits Infant Victims*, *supra* note 36 (acknowledging that babies withdrawing from drugs used to be a rare occurrence confined to inner cities, but today, throughout the Commonwealth, they are a regular presence as the "opioid epidemic cascades down to the next generation").

⁶⁵ See Kocherlakota, *supra* note 48, at e549 (explaining that NAS has become more common and more complex "not only because of an increase in the use of opioids, but also because of the simultaneous use of multiple opioids").

⁶⁶ "Approximately 13,500 neonates born in the United States each year develop NAS, and this number has increased nearly [five]-fold between 2000 and 2012." Peltz & Anand, *supra* note 35, at 2023.

⁶⁷ See J.C. Monahan, *Cape Facing Epidemic of Drug-Addicted Newborns*, WCVB.COM (Nov. 14, 2013) <http://www.wcvb.com/article/cape-facing-epidemic-of-drug-addicted-newborns/8191295>. [<https://perma.cc/VS3N-FLNC>] (referring to a 44 percent increase of babies born with NAS at Cape Cod Hospital between 2011 and 2012, the cost of which falls on Massachusetts taxpayers); see also *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome> [<https://perma.cc/3UAS-T6ZQ>] (last updated Sept. 2015) (estimating NAS is costing hospitals approximately \$1.5 billion, 81 percent of which was paid by state Medicaid programs).

R
R
R

R
R

R

R

exposure to addictive chemicals.⁶⁸ The average hospital stay for a baby withdrawing from opioids is about sixteen days, with a mean cost per stay of \$93,400 for pharmacologically treated cases.⁶⁹ A 2015 nationwide study conducted by the *Journal of Perinatology* estimated that NAS-related hospital stays cost \$1.5 billion per year, eighty percent of which is paid by state Medicaid programs.⁷⁰ Hit particularly hard by the national opioid crisis, Massachusetts absorbs more than its share of these costs.⁷¹ Between March 1, 2014, and March 31, 2015, the Massachusetts Department of Children and Families responded to 2,265 cases of NAS in the Commonwealth.⁷² This thirteen-month span alone proved tremendously costly to Massachusetts' taxpayers, costing them approximately \$169 million.⁷³ The opioid epidemic continues to victimize citizens at record high rates, and despite recent progress by the Baker administration, does not appear to be waning.⁷⁴

III. THE BEGINNINGS OF OPIOID MISUSE TREATMENT

Scientific and medical advances over the last few decades have ended the debate over whether substance use disorder is a disease or a moral choice.⁷⁵ Research has proven that the disorder is a brain disease that affects an individual's behavior.⁷⁶ The disease can be effectively treated and managed, usually requiring a detoxification period, substantial counseling, and often times, pharmacological treatment.⁷⁷ Medication is a key component in treating opioid misuse, and in conjunction with adequate behavioral therapy, can guide substance misusers toward full recovery.⁷⁸

Long-term opioid misuse desensitizes the brain's opiate receptors to endorphins, hormonal groups naturally produced by the body to endure pain or

⁶⁸ See Peltz & Anand, *supra* note 35, at 2023.

⁶⁹ See Katie Lannan, *New Program in Massachusetts for Newborns Exposed to Drugs*, STATE HOUSE NEWS SERV. (Dec. 24, 2015), <http://www.telegram.com/article/20151224/NEWS/151229446> [<https://perma.cc/F45U-TCKP>]; see also Freyer, *Hospitals Adapt as Opioid Epidemic Hits Infant Victims*, *supra* note 36 (stating the average hospital stay for a baby withdrawing from drugs is sixteen days).

⁷⁰ Freyer, *Hospitals Adapt as Opioid Epidemic Hits Infant Victims*, *supra* note 36.

⁷¹ *Id.*

⁷² *Id.*

⁷³ Multiplying \$93,400 (the average cost for a pharmacologically treated NAS case) by 2,265, (cases of children exposed to drugs over the thirteen-month period) yields a product of \$211,551,000. 80% of this figure is \$169,240,800. See *id.*

⁷⁴ DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9.

⁷⁵ See Alan I. Leshner, *Addiction Is a Brain Disease*, 17 ISSUES IN SCI. AND TECH., no. 3 (2001) (defining addiction as a brain disease expressed in the form of compulsive behavior).

⁷⁶ See NAT'L INST. ON DRUG ABUSE, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PRESCRIPTION DRUGS: ABUSE AND ADDICTION 11 (April 2001) ("Years of research have shown that addiction to any drug, illicit or prescribed, is a brain disease that can . . . be effectively treated.").

⁷⁷ See *id.*

⁷⁸ See *id.*

R

R

R

R

extreme physical exertion.⁷⁹ Opioid agonist medications, which activate the same receptors as heroin, morphine, and endorphins, alleviate withdrawal symptoms and reduce opioid cravings.⁸⁰

There are currently two nationally approved opioid agonist medications commonly prescribed to treat opioid dependence during pregnancy: methadone and buprenorphine.⁸¹ Although other medications are available, there is clear consensus that these medications are the most effective means of treatment for opioid misuse.⁸² Notwithstanding their utility in treating opioid use disorder, methadone and buprenorphine are synthetic opioids with many of the same properties as heroin, oxycodone, hydrocodone, and other opiate derivatives.⁸³ Thus, despite the advantages and benefits provided by medication-assisted therapy (MAT), newborns continue to display withdrawal symptoms from in utero exposure to methadone, and, albeit to a lesser degree, buprenorphine.⁸⁴ With opioid misuse reaching ever-increasing levels, and MAT more common and complex than ever before, NAS rates have increased exponentially, causing serious social and economic damage.⁸⁵

⁷⁹ See NAT'L INST. ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PRINCIPLES OF DRUG ABUSE TREATMENT FOR CRIMINAL JUSTICE POPULATIONS 24, <http://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/what-role-medications-in-treating-substance-abusing> [<https://perma.cc/4F7Y-YMBX>] (last updated April 2014); see also *Endorphin*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/endorphin> [<https://perma.cc/EVF4-ASYQ>] (last visited Feb. 1, 2016).

⁸⁰ See PRINCIPLES OF DRUG ABUSE TREATMENT FOR CRIMINAL JUSTICE POPULATIONS, *supra* note 79 at 24.

⁸¹ National guidelines from the American College of Obstetricians and Gynecologists (ACOG) and the Substance Abuse and Mental Health Services Administration (SAMSHA) and international guidelines from the World Health Organization recommend that pregnant women be treated with methadone or buprenorphine. See SHANNON HERTZ, FOOD AND DRUG ADMIN. CTR. FOR DRUG EVALUATION AND RES., FDA BRIEFING DOCUMENT: RISK COMMUNICATION ADVISORY MEETING 17 (2015), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM449600.pdf> [<https://perma.cc/9WHN-WA8V>]; SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERV., THE N-SSATS REPORT: TRENDS IN THE USE OF METHADONE AND BUPRENORPHINE AT SUBSTANCE ABUSE TREATMENT FACILITIES: 2003 TO 2011 1 (2013).

⁸² See Marjorie Meyer & Julie Phillips, *Caring for Pregnant Opioid Abusers in Vermont: A Potential Model for Non-urban Areas*, 80 PREVENTIVE MED. 18, 18 (2015).

⁸³ See Elinore F. McCance-Katz et al., *Drug Interactions of Clinical Importance among the Opioids, Methadone and Buprenorphine, and other Frequently Prescribed Medications: A Review*, 19(1) AM. J. ADDICT 4, 5 (2010).

⁸⁴ See Hendree E. Jones et al., *Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure*, 363 N. ENG. J. MED. 2320, 2327 (2010) (finding no significant differences in overall rates of NAS among infants exposed to buprenorphine and those exposed to methadone, but concluding that fetal exposure to the former results in shorter, less severe symptoms than in utero exposure to the latter); Minozzi et al., *Maintenance Agonist Treatments for Opiate-dependent Pregnant Women*, 12 COCHRANE DATABASE SYSTEMATIC REV. 1, 2 (2013).

⁸⁵ See Kocherlakota, *supra* note 48, at e549 (referring to the worsening of the spectrum of NAS, not only because of increased opioid use, but also because of the simultaneous use of multiple opioids available with a prescription or on the street).

R

R

A. *Methadone – Lesser of Two Evils*

In response to the post-World War II heroin epidemic in New York City, methadone emerged in 1964 as a replacement treatment for opioid dependence.⁸⁶ Methadone is a long acting agonist that effectively occupies the brain receptor sites also affected by heroin and other opioids.⁸⁷ As the result of occupying these opiate receptors, methadone blocks the euphoric and sedating effects of opioids while relieving cravings and other symptoms associated with withdrawal.⁸⁸ Methadone is considered a corrective treatment rather than a cure for opioid misuse, and it has proven most successful when administered for indefinite, or in some cases, life-long periods.⁸⁹ The methadone maintenance treatment (MMT) model, which began as a research project on six seasoned heroin misusers, has proved to be the most successful treatment for opioid use disorder.⁹⁰

Opioid misuse during a woman's pregnancy subjects her and her fetus to constant fluctuations of drug levels—a roller coaster of highs and lows that can prove fatal to both the woman and her fetus.⁹¹ Aside from the substantial risk of overdose inherent in heroin and prescription pill dependence, withdrawal symptoms can result in stillbirth, premature delivery, low birth weight, and sudden infant death syndrome.⁹² Methadone, due to its long-acting nature and capability to reduce cravings and stave off withdrawal symptoms, promotes a healthier environment for the pregnant woman and her fetus.⁹³ Moreover, methadone maintenance reduces the incidence of some medical and obstetrical complications germane to pregnant women who misuse street drugs.⁹⁴ Malnutrition, susceptibility to infectious diseases such as HIV and hepatitis, premature rupture of membranes, pre-term labor, and toxemia are examples of complications that are often thwarted by MMT during pregnancy.⁹⁵

Not surprisingly, a general comparison of heroin use and MMT during pregnancy depicts the latter as the more desirable path for a pregnant woman

⁸⁶ See Herman Joseph et al., *Methadone Maintenance Treatment (MMT): A Review of Historical and Clinical Issues*, 67 *MT. SINAI J. MED.* 347, 347 (2000).

⁸⁷ See *id.*

⁸⁸ See *id.*

⁸⁹ See *id.* at 361.

⁹⁰ See *id.* at 348. A 1964 experiment conducted on six male heroin misusers at Rockefeller University administered methadone to withdraw the test subjects from heroin. *Id.* Rather than discontinuing the methadone once withdrawal symptoms subsided, the research team continued to administer methadone and study its effects. *Id.* As the patients adapted to methadone, their cravings and obsession with drugs began to subside. *Id.* All six of these volunteers found employment shortly after undergoing MMT. *Id.*

⁹¹ See *id.* at 355.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

and her fetus.⁹⁶ In fact, MMT is currently the standard of care for treating women who misuse opioids while pregnant.⁹⁷ Notwithstanding its medical and social acceptance, MMT certainly has its drawbacks, particularly when administered to pregnant misusers.⁹⁸ First, the severity and duration of withdrawal symptoms exhibited by newborns exposed to methadone in utero are substantial.⁹⁹ Typically, infants born to methadone-maintained mothers cry incessantly, respond poorly to visual stimuli, have less motor maturity, and tend to be tremulous, irritable, and easily overexcited.¹⁰⁰ Due to methadone's relatively long half-life, NAS symptoms are delayed; yet fetal exposure to methadone yields longer, more severe withdrawal symptoms than NAS associated with shorter-acting opioids, such as heroin.¹⁰¹ Second, the significant increase in the number of pregnant opioid misusers treated with methadone has contributed to a drastic rise in cases of NAS, both nationwide and in Massachusetts.¹⁰² Indeed, the simultaneous increase in pregnant misusers treated with methadone and infants born into methadone-induced abstinence syndrome share a causal connection. The formation of this unfortunate and extraordinarily costly nexus is one of the many dismal realities attributable to the larger opioid epidemic.

B. Buprenorphine – A Step in the Right Direction

Initially introduced in France in 1996, buprenorphine was approved by the United States Food and Drug Administration (FDA) as a treatment for opioid dependence in October 2002.¹⁰³ Buprenorphine is a partial agonist that occupies the same receptors as methadone, and, unlike full agonist medications, results in minimal withdrawal effects upon discontinuation.¹⁰⁴ Suboxone is a unique formulation of buprenorphine that contains naloxone, an opioid antagonist that limits diversion of the combined drug for recrea-

⁹⁶ See *id.* at 356 (summarizing that the use of methadone fosters both a healthy infant and a healthy mother).

⁹⁷ Jones, *supra* note 84, at 2329.

⁹⁸ See Hendree E. Jones et al., *Buprenorphine Treatment of Opioid-dependent Pregnant Women: A Comprehensive Review*, 107 *ADDICT.* 5, 5 (2012).

⁹⁹ See Rolley E. Johnson et al., *Use of Buprenorphine in Pregnancy: Patient Management and Effects on the Neonate*, 70 *DRUG & ALCOHOL DEPENDENCE* S87, S88 (2003).

¹⁰⁰ *Id.*

¹⁰¹ *Id.*; see also Carl Kuschel, *Managing Drug Withdrawal in the Newborn Infant*, 12 *SEMINARS FETAL & NEONATAL MED.* 127, 128 (2007).

¹⁰² See, e.g., Jennifer McKim & Michael Bottari, *Cases of Newborns with Addictions Soaring*, *BOS. GLOBE* (Mar. 30, 2014), <https://www.bostonglobe.com/metro/2014/03/29/explosion-drug-exposed-infants-reveals-weakness-massachusetts-child-protection/0ZhSZUhIBbn0jVEIOBgIsJ/story.html> [<https://perma.cc/X7RH-UQUX>]. The majority of the 106 infants born with NAS at Boston Medical Center in 2013 suffered withdrawal symptoms from in utero exposure to methadone or buprenorphine. *Id.*

¹⁰³ Johnson, *supra* note 99, at S98; see also THE N-SSATS REPORT: TRENDS IN THE USE OF METHADONE AND BUPRENORPHINE AT SUBSTANCE ABUSE TREATMENT FACILITIES: 2003 TO 2011, *supra* note 81, at 1.

¹⁰⁴ See Jones, *Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure*, *supra* note 84 at 2321.

R

R

R

R

tional use by causing severe withdrawal symptoms in users who inject it to get “high.”¹⁰⁵ Both medications are available through clinics and office-based practices by specifically certified physicians and have no adverse effects when taken orally, as prescribed.¹⁰⁶ Due to insufficient clinical data, suboxone is not a recommended medication for pregnant opioid misusers; buprenorphine alone is considered the safest method of pharmacological treatment.¹⁰⁷

Whereas MMT during pregnancy often subjects the newborn to serious and lengthy withdrawal symptoms, NAS associated with buprenorphine treatment is shorter and clinically less severe than that observed with methadone.¹⁰⁸ As a consequence of the comparatively mild NAS associated with buprenorphine treatment of pregnant misusers, the mean length of NAS treatment for infants born to such women is significantly shorter than the average treatment for prenatally methadone exposed neonates.¹⁰⁹

IV. A FORMULA FOR DISASTER – OXYCONTIN AND LIBERAL PRESCRIPTIONS

*“We have lost an entire generation. Half the pharmacies in Pike County have bulletproof glass. We had FedEx trucks being knocked off. It was the Wild West.”*¹¹⁰

As developments in the arena of pharmacological treatment for substance use disorder continued to progress, the 1990s marked a relatively peaceful period in America’s war on drugs.¹¹¹ Drug-related violence dropped

¹⁰⁵ See PRINCIPLES OF DRUG ABUSE TREATMENT FOR CRIMINAL JUSTICE POPULATIONS, *supra* note 79, at 24.

¹⁰⁶ See *id.*

¹⁰⁷ See Ingunn O. Lund et al., *A Comparison of Buprenorphine + Naloxone to Buprenorphine and Methadone in the Treatment of Opioid Dependence during Pregnancy: Maternal and Neonatal Outcomes*, SUBSTANCE ABUSE RES. & TREATMENT 61, 72 (2013).

¹⁰⁸ See Jones, *Buprenorphine Treatment of Opioid-dependent Pregnant Women: A Comprehensive Review*, *supra* note 98, at 5; see also Johnson, *supra* note 99, at S97 (acknowledging a mild to severe NAS in infants born to buprenorphine maintained mothers but noting that such cases are less frequent, less severe, and of shorter duration).

¹⁰⁹ Jones, *Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure*, *supra* note 98, at 22. The mean duration of hospital stay for NAS treatment for 27 buprenorphine-exposed neonates in the MOTHER study was 9.7 days whereas the mean length of hospital stay for NAS treatment of 41 prenatally methadone-exposed infants was 17.8 days. *Id.* at 18.

¹¹⁰ David Armstrong, *Purdue Says Kentucky Suit Over OxyContin Could Be Painful*, BLOOMBERG (Oct. 20, 2014), <https://www.bloomberg.com/news/articles/2014-10-20/purdue-says-kentucky-suit-over-oxycontin-could-be-painful> [https://perma.cc/Z4VG-S8AQ]. These are the words of Kentucky Attorney General Jack Conway in a statement to press declining Purdue Pharma’s \$500,000 settlement offer in connection with a civil suit filed by Kentucky against Purdue.

¹¹¹ See Roland G. Fryer et al., *Measuring Crack Cocaine and its Impact*, 51 ECON. INQUIRY 1651 (2013) (finding that crack rose sharply beginning in 1985, peaked in 1989, and slowly declined thereafter); see also Johnson, *supra* note 99, at S88.

R

R

R

R

significantly, particularly in African-American communities.¹¹² Due to so-called “opiophobia”¹¹³ among physicians, substance use disorder rates were, for the most part, temperate.¹¹⁴ This glimmer of hope was short lived as a social enigma—one of the darkest and most complex that America has ever faced—cast a portentous shadow over the nation.

In 1996, Purdue Pharma introduced OxyContin, the brand name for a sustained release formula of oxycodone,¹¹⁵ designed to manage pain.¹¹⁶ Through aggressive advertising and marketing efforts, the company conducted more than forty national conferences from 1996 through 2001, through which it endorsed liberal prescription of opioids and promoted its newly prepared formula, OxyContin.¹¹⁷ In 2001, Purdue’s sales representatives, encouraged to sell the company’s newly designed painkiller in high volumes, received an average bonus of \$71,500 in addition to their \$55,000 salary.¹¹⁸ Also in 2001, Purdue spent \$200 million recruiting and training physicians, pharmacists, and nurses to board the “OC” train and tout its efficacy and safety.¹¹⁹ Utilizing state-of-the-art databases containing records of prescribing practices of individual physicians, the pharmaceutical company identified and targeted its marketing efforts to those who prescribed opioids frequently.¹²⁰ A particular promotional strategy—uncomfortably, yet strikingly similar to sales tactics of some street dealers—used a starter coupon program for OxyContin, providing patients with a free, limited-time prescription of the new product.¹²¹ By 2001, when the program ended, approximately 34,000 coupons had been redeemed nationally.¹²²

¹¹² See Fryer, *supra* note 111, at 1655 (observing, by the year 2000, a correlation between the decline in the impact of crack prevalence and the recovery of homicide rates in Black communities).

¹¹³ The term refers to a doctor’s unwillingness or fear of prescribing opioids to patients. *Opiophobia*, SEGEN’S MEDICAL DICTIONARY, retrieved from <http://medical-www.merriam-webster.com/dictionary.thefreedictionary.com/opiophobia> [https://perma.cc/ERG4-3MN7] (last visited Jan. 23, 2017).

¹¹⁴ Prior to the introduction of OxyContin, many physicians were reluctant to prescribe opioids on a long-term basis because of their concerns about potential substance use disorder. Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 562 (2015).

¹¹⁵ Oxycodone is an opioid that produces heroin-like effects and is commonly used to treat pain. Leanna Skarnulis, *OxyContin: Pain Relief vs. Abuse*, WEBMD (June 19, 2007), <http://www.webmd.com/pain-management/features/oxycotin-pain-relief-vs-abuse?page=5> [https://perma.cc/VZS2-QWHG].

¹¹⁶ *Id.*; Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221 (2009).

¹¹⁷ See Van Zee, *supra* note 116, at 221.

¹¹⁸ *Id.* at 222.

¹¹⁹ *Id.* at 221. After its introduction, OxyContin quickly earned itself street names such as Oxy, Oxycotton, hillbilly heroin, and blue. “OC” was one of the more common nicknames for the drug.

¹²⁰ *Id.* at 222.

¹²¹ *Id.*

¹²² *Id.*

R

R

Purdue's marketing campaign to use opioids to treat pain not associated with a malignancy¹²³ was a critical aspect of its success.¹²⁴ As a result of Purdue's relentless promotion, OxyContin prescriptions for non-cancerous pain increased ten-fold between 1997 and 2002, with non-cancer pain management accounting for eighty-six percent of opioid prescriptions nationwide.¹²⁵ By 2004, OxyContin had become the most heavily misused opioid in the United States.¹²⁶ Purdue's aggressive marketing strategies and the persuasive promotional efforts by its agents during a time of liberal prescribing practices generated tremendous profit for the pharmaceutical company.¹²⁷ Since its introduction twenty years ago, OxyContin sales have earned the Sackler family, Purdue Pharma's sole owners, \$35 billion and the sixteenth spot in the 2015 *Forbes* list of America's richest families.¹²⁸

What Purdue's seemingly flawless campaign to promote OxyContin failed to disclose, however, has likely caused irreparable harm to the public.¹²⁹ The thriving pharmaceutical company misrepresented the risks of iatrogenic¹³⁰ addiction accompanying long-term use of the medication for non-malignant pain.¹³¹ Sales representatives were instructed to carry the message that risks of developing substance use disorder from OxyContin were less than one percent.¹³² Although this percentage holds some validity when OxyContin is used to treat acute pain, it grossly underrepresents the risks of misuse that accompany long-term OxyContin use to manage chronic, non-cancer-related pain.¹³³ Purdue's commercial success was further tarnished by

¹²³ Cancer patients often experience pain which manifests in various ways. See *Cancer Pain Management*, UNIV. OF TEX. MD ANDERSON CANCER CTR., <https://www.mdanderson.org/patients-family/diagnosis-treatment/emotional-physical-effects/cancer-pain-management.html> [https://perma.cc/TL4B-CYMS].

¹²⁴ See Van Zee, *supra* note 116, at 225 (noting Purdue's commercial success was fueled by its unprecedented promotion and marketing campaign). R

¹²⁵ *Id.* at 223. Between 1997 and 2002, sales grew from 48 million in 1996 to almost 1.1 billion in 2000. *Id.*

¹²⁶ *Id.* at 225.

¹²⁷ See Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES (July 1, 2015), <http://www.forbes.com/sites/alexmorrell/2015/07/01/the-Oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#50f12264c0e2> [https://perma.cc/EM4V-Q6W5].

¹²⁸ *Id.*

¹²⁹ See Van Zee, *supra* note 116, at 223 (referring to Purdue's misrepresentation of the risks of misuse associated with OxyContin). R

¹³⁰ Iatrogenic addiction is a substance use disorder "induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures." *Iatrogenic*, MERRIAM-WEBSTERMEDLINE PLUS ONLINE DICTIONARY, <https://www.nlm.nih.gov/medlineplus/implusdictionary.html> [https://perma.cc/5WS7-A3PY]. (last visited Feb. 1, 2015).

¹³¹ *Id.*

¹³² *Id.*

¹³³ Studies have shown abuse rates among patients with opioid prescriptions for chronic non cancer-related pain are quite substantial. See, e.g., Charles Chabal et al., *Prescription Opiate Abuse in Chronic Pain Patients: Clinical Criteria, Incidence, and Predictors*, 13 CLINICAL J. PAIN 150, 150 (1997) (conducting a study where 34% of patients using opioids to treat chronic pain met at least one of the criteria for abuse); Nathaniel P. Katz et al., *Behavioral Monitoring and Urine Toxicology Testing in Patients Receiving Long-Term Opioid Therapy*, 97 ANESTHESIA & ANALGESIA 1097, 1097 (2003) ("For 122 patients maintained on

the inadequacy of OxyContin’s sustained-release mechanism.¹³⁴ Almost immediately, users learned to circumvent the pill’s time-release feature by removing the outer film and crushing the tablet into a fine powder which could be inhaled or injected, immediately giving the user an intense and euphoric heroin-type high.¹³⁵ These newly-found routes to administer the powerful opioid and its general medical and social acceptance—a result of Purdue’s aggressive marketing and misrepresentation of iatrogenic addiction associated with OxyContin—paved the way for a period of substance misuse that would escalate to a full-blown epidemic.¹³⁶

V. FEDERAL AND STATE REFORMATIVE ACTION

*The solution to eradicating opioids is not a one-size-fits-all approach, and will require all of us to rethink the way we treat addiction. Today’s announcements are a first step and we will aggressively pursue reforms to save lives.*¹³⁷

Because the number of newborns treated for opioid withdrawal has risen on a similar trajectory to that of the opioid misuse rate, it is foreseeable that the number will decrease accordingly provided federal and state governments successfully overcome the larger crisis.¹³⁸ With the opioid epidemic’s devastating effects immediately apparent, many of America’s federal and state government leaders are acting affirmatively to limit further suffering.¹³⁹

chronic opioid therapy, 43% had a ‘problem’ (either positive urine toxicology or one or more of the aberrant drug-taking behaviors.); Edward Michna et al., *Urine Toxicology Screening Among Chronic Pain Patients on Opioid Therapy: Frequency and Predictability of Abnormal Findings*, 23 CLINICAL J. PAIN 173, 173 (2007) (An analysis of data from 470 urine screens was performed. Samples were categorized as “normal” (expected findings based on their prescribed drugs) or abnormal. Abnormal findings consisted of (1) absence of a prescribed opioid, (2) presence of an additional non-prescribed controlled substance, (3) detection of an illicit substance, and (4) an adulterated urine sample. Forty-five percent of the samples were abnormal.).

¹³⁴ See Van Zee, *supra* note 116, at 223.

¹³⁵ See *id.*

¹³⁶ See *id.* at 224 (correlating the high rates of opioid abuse and diversion with the high availability of OxyContin); see also Kolodny et al., *supra* note 114 (noting a dramatic increase in opioid-related overdose deaths, substance use disorder treatment admissions, and other adverse health outcomes since 2002).

¹³⁷ Governor Baker made this statement to the press following the release of his 65-step plan to curb the opioid epidemic.

¹³⁸ Massachusetts officials and doctors attribute the 1,700 infants born opioid-dependent in 2014 to the statewide opioid crisis. See Levenson, *supra* note 25. Dr. Elisha Wachman, a neonatologist at Boston Medical Center, calls prescription pills the driving force behind the alarming number of infants born into withdrawal from substance exposure in utero. *Id.*

¹³⁹ See DATA BRIEF: FATAL OPIOID-RELATED OVERDOSES AMONG MASSACHUSETTS RESIDENTS, *supra* note 9; see, e.g., Press Release, The White House: President Barack Obama, Office of the Press Secretary, FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use (Oct. 21, 2015), <https://obamawhitehouse.archives.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector> [<https://perma.cc/YJT6-FZCM>] (On October 21, 2015, President Obama issued a memorandum to federal departments and agencies directing

R

R

R

A. Federal Reformative Measures

A 2003 reauthorization of the Child Abuse and Prevention Treatment Act (CAPTA) directed states to implement policies and procedures for reporting substance-exposed newborns to child protection services (CPS) agencies in order to receive federal funding.¹⁴⁰ The bill amending CAPTA, commonly referred to as the Keeping Children and Families Safe Act, requires health care providers to notify CPS of infants born and identified as affected by maternal substance misuse or withdrawal symptoms resulting from prenatal substance exposure.¹⁴¹ The law also mandates that state CPS agencies develop safe recovery plans for such substance-exposed newborns.¹⁴² Currently, all fifty states and the District of Columbia have statutes conveying CAPTA's notification and recovery development plan requirements.¹⁴³

Massachusetts, which abides by CAPTA's mandates in its reporting statute,¹⁴⁴ received a \$3.5 million federal grant in August 2015 to assist hospitals and health systems in the management and care of the overwhelming number of infants diagnosed with NAS.¹⁴⁵ The Health Policy Commission (HPC), an independent state agency that develops policy to improve the quality of health care throughout Massachusetts,¹⁴⁶ matched the federal

them to implement prescriber training programs and expand access to treatment.); FINDINGS OF THE OPIOID TASK FORCE AND DEPARTMENT OF PUBLIC HEALTH RECOMMENDATIONS ON PRIORITIES FOR INVESTMENTS IN PREVENTION, INTERVENTION, TREATMENT AND RECOVERY, *supra* note 10, at 1 (In 2014, former Massachusetts Governor Deval Patrick declared the opioid crisis an epidemic, instructing the Department of Health to craft long-term solutions to combat opioid misuse in the Commonwealth.); VT. ASS'N FOR MENTAL HEALTH AND ADDICTION RECOVERY, *THE SCOPE OF THE OPIATE CRISIS IN VERMONT* (Pear Vermont Publications, 2015) (Since Vermont Governor Peter Shumlin dedicated his entire 2014 state of the state message to what he called a "full-blown heroin crisis," Vermont has implemented several programs and resources to address the opioid epidemic.).

¹⁴⁰ See Child Abuse and Prevention Treatment Act, 42 U.S.C. § 5106(a)(1)(B) (2012) ("The Secretary may award grants to public or private organizations . . . to improve the recruitment, selection, and training of volunteers serving in public and private children, youth, and family service organizations in order to prevent child abuse and neglect.").

¹⁴¹ See Keeping Children and Families Safe Act of 2003, Pub. L. No. 108-36, 117 Stat. 800 (codified as amended at 42 U.S.C. § 5106, 5106(b)(2)(B)(i) (2012)).

¹⁴² See 42 U.S.C. § 5106(b)(2)(B)(ii) (2012).

¹⁴³ NAT'L CONFERENCE OF STATE LEGISLATURES, MANDATORY REPORTING OF CHILD ABUSE AND NEGLECT STATUTES 1 (2011), <http://www.ncsl.org/research/human-services/child-abuse-and-neglect-reporting-statutes.aspx> [<https://perma.cc/WG68-2L8J>].

¹⁴⁴ See MASS. GEN. LAWS ch. 119, § 51A(a)(iii) (2012) ("A mandated reporter who, in his professional capacity, has reasonable cause to believe that a child is suffering physical or emotional injury resulting from . . . physical dependence upon an addictive drug at birth, shall immediately communicate with the department orally and, within 48 hours, shall file a written report with the department detailing the suspected abuse or neglect.").

¹⁴⁵ Katie Lannan, *New Program Targets Growing Problem of Newborns Exposed to Drugs*, HERALD NEWS (Dec. 23, 2015, 9:07 AM), <http://www.heraldnews.com/article/20151223/NEWS/151228297> [<https://perma.cc/DU9N-Z2NK>].

¹⁴⁶ See The Official Website of the Executive Office for Administration and Finance, *Health Policy Commission*, <http://www.mass.gov/anf/budget-taxes-and-procurement/over-sight-agencies/health-policy-commission/> [<https://perma.cc/TVS3-6N7X>].

award with \$3.5 million from its own funds, \$500,000 of which is designated to launching the delivery-to-discharge initiative.¹⁴⁷ The overarching goal of the delivery-to-discharge project seeks to reduce the total cost of NAS-related care by adopting evidence-based practices and successful programs used in other regions.¹⁴⁸ The pilot program will implement a detailed model of post-natal support for substance-exposed newborns and their families in up to three Massachusetts medical facilities.¹⁴⁹ HPC executive director David Seltz envisions the delivery-to-discharge program reducing length of hospital stays and the need to intensively treat substance-exposed newborns, resulting in substantial savings in NAS-related expenditures.¹⁵⁰

Less than six months after Massachusetts announced its plan to move forward with the delivery-to-discharge project, Congress passed legislation in an effort to stifle nationwide increases in NAS.¹⁵¹ Like the Commonwealth's delivery-to-discharge program, but on a larger scale, the Protecting Our Infants Act of 2015 was designed to identify evidence-based approaches to care for mothers who misuse opioids and newborns withdrawing from in utero opioid exposure.¹⁵² The act requires the U.S. Secretary of Health and Human Services to identify gaps in research concerning the most appropriate types of treatment for pregnant opioid misusers, the most effective ways to treat NAS, and the long-term effects of in utero opioid exposure on children.¹⁵³ The act also charges the Secretary of Health and Human Services with identifying gaps or overlap in federal substance use disorder treatment programs for pregnant and postpartum women, treatment options for infants with NAS, and federal efforts to prevent NAS.¹⁵⁴ A noteworthy provision of the Protecting Our Infants Act of 2015 instructs the Secretary of Health and Human Services to catalogue research and findings into a report, evaluating current efforts to manage NAS and recommending ideas to improve NAS prevention and treatment.¹⁵⁵ Upon completion, the report shall be submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to ensure future legislation relative to NAS management is narrowly tailored to address the most current data.¹⁵⁶

¹⁴⁷ *Id.*; COMMONWEALTH OF MASS. HEALTH POL'Y COMM'N, QUALITY IMPROVEMENT AND PATIENT PROTECTION COMMITTEE 31 (2015).

¹⁴⁸ COMMONWEALTH OF MASS. HEALTH POL'Y COMM'N, *supra* note 147, at 31.

¹⁴⁹ *See id.*

¹⁵⁰ *See* Lannan, *supra* note 145.

¹⁵¹ The Protecting Our Infants Act of 2015 was enacted on November 18, 2015. Protecting Our Infants Act of 2015, Pub. L. No. 114-91, 129 Stat. 723, 723-25 (2015).

¹⁵² *See generally* Protecting Our Infants Act of 2015 (The Secretary of Health and Human Services shall review current programs that focus on managing NAS, address gaps in such programs, and develop recommendations to expand and improve current treatment and prevention measures.).

¹⁵³ *See* Protecting Our Infants Act of 2015, 129 Stat. at 723.

¹⁵⁴ *Id.*

¹⁵⁵ 129 Stat. at 724.

¹⁵⁶ 129 Stat. at 723.

In addition to the 2003 amendment to CAPTA and the Protecting Our Infants Act of 2015, there are other recent and ongoing federal initiatives geared toward ensuring pregnant women who struggle with substance use disorder have access to prenatal care as well as effective and safe treatments. The Centers for Disease Control and Prevention (CDC), continues to assist states in improving the availability and quality of NAS-related data, encouraging collaborative public health measures to decrease its prevalence.¹⁵⁷ The CDC's "Treating for Two"¹⁵⁸ initiative, a movement to improve the availability and quality of data with intentions of producing better informed decisions concerning prescription medication during pregnancy, has included opioid use during pregnancy in its research, emphasizing the importance of reducing unnecessary risks if and when possible.¹⁵⁹ Another example of recent federal action addressing the NAS issue was carved into the Obama Administration's 2015 National Drug Control Strategy (NDCS).¹⁶⁰ In its fifth year of existence, the 2015 NDCS set goals to reduce NAS through collaborative efforts within states and smaller communities, develop treatment guidelines for opioid-dependent pregnant women, and publish guidelines encouraging providers to safely prescribe pain medications to pregnant women with chronic pain.¹⁶¹ These initiatives show that the opioid epidemic has attracted nationwide attention.

B. Aggressive STEPs Forward in Massachusetts

Under Governor Baker's leadership, Massachusetts has taken strong initiatives to address the opioid epidemic by making the Commonwealth's work to curb opioid misuse a top priority.¹⁶² In addition to the sixty-five step plan to confront the epidemic head on, Governor Baker charged the Massachusetts Drug Formulary Commission with the task of ensuring that opioids

¹⁵⁷ Michael Botticelli, *Protecting Our Infants*, THE WHITE HOUSE: PRESIDENT BARACK OBAMA (Nov. 25, 2015, 4:26 PM), <https://obamawhitehouse.archives.gov/blog/2015/11/25/protecting-our-infants> [https://perma.cc/MY37-VMSH].

¹⁵⁸ The CDC's Treating for Two Initiative aims to improve the health of women and babies by working to identify the safest treatment options for the management of common conditions before and during pregnancy. The initiative aligns with three key drivers of safer medication use in pregnancy: better research, reliable guidance, and informed decisions. *Treating for Two*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/pregnancy/meds/treatingfortwo/aboutus.html> [https://perma.cc/T8AX-LRHK].

¹⁵⁹ The NDCS is an official report produced annually by the Office of National Drug Control Policy. Piloted in 2010, the NDCS outlines the Obama Administration's efforts to reduce illicit drug use, manufacturing and trafficking, drug-related crime and violence, and drug-related health consequences. OFFICE OF NAT'L DRUG CONTROL POL'Y, NAT'L DRUG CONTROL STRATEGY (2015).

¹⁶⁰ See generally *id.*

¹⁶¹ *Id.* at 101.

¹⁶² See *Governor Announces New Panel on Opioids*, *supra* note 18; see also *MA Governor Baker Announces Initial Steps To Combat Opioid Addiction Crisis*, *supra* note 19.

comport with the latest misuse deterrent mechanisms.¹⁶³ The Commission, originally established to create a drug formulary, or list of interchangeable drug products, for use by health care providers and pharmacists in an effort to raise consumer awareness to cost-effective alternatives,¹⁶⁴ now assesses and evaluates the most powerful opioids for four components—accessibility, cost, effectiveness, and misuse-deterrent properties.¹⁶⁵ When two drugs are chemically equivalent, but only one has misuse-deterrent properties, the Commission may deem this drug “interchangeable” with the non-deterrent formula.¹⁶⁶ The new formulary will assume a role in containing the opioid epidemic by providing clinicians with the safest options to manage pain in patients at risk for substance use disorder.¹⁶⁷ Massachusetts Department of Health Commissioner, Monica Bharel, a key player in the Commonwealth’s efforts to curtail opioid use disorder rates, views implementation of the misuse deterrent plan as a critical step forward in the cross-disciplinary initiative to prevent opioid use disorder.¹⁶⁸

In October of 2015, Governor Baker drafted a bill entitled “An Act Relative to Substance Use Treatment, Education, and Prevention” (hereinafter referred to as the “STEP Act”) which urged the legislature to promptly enact specific measures to improve statewide opioid misuse prevention, intervention, treatment, and recovery services.¹⁶⁹ The STEP Act identified availability, over-prescription, and misuse of prescription opioids as the leading causes of the opioid epidemic.¹⁷⁰ Moreover, the Act proposed some sweeping measures to limit prescribing practices, to enhance detection and prevention, to implement treatment, and to ensure that insurance companies comply with federal laws relative to the availability of coverage for substance use disorder treatment.¹⁷¹

In March 2016, and after weeks of intensive review, the STEP Act passed with unanimous votes in both the Senate and the House.¹⁷² Multiple

¹⁶³ Press Release, The Official Website of the EOHHS, Governor Names Drug Formulary Commission on Opioids (Aug. 3, 2015) <http://www.mass.gov/eohhs/gov/newsroom/press-releases/eohhs/governor-names-drug-formulary-commission-on-opioids.html> [<https://perma.cc/3KYJ-2PCP>].

¹⁶⁴ See 105 Mass. Code Regs. § 720.001 (2016).

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ The Official Website of the EOHHS, Governor Names Drug Formulary Commission on Opioids, *supra* note 163.

¹⁶⁸ See *id.* “While the majority of opioids are prescribed and used responsibly, every step we can take to prevent the opportunity for misuse is a critical step forward.” *Id.*

¹⁶⁹ H.R. 4209, 189th General Court, Reg. Sess. (Ma. 2015).

¹⁷⁰ See generally *id.*

¹⁷¹ See *id.*; see also Nora D. Volkow et al., *Medication-Assisted Therapies—Tackling the Opioid Overdose Epidemic*, 370 *NEW ENG. J. MED.* 2063, 2065 (2014) (explaining that the Affordable Care Act (ACA) extends the reach of the Mental Health Parity and Addiction Equity Act, which requires insurance plans offering coverage for mental health or substance-use disorders provide the same level of benefits that they do for general medical treatment).

¹⁷² Press Release, The Official Website of the Governor of MA, Governor Baker Signs Landmark Opioid Legislation into Law (March 14, 2016), <http://www.mass.gov/governor/>

provisions of the bill contained proposals from Governor Baker's draft, including the controversial¹⁷³ law limiting first-time opioid prescriptions to a seven-day supply, subject to narrow exceptions promulgated at the discretion of the Commissioner of Public Health.¹⁷⁴ Another notable provision of the STEP Act extracted from Governor Baker's draft requires that information on opioid misuse be incorporated in annual head injury safety programs for high school athletes.¹⁷⁵ Requirements that physicians, dentists, and other persons who prescribe controlled substances complete at least five hours of training every two years on the risks of misuse associated with prescription opioids were also adopted as originally proposed by the Governor in the bill's initial draft.¹⁷⁶ A final piece of the original draft to remain intact throughout the deliberation process imposes a legal requirement that all prescribers enroll in and utilize the Prescription Monitoring Program (PMP) before issuing opioid prescriptions.¹⁷⁷

Another component of the legislation focuses on enhancing the efficacy of opioid abuse detection and prevention protocol.¹⁷⁸ Adults best positioned to detect and prevent opioid misuse among young people will be required to receive regular training on the dangers associated with prescription painkillers.¹⁷⁹ Prompt implementation of this training in venues such as high schools and universities will increase awareness of the signs and symptoms of misuse, ultimately providing a better first-line defense against opioid use disorder.¹⁸⁰

press-office/press-releases/fy2016/governor-signs-landmark-opioid-legislation-into-law.html [https://perma.cc/7HFG-WA3J].

¹⁷³ Dr. Dennis Dimitri, president of the Massachusetts Medical Society, opposed a limit on first time opioid prescriptions stating, "[I]t doesn't necessarily allow for the clinical judgment of physicians – to adjust their prescriptions for different patients with different situations." Joshua Miller, *Facing Epidemic, Baker Seeks to Limit Opioid Prescriptions*, BOS. GLOBE (Oct. 15, 2015), https://www.bostonglobe.com/metro/2015/10/15/baker-unveil-opioid-bill-looking-address-crisis/JY30aF11N5s_QiHz4kKSriL/story.html [https://perma.cc/6HUD-T8U7]. Dr. David P. Lustbader, oral surgeon and vice president of the Massachusetts Dental Society, referred to the limit as a simplistic approach to a complex problem. *Id.* Dr. Patrice A. Harris, chairwoman-elect of the American Medical Association (AMA), expressed the AMA's "concerns over sections of the bill, including universal mandates that may be well-intentioned, but may have unintentional consequences to the patient-physician relationship." *Id.*

¹⁷⁴ Governor Baker Signs Landmark Opioid Legislation into Law, *supra* note 172.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *See id.*; *see also* MA DEP'T PUB. HEALTH, THE MASSACHUSETTS PRESCRIPTION MONITORING PROGRAM: A REPORT TO THE MASSACHUSETTS GENERAL COURT 4–5 (2015) (The PMP, established in 1992, serves as a repository of data for all Schedule II – V prescription drugs dispensed in the Commonwealth. The PMP enables health care providers to look into a patient's prescription drug history and make informed decisions in regard to opioid prescription. Prior to 2012, PMP enrollment was voluntary for prescribers. However, Chapter 244 of the Acts of 2012, and a series of minor statutory amendments thereafter, mandated enrollment of all prescribers.).

¹⁷⁸ H.R. 4209.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

R

During the draft phase, a piece of Governor Baker's legislation did walk a fine constitutional line by authorizing compulsory treatment for the sickest of misusers.¹⁸¹ This provision of the STEP Act had permitted a physician to hold a patient for an initial three-day (72-hour) period at a hospital or treatment center if the physician determined that the patient suffered from a substance use disorder and that a failure to treat the patient would have presented a serious risk of harm.¹⁸² The provision required a physician who would have held a patient for emergency treatment to encourage the patient to consent to treatment. The physician would also have been permitted to seek a court order for an involuntary ninety-day inpatient treatment should the patient have refused consent.¹⁸³

This 72-hour hold and physician-elected involuntary treatment did not survive the draft phase of the STEP Act and were not ultimately included in its final passage.¹⁸⁴ Without these original extremes, the version that was passed survives as a reflection of the work cut out for Massachusetts in confronting the opioid epidemic and also the Commonwealth's strong resolve in ameliorating this issue.

As political leaders continue collaborating proactively to reduce NAS rates and opioid misuse at both federal and state levels, individual communities must also continue the offensive against the epidemic. The time is ripe for developing reformative ideas and creating solutions to contain NAS rates, and the ominous opioid epidemic from which they have snowballed. Relentless multi-sector approaches and proposals—from all stakeholders—are key ingredients to curbing the epidemic and “taking back the town.”

VI. FACILITATIVE RENOVATIONS – A PREVENTATIVE SYSTEM TO SUPPRESS NEONATAL ABSTINENCE SYNDROME

Government bodies may promote maternal and infant health by implementing systems that adhere to one of two general structures.¹⁸⁵ The adversarial model, frequently utilized in the 1980s in response to the “crack baby”¹⁸⁶ crisis resulting from a national cocaine epidemic, views the woman

¹⁸¹ *See id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *See generally* Act Relative to Substance Use, Treatment, Education, and Prevention, 2016 Mass. Acts, ch. 52.

¹⁸⁵ *See generally* Dawn Johnsen, *Shared Interests: Promoting Healthy Births without Sacrificing Women's Liberty*, 43 HASTINGS L. J. 569, 571 (1992) (referring to the two dramatically different governmental approaches to promote the health of newborns).

¹⁸⁶ *See generally* David F. Chavkin, “*For Their Own Good*”: *Civil Commitment of Alcohol and Drug-Dependent Women*, 37 S.D. L. REV. 224 (1992). According to the National Institute on Drug Abuse, 15% of women of child bearing age regularly abused substances in 1989. *Id.* at 230. Experts attribute this notable increase to the wide spread availability of crack-cocaine and its popularity among women. *Id.* at 230–31. Due to its effect on women of child bearing age, the infant population was also impacted by the national spike in cocaine use among women. *Id.* at 231. In utero exposure to cocaine often causes lower birth weight, withdrawal and

and fetus as distinct legal entities with adverse interests.¹⁸⁷ This view operates on the assumption that the government's role is to protect the unborn from its expectant mother.¹⁸⁸ Often times an adversarial approach to promote fetal rights involves criminal prosecution for a woman's conduct while pregnant.¹⁸⁹ A recently expired Tennessee sunset law,¹⁹⁰ enacted in 2014 to incentivize pregnant misusers to seek treatment, is a prominent example. The controversial Tennessee fetal assault law authorized prosecution of misusers bearing chemically-dependent children as a result of narcotics misuse during pregnancy.¹⁹¹ A provision in the statute considered it an affirmative defense if the woman enrolls in a recovery program before giving birth, remains in the program after giving birth, and successfully completes the program.¹⁹² The defense applied regardless of the newborn's abstinence-related injuries.¹⁹³ Failing to achieve its intended purpose and having produced unintended consequences¹⁹⁴ that conflicted with state interests in maternal and infant health, Tennessee's fetal assault law was not renewed by its June 30, 2016 expiration date.¹⁹⁵

The second general methodology by which the government may promote infant and maternal health and welfare presumes that the pregnant woman and state share an interest in promoting healthy childbirth.¹⁹⁶ This notion—a facilitative approach—strives not to punish women affected by substance use disorder during pregnancy, but aims to form a more harmonious relationship whereby the government assists pregnant misusers in making choices most likely to further a common objective—the best interests of

irritability after birth, smaller head circumference, and long-term learning disabilities. *Id.* at 233.

¹⁸⁷ Johnsen, *supra* note 185, at 571.

¹⁸⁸ *Id.*

¹⁸⁹ *See id.* at 577 (illustrating three instances where women were prosecuted under statutes that were not intended to criminalize a woman's conduct during pregnancy).

¹⁹⁰ A sunset law is a statute under which a governmental agency or program automatically terminates at the end of a fixed period unless it is formally renewed. *Sunset law*, BLACK'S LAW DICTIONARY (9th ed. 2009).

¹⁹¹ *See* TENN. CODE ANN. § 39-13-107 (2014).

¹⁹² Alleged violators were charged under Tennessee's assault statute. TENN. CODE ANN. § 39-13-101 (West 2014).

¹⁹³ TENN. CODE ANN. § 39-13-107 (2014).

¹⁹⁴ *See* Mallory Yu et al., *In Tennessee, Giving Birth To A Drug-Dependent Baby Can Be A Crime*, ALL THINGS CONSIDERED, NPR (Nov. 18, 2015, 3:22 PM), <http://www.npr.org/sections/health-shots/2015/11/18/455924258/in-tennessee-giving-birth-to-a-drug-addicted-baby-can-be-a-crime> [<https://perma.cc/L825-7ZVM>] (explaining that substance-dependent women, like Brittany Crowe, were afraid of the law and neglected to seek proper medical care during pregnancy).

¹⁹⁵ TENN. CODE ANN. § 39-13-107 (2014), *amended by* An Act to Amend Tennessee Code Annotated, Title 39, relative to Criminal Law, Pub. L. No. 820, § 1391 (July 1, 2016); *see* Clint Cooper, *Fetal Assault Law Rightly Will Sunset*, TIMES FREE PRESS (Mar. 26, 2016), <http://www.timesfreepress.com/news/opinion/freepress/story/2016/mar/26/cooper-fetal-assault-law-rightly-will-sunset/357198/> [<https://perma.cc/K6H3-ZMYK>].

¹⁹⁶ *See* Johnsen, *supra* note 185, at 573.

R

R

woman and child.¹⁹⁷ Inherent within the facilitative model is an appreciation for the concept that the vast majority of pregnant women who use illicit substances do so because they are affected by a disease of the brain, not because they desire to give birth to an unhealthy infant.¹⁹⁸ Hence, a successful facilitative policy is one that helps pregnant misusers overcome adversity and equips them with the resources necessary to deliver a healthy child.¹⁹⁹

Fortunately, Massachusetts policymakers recognize that the facilitative approach is better suited to manage the current opioid epidemic than its adversarial alternative. The multi-dimensional efforts demonstrated by Governor Patrick’s Opioid Task Force,²⁰⁰ Governor Baker’s sixty-five step collaborative plan,²⁰¹ the Health Policy Commission’s federally backed delivery-to-discharge program,²⁰² the Massachusetts Opioid Drug Formulary Commission’s creation,²⁰³ and other state-led initiatives, have sought to achieve the end-state goal of containing the epidemic through similar facilitative approaches, all of which are grounded in collaboration.²⁰⁴ A bird’s-eye view of these cross-disciplinary group efforts to confront the epidemic reveals facilitative commonalities geared toward expanding access to treatment, updating data through rigorous research, educating patients, families, and prescribers, implementing safe prescribing practices, and reducing the stigma of substance abuse disorders.²⁰⁵ As Commonwealth leaders have

¹⁹⁷ See *id.* at 613 (concluding that government, women, and future children all have shared interests in taking the steps necessary to promote healthy births).

¹⁹⁸ See *id.* at 575 (noting that the majority of women with substance use disorder continue to misuse during pregnancy because they suffer from strong physical and psychological dependencies developed prior to conception, not because they desire to give to birth to an unhealthy baby).

¹⁹⁹ See *id.* at 574.

²⁰⁰ See *supra* notes 10–17 and accompanying text.

²⁰¹ See RECOMMENDATIONS OF THE GOVERNOR’S OPIOID WORKING GROUP, *supra* note 20, at 2 (recognizing an effective response to the opioid epidemic requires strong partnerships between the medical community, law enforcement, the judiciary, insurers, providers, health and human services agencies, elected officials, and the public).

²⁰² See *supra* notes 147–150 and accompanying text.

²⁰³ See *supra* notes 163–167 and accompanying text.

²⁰⁴ See, e.g., Press Release, The Official Website of the EOHHS, Baker-Polito Administration, MA Dental Schools, and the MA Dental Society Announce Dental Core Competencies to Combat the Opioid Epidemic (Feb. 11, 2016) <http://www.mass.gov/eohhs/gov/newsroom/press-releases/eohhs/dental-core-competencies-to-combat-addiction-announced.html> [<https://perma.cc/T664-YQHU>] (“Dental medicine has an expanding role in promoting public health, with an increased attention to inter-professional collaboration across a range of healthcare disciplines. The need for this collaborative effort is most evident when the patient presents with complex medical and psychiatric comorbidities.”).

²⁰⁵ See RECOMMENDATIONS OF THE GOVERNOR’S OPIOID WORKING GROUP, *supra* note 20, at 7–9 (recommending strategies to develop new pathways to treatment, increase access to medication-assisted treatment, abolish the stigma of substance abuse disorders, support substance use prevention education in schools, and require all practitioners to receive training about addiction and safe prescribing practices); see also FINDINGS OF THE OPIOID TASK FORCE AND DEPARTMENT OF PUBLIC HEALTH RECOMMENDATIONS ON PRIORITIES FOR INVESTMENTS IN PREVENTION, INTERVENTION, TREATMENT AND RECOVERY, *supra* note 10, at 1 (summarizing the findings of Governor Patrick’s Opioid Task Force and recommending action, including, but not limited to: the expansion of treatment beds; the formation of a centralized system for

R
R

R
R

R

R

acknowledged, a collaborative offensive is most effective when all members of the community are on board, with those directly affected by the epidemic playing a particularly vital role.²⁰⁶

A. *Mandatory Reporting is Insufficient*

The grave increase in statewide neonatal abstinence rates germane to the opioid crisis has reached a level that warrants immediate action. At the present time, Massachusetts is ill-equipped to effectively deal with the inordinate number of opioid-dependent newborns. Although well-intended, the Commonwealth's mandatory reporting statute, standing alone, does not pack the requisite punch to adequately deal with the opioid epidemic. The law—the sole means of statutory redress for babies born with neonatal abstinence syndrome—requires physicians, nurses, and other hospital personnel with reasonable cause to believe a newborn is suffering from physical withdrawals to immediately notify the Massachusetts Department of Children and Families (DCF).²⁰⁷ The physician, nurse, or other personnel who suspects the infant is withdrawing from in utero substance exposure must file a written report with the DCF detailing the observations leading to the suspected abuse or neglect within forty-eight hours.²⁰⁸ By identifying maternal substance abuse within the first few days of an infant's birth, the statute permits early intervention to serve the child's postnatal interests. In most cases, newborns displaying withdrawal symptoms return to their families after a detoxification period at the hospital because the DCF does not have the resources to deal with the inundation of babies born with neonatal abstinence syndrome.²⁰⁹ As such, the current explosion of opioid-dependent newborns

patients, families, and first responders to locate treatment services; additional opioid prevention coalitions for support and education; and more stringent safeguards for those opioids, which are most frequently abused and misused).

²⁰⁶ See, e.g., Julie Beck, *Any Addict Who Asks for Help Will NOT Be Charged*, ATLANTIC (May 11, 2015), <http://www.theatlantic.com/health/archive/2015/05/gloucester-massachusetts-police-department-helping-not-arresting-drug-addicts/392873/> [https://perma.cc/8AED-Y3EP] (referring to a new policy in Gloucester, MA whereby a person who misuses substances and voluntarily walks into the police department, surrenders his or her drugs, and asks for help, will not be charged. Rather, the person will be assigned an "angel" who will immediately begin to guide the person toward treatment and recovery).

²⁰⁷ See MASS. GEN. LAWS ch. 119, § 51A(a) (2012); see also MASS. GEN. LAWS ch. 119, § 21 (2013) (Defining A mandated reporter as "a person who: (i) a physician, medical intern, hospital personnel engaged in the examination, care or treatment of persons, medical examiner, psychologist, emergency medical technician, dentist, nurse, chiropractor, podiatrist, optometrist, osteopath, allied mental health and human services professional licensed under section 165 of chapter 112, drug and alcoholism counselor, psychiatrist or clinical social worker.").

²⁰⁸ See MASS. GEN. LAWS ch. 119, § 51A(a).

²⁰⁹ See McKim & Bottari, *supra* note 27 (Most substance-exposed newborns, like Mya Barry, return to their families despite DCF's awareness that the mother misuses substances. In Mya's case, DCF officials permitted Mya to go home with her father and grandfather provided that her mother would have no unsupervised time with Mya. According to child welfare experts, there is an inherent weakness in these types of arrangements, as parents with substance use disorders often manipulate or coerce such designated caretakers.).

has exacerbated a pre-existing defect within the Commonwealth's children's services agency, burdening an already overstretched DCF well beyond capacity.

Aside from the mandatory reporting statute's futile effects on ensuring postnatal health and wellness of children, neonatal abstinence syndrome preventative measures are not included within the scope of the law. Rather, predicated upon principles of intervention, the statute essentially identifies infants harmed by in utero exposure to substances and intervenes postnatally to protect newborns from further harm by mothers who continue to misuse. Neither the mandatory reporting statute itself, nor the child protection services which it triggers, is capable of managing the sizeable upswing of infants born opioid-dependent during the current epidemic.

B. Proposal for Reform – Facilitative Prevention through Aggressive Identification

Massachusetts has demonstrated, through multi-dimensional collaborative initiatives to hinder the epidemic's destructive momentum, an intuitive awareness that existing legal frameworks are not sufficiently robust to defend against such an intense wave of substance use disorder. With the Baker administration leading the charge, all Commonwealth residents who have joined the fight to resolve the current crisis should be applauded for their support. As policymakers continue to formulate solutions to the epidemic, and legislators deliberate on recently proposed bills, Massachusetts should consider adopting a uniform facilitative system designed to reduce the aggregate of NAS diagnoses through preventative measures. A successful plan adheres to facilitative principles, yet is implemented aggressively to be commensurate with the severity of the issue. The system aims to lower the statewide NAS rate by preventing the disorder through a comprehensive plan predicated upon early identification of substance use during pregnancy. To achieve optimal success, the plan should not only be carried out promptly and aggressively, but should be adopted uniformly throughout the Commonwealth.

Identification is the imperative component of the proposed model. Detecting opioid misuse among pregnant patients at the earliest possible point in gestation permits providers to make appropriate treatment referrals to further maternal and child health interests. The identification process shall commence at the patient's first prenatal visit.²¹⁰ The examining nurse or physician, adhering to a statewide standard, educates the patient, orally and in writing, on the current opioid epidemic and the toll it has taken on newborns, hospitals, and the community as a whole. The provider shall further explain that all Massachusetts hospitals are taking a new approach to

²¹⁰ A gestation period is the timespan between conception and labor. In humans the period is approximately 38 weeks. *Gestation Period*, MOSBY'S MED. DICTIONARY (9th ed. 2009).

prevent the problem from further expansion. The provider shall also inform the patient that communication and disclosures made during prenatal appointments, and information gathered through the Commonwealth's new assessment protocol, are strictly reserved for the purpose of protecting maternal and fetal health interests.²¹¹ The patient shall be further advised that all information volunteered in regard to substance use of any kind is afforded a high degree of privacy, and will be strictly protected from access by law enforcement or other outside entities. The information may, however, be transmitted to a substance use disorder professional for further evaluation. Specialized women's treatment providers may also access the content gleaned from the assessment should the substance use disorder professional believe treatment is necessary to promote maternal and fetal health. In compliance with the tenets of informed consent and general fairness principles, patients shall be notified of the mandatory reporting statute that is triggered after the child is born.

All patients are screened with a standardized tool,²¹² deemed efficacious and reliable among substance misuse and behavioral health experts. All screenings, regardless of the patient's self-reports and clinical history, are supplemented with a toxicology test to corroborate self-evaluations and ensure screening accuracy.²¹³ Toxicology tests shall be standardized throughout the state, conforming with the latest advances in science and technology. Patients who fall under one of four categories are referred to a substance use disorder professional with training and experience treating pregnant women who misuse opioids. The four categories are: (1) screens that indicate any opioid use during pregnancy; (2) current MAT or other treatment for opioid dependence; (3) clinically documented or self-reported opioid abuse within the last two years; and (4) toxicology tests showing presence of opioids.

²¹¹ Essential to a successful policy of this nature is the patient's trust and confidence in her examining nurse or physician. As such, the provider shall ensure the patient is aware of the confidentiality of the doctor-patient relationship, emphasizing its applicability at the present time, and in all future pre or post-natal visits.

²¹² The DAST-10, a ten-item questionnaire that can be administered in an interview or self-report format, is an example of a universally accepted screening tool that should be considered for uniform implementation in this policy. See *Instrument: Drug Abuse Screening Test (DAST-10)*, NIDA CTN Common Data Elements, <https://cde.drugabuse.gov/instrument/e9053390-ee9c-9140-e040-bb89ad433d69/module/e9053390-eea5-9140-e040-bb89ad433d69> [https://perma.cc/YU6W-XVE4].

²¹³ State imposed toxicology tests have gained considerable attention in Fourth Amendment jurisprudence. In 2001, the United States Supreme Court declared urine tests administered to pregnant patients based on certain government generated criteria were unreasonable searches because the test results were turned over to the police for purposes of prosecution. *Ferguson v. City of Charlestown*, 532 U.S. 67, 85–86 (2001). The Court, finding the specific purpose of the policy was designed to incriminate patients without a warrant or probable cause, ruled the toxicology testing policy unconstitutional. *Id.* at 86. The policy proposed in this Article will successfully overcome challenges on Fourth Amendment grounds because the toxicology tests are administered solely for the medical purposes of promoting maternal and child health and welfare. Furthermore, the proposed model expressly excludes law enforcement interests, precluding the admissibility of prenatal toxicology tests in any subsequent court proceedings in which the patient is a party.

The substance use disorder professional further evaluates patients making factual and circumstantial decisions concerning treatment on a case-by-case basis.²¹⁴ Patients falling into one of the four categories above that are subsequently determined by the substance use disorder professional not to misuse are encouraged to follow up with the evaluator over the course of the pregnancy to ensure continued accuracy of the original evaluation. Follow-up appointments shall be scheduled as agreed upon by the evaluator and patient. Patients requiring treatment are referred to a specialized women's treatment center. The treatment center integrates the latest and most effective opioid use disorder treatment with medical services related to pregnancy and birth. Providing pregnant opioid misusers with comprehensive treatment and prenatal care optimally serves maternal, child, and governmental interests. Such a facilitative approach, if implemented in public hospitals throughout the Commonwealth, would decrease opioid use disorder during pregnancy, thereby reducing statewide NAS rates.

Upon arriving at the specialized women's treatment center, patients shall undergo further screening and another toxicology test as part of a process that classifies the severity of the disorder. This part of the identification phase shall use a standardized operational protocol to categorize each patient's substance use disorder.²¹⁵ Information recorded at the initial screening with the nurse or physician, toxicology results, and recommendations by the substance use disorder professional are also considered.

After completing screening at the treatment center, a team of professionals, well-trained in treating substance use and behavioral health disorders, shall compile an individualized recovery plan for each patient. All patients, regardless of the level of recommended treatment, undergo MAT dosed in accordance with standardized withdrawal assessments and the professional opinions of the examiners.²¹⁶ Buprenorphine, due to its milder fetal

²¹⁴ A prototypical scenario where the substance use disorder professional may not recommend treatment arises when a patient's toxicology test indicates opioid use. Further evaluation reveals no signs of abuse or dependence and the patient is taking an opioid, as prescribed, to manage pain. The patient will not be referred to the specialized women's treatment center, but nevertheless will be monitored in subsequent prenatal visits to ensure the original non-abusive assessment has not changed.

²¹⁵ An example of such a standardized assessment that categorizes substance use disorder is the Addiction Severity Index (ASI). The ASI is a semi-structured interview designed to address seven potential problem areas in substance-abusing patients: medical status, employment and support, drug use, alcohol use, legal status, family/social status, and psychiatric status. In one hour, a skilled interviewer can gather information on recent (past 30 days) and lifetime problems in all of the problem areas. The ASI provides an overview of problems related to substance, rather than focusing on any single area. NAT'L INST. ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *ASSESSING ALCOHOL PROBLEMS: A GUIDE FOR CLINICIANS AND RESEARCHERS* 245 (2003), http://pubs.niaaa.nih.gov/publications/AssessingAlcohol/InstrumentPDFs/04_ASI.pdf [<https://perma.cc/NQ8X-39H5>].

²¹⁶ Examples of standardized withdrawal assessment are the Clinical Opiate Withdrawal Scale (COWS) or Clinical Institute Narcotic Assessment Scale for Withdrawal Symptoms (CINA). These tools measure signs and symptoms commonly seen in patients during opioid withdrawal and aid clinicians in treatment-related decisions. By quantifying the severity of withdrawal symptoms, clinicians are able to monitor treatment progress and develop evidence-

effects and recently proven success rate, shall be the standard of care for initiating MAT at the specialized women's treatment centers.²¹⁷ Patients currently on methadone maintenance plans shall continue with methadone; however, dosages will be recalibrated and split throughout the day to best protect the fetus from exposure to daily fluctuations.²¹⁸ Individualized treatment plans place patients in one of two treatment settings, both of which are located in public hospitals to effectively serve treatment and prenatal needs. Patients going into labor while attending opioid treatment services are transported to the maternal services unit of the hospital and receive care by that unit's doctors, nurses, and staff. Medication shall be administered as prescribed through labor and delivery to avoid maternal and fetal withdrawal.

Moderate and severe misusers are placed in specialized residential treatment facilities within public hospitals. Each residential treatment center dispenses medication to patients as prescribed. During treatment, patients are guided through the turbulent transition from a lifestyle marked by active substance use disorder to one of recovery, health, and wellness. The length of stay for patients in residential treatment is determined by several factors including, but not limited to, severity of misuse as determined by standardized tools, substance abuse history, criminal history, and existence of co-occurring disorders or other mental health diagnoses. Recommendations by residential treatment staff may also influence length of stay, however, patients will not, absent extraordinary circumstances, be permitted to stay in residential treatment more than ninety days after admission.

An outpatient facility is located in the same hospital as the residential treatment facility. Patients attending intensive outpatient treatment are provided medication as prescribed at the facility. A typical day of treatment consists of extensive group therapy and individual counseling, with a twelve-step recovery meeting to conclude each day. Essentially, the outpatient treatment program trains patients to become proficient in key aspects of recovery such as trigger²¹⁹ avoidance, craving management, and successful reintegration into society. A focal point of outpatient treatment seeks to ensure that before discharge all patients grasp the important principle that recovery is a lifelong journey—one requiring constant maintenance.

based data. See D.R. Wesson & W. Ling, *The Clinical Opiate Withdrawal Scale (COWS)*, 35(2) J. PSYCHOACTIVE DRUGS 253, 253–59 (2003); see also J.E. Peachey & H. Lei, *Assessment of opioid dependence with naloxone*, 83(2) BRITISH J. ADDICTION 193201 (1988).

²¹⁷ See *supra* notes 103–109 and accompanying text.

²¹⁸ Split dosing might be a preferable strategy for pregnant women maintained on methadone because it reduces fetal neurobehavioral effects without significantly altering maternal physiological indicators. See generally, Lauren M. Jansson et al., *Maternal Methadone Dosing Schedule and Fetal Neurobehavior*, 22(1) J. MATERN. FETAL NEONATAL MED. 29–35 (2009).

²¹⁹ A trigger is an event that occurs before a person uses drugs or alcohol and increases the likelihood of using. See ALAN J. BUDNEY & STEPHEN T. HIGGINS, NAT'L INST. ON DRUG ABUSE, THERAPY MANUALS FOR DRUG ADDICTION, A COMMUNITY REINFORCEMENT APPROACH: TREATING COCAINE ADDICTION 57 (1998), <https://archives.drugabuse.gov/pdf/CRA.pdf> [<https://perma.cc/8KXF-7YN3>].

The outpatient program targets two main groups of patients. One group consists of patients who naturally progress to the intensive outpatient program upon successful completion of residential treatment. Patients with recently developed, less severe disorders, and patients who misuse opioids but do not display withdrawal symptoms, are also assigned to this mode of treatment. Treatment scheduling is determined on a case-by-case basis taking into account factors such as employment, transportation, medical appointments, and recommendations by referring providers. Random toxicology tests are administered throughout intensive outpatient treatment; however, positive screens are not grounds for dismissal.²²⁰ Outpatient treatment services will be rendered for a length of time to be decided by staff and shall not exceed six months from the date of patient admittance.

Discharge from intensive outpatient treatment marks completion of the proposed model to prevent incidence of NAS through a facilitative system. For the recovering misuser, however, the journey has just begun. Unlike the congressional feud that resulted over President Obama's proposal to allocate \$1.1 billion of mandatory funding to expand access to treatment for opioid misuse,²²¹ Massachusetts residents are urged to continue the initiative against opioid misuse by collaboratively forming solutions to curb the epidemic. The preventative system described above, if uniformly implemented throughout the state, would successfully lower NAS rates sparing the epidemic's most vulnerable and innocent victims substantial pain and suffering while easing burdens on Massachusetts taxpayers. On a larger scale, state-wide adoption of the system would successfully contribute to containing the epidemic as a whole by lowering the rate of opioid use disorder among pregnant women through standardized, effective, and accessible treatment.

²²⁰ Although it is not a *necessary* part of recovery, relapse may be considered a *normal* part of recovery. Many misusers require multiple attempts to achieve long-term recovery, often learning valuable lessons from these setbacks and slips along the way. See Carol A. Shivley, *Relapse and Recovery in Addictions*, 347 N. ENGL. J. MED. 225-26 (2002) (Substance abuse is a chronic, relapsing disease — a view that allows relapse to be expected as a normal part of recovery and that considers treatment successful if the disease is managed, not cured.). See also NAT'L INST. ON DRUG ABUSE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *PRINCIPLES ON DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE* 3 (2012) (Recovery from drug addiction is a long-term process and frequently requires multiple episodes of treatment. As with other chronic illnesses, relapses to drug abuse can occur and should signal a need for treatment to be reinstated or adjusted.).

²²¹ See The White House Office of the Press Secretary, *Fact Sheet: President Obama Proposes \$1.1 Billion in New Funding to Address the Prescription Opioid Abuse and Heroin Use Epidemic*, THE WHITE HOUSE: PRESIDENT BARACK OBAMA (Feb. 2, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/02/02/president-obama-proposes-11-billion-new-funding-address-prescription> [<https://perma.cc/WP4G-CYJX>]; see also Gardiner Harris, *Congress Splits Over Bill Aimed at Nation's Opioid Epidemic*, N.Y. TIMES (Jul. 6, 2016), <https://www.nytimes.com/2016/07/07/us/politics/congress-to-hash-out-final-bill-aimed-at-opioid-epidemic.html> [<https://perma.cc/ZHQ2-AGLX>].

VII. CONCLUSION

What originally appeared as a classic success story for stakeholders in pharmaceutical companies has proven to be disastrous for society at large. Effectively fulfilling the prophecy of President Nixon's words in his 1971 message to Congress on substance use disorder, a socio-cultural phenomenon has emerged from the convergence of two social factors. Specifically, the introduction and mass production of OxyContin and other opioid pain medications during a time of liberal prescription practices, accompanied by a dramatic increase in production and distribution of potent heroin by drug cartels, has crept into American homes and neighborhoods quietly, causing mass destruction from within.

The nation is currently in the midst of an opioid epidemic, and Massachusetts has been hit particularly hard. Governor Baker, a key driving force behind Massachusetts' efforts to combat the crisis, has taken an aggressive stance on the issue that should be emulated. Meanwhile, state leaders from various sectors and fields have joined forces to develop solutions to quell the epidemic. Such bipartisan efforts in Massachusetts are laudable.

In addition to burying four opioid overdose victims per day, the Commonwealth is home to a high number of opioid-associated neonatal abstinence syndrome cases. NAS, the clinical disorder in newborns due to in utero exposure to certain substances, causes infants to endure unnecessary, and certainly involuntary, pain and discomfort. Moreover, infants diagnosed with NAS require longer hospital stays and accumulate significant treatment-related expenses while detoxifying from opioids. This Article has suggested that Massachusetts policy and state lawmakers should consider implementing a standardized protocol specifically aimed at reducing statewide incidence of NAS. The proposed system is grounded in a facilitative approach—the government, mother, and child share the common objective of promoting maternal and fetal health—that identifies opioid use during pregnancy at the first prenatal appointment through a screening process and toxicology test administered to all patients. Patients with responses reflecting current opioid use or positive toxicology tests undergo further evaluation by a substance abuse professional. The professional assesses such patients and either refers them to a specialized women's center for treatment or recommends follow-up assessments at all subsequent appointments.

The proposed model will not eradicate NAS entirely. Some patients may refuse treatment. Others, despite valiant efforts to achieve and maintain recovery, will be unable to overcome the severity of substance use disorder. Others may comply with the system, achieve and maintain a state of recovery, yet bear a child with methadone- or buprenorphine-induced NAS. However, the proposed facilitative preventative approach, if adopted uniformly throughout the Commonwealth, ensures access to treatment for all pregnant opioid misusers, and should lower statewide NAS rates and opioid dependence among pregnant women in Massachusetts. Undertaking this plan ur-

2017]

Neonatal Abstinence Syndrome

333

gently and thoughtfully should result in a vital, humane victory for Massachusetts, allowing its citizens to shift the momentum against the opioid epidemic.

