October 7, 2015

The Honorable Fred Upton
Chairman
House Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Upton and Ranking Member Pallone:

The Drug Policy Alliance (DPA) appreciates the opportunity to provide this letter for the record of today's hearing, "Examining Legislative Proposals to Combat our Nation's Drug Abuse" and the following bills that are being considered during today's hearing:

- H.R. 3537, the Synthetic Drug Control Act of 2015
- H.R. 2536, the Recovery Enhancement for Addiction Treatment Act
- H.R. 2872, the Opioid Addiction Treatment Modernization Act
- H.R. ___, the Co-Prescribing to Reduce Overdoses Act of 2015
- H.R. ___, the Improving Treatment for Pregnant and Postpartum Women Act of 2015
- H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015
- H.R. 3014, the Medical Controlled Substances Transportation Act of 2015

DPA advocates for new drug policies that are grounded in science, compassion, health and human rights, with a core mission to reduce the harms associated with drug use and drug prohibition. DPA views drug use as a health issue best managed by health and treatment practitioners and supported by policies that expand access to treatment, harm reduction and prevention services. DPA accordingly opposes policies that rely on the criminal justice system to address drug use and we work to eliminate draconian drug sentencing laws that fuel mass incarceration.

H.R. 3537 – the Synthetic Drug Control Act of 2015

DPA opposes this legislation. Synthetic drugs have already been harshly criminalized at the federal level through a combination of temporary scheduling as well as passage by Congress of the Synthetic Drug Abuse Prevention Act of 2012. Despite these prohibitions, however, there is no indication that laws criminalizing synthetic compounds have contributed to decreasing the already low rates of use.

We are the Drug Policy Alliance.

Mandatory Sentencing

H.R. 3537 proposes to permanently place more than 200 synthetic compounds on Schedule I. Doing so will expand the use of federal mandatory sentencing and expand the criminalization of individuals for drug law violations. The legislation would authorize federal prosecutors to seek up to 20 years for individuals convicted of intent to distribute, distribution, importation or manufacturing of certain synthetic drugs. Individuals with certain aggravating circumstances could face a mandatory minimum sentence of 20 years to life imprisonment.

Under this proposal there are no specified quantity thresholds that would trigger mandatory minimum sentences if death or serious bodily injury results from the use of such substance. The person does not have to have the intent to distribute the drug nor the intent to injure or harm the recipient. *Any quantity* of a synthetic drug or chemical compound listed in this legislation could be treated as sufficient cause for the imposition of a mandatory minimum or otherwise lengthy sentence under the Controlled Substances Act. Should this legislation become law, more people would be subjected to a criminal record, subjecting a person to years of debilitating stigma and a large number of destructive collateral consequences including denied job opportunities, and barriers to professional licensing, public assistance, education loans, participation in public elections and other integral ways to be a productive member of society.

Criminalization can also exacerbate health risks from using drugs, by pushing risky behavior underground where people who need help the most are the least likely to get it. "Spice," "bath salts," and a slew of new emerging chemicals can be acquired through online retailers, many based in foreign countries – a threat that will not be removed if these products are prohibited in the United States. Moreover, the use of scarce government funds to enforce, prosecute, and incarcerate people who use these substances would put further strain on criminal justice resources. Expanding drug prohibition to include new synthetic drugs will result in significantly more wasteful drug war spending without deceasing rates of distribution or use.

Scientific Research

DPA is also very concerned about the chilling effect that listing the delineated synthetic compounds under Schedule I could have on research exploring the potential that these new substances might have for medical, scientific or industrial purposes. The additional hurdles that a researcher would need to overcome in order to work with and study the delineated synthetic substances placed on Schedule I by this legislation, combined with the novel nature of these synthetic substances, may mean that certain uses for these substances may go undiscovered. This legislation will subject researchers to burdensome bureaucratic red tape to study the delineated synthetic compounds that does not exist today. Scientists from university research centers have warned Congress in the past that placement of synthetic compounds into Schedule I could impede research exploring treatments for a range of diseases and disorders. Given that little is known about these synthetic substances, and some may not even be present in the United States, it does not make sense to hinder research on the potentially beneficial aspects of these compounds as well as their safety (or danger) for consumption.

Analogues

DPA is very concerned that the proposed revision to the analogue definition will unnecessarily and unfairly ensnare new people in the criminal justice system with no chances of actually decreasing rates of use. Whereas it was previously required that an analogue's chemical structure must be *substantially* similar to a controlled substance ***and*** actually have a *substantially* similar effect *or* have been intended by the person to have a *substantially* similar effect, H.R. 3537 only requires that one of these three conditions be met and that the chemical structure, effect, or intended effect of the analogue need only be *similar* to a controlled substance. This is a "substantially" lower burden which will unnecessarily and unfairly ensnare new people in the criminal justice system with no chances of actually decreasing rates of use.

As just one example of the myriad problems that could result from requiring only one of the three conditions to be met, there could be an analogue which is *not* chemically similar to a controlled substance and which does *not* produce any stimulant, depressant, or hallucinogenic effect on the central nervous system similar to a controlled substance but which remains criminalized because someone *intended* for the analogue to have that effect. This result flies in the face of common sense, the basic understanding of what "analogue" means, and the purpose of the law. An "analogue" which is not chemically similar to a controlled substance and which does not produce similar effects on the nervous system is not an analogue, but, with this legislation, will be punished as such.

With respect to the removal of the word "substantially," Congress has also removed any ability a person has to understand and determine whether their conduct is lawful or unlawful – a basic attribute and tenant of criminal law. The Court in *McFadden v. United States* recently held that there is a "mental state requirement" to be convicted of distributing an analogue. This knowledge requirement can be established in two ways: 1) by evidence that a defendant knew that the substance he was distributing is controlled under the CSA or Analogue Act, regardless of whether he knew the substance's identity; or 2) by evidence that the defendant knew the specific analogue he was distributing, even if he did not know its legal status as a controlled substance analogue. The current Act is attempting to eviscerate the latter manner of proving knowledge as it no longer requires that the analogue be "substantially" similar in chemical structure and pharmacological effect, rendering the potential defendant clueless as to whether he is, in fact, breaking the law.

Recommendation

DPA recommends that the Committee consider an alternative approach to dealing with synthetic drug use; one that implements a comprehensive drug education program coupled with legislation that commissions a task force to study and determine how best to regulate synthetic substances.

Comprehensive drug education is working for tobacco, a far more harmful drug that has contributed to more deaths than alcohol and illicit drugs combined. As a result of education initiatives and marketing restrictions, tobacco use has declined. Age controls,[1] product-labeling requirements,[2] as well as marketing,[3] branding[4] and retail display[5] restrictions are proven to reduce youth access to tobacco products and

impulse tobacco purchases among adults.[6] These kinds of strategies, combined with prevention and education programs, have resulted in a massive reduction of tobacco use.[7]

Both youth and adults would be better served by education programs to dissuade synthetic drug use, and a proactive effort by Congress and the states to fund studies and evaluations that give the public, lawmakers, and health authorities a better understanding of the health risks of synthetic drugs – as well as a better grasp on how to proactively reduce availability of these products to minors through market regulation.

There are other potential approaches to regulating synthetic drug use other than outright prohibition and criminalization. In July 2013, New Zealand's parliament enacted a historic new law that created an FDA-like process for approving synthetic drugs if their relative safety can be demonstrated. While the outlines of the law are unique to New Zealand, it is one example of a different approach to a public health issue. Congress should task a commission with evaluating different approaches, including a New Zealand-style model, to the regulation of synthetic drugs and to thereafter make appropriate recommendations to Congress. Finally, demand for synthetic cannabinoids and other new psychoactive substances could drop if people could get legal and regulated access to marijuana. The vast majority of synthetic cannabinoids likely would not exist today if not for the prohibition of marijuana itself.

We urge the Committee to keep in mind our view that concern regarding synthetic drugs has largely driven by sensationalized media reports rather than facts. Indeed, according to the federally funded *Monitoring the Future* survey, use of synthetic cathinones (e.g., "bath salts," "flakka," etc.) among teens remains "very low."[8] A 2015 national study found that only 1.1 percent of high school seniors reported using "bath salts" in the past year.[9] Rates of synthetic cannabinoids (e.g., "K2," "Spice," "synthetic marijuana," etc.) among youth also remains low.[10] Notably, only 0.5% of non-marijuana users reported use of synthetic cannabinoids.[11] Federal arrests for distribution similarly confirm that demand for synthetics is minimal. According to the United States Sentencing Commission, in FY2014, only 4.5% (N=81) of offenders were convicted of distribution of synthetic cannabinoids.[12] These statistics do not support the notion that synthetic drug prevalence has reached the alarming levels depicted in media reports and from law enforcement officials. DPA certainly does not agree with the approach taken in H.R. 3537 to dealing with synthetic drug compounds.

H.R. 2536, the Recovery Enhancement for Addiction Treatment (TREAT) Act

The Drug Policy Alliance supports this legislation. There is broad consensus among experts that an individual struggling with opioid dependence should have access to the full spectrum of behavioral, pharmacological, and psychosocial treatments. However, nearly 80 percent of people experiencing opioid dependence do not receive treatment because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.[13] Expanding access to drug treatment is a key strategy to reducing demand for opioid analgesics and heroin. Effective treatment modalities should be available to people at all stages of the recovery spectrum.

It is critical that people experiencing dependence to opioid analgesics or heroin can enroll in medication assisted treatment. Scientific research has established that medication assisted treatment increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.[14] Medication assisted treatments are cost effective[15] and have been proven equally effective in treating heroin or prescription-type opioid dependence.[16] Opioid dependent individuals should have access to affordable, judgment-free, individualized counseling and pharmacological replacement therapies such as methadone and buprenorphine. Under medication assisted treatment, doctors prescribe one or more pharmaceutical drugs to people with drug-related problems to eliminate or reduce their problematic use of drugs and improve their mental and physical well-being.

At present, the FDA has approved only three medications for the treatment of opioid dependence.[17] Methadone is one of the most widely studied medicines and is employed effectively around the world to treat opioid dependence. Methadone therapy is widely regarded as the most effective treatment for heroin addiction.[18] Methadone and other medication assisted therapies lead to better health and social outcomes than any other treatment modality.[19] The Centers for Disease Control and Prevention,[20] the Institute of Medicine[21] of the National Institutes of Health,[22] the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services,[23] the National Institute on Drug Abuse (NIDA),[24] the World Health Organization,[25] and over four decades of government-funded, peer-reviewed medical research[26] have unequivocally and repeatedly proven that medication assisted therapies are the most effective treatments for opioid dependence.[27] Yet, extensive federal and state regulations and restrictions stand in the way of providing methadone and buprenorphine treatment services to patients.[28] The Drug Policy Alliance supports expansion of access to buprenorphine and accordingly supports passage of the TREAT Act.

H.R. 2872, the Opioid Addiction Treatment Modernization Act

DPA opposes this legislation, which we interpret to impose numerous new prerequisites on health practitioners that want to become certified to deliver medication assisted treatment (MAT) and already face numerous hurdles to carry out their duties:

- Annually submit to the HHS Secretary a notification of intent to dispense MAT medications;
- Training every two years for practitioners prescribing and dispensing MAT medications;
- Submit certification that practitioner will provide directly or by referral all drugs approved by the FDA for the treatment of opioid addiction including opioid maintenance, detoxification and overdose reversal and relapse prevention, and counseling and other services;
- Maintain a "diversion control plan";
- Requires at least eight hours of opiate-dependent patient training at least every two years; and

- Requires practitioners to obtain from patients under their care a signed acknowledgment that the patient will be subjected to medication adherence and monitored among other stipulations.

DPA is concerned that these new requirements could have a chilling effect on the delivery of MAT. Medication assisted treatment is so difficult to obtain as it is, and difficult for physicians to gain certification and practice with so much red tape. These new requirements would be in addition to significant hurdles that health practitioners who want to deliver medication assisted treatment services must currently overcome. Health practitioners who are currently delivering methadone maintenance, for example, already must contend with numerous federal and state laws and regulations that have a stigmatizing chilling effect on the delivery of service and morale of practitioners who provide these services which in turn adversely impacts patients in need. In addition to methadone maintenance, H.R. 2872 seems to put more restrictions on buprenorphine treatment, the opposite direction of where we want to go to incentivize health practitioners to prescribe buprenorphine and patients to have access to it. DPA also questions whether the "Inspection Authority" as proposed is necessary.

H.R. ___, the Improving Treatment for Pregnant and Postpartum Women Act of 2015

DPA supports this legislation as we interpret it to enhance treatment capacity for pregnant and postpartum women. Treatment programs often fail to meet the needs of populations that have historically confronted barriers to accessing treatment, such as women, people of color, lesbian, gay, bisexual and transgendered (LGBT) individuals, and rural populations. Women face unique obstacles to recovery, ranging from being the primary caretaker of their children to having been physically, emotionally or sexually abused. Yet, a 2013 U.S. government study found that only 32 percent of treatment facilities in the U.S. have unique programs for women, and only 13 percent have special programs for pregnant or postpartum women.[29] There is a strong need for expanded access to treatment for women, including daycare, transportation and other indirect treatment services that improve the likelihood that women succeed in treatment.

H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015

DPA has several concerns about this legislation, as well as specific recommendations for improvement, all of which are outlined as follows.

Reauthorization of Byrne-JAG Program

DPA urges the Committee to strike this section from H.R. 2805. DPA opposes the reauthorization of the Byrne-JAG Program. Historically, Byrne Grants have been used primarily to finance drug task forces, which have a record of racially disproportionate low-level drug arrests and increased local and state costs with no measurable impact on public safety.[30] This troubled history led to the near elimination of the program in the mid-2000s. Through task forces, Byrne Grants

bring large numbers of people into the criminal justice system for low-level drug violations, but provide no subsidy for the resulting court proceedings or incarceration costs. In California, for example, it is estimated that every Byrne Grant dollar spent on arrests generates roughly $10 in new costs to local and state governments – none of which is covered by Byrne Grants.

Task forces typically combine local, state and federal law enforcement officers who, in theory, collaborate to take down large-scale drug dealers and crime organizations and seize large quantities of drugs. In reality, however, there is little oversight of drug task forces, who they arrest and what assets they seize. A 2009 Department of Justice evaluation found that "Not only were data insufficient to estimate what task forces accomplished, data were inadequate to even tell what the task forces did as routine work."[31] Task forces typically measure their own success in terms of numbers – not types – of arrests.[32] Thus, the programs unintentionally reward low-level arrests, rather than resource-intensive higher-level ones. Task forces may also focus within certain geographies, exacerbating racially disparate drug arrest rates. Although drug task forces routinely tout their "successes," they have failed to make drugs less available or the public more safe. Similarly, DPA does not accept the logic that reauthorization of Byrne-JAG is pivotal to the elimination of heroin and diverted opioid trafficking.

Expansion of Federal Funding for PDMPs

DPA urges the Committee to strike this section from H.R. 2805. The Drug Policy Alliance opposes federal funding for prescription drug monitoring programs (PDMPs) designed for use by law enforcement to target patients and prescribing physicians. PDMPs can be a valuable health promotion tool. The use of PDMPs by physicians can enhance their ability to make informed decisions about pain management for patients and prevent overprescribing or medication errors. However, PDMP data should not be available for fishing expeditions by law enforcement. However, most states have passed laws implementing the use of PDMPs as a tool to monitor prescription sales of controlled substances.[33] Law enforcement in many states are given varying levels of authority in each state to monitor PDMPs and launch investigations against health practitioners and patients based upon evidence that, in a law enforcement agency's view, a physician is writing too many prescriptions for opioid analgesics, or a patient is engaging in "doctor shopping." Prescribing practices by physicians who specialize in pain management and treat patients with chronic pain are often scrutinized by law enforcement for running "pill mills." In turn, law enforcement agencies routinely use PDMP sourced data to raid and shut down clinics that treat chronic pain patients and prosecute physicians for "overprescribing" as well as patients for doctor shopping. Yet, evidence is underwhelming that PDMPs have any impact on overdose rates or unsanctioned use of opioid analgesics.[34] In fact, federal survey data indicates that the vast majority of people engaged in unsanctioned use of prescription drugs are not obtaining them from a physician or from engaging in doctor shopping. 53 percent of people who engaged in unsanctioned use of prescription drugs in the past year obtained them for free from friends and family; 15 percent bought or took them from a friend or relative.[35]

Law enforcement agencies should not be empowered to decide when a physician has prescribed too much or a patient is being prescribed too many. Too often the assumption is made that a physician is prescribing too much pain medication, an assumption that is often fostered by law enforcement officials and echoed by lawmakers. Prosecuting prescribers believed to be overprescribing certain medications can lead to stigma against patients using those medications, as well as reduced access to certain medications that physicians may be reluctant to prescribe out of fear of law enforcement investigation.[36] Medical boards and the scientific community should determine what constitutes overprescribing by physicians, and physicians should be permitted to make decisions about pain management for patients. Pain remains one of the most severely undertreated conditions in the U.S. today.[37] As the general population in the United States trends older,[38] and more people are surviving illnesses and undergoing surgical operations, demand for prescription opioid analgesics will likely increase.[39]

Supply-side strategies do not address the underlying behavioral and physical health needs of people experiencing opioid dependence. Tragically, heavy emphasis on supply-side strategies can inadvertently worsen drug misuse in a community if demand-side strategies are not given equal emphasis. Case in point, as law enforcement agencies and lawmakers have stepped up restrictions on opioid analgesic prescribing, evidence suggests that opioid-dependent people who can no longer afford or find diverted medication on the illicit market or a health practitioner willing to prescribe it, are switching to heroin.[40] From a public health and safety standpoint, heroin use is much riskier than unsanctioned opioid medication use.[41] Whereas pharmaceutical opioids generally deliver a reliable and stable dose, people who turn to the illicit market to obtain and use heroin face a greater overdose risk.[42] Evidence indicates that a growing number of individuals who have been using opioid analgesics are substituting heroin, and that dependence on opioid analgesic medications is a strong risk factor for heroin dependence.[43]

Naloxone Demonstration Programs

Naloxone (Narcan) is a low-cost medication available by prescription and is the first line of treatment for paramedics and emergency room physicians who encounter an opioid overdose victim.[44] Naloxone takes as little as two minutes to start working, and provides additional time to obtain necessary medical assistance during an overdose. Evidence suggest that prompt administration of naloxone and provision of emergency care by a bystander can reduce health complications and attendant health care costs to government and private insurers.[45] DPA supports efforts to expand access to naloxone both inside and outside conventional medical settings. There is an enormous, unmet need for affordable access to lifesaving naloxone in communities hit hard by heroin and opioid misuse. DPA supports legislation that expands access to naloxone into community-based settings, as "**the Co-Prescribing to Reduce Overdoses Act of 2015**," also before the Committee, proposes to do.

The section of H.R. 2805 authorizing naloxone demonstration programs for first responders is also an important first step to expanding the utilization of naloxone to combat opioid overdoses. However, we urge the Committee to expand the definition of "first responder" to ensure that properly trained individuals prescribed naloxone and trained on its use by a government or community agency are also eligible for

participation in these demonstration programs. Often, the true first responders to an overdose are friends, family members and other bystanders equipped with naloxone and trained in its use by a government or community agency. In these scenarios, trained bystanders at the scene of an overdose are often best positioned to reverse the opioid overdose and stabilize the victim until paramedics arrive. Every second counts in a life threatening opioid overdose situation. First responders can be many miles away from the scene of an overdose, especially in rural areas.

Government and community agencies that equip citizens with naloxone, train on its proper use and provide linkages to treatment and other services deserve to be included as eligible recipients of demonstration program funds under this section. A recent CDC report credits these overdose prevention services provided by government and community agencies with training more than 150,000 potential bystanders who successfully reversed more than 26,000 overdoses using naloxone.[46] The administration of naloxone at the scene of an overdose by a citizen properly trained in its use deserves to be studied and evaluated, as they would through participation in these demonstration grants, as an effective way to prevent opioid overdose fatalities – especially in situations where first responders are not summoned to the scene or are many minutes away from being able to intervene.

"Drug-Free" Media Campaign

The Drug Policy Alliance is concerned about the proposed "Drug-Free Media Campaign" in this bill. The proposed media campaign would be established by ONDCP in coordination with the HHS Secretary and the Attorney General. ONDCP is the wrong government agency to administer a drug awareness media campaign. The last time ONDCP managed a drug awareness media campaign, studies showed that its over-the-top ads designed to deter young people from using marijuana actually had the opposite effect. Evaluations of ONDCP's media campaigns were so abysmal that Congress eliminated funding for the program – citing their ineffectiveness and waste of tax dollars.

ONDCP has a long track record of ignoring scientific evidence and best practices when it comes to how to communicate to young people and the general public about the health effects of drug use. After all, ONDCP has traditionally served as a political and policy making office, not a hub for scientific evaluation or strict application of science in its drug policies. Accordingly, ONDCP is poorly equipped to develop objective public awareness messaging for the media.

The public deserves accurate, honest information about the health risks of heroin and opioid misuse, including tips on how to reduce health related harm from its use and an effective, objective, science-based drug awareness campaign. DPA urges the Committee to transfer ownership of this media campaign to the Secretary of Health and Human Services. The media campaign should not be framed as a "drug-free" campaign or referred to it as such. Messaging espousing the myth of a "drug-free America" turns off many young people and others who should otherwise hear the campaign's important health messages. Most importantly, the Committee should specify that the substance of the media campaign be grounded in the latest available scientific evidence and public health research.

H.R. 3014, the Medical Controlled Substances Transportation Act of 2015

Currently prescriptions for controlled substances must be written from locations that are registered in advance with the DEA, and can only be stored and dispensed from locations where prior authority has been granted. Thus, transportation by a physician to an unregistered location causes physicians to be in technical violation of federal law.

The Drug Policy Alliance supports the intention of the legislation to provide statutory relief to health practitioners who wish to transport controlled substances. However, we are concerned that the proposed 72 hour limit provided to transport controlled substances and the reporting requirements could ensnare health practitioners in legal troubles. We are concerned about the requirement for physicians to notify DEA before transporting substances and that the DEA may not have the proper mechanisms and oversight in place to properly record registrations that in turn could place physicians in legal jeopardy because of bureaucratic errors. We are also concerned that physicians could get into legal trouble for circumstances – including emergency circumstances - that result in the transportation of medications beyond the 72 hour transportation limit. DPA recommends that the timeframe be eliminated or extended significantly and that the legislation account for emergency circumstances.

Conclusion

The Drug Policy Alliance urges the Committee to confront drug use as a health issue, rather than a criminal justice issue and develop policies and programs accordingly. The federal government has spent billions of dollars on counterproductive supply-side strategies. Laws criminalizing synthetic compounds will only further exacerbate harms of failed drug policies and may impede scientific research. The Committee should prioritize the elimination of federal roadblocks to accessible and affordable medication assisted treatment and facilitate the expansion of policy and programmatic solutions that address core issues that drive substance use.

Thank you for considering our views.

Respectfully Submitted,

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Drug Policy Alliance

[1] Federal law prohibits the sale of tobacco to anyone under 18. 21 C.F.R. § 1140.14 2009. (setting this standard and mandating age confirmation with a photo ID). Some states have raised their own minimum

age to 19 or even 21. Hawaii Revised Statutes § 709-908 (banning the sale of tobacco in Hawaii to anyone under 21 effective in 2016).

[2] Since 1970, health warnings have been mandated on cigarette packages. These requirements, which were strengthened by Congress in 1984 and in 2009, require the conspicuous placement of such phrases as "Cigarettes cause cancer," "Smoking can kill you," and "Tobacco smoke can harm your children" as well as images depicting the harm caused by cigarette smoking. Public Health Cigarette Smoking Act, U.S. Code 15 (1969), § 1333(a) (listing the complete labeling requirements).

[3] Cigarette advertising has been banned on radio and television since 1971. Public Health Cigarette Smoking Act, U.S. Code (1969), § 1335 (making such advertisements unlawful "on any medium of electronic communication subject to the jurisdiction" of the FCC). Cigarette advertisements in lawful mediums such as magazines must contain the same type of warning labels required on cigarette packaging. Federal Cigarette Labeling and Advertising Act, U.S. Code 15 (1965), § 1333(b) (listing the warning label requirements for advertisements).

[4] Legislation in 2009 restricted the ability of tobacco companies to label products as "light," "mild," or "low" to limited circumstances. Family Smoking Prevention and Tobacco Control Act, U.S. Code 21(2009), § 387(k) (denying the ability to use these and similar adjectives without prior approval from the FDA).

[5] While there are no direct federal regulations of retail displays, states have passed their own regulations. New York Public Health Law §1399-cc(7) (mandating that tobacco products be placed behind the counter of a store or within a locked case).

[6] Janine Paynter, "Point of Sale Tobacco Displays and Smoking among 14-15 Year Olds In New Zealand," Tobacco Control 18(4): 268 (2009) (presenting the results of a cross-sectional study which concludes that display restrictions for tobacco products reduce use rate among teens); M. O'Hegarty et al., "Reactions of Young Adult Smokers to Warning Labels on Cigarette Packages," American Journal of Preventative Medicine 30(6): 467 (2006) (showing that smokers report that conspicuous warning labels reduce smoking and increase a desire to quit); Ron Borland, "Tobacco Health Warnings and Smoking-Related Cognitions and Behaviors," Addiction 92(11): 1435 (1997) (concluding that health warnings on cigarette packages are effective at reducing cigarette smoking).

[7] When warning labels were first mandated on cigarette packaging in 1965, the national rate of smoking among adults was 42.4%. Today, that rate has fallen to 19%. Use rates among youth have fallen over this period as well. "Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965-2011," CDC, last modified Nov. 14, 2013) http://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/.

[8] D. Johnston et al., Monitoring the Future, national survey results on drug use, 1975–2012: Volume I, Secondary school students (Ann Arbor: Institute for Social Research, The University of Michigan, 2013).

[9] Joseph J. Palamar, "Bath salt use among a nationally representative sample of high school seniors in the United States," The American Journal on Addictions (2015).

[10] Joseph J. Palamar and Patricia Acosta, "Synthetic cannabinoid use in a nationally representative sample of US high school seniors," Drug and Alcohol Dependence 149(2015); Johnston et al., Monitoring the Future (2015).

[11] Id.

[12] United States Sentencing Commission, 2014 Sourcebook of Federal Sentencing Statistics, Drug Cases, Figure K. http://www.ussc.gov/sites/default/files/pdf/research-and-publications/annual-reports-and-sourcebooks/2014/FigureK.pdf

[13] C.L. Arfken, et al., "Expanding Treatment Capacity for Opioid Dependence with Buprenorphine: National Surveys of Physicians," Journal of Substance Abuse Treatment 96, 39 (2010).

[14] National Institute on Drug Abuse, "Medication-Assisted Treatment for Opioid Addiction," NIDA Topics in Brief (April 2012), https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf.

[15] The American Society of Addiction Medications, "Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment, Part II: Economic Evaluation of Pharmacotherapies for the Treatment of Opioid Disorders:," (Chevy Chase, MD, ASAM: 2013), 8, 65- 91, http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final; M. Connock, et al., "Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation," Health Technology Assessment 11, 9 (2007): 1-192.

[16] C. Banta-Green, et al., "Retention in Methadone Maintenance Drug Treatment for Prescription-Type Opioid Primary Users Compared to Heroin Users," Addiction 104 (2009): 775-783.

[17] Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid dependence for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both Federal and state regulation. Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced

synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid dependence. Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol™. See: American Society of Addiction Medicine, Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment (2013), http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioidaddiction-treatment_final

[18] The National Institutes of Health has explicitly recognized methadone is the most successful treatment to date for opioid dependence, and recommended a reduction in the unnecessary regulation of methadone maintenance therapy and other medication assisted treatment programs. National Institutes of Health, "Effective Medical Treatment of Opiate Addiction," NIH Consensus Statement 15, 6 (1997), 4, http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf; and National Institute on Drug Abuse (NIDA) "Research Report: Heroin Abuse and Addiction," (Revised 2005), http://www.drugabuse.gov/ResearchReports/heroin/heroin.html; and National Institute on Drug Abuse, "Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research-Based Guide," (National Institutes of Health, 2006), 5, 22, https://www.drugabuse.gov/sites/default/files/txcriminaljustice_0.pdf; and D.A. Fiellin, et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial," JAMA 286 (2001):1764-1765; and J.C. Ball and A. Ross, The Effectiveness of Methadone Maintenance Treatment (New York: Springer-Verlag, 1991); and Y.I. Hser, et al., "A 33-Year Follow-Up of Narcotics Addicts," Archives of General Psychiatry 58 (2001): 503-508; and J. Ward, W. Hal, and R.P. Mattick, "Role of Maintenance Treatment in Opioid Dependence," The Lancet 353 (1999): 221-226; and D.M. Novick and H. Joseph. "Medical Maintenance: The Treatment of Chronic Opiate Dependence in General Medical Practice," Journal of Substance Abuse Treatment 8 (1991): 233-239; and Centers for Disease Control and Prevention, "Methadone Maintenance Treatment," February 2002, accessed June 4, 2015, http://www.cdc.gov/idu/facts/Methadone.htm; and M. Connock, et al., "Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation," Health Technology Assessment 11, 9 (2007); Center for Substance Abuse Treatment, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (Tip) Series 43 (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005); World Health Organization, Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention (United Nations Office on Drugs and Crime, 2004), http://www.unodc.org/docs/treatment/Brochure_E.pdf; and R.P. Mattick, et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence," Cochrane Database System Review, 3 (2009).

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