2013-2014 Federal Bills Table

2013-2014 Federal Bills Applicable to NAMSDL
(updated as of March 6, 2014)

	HOUSE	
HR315	*Synthetic Cathinones Control Act of 2013* Official Title: To provide for the placement of certain synthetic drugs on Schedule I under the Controlled Substances Act. Introduced by: Jo Ann Emerson (R-MO-8) (No Co-sponsors) (Emerson has since resigned from Congress) Directs the Attorney General to issue a final order within 60 days of this Act's enactment that schedules specified synthetic drugs on Schedule I of the Controlled Substances Act. Amends the Controlled Substances Act to provide that Schedules I, II, III, IV, and V shall consist of the drugs and other substances that are set forth in the respective schedules in part 1308 of title 21 of the Code of Federal Regulations.	2/28/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 1/18/13 - Referred to the House Judiciary Committee 1/18/13 - Referred to the Subcommittee on Health 1/18/13 - Referred to House Energy and Commerce 1/18/13 - Referred to the Committee on Energy and Commerce, and to the Committee on the Judiciary, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
HR 486	*Stop Tampering of Prescription Pills Act of 2013* Official Title: To amend the Federal Food, Drug and Cosmetic Act to incentivize the development of abuse-deterrent drugs. Introduced by: William Keating (D-MA-9) (14 Co-sponsors) Amends the Federal Food, Drug and Cosmetic Act to prescribe new drug application requirements for abuse-deterrent drugs:	2/8/13 - Referred to the Subcommittee on Health 2/4/13 - Referred to the House Energy and Commerce Committee

	(1) containing as an active moiety (the part of the drug that makes it work the way it does) a controlled substance classified as opium, an opiate or a derivative; (2) formulated for oral administration; (3) exhibiting physicochemical properties making them significantly more difficult or ineffective in altering the drug's characteristics for purposes of misuse or abuse; and (4) containing one or more additional ingredients intended to deter abuse through potential pharmacological effects. Requires the Secretary to refuse a new drug application for any new (brand name) drug containing opium, an opiate or a derivative as an active moiety that is not abuse-deterrent if an abuse-deterrent drug containing the same active moiety has been approved and has not been discontinued from marketing. Authorizes the Secretary to approve an application failing to meet such requirements, however, if approval is necessary to prevent or alleviate a drug shortage or otherwise address a significant unmet public health need. Requires an abbreviated new (generic) drug application for an abuse-deterrent drug to include testing information demonstrating that the generic drug resists manipulation or the effect of manipulation to a degree at least comparable to the listed drug. Authorizes the Secretary to deny approval of a generic application if the listed drug is abuse-deterrent and one or more of the generic drug's active moieties differ in any material respect from those of the listed drug. Declares that an approved generic drug shall not be considered bioequivalent to, or as having the same therapeutic effect as, a listed drug if the listed drug becomes abuse-deterrent unless and until the generic drug demonstrates that it resists manipulation or the effect of manipulation to a degree at least comparable to the listed drug. Prescribes requirements governing when a drug which is not abuse-deterrent may have its approval withdrawn or suspended.	
HR 498	*Sober Truth on Preventing Underage Drinking Reauthorization Act* Official Title: To provide for programs and activities with respect to the prevention of underage drinking Introduced by: Lucille Roybal-Allard (D-CA-40) (58 Co-sponsors) Amends the Public Health Service Act to reauthorize the program to reduce underage drinking for FY2014-FY2018. Revises reporting requirements for state programs on underage drinking. Specifies additional requirements for the development of the national media campaign to prevent underage drinking. Directs the Administrator of SAMHSA to make grants to professional pediatric provider organizations to increase effective practices, including the screening of children and	2/14/13 - Sponsor's introductory remarks on measure 2/8/13 - Referred to the House Subcommittee on Health 2/5/13 - Referred to the House Energy and Commerce Committee

	adolescents for alcohol use, to reduce the prevalence of alcohol use among individuals under the age of 21, including college students. Directs the Secretary of HHS to collect data and conduct or support new research on underage drinking that improves and conducts public health surveillance of alcohol use and alcohol-related conditions in states among individuals between age 18 and 20 by increasing the use of surveys, such as the Behavioral Risk Factor Surveillance System, to monitor binge and excessive drinking and related harms.	
HR 499	*Ending Federal Marijuana Prohibition Act of 2013* Official Title: To decriminalize marijuana at the federal level, to leave to the states a power to regulate marijuana that is similar to the power they have to regulate alcohol, and for other purposes. Introduced by: Jared Polis (D-CO-2) (16 Co-sponsors) Directs the Attorney General to issue a final order that removes marijuana in any form from all schedules of controlled substances under the Controlled Substances Act. Amends such Act to: (1) provide that Schedules I, II, III, IV, and V shall consist of the drugs and other substances that are set forth in the respective Schedules in part 1308 of title 21 of the CFR; (2) exempt marijuana from such Act except as provided in this Act; (3) revise the definition of "felony drug offense" to exclude conduct relating to marijuana; and (4) eliminate marijuana from provisions setting forth penalties applicable to prohibited conduct under such Act. Prohibits shipping or transporting marijuana from any place outside a jurisdiction of the United States into such a jurisdiction in which its possession, use, or sale is prohibited. Eliminates marijuana as: (1) a controlled substance for purposes of the Controlled Substances Import and Export Act or the National Forest System Drug Control Act of 1986, (2) a dangerous drug for purposes of federal criminal code provisions authorizing interception of communications, and (3) a targeted drug for purposes of provisions of the national youth anti-drug media campaign under the ONDCP Reauthorization Act of 1998. Amends the Federal Alcohol Administration Act to set forth procedures for the issuance and revocation by the Secretary of the Treasury of permits for importing, shipping or selling in interstate or foreign commerce, purchasing for resale, producing, packaging, or warehousing marijuana. Prohibits any person from engaging in such conduct without a permit, subject to a $1,000 fine and/or a $500 payment. Sets forth criteria for ineligible applicants and disqualifying offenses. Subjects marijuana to the provisions that apply to: (1) intoxicating liquors under the Original Packages Act, the Webb-Kenyon Act, and the Victims of Trafficking and	2/28/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 2/25/13 - Referred to the Subcommittee on Conservation, Energy and Forestry 2/14/13 - Referred to the Subcommittee on Public Lands and Environmental Regulation 2/8/13 - Referred to the Subcommittee on Health 2/5/13 - Referred to the House Agriculture Committee 2/5/13 - Referred to the House Natural Resources Committee 2/5/13 - Referred to the House Ways and Means Committee 2/5/13 - Referred to the House Energy and Commerce Committee 2/5/13 - Referred to the House Judiciary Committee

	Violence Protection Act of 2000; and (2) distilled spirits under the Federal Alcohol Administration Act. Grants the FDA the same authorities with respect to marijuana as it has for alcohol. Transfers functions of the Administrator of the DEA relating to marijuana enforcement to the Director of the Bureau of ATF. Renames: (1) ATF as the Bureau of Alcohol, Tobacco, Marijuana, Firearms and Explosives; and (2) the Alcohol and Tobacco Tax and Trade Bureau as the Alcohol, Tobacco, and Marijuana Tax and Trade Bureau. Directs the Comptroller General to review federal laws, regulations and policies to determine if changes are desirable in light of this Act.	2/5/13 - Referred to the House Judiciary Committee and to the Committees on Energy and Commerce, Ways and Means, Natural Resources and Agriculture for consideration of such provisions as fall within the jurisdiction of the committee concerned.
HR 501	*Marijuana Tax Equity Act of 2013* Official Title: To amend the Internal Revenue Code of 1986 to provide for the taxation of marijuana, and for other purposes. Introduced by: Earl Blumenauer (D-OR-3) (9 Co-sponsors) Amends the Internal Revenue Code to impose an excise tax on: (1) the sale of marijuana by producers or importers of such drug equal to 50% of the sales price, and (2) each person who is engaged in a marijuana enterprise. Defines "marijuana enterprise" to mean a producer, importer, manufacturer, distributor, retailer or any person who transports, stores, displays or otherwise participates in any business activity that handles marijuana or marijuana products. Requires any person who engages in a marijuana enterprise to obtain a permit to engage in such business. Imposes civil and criminal penalties for violations of the requirements of this Act.	2/5/13 - Referred to the House Ways and Means Committee
HR 689	*States' Medical Marijuana Patient Protection Act* Official Title: To provide for the rescheduling of marijuana and for the medical use of marijuana in accordance with the laws of the various states. Introduced by: Earl Blumenauer (D-OR-3) (22 Co-sponsors) Requires the Secretary of HHS, within six months of enactment of this Act, to submit to the Administrator of the DEA a recommendation on the listing of marijuana within the Controlled Substances Act (CSA) and to recommend listing it as other than a schedule I or schedule II substance. Requires the Administrator of DEA, within one year of enactment of this Act, based upon such recommendation, to issue a notice of proposed rulemaking for the rescheduling of marijuana within the CSA, which shall include a recommendation to list marijuana as other than a schedule I or schedule II substance.	4/8/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 2/15/13 - Referred to the Subcommittee on Health 2/14/13 - Referred to the House Judiciary Committee 2/14/13 - Referred to the House Energy and Commerce Committee

	Declares that no provision of the CSA or the Federal Food, Drug and Cosmetic Act shall, in a state in which the medical use of marijuana is legal under state law, prohibit or otherwise restrict: (1) the prescription or recommendation of marijuana for medical use by a medical professional or the certification by a medical professional that a patient has a condition for which marijuana may have therapeutic benefit; (2) an individual from obtaining, manufacturing, possessing, or transporting within his or her state marijuana for medical purposes, provided the activities are authorized under state law; (3) a pharmacy or other entity authorized to distribute medical marijuana from obtaining, possessing or distributing marijuana to authorized individuals; or (4) an entity authorized by a state or local government from producing, processing or distributing marijuana for such purposes. Requires the Attorney General to delegate responsibility for control over access to marijuana for research into its potential therapeutic and medicinal uses to an entity of executive branch that is not focused on researching the addictive properties of substances. Requires such entity to take appropriate actions to ensure that an adequate supply of marijuana is available for therapeutic and medicinal research.	2/14/13 - Referred to the Committee on Energy and Commerce and to the Committee on the Judiciary, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
HR 672	*Prescription Drug Abuse Prevention and Treatment Act of 2013* Official Title: To provide for increased federal oversight of prescription opioid treatment and assistance to states in reducing opioid abuse, diversion and deaths. Introduced by: Nick Rahall (D-WV-3) (No Co-sponsors) Amends the Public Health Service Act to direct the Administrator of SAMHSA to award grants to states and nonprofit entities for consumer education about opioid abuse, including methadone abuse. Amends the Controlled Substances Act to: (1) set forth training requirements for practitioners registered to prescribe or dispense methadone or other opioids, and (2) require each registered opioid treatment clinic to make acceptable arrangements for each patient who is restricted from having a take-home dose of a controlled substance related to treatment to receive a dose of that substance under appropriate supervision when the clinic is closed. Prohibits any individual or entity (except hospitals that provide direct patient supervision) from prescribing or dispensing a 40-mg diskette of methadone unless such prescription or dispensation is consistent with the current DEA methadone policy, until the date the Controlled Substances Clinical Standards Commission: (1) publishes dosing guidelines for methadone, and (2) finds that such 40-mg diskettes are safe and clinically appropriate. Requires the Secretary of HHS to establish such Commission to develop and publish guidelines related to methadone use,	4/8/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 2/15/13 - Referred to the Subcommittee on Health 2/13/13 - Referred to the House Judiciary Committee 2/13/13 - Referred to House Energy and Commerce Committee 2/13/13 - Referred to the Committee on Energy and Commerce and to the Committee on the Judiciary, in each case for consideration of such provisions as fall within the jurisdiction

	including safe dosing guidelines for all forms of methadone and benchmark guidelines for the reduction of methadone abuse. Requires states receiving controlled substances monitoring program grants to: (1) provide information, upon request, to drug enforcement officials relating to an individual who is the subject of an active drug-related investigation; and (2) require opioid-related deaths to be reported to the Administrator. Directs the Administrator to develop a Model Opioid Treatment Program Mortality Report. Requires the Administrator to establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry to track opioid-related deaths. Requires the Secretary, acting through the Director of the Agency for Healthcare Research and Quality (AHRQ), to require the development and application of specific prescription drug abuse prevention and treatment quality measures for each relevant health care provider setting.	of the committee concerned.
HR 710	*Truth in Trials Act* Official Title: To amend title 18 of the United States Code to provide an affirmative defense for the medical use of marijuana in accordance with the laws of the various states, and for other purposes. Introduced by: Sam Farr (D-CA-20) (12 Co-sponsors) Amends the federal criminal code to: (1) allow any person on trial for a federal marijuana-related offense to introduce evidence that the alleged marijuana-related activities were performed in compliance with state law regarding the medical use of marijuana, (2) allow an affirmative defense to a marijuana prosecution that the alleged marijuana-related activities complied with state law regarding the medical use of marijuana, (3) limit the criminal liability of persons convicted of federal marijuana-related offenses, (4) require the preservation and return (if a defendant is acquitted) of property seized in connection with a marijuana prosecution, and (5) prohibit the seizure of plants grown or stored under a physician's recommendation or by order of a state or municipal agency in accordance with state law regarding the medical use of marijuana.	4/8/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 2/14/13 - Referred to the House Judiciary Committee
HR 752	*Methamphetamine Education, Treatment, and Hope Act of 2013* Official Title: To amend the Public Health Service Act to provide for the establishment of a drug-free workplace information clearinghouse, to support residential methamphetamine treatment programs for pregnant and parenting women, to improve the prevention and treatment of methamphetamine addiction, and for other purposes.	2/15/13 - Referred to the Subcommittee on Health 2/15/13 - Referred to the House Energy and Commerce Committee

	Introduced by: Jerry McNerney (D-CA-9) (12 Co-sponsors) Amends the Public Health Service Act to require the Director of CSAT to collaborate with professionals in the addiction field and primary health care providers to raise awareness about how to: (1) recognize the signs of a substance abuse disorder; and (2) apply evidence-based practices for screening and treating individuals with, or at-risk for developing, an addiction. Revises requirements governing a grant program for substance abuse residential treatment for pregnant and parenting women (currently, for postpartum women), to include treatment for addiction to methamphetamine, outpatient treatment services, and referrals for dental services. Requires the Director to give grant priority to a program serving an area that: (1) is a rural area, an area with a shortage of mental health professionals, or an area with a shortage of family-based substance abuse treatment options; and (2) has high rates of addiction to methamphetamine or other drugs. Revises requirements for biennial reports to Congress to require such reports to include: (1) data on the number of pregnant and parenting women in need of, but not receiving, treatment for substance abuse; and (2) data on recovery and relapse rates of women receiving treatment for substance abuse under the grant program. Requires the Director to expand, intensify, and coordinate efforts to provide pregnant and parenting women treatment for addiction to methamphetamine or other drugs. Requires the Director of the Office for Substance Abuse Prevention to: (1) maintain a clearinghouse that provides information and educational materials to employers and employees about comprehensive drug-free workplace programs and substance abuse prevention and treatment resources; and (2) support the involvement of youth in the development and implementation of prevention strategies focused on youth.	
HR 784	*States' Medical Marijuana Property Rights Protection Act* Official Title: To amend the Controlled Substances Act so as to exempt real property from civil forfeiture due to medical-marijuana-related conduct that is authorized by State law. Introduced by: Barbara Lee (D-CA-13) (9 Co-sponsors) Exempts real property from civil forfeiture under the Controlled Substances Act due to medical marijuana-related conduct that is authorized by state law.	4/8/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 2/15/13 - Referred to the Subcommittee on Health 2/15/13 - Referred to the House Energy and Commerce Committee

		2/15/13 - Referred to the House Judiciary Committee 2/15/13 - Referred to the Committee on the Judiciary and to the Committee on Energy and Commerce, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
HR 923	*Say No to Drug Ads Act* Official Title: To amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs. Introduced by: Jerrold Nadler (D-NY-10) (No Co-sponsors) Amends the Internal Revenue Code to deny a tax deduction for the cost of direct-to-consumer advertisement of a prescription drug.	2/28/13 - Referred to the House Ways and Means Committee
HR 964	*Respect States' and Citizens' Rights Act of 2013* Official Title: To amend the Controlled Substances Act to provide that federal law shall not preempt state law. Introduced by: Diana DeGette (D-CO-1) (8 Co-sponsors) Amends the Controlled Substances Act to provide that, in the case of any state law that pertains to marijuana, no provision of such Act shall be construed as indicating Congressional intent to: (1) occupy the field in which that provision operates, including criminal penalties, to the exclusion of state law on the same subject matter; or (2) preempt any such state law.	4/8/2013 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 3/8/13 - Referred to the Subcommittee on Health 3/5/13 - Referred to the House Energy and Commerce Committee 3/5/13 - Referred to the House Judiciary Committee 3/5/13 - Referred to the Committee on the Judiciary and to the Committee on Energy and Commerce, in each case for consideration

		of such provisions as fall within the jurisdiction of the committee concerned.
HR 1069	*TANF Substance Abuse Prevention Act* Official Title: To amend title IV of the Social Security Act to require states to implement a drug screening and testing program for applicants for and recipients of assistance under the Temporary Assistance for Needy Families (TANF) program, and for other purposes. Introduced by: Charles Boustany (R-LA-3) (No Co-sponsors) Amends part A (Temporary Assistance for Needy Families) (TANF) of title IV of the Social Security Act to require state TANF programs to operate a program to screen and test all TANF applicants and recipients of assistance for illegal drug use. Requires state TANF programs to deny assistance to individuals who have not been screened for the use of illegal drugs, or who, having been found as a result of the screening to have a high risk of substantive abuse, have not been tested for the use of illegal drugs.	3/12/13 - Referred to the House Ways and Means Committee
HR 1285 (*See also* S 621)	*To Amend the Controlled Substances Act to Make Any Substance Containing Hydrocodone a Schedule II Drug* Official Title: To amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug. Introduced by: Vern Buchanan (R-FL-16) (54 Co-sponsors) Amends the Controlled Substances Act to remove dihydrocodeinone (hydrocodone) from classification as a schedule III controlled substance. Directs the Attorney General to immediately allow manufacturers and distributors to store hydrocodone compound products in accordance with the physical security requirements for schedule III, IV, and V controlled substances for three years beginning on the date enactment of this Act. Requires the Comptroller General to submit a report on the reclassification of hydrocodone products under this Act, including: (1) an assessment of the degree to which the reclassification of such products under this Act impacts the ability of patients with legitimate medical needs, particularly those in rural areas and nursing home facilities, to access adequate pain management; and (2) recommendations necessary to address any issues relating to patient access to adequate pain management.	4/15/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 3/22/13 -Referred to the Subcommittee on Health 3/20/13 - Referred to the House Judiciary Committee 3/20/13 - Referred to the House Energy and Commerce Committee 3/20/13 - Referred to the Committee on Energy and Commerce and to the Committee on the Judiciary, in each case for consideration of such provisions as fall

		within the jurisdiction of the committee concerned.
HR 1366	*Stop Oxy Abuse Act of 2013* Official Title: To direct the Commissioner of Food and Drugs to modify the approval of any drug containing controlled-release oxycodone hydrochloride to limit such approval to use for the relief of severe-only instead of moderate-to-severe pain, and for other purposes. Introduced by: Stephen Lynch (D-MA-8) (8 Co-sponsors) Directs the Commissioner of Food and Drugs (FDA), within 90 days, to take such actions as may be necessary to modify the approval of, and limit any subsequent approval of, any drug containing controlled-release oxycodone hychloride to use for the relief of severe-only pain instead of moderate-to-severe pain.	3/22/13 - Referred to the Subcommittee on Health 3/21/13 - Referred to the House Energy and Commerce Committee
HR 1523	*Respect State Marijuana Laws Act of 2013* Official Title: To amend the Controlled Substances Act to provide for a new rule regarding the application of the Act to marijuana, and for other purposes. Introduced by Dana Rohrabacher (R-CA-38) (25 Co-sponsors) Amends the Controlled Substances Act to provide that provisions of such Act related to marihuana shall not apply to any person acting in compliance with state laws relating to the production, possession, distribution, dispensation, administration or delivery of marijuana.	4/30/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 4/12/13 - Referred to the Subcommittee on Health 4/12/13 - Referred to the House Energy and Commerce Committee 4/12/13 - Referred to the House Judiciary Committee 4/12/13 - Referred to the Committee on the Judiciary and to the Committee on Energy and Commerce, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

HR 1635	*National Commission on Federal Marijuana Policy Act* Official Title: To establish the National Commission on Federal Marijuana Policy. Introduced by Steve Cohen (D-TN-9) (9 Co-sponsors) Establishes the National Commission on Federal Marijuana Policy to undertake a comprehensive review of current policies of the federal government toward marijuana in light of the growing number of states in which marijuana is legal for medicinal or personal use. Requires such review to include: (1) how federal policy should interact with state laws that make marijuana legal for such use; (2) the cost of the prohibition and potential regulation of marijuana and the potential revenue generated by taxation of marijuana; (3) the impact of federal banking and tax laws on businesses operating in compliance with state laws related to marijuana; (4) the health impacts related to marijuana use, and in comparison to alcohol and tobacco use; (5) the public safety effects and impact of the prohibition, and the regulation and control, of marijuana; (6) the impact of marijuana prohibition on criminal justice and the collateral consequences of prosecution for marijuana possession; (7) recommendations for the appropriate placement of marijuana in the schedule of the Controlled Substances Act; and (8) the effects of the prohibition or future regulation and control of marijuana on international relationships and treaty obligations.	4/30/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 4/19/13 - Referred to the Subcommittee on Health 4/18/13 - Referred to the House Foreign Affairs Committee 4/18/13 - Referred to the Subcommittee on Financial Services 4/18/13 - Referred to the House Ways and Means Committee 4/18/13 - Referred to the House Energy and Commerce Committee 4/18/13 - Referred to House Judiciary 4/18/13 - Referred to the Committee on the Judiciary and to the Committees on Energy and Commerce, Ways and Means, Financial Services and Foreign Affairs, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
HR 1919	*Safeguarding America's Pharmaceuticals Act of 2013* Official Title: To amend the Federal Food, Drug and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes. Introduced by Robert Latta (R-OH-5) (20 Co-sponsors)	6/4/13 - Received in the Senate and read twice and referred to the House Health, Education, Labor and Pensions Committee

	Establishes national standards for the FDA to monitor the distribution of prescription drugs. Imposes new regulatory requirements on the network of companies that produce, handle, distribute and dispense drug products. Entities in the distribution chain would be required to provide notification to state and federal regulators about products that may be unsuitable to distribute and would be required to comply with record-keeping standards. The FDA would establish a licensing program for third-party providers of logistics services, and would be permitted to collect fees and spend the money to cover the program's costs. Pharmaceutical tracing requirements for drug lots would be established for makers, wholesale distributors, pharmacies and re-packagers. Drug suppliers, including third-party logistics providers, would be required to do business only with registered or licensed entities. Makers would have to serialize prescription drugs at the unit level.	6/3/13 - Passed in House 6/3/13 - On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. 6/3/13 - DEBATE: The House proceeded with forty minutes of debate 6/3/13 - Considered under suspension of the rules 6/3/13 - Mr. Latta moved to suspend the rules and pass the bill, as amended 6/3/13 - Reported (Amended) by the House Energy and Commerce Committee 5/15/13 - Ordered to be reported to the House Energy and Commerce Committee 5/10/13 - Referred to the Subcommittee on Health 5/9/13 - Referred to the House Energy and Commerce Committee
HR 1930	*Drug Testing Integrity Act of 2013* Official Title: To prohibit the manufacture, marketing, sale or shipment in interstate commerce of products designed to assist in defrauding a drug test. Introduced by Eliot Engel (D-NY-16) (1 Co-sponsor) Makes it unlawful to knowingly manufacture, market, sell, ship or otherwise provide to another individual any product with the	5/10/13 - Referred to the Subcommittee on Commerce, Manufacturing and Trade 5/9/13 - Referred to the House Energy and Commerce Committee

	intent to assist such individual to use such product to defraud a drug test. Treats a violation of this Act as an unfair or deceptive act or practice under the Federal Trade Commission Act.	
HR 2130	*Access to Substance Abuse Treatment Act of 2013* Official Title: To amend the Public Health Service Act to provide grants for treatment of heroin, cocaine, methamphetamine, 3,4-methylenedioxymethamphetamine (ecstasy), and phencyclidine (PCP) abuse and for other purposes. Introduced by Matthew Cartwright (D-PA-17) (27 Co-sponsors) Amends the Public Health Service Act to authorize the Secretary of Health and Human Services (HHS) to make grants to: (1) increase the availability of treatment for abuse of heroin, cocaine, methamphetamine, 3,4-methylenedioxymethamphetamine (ecstasy), and phencyclidine (PCP); (2) provide vouchers to individuals in underserved populations for authorized services related to such treatment; and (3) establish programs to provide for and coordinate the provision of wrap-around services, such as medical services, job training services, and housing assistance, to individuals re-entering the community after successfully receiving treatment for abuse of such substances. Revises the grant program to provide residential substance abuse treatment to pregnant and postpartum women to: (1) make caregiver parents eligible for such program, (2) make Indian tribes and tribal organizations eligible for grants and (3) set forth the priority for allocation of grants. Requires the Director of the National Institute on Drug Abuse to conduct research on the effectiveness of the use of agonist and antagonist drugs to reduce the problems associated with stimulant abuse, including cocaine and methamphetamine abuse. Requires the Secretary to seek to enter into a contract with the Institute of Medicine to complete a literature review on the effectiveness of agonist and antagonist drugs for the treatment of stimulant abuse, including cocaine and methamphetamine abuse. Requires the Comptroller General to study: (1) the impact of the programs authorized by this Act on the effectiveness and availability of treatment for abuse of heroin, cocaine, methamphetamine, 3,4-methylenedioxymethamphetamine and	5/24/13 - Referred to the Subcommittee on Health 5/23/13 - Referred to the House Energy and Commerce Committee

	phencyclidine; (2) how the level of federal funding available for such treatment compares to the amount necessary to provide adequate treatment; and (3) the impact of effective treatment on cost savings due to the reduced need for criminal justice and other services. Declares that this Act shall not be construed to increase the amount of appropriations that are authorized to be approved for any fiscal year.	
HR 3204 Public Law No: 113-54	*Drug Quality and Security Act* Official Title: To amend the Federal Food, Drug and Cosmetic Act with respect to human drug compounding and drug supply chain security and for other purposes. Introduced by Fred Upton (R-MI-06) (10 Co-sponsors) Track and Trace Legislation - Expands the FDA's oversight of compounded drugs, and for the first time, the U.S. imposes uniform standards to monitor drug distribution from factories to pharmacies. The bill reflects an informal House - Senate agreement on the issues and allows the FDA to collect and spend fees to cover the costs of inspecting drug compounding sites and to license programs for providers of logistics services for drug makers, wholesalers and dispensers. The measure imposes handling and recordkeeping requirements on drug companies and creates notification rules for drugs that are potentially unsuitable for distribution.	11/27/13 - Became Public Law No: 113-54 11/27/13 - Signed by President 11/18/13 - Message on Senate action sent to House 11/18/13 - Passed Senate by voice vote 9/30/13 - Received in Senate 9/28/13 - Motion to suspend the rules, bill passed (agreed to by voice vote) 9/27/13 - Referred to the House Energy and Commerce Committee
HR 3528	*National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act of 2013* Official Title: To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act. Introduced by Ed Whitfield (R-KY-01) (2 Co-sponsors) Provides grants to states to enhance their prescription monitoring programs (PMPs).	11/22/13 - Referred to the Subcommittee on Health 11/18/13 - Referred to the House Committee on Energy and Commerce
HR 3717	*Helping Families in Mental Health Crisis Act of 2013* Official Title: To make available needed psychiatric, psychological and supportive services for individuals diagnosed	1/27/14 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations.

	with mental illness and families in mental health crisis, and for other purposes Introduced by Tim Murphy (R-PA-18) (40 Co-sponsors) Among other things, adds an Assistant Secretary for Mental Health and Substance Use Disorders	1/8/14 - Sponsor Introductory Remarks and Referred to the Subcommittee on Research and Technology 12/12/13 - Referred to House Science, Space, and Technology; Referred to House Ways and Means; Referred to House Education and the Workforce; Referred to House Judiciary; Referred to House Energy and Commerce
HR 2652	*Marijuana Businesses Access to Banking Act of 2013* Official Title: To create protections for depository institutions that provide financial services to marijuana-related businesses. Introduced by Ed Perlmutter (D-CO-7) (28 Co-Sponsors) Prohibits a federal banking regulator from: (1) terminating or limiting the deposit insurance of a depository institution solely because it either provides or has provided financial services to a marijuana-related legitimate business; or (2) prohibiting, penalizing or otherwise discouraging a depository institution from providing financial services to a marijuana-related legitimate business. Prohibits a federal banking regulator, in addition, from recommending, motivating, providing incentives or encouraging a depository institution not to offer financial services to an individual, or to downgrade or cancel financial services offered to an individual, solely because the individual: (1) is or later becomes a manufacturer, producer, owner or operator of a marijuana-related legitimate business; or (2) the depository institution was not aware that the individual is the owner or operator of a marijuana-related legitimate business. Prohibits a federal banking regulator from taking any action on a loan to an owner or operator of: (1) a marijuana-related legitimate business, or (2) real estate or equipment that is leased to a marijuana-related legitimate business. Grants immunity from federal criminal prosecution or investigation to a depository institution providing financial services to a marijuana-related legitimate business. Prohibits the Secretary of the Treasury from requiring a depository institution, and any	2/14/14 - The Treasury Department announced that it would allow banks to accept accounts from legal marijuana businesses The Treasury Department's new policy would allow an industry that is illegal in a majority of U.S. states to open business-checking accounts and accept credit cards. To contain the dangers of operating an all-cash business, the Treasury's FinCen issued guidelines for banks. The guidelines were sought by marijuana businesses and the governors of Colorado and Washington state, whose voters in 2012 approved ballot measures allowing

	director, officer, employee or agent of a depository institution, to report a transaction as suspicious solely because a party to the transaction is a marijuana-related legitimate business.	marijuana sales and use for recreation. 9/13/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations 7/10/13 - Referred to House Financial Services and House Judiciary
HR 4069	*Ensuring Patient Access and Effective Drug Enforcement Act of 2013* Official Title: To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes Introduced by Tom Marino (R-PA-10) (3 Co-sponsor) Amends the Controlled Substances Act by requiring that companies registered with the DEA ensure employees with access to controlled substances meet criminal background checks and drug tests, and manufacturers and distributors who may be at risk of losing their registration be given the chance to submit a corrective action plan. Sets up a Combating Prescription Drug Abuse Working Group consisting of 20 members, including those representing DEA, FDA, ONDCP, patients, pharmacies and manufacturers. The group's main duties would be to report to Congress on federal efforts to reduce prescription drug abuse, identify gaps, review recommendations to transfer controlled substances from Schedule III to Schedule II under the Controlled Substances Act, and propose ways to reduce diversion or abuse. One year after the act is passed, the group would be required to provide recommendations on the following topics: (1) Systems for prescription drug monitoring; (2) Illegal internet sites and facilities that distribute and fill prescriptions indiscriminately; (3) Facilitation of proper disposal of prescription drugs; (4) Identification of geographic areas where prescription drug abuse is prevalent; (5) Access to prescription drugs for legitimate medical purposes; (6) Collaboration among agencies, especially the DEA and FDA, to coordinate prevention and enforcement efforts; (7) Collaboration among federal and state agencies; (8) Resources for law enforcement; (9) Education of providers, patients, parents and youth on prescription drug	2/18/14 - Referred to the House Energy and Commerce Committee 2/18/14 - Referred to the House Judiciary Committee

	abuse; (10) Development of abuse-resistant prescription drug products; (11) Ways to reduce robberies, burglaries and cargo theft of prescription drugs. The working group would terminate two years after the members are appointed.	
HR 161	*Expressing the Sense of the House of Representatives that the Food and Drug Administration Should Encourage the Use of Abuse-deterrent Formulations of Drugs* Official Title: Expressing the sense of the House of Representatives that the Food and Drug Administration should encourage the use of abuse-deterrent formulations of drugs. Introduced by Hal Rogers (R-KY-5) (7 Co-sponsors) Expresses the sense of the House of Representatives that the Food and Drug Administration should exercise its acknowledged authority to: (1) refuse to approve generic versions of non-abuse-deterrent opioid products that have been replaced in the market with abuse-deterrent formulations; and (2) require generic versions of abuse-deterrent opioid products to be formulated with comparable abuse-deterrent features.	4/19/13 - Referred to the Subcommittee on Health 4/15/13 - Referred to the House Energy and Commerce Committee
	SENATE	
S 348	*Prescription Drug Abuse Prevention and Treatment Act of 2013* Official Title: A bill to provide for increased federal oversight of prescription opioid treatment and assistance to states in reducing opioid abuse, diversion and deaths. Introduced by John Rockefeller (D-WV) (4 Co-sponsors) Amends the Public Health Service Act to direct the Administrator of SAMHSA to award grants to states and nonprofit entities for consumer education about opioid abuse, including methadone abuse. Amends the Controlled Substances Act to: (1) set forth training requirements for practitioners registered to prescribe or dispense methadone or other opioids, and (2) require each registered opioid treatment clinic to make acceptable arrangements for each patient who is restricted from having a take-home dose of a controlled substance related to treatment to receive a dose of that substance under appropriate supervision when the clinic is closed. Prohibits any individual or entity (except hospitals that provide direct patient supervision) from prescribing or dispensing a 40-mg diskette of methadone unless such prescription or dispensation is consistent with the current DEA methadone policy, until the date the Controlled Substances Clinical Standards Commission: (1) publishes dosing guidelines for methadone, and (2) finds that such 40-mg diskettes are safe and clinically appropriate. Requires the Secretary of HHS to establish such Commission to	2/14/13 - Read twice and referred to the Health, Education, Labor and Pensions Committee

	develop and publish guidelines related to methadone use, including safe dosing guidelines for all forms of methadone and benchmark guidelines for the reduction of methadone abuse. Requires states receiving controlled substances monitoring program grants to: (1) provide information, upon request, to drug enforcement officials relating to an individual who is the subject of an active drug-related investigation; and (2) require opioid-related deaths to be reported to the Administrator. Directs the Administrator to develop a Model Opioid Treatment Program Mortality Report. Requires the Administrator to establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry to track opioid-related deaths. Requires the Secretary, acting through the Director of the Agency for Healthcare Research and Quality (AHRQ), to require the development and application of specific prescription drug abuse prevention and treatment quality measures for each relevant health care provider setting.	
S 621 (*See also* HR 1285)	*Safe Prescribing Act of 2013* Official Title: A bill to amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug. Introduced by: Joe Manchin (D-WV) (9 Co-sponsors) Amends the Controlled Substances Act to remove dihydrocodeinone (hydrocodone) from classification as a schedule III controlled substance. Directs the Attorney General to immediately allow manufacturers and distributors to store hydrocodone combination products in accordance with the physical security requirements for schedule III, IV, and V controlled substances for three years beginning on the date of enactment of this Act. Requires the Comptroller General to submit a report on the reclassification of hydrocodone products under this Act, including: (1) an assessment of the degree to which the reclassification of such products under this Act impacts the ability of patients with legitimate medical needs, particularly those in rural areas and nursing home facilities, to access adequate pain management; and (2) recommendations necessary to address any issues relating to patient access to adequate pain management.	3/20/13 - Read twice and referred to the Senate Judiciary Committee
S 644	*PACT Act* Official Title: A bill to amend the Federal Food, Drug and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes. Introduced by: Robert Casey (D-PA) (5 Co-sponsord)	3/21/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee

	Amends the Federal Food, Drug, and Cosmetic Act to prohibit the sale or offering for sale of a drug containing dextromethorphan, and not subject to practitioner supervision requirements, to an individual under age 18, except if the sale is made: (1) pursuant to a validly issued prescription; or (2) to an individual who provides proof of being actively enrolled in the military, including a valid military identification card. Imposes civil monetary penalties that escalate upon repeated violation. Deems to be adulterated any unfinished dextromethorphan that is possessed, received or distributed in violation of this Act. Prohibits a person from: (1) possessing or receiving unfinished dextromethorphan unless the person is registered with the Secretary of HHS as a producer of a drug or device or otherwise registered, licensed or approved under federal or state law to engage in the practice of pharmacy, pharmaceutical production or manufacture or distribution of drug ingredients; or (2) distributing unfinished dextromethorphan to any person other than a registered or otherwise authorized person. Excludes from such prohibitions common carriers that possess, receive or distribute unfinished dextromethorphan for purposes of distributing it between registered, licensed or approved persons. Imposes additional civil monetary penalties for such possession and distribution violations.	
S 689	*Mental Health Awareness and Improvement Act of 2013* Official Title: A bill to reauthorize and improve programs related to mental health and substance use disorders. Introduced by: Tom Harkin (D-IA) (23 Co-sponsors) Title I: Education Programs - Achievement Through Prevention Act - (Sec. 103) Amends part A of title I of the Elementary and Secondary Education Act of 1965 (ESEA) to allow states, local educational agencies (LEAs), and schools to use school improvement funds to implement school-wide positive behavioral interventions and supports and early intervening services and coordinate them with similar activities carried out under the Individuals with Disabilities Education Act. (Early intervening services are a set of coordinated services for students in kindergarten through grade 12 who are not currently identified as needing special education or related services, but who need additional academic and behavioral support to succeed in a general education environment.)Revises requirements for state educational agency (SEA) reports and LEA plans to include information relating to such interventions and services. Requires school-wide programs to implement such interventions and services, and LEAs to ensure the provision of technical assistance to schools for that implementation. Requires school improvement plans to specify	4/11/13 - Placed on Senate Legislative Calendar 4/11/13 - Placed on Senate Legislative Calendar 4/11/13 - Committee on Health, Education, Labor and Pensions. 4/10/13 - Reported by Senator Harkin (with an amendment) in the and ordered to be reported to the Senate Health, Education, Labor and Pensions Committee 4/9/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee

	whether the LEA or school will adopt and implement related policies or practices. Allows LEA improvement plans to improve or expand such interventions and services. Applies similar requirements to statewide systems for support for LEAs and schools. Requires states that receive funds for the education of neglected or delinquent children or at-risk youth to coordinate the use of positive behavioral interventions and supports, early intervening services, and school-based mental health programs to improve such students' academic performance and reduce their need for discipline. Requires an LEA to use sub-grant funds to carry out in-service training for school personnel in: (1) the techniques and supports needed to identify early any children with trauma histories and children with, or at risk of, mental illness; and (2) the use of mechanisms to refer such children to appropriate treatment and intervention services. Authorizes programs to prevent the illegal use of drugs and violence among students to include development of school-based mental health programs. Prescribes requirements for school-based mental health services partnership programs. Title II: Health Programs - (Sec. 201) Amends the Public Health Service Act to reauthorize appropriations for FY2014-FY2018 and revise requirements for a youth interagency research, training, and technical assistance resource center to expand its focus from youth suicides to suicides among all ages, particularly among groups at high risk for suicide. Reauthorizes appropriations for FY2014-FY2018 a program of grants for the development of state or tribal youth suicide early intervention and prevention strategies. Changes the term "substance abuse" to "substance use disorder." Reauthorizes for FY2014-FY2018 and revises a grant program to enhance services for students with mental health or substance use disorders at institutions of higher education. (Sec. 202) Renames mental illness awareness training grants "mental health awareness training grants." Authorizes the use of grant funds for evidence-based programs for the purpose of the safe de-escalation of crisis situations involving individuals with a mental illness. (Sec. 203) Revises requirements for grants to address the problems of persons who experience violence-related stress to specify their use for the continued operation of the National Child Traumatic Stress Initiative (NCTSI) focusing on the mental, behavioral, and biological aspects of psychological trauma response. Requires programs funded by such grants also to develop knowledge about evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event. Directs the Secretary of HHS, in awarding such grants, to give priority to universities and hospitals as well as mental health agencies and other programs meeting specified criteria	

	(as under current law). Directs the NCTSI coordinating center to: (1) collect, analyze, and report NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of such treatment and services; (2) facilitate coordination of training initiatives in such treatments, interventions, and practices; and (3) collaborate with the Secretary in disseminating interventions, treatments, products and other resources to appropriate stakeholders. Requires the Secretary to ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus review process. Requires payments under a grant award to be made to the recipient for at least four of the five years of the grant. Authorizes appropriations for FY2014-FY2018. (Sec. 204) Directs the Comptroller General (GAO) to report to specified congressional committees on federal requirements that impact access to treatment of mental health and substance use disorders related to integration with primary care, administrative and regulatory issues, quality measurement and accountability, and data sharing. (Sec. 205) Authorizes the Secretary, acting through the Administrator for the Substance Abuse and Mental Health Services Administration, to advance, through existing programs as appropriate, the education and awareness of providers, patients, and other appropriate stakeholders regarding all products approved by the FDA)to treat opioid use disorders. (Sec. 206) Directs the Comptroller General to evaluate the utilization of mental health services for children, including the usage of psychotropic medications. (Sec. 207) Amends the Public Health Service Act to require Secretary to provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric substance use and mental health disorders, as well as disseminate information about such practices to states and non-grantees. (Sec. 208) Encourages the Secretary, acting through the Director of the CDC, to improve, particularly through the voluntary inclusion of additional states, the National Violent Death Reporting System. (Sec. 209) Directs the Comptroller General to evaluate the status of implementation of recommendations made in the report to the President, "On Issues Raised by the Virginia Tech Tragedy."	
S 706	*Transnational Drug Trafficking Act of 2013* Official Title: A bill to provide the Department of Justice with additional tools to target extraterritorial drug trafficking activity, and for other purposes. Introduced by: Dianne Feinstein (D-CA) (6 Co-sponsors) Amends the Controlled Substances Import and Export Act to prohibit the manufacture or distribution of a controlled	4/11/13 - Read twice and referred to the Senate Judiciary Committee

	substance in schedule I or II, flunitrazepam, or a listed chemical by individuals having reasonable cause to believe that such substance or chemical will be unlawfully imported into the United States or into waters within 12 miles of the U.S. coast. Prohibits the manufacture or distribution of a listed chemical: (1) intending or knowing that it will be used to manufacture a controlled substance; and (2) intending, knowing, or having reasonable cause to believe that the substance will be unlawfully imported into the United States. Amends the federal criminal code to revise the prohibition against, and penalties for, intentionally trafficking in a counterfeit drug to apply to intentionally trafficking in a drug and knowingly using a counterfeit mark on or in connection with such drug.	
S 959	*Pharmaceutical Quality, Security and Accountability Act* Official Title: A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to compounding drugs. Introduced by: Tom Harkin (D-IA) (5 Co-sponsors) Amends the Federal Food, Drug and Cosmetic Act (FFDCA) to expand the regulation of compounded drugs. Subjects a compounded drug to all FFDCA requirements applicable to new drugs. Sets forth exceptions from new drug requirements, biological product requirements, labeling requirements, and good manufacturing practice requirements for a drug that: (1) is compounded by a traditional compounder, and (2) meets applicable requirements. Defines & ldquo; traditional compounder & rdquo; as a facility operating pursuant to state law that meets certain criteria, including that a drug is compounded by a licensed pharmacist or licensed physician pursuant to a prescription order for an identified individual patient or compounded in limited qualities before a prescription order based on history of receiving such prescription orders. Includes as a traditional compounder hospitals and health systems (collection of hospitals) that compound drugs only to dispense or administer them to patients of the hospital or health system. Exempts from labeling requirements, new drug requirements and biological product requirements a compounded prescription drug that: (1) is compounded by a compounding manufacturer that is not licensed as a pharmacy in any state but is in compliance with this Act, and (2) meets the applicable requirements for drugs compounded by a compounding manufacturer. Defines & ldquo; compounding manufacturer & rdquo; as a facility at one geographic location or address that: (1) compounds any sterile drug without receiving a prescription order for an identified individual patient before beginning compounding, and distributes or offers to sell such compounded sterile drug in interstate commerce; or	6/19/13 - Placed on Senate Legislative Calendar 6/19/13 - Reported by Senator Harkin (with two amendments) to the Senate Health, Education, Labor and Pensions Committee 5/22/13 - Ordered to be reported to the Senate Health, Education, Labor and Pensions Committee 5/15/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee

	(2) repackages any preservative-free sterile drug or engages in sterile pooling. Excludes from such definition a compounding nuclear pharmacy or a hospital or health system that repackages a drug because of a drug shortage and does not otherwise meet the definition of compounding manufacturer. Sets forth a list of drugs that may not be compounded, which includes: Prohibits the compounding of biological products unless the compounded variation: (1) is compounded solely using a licensed biological product or solely using such a product and one or more ingredients in compliance with established standards for medicines and pharmaceuticals, (2) produces for the patient a clinical difference, (3) is produced for an individually identified patient with a prescription or for an identified patient or patients pursuant to a duly authorized medical order from a health care entity, or (4) is a radioactive biological product that is compounded by a nuclear pharmacy. Permits a traditional compounder to begin compounding a variation on a licensed biological product before receiving a prescription order if it is for emergency use in pediatric patients and produces a clinical difference for the patient. Prohibits the compounding of an allergenic product that is a variation of a licensed biological product unless the compounded variation is compounded solely using one or more licensed allergenic products and one or more ingredients in compliance with established standards for medicines and pharmaceuticals. Establishes standards for the bulk drug substances or ingredients used to compound a drug or product, including that such substances or ingredients must: (1) comply with established standards for medicines and pharmaceuticals, (2) use substances manufactured by registered establishments, (3) be accompanied by valid certificates of analysis for each specific lot of substance, and (4) comply with established pharmacy compounding standards. Authorizes the Secretary to identify bulk substances that may not be used in compounding a drug because of public health concerns. Prohibits a compounded drug from being sold by an entity other than the one that compounded it. Allows a compounding manufacturer to sell or transfer a compounded drug to: (1) a health care entity that provides medical services through licensed practitioners directly to patients, or (2) a licensed pharmacy without profit under certain circumstances. Requires a compounded drug offered for sale to be labeled as & ldquo; not for resale & rdquo; Requires a compounding manufacturer to ensure that a licensed pharmacist in the state where the compounding manufacturer is located exercises direct supervision over its operations. Establishes requirements for a compounding manufacturer to include: (1) annual registration, (2) biannual reporting on the drugs it compounds, (3) reporting of serious adverse events associated with the use of a compounded drug, and (4) labeling of compounded drugs.	

	Subjects compounding manufacturers to inspection of their facilities according to a risk-based schedule. Directs the Secretary to assess an annual establishment fee on each compounding manufacturer and a re-inspection fee from each compounding manufacturer subject to a re-inspection in a fiscal year. Directs the Secretary to encourage states to identify any state-licensed pharmacies that appear to be compounding manufacturers required to register with the Secretary. Requires the Comptroller General to study the safety of animal drug compounding and the availability of safe and effective drugs for animals. (Sec. 103) Deems a compounded drug to be misbranded if: (1) the labeling does not include the required information established under this Act, (2) the advertising or promotion of a compounded drug is false or misleading in any particular, or (3) the compounding manufacturer did not pay required fees. (Sec. 104) Requires the Secretary to consult with relevant stakeholders in implementing this Act. Requires the Secretary, in promulgating any implementing regulations, to issue a notice of proposed rulemaking that includes the proposed regulation, provide a period of at least 60 calendar days for comments, and publish the final regulation within 18 months and at least 30 calendar days before the effective date of the final regulation. (Sec. 105) Makes this title effective one year after enactment.- Drug Supply Chain Security Act - (Sec. 202) Amends the Federal Food, Drug and Cosmetic Act to establish requirements to facilitate the tracing of drug products through the pharmaceutical supply distribution chain. Requires the Secretary to establish standards for the exchange of transaction documentation that consists of: Requires the Secretary to establish processes to: (1) provide waivers of requirements, including for undue economic hardship or emergency medical reasons; (2) provide exceptions to requirements relating to product identifiers if a product is packaged without sufficient space to bear the information; and (3) determine other products or transactions that should be exempt from the requirements of this section. Permits certain requirements of this Act applicable to manufacturers, re-packagers, wholesale distributors, third-party logistics providers, and dispensers to be enforced without further regulations or guidance from the Secretary. Requires the Secretary to finalize guidance within two years specifying whether and under what circumstances a product that is not labeled with a product identifier, and that is in the pharmaceutical distribution supply chain when applicable requirements go into effect, shall be exempted from such requirements. Exempts products that entered the pharmaceutical distribution supply chain before the date that is one year after enactment of this Act from requirements related to transaction documentation. Requires drug manufacturers to provide	

	transaction documentation before, or at the time of, each transfer of ownership of a product or transfer of possession to a third-party logistics provider for subsequent transfer of ownership. Requires a wholesale distributor, dispenser, or re-packager to provide to the subsequent purchaser transaction documentation for the product. Prohibits a wholesale distributor, dispenser, or re-packager from accepting ownership of a product unless the previous owner before, or at the time of, the transaction provides such transaction documentation. Prohibits a third-party logistics provider from accepting possession of a product unless such documentation is provided. Requires the manufacturer, wholesale distributor, dispenser, re-packager, or third-party logistics provider to maintain the transaction documentation for each transaction (or, for a third-party logistics provider, each transfer of possession) for at least six years. Requires a manufacturer, wholesale distributor, dispenser, re-packager, or third-party logistics provider, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, to provide within 24 hours (or, for a dispenser, within two business days), or in such other reasonable time as determined by the Secretary, the applicable transaction documentation upon request by the Secretary or other appropriate federal or state official. Requires a manufacturer within four years (for re-packagers, within five years) to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Requires a manufacturer and re-packager to maintain product identifier information for at least six years from the date of transaction. Allows a wholesale distributor, dispenser, re-packager, or third-party logistics provider to engage in transactions involving a product, or accept possession of a product, only if the product has a product identifier. Sets the effective date of this requirement for re-packagers at five years after enactment, with later effective dates for the other entities. Requires the trading partners of a manufacturer, wholesale distributor, dispenser, re-packager or third-party logistics provider to be authorized trading partners (i.e., properly registered or licensed by the state).Requires a manufacturer, wholesale distributor, dispenser, re-packager or third-party logistics provider to have systems in place to: (1) quarantine a suspect product; (2) promptly conduct an investigation to determine whether the product is an illegitimate product or, for a third-party logistics provider, notify the owner of the need to conduct such an investigation; and (3) for manufacturers, beginning four years after enactment, verify the product at the package level, including the standardized numerical identifier. Requires entities to maintain records of such activities for six years. Requires a manufacturer, wholesale distributor, dispenser or re-packager, upon a determination that	

	a product in its possession or control is an illegitimate product, to: (1) quarantine the product (except that this does not apply to dispensers), (2) remove the product from the pharmaceutical distribution supply chain, (3) take reasonable and appropriate steps to assist a trading partner to remove such product from the supply chain, (4) retain a sample of the product for further physical examination or laboratory analysis, and (5) notify the Secretary and all immediate trading partners within 24 hours. Requires a third-party logistics provider, upon such a determination, to promptly notify the owner of the need to remove the product from the pharmaceutical distribution supply chain, promptly transfer possession of the product to the owner, and notify the Secretary within 24 hours. Requires a manufacturer to notify the Secretary and immediate trading partners within 24 hours if the manufacturer has reason to believe that there is a high risk that a product in the trading partner & rsquo; possession is an illegitimate product. Requires a manufacturer or re-packager to respond within 24 hours or in other reasonable time as determined by the Secretary after receiving a verification request from an authorized re-packager, wholesale distributor or dispenser whether the product identifier corresponds to the product identifier it affixed or imprinted. Requires the manufacturer, wholesale distributor, or re-packager to verify the product identifier of a returned product that it intends to further distribute. Allows the wholesale distributor to accept a returned product from a dispenser and distribute it without the transaction history for the next six years. Permits a wholesale distributor, beginning six years after enactment, to accept a returned product from a dispenser only if the wholesale distributor can associate the returned product with the transaction information and transaction statement associated with that product. Allows a dispenser or re-packager to return a product to the trading partner from which the dispenser purchased the product without providing the transaction documentation. Authorizes a dispenser to enter into an agreement under which a third party confidentially maintains transaction documentation on the dispenser's behalf. Exempts a wholesale distributor that does not physically handle or store products from the provisions of this Act, except the notification requirements related to illegitimate products, provided the transaction documentation is given to the dispenser by the manufacturer, re-packager, or other wholesale distributor that distributes the product. (Sec. 203) Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect ten years after enactment of this Act, including those relating to: Requires the Secretary to provide alternative methods of compliance with such requirements, including establishing a timeline for compliance by small businesses. Directs the Secretary to enter into a	

	contract with a consulting firm to conduct a technology and software assessment that looks at the feasibility of dispensers conducting interoperable, electronic tracing of products at the package level. Sets forth guidance documents to be issued by the Secretary related to suspect and illegitimate products, secure tracing at the package level, and the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain. Requires the Secretary to establish pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. (Sec. 204) Requires wholesale distributors operating in a state without licensure requirements to be licensed by the Secretary. Requires wholesale distributors to be licensed by the state into which the drug is distributed if the state requires it. Establishes annual reporting requirements for wholesale distributors. Requires the Secretary to establish a database of licensed wholesale distributors. Authorizes the Secretary to collect fees for licensure. Requires third-party logistics providers to obtain a license from the Secretary, but not a license as a wholesale distributor if the entity never assumes an ownership interest in the products it handles. Requires the Secretary to establish minimum standards, terms, and conditions for the state or federal licensing of wholesale distributors. Lists the requirements for such minimum standards. (Sec. 205) Prohibits a third-party logistics provider in any state from conducting activities unless each facility of the provider is: (1) licensed by the state from which the drug is distributed by the provider and the state into which the drug is distributed, or (2) licensed by the Secretary if the state has not established a licensure requirement. Establishes annual reporting requirements for the facilities of a third-party logistics provider. Authorizes the Secretary to assess licensure fees. Requires the Secretary to establish minimum requirements for the licensure of third-party logistics providers. Preempts state or local government requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements under this Act, or which are inconsistent with any waiver, exception, exemption or restriction under this Act. Prohibits any state or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or third-party logistics providers that are less stringent than the standards under this Act. Prohibits a state from regulating a third-party logistics providers as a wholesale distributor. (Sec. 206) Deems a drug to be misbranded if it does not contain a product identifier as required by this Act.	

S 1277	*Combatting Prescription Drug Abuse Act* Official Title: A bill to establish a commission for the purpose of coordinating efforts to reduce prescription drug abuse, and for other purposes. Introduced by: Barbara Boxer (D-CA) (1 Co-sponsor) Establishes the Combating Prescription Drug Abuse Commission composed of 30 members that include an equitable balance of individuals representing health care groups and law enforcement groups, including: (1) a representative of the DEA; (2) a representative of the FDA; (3) a representative of ONDCP; (4) representatives of patient, advocacy and community-based groups; (5) representatives of pharmacy, prescribers, hospitals, wholesalers, dispensers, manufacturers and other health care groups; (6) public policy experts; (7) representatives of state attorneys general; and (8) representatives of law enforcement officials, including local law enforcement officials.	7/16/13 - Sponsor introductory remarks on measure 7/10/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee
S 1322	*Synthetic Abuse and Labeling of Toxic Substances Act of 2013 (SALTS Act)* Official Title: A bill to amend the Controlled Substances Act relating to controlled substance analogues. Introduced by: Amy Klobuchar (D-MN) (3 Co-sponsors) Amends the Controlled Substances Act to consider certain factors in determining whether a controlled substance analogue was intended for human consumption. Moreover, adds that "evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, shall not be sufficient to establish that the substance was not intended for human consumption."	9/25/13 - Hearing by the Senate Caucus on International Narcotics Control 7/18/13 - Read twice and referred to the Committee on the Judiciary
S 1323	*Protecting our Youth from Dangerous Synthetic Drugs Act of 2013* Official Title: A bill to address the continued threat posed by dangerous synthetic drugs by amending the Controlled Substances Act relating to controlled substance analogues. Introduced by: Dianne Feinstein (D-CA) (7 Co-sponsors) Amends the Controlled Substances Act to define a controlled substance analogue as (1) a substance whose chemical structure is substantially similar to the chemical structure of a controlled substance in schedule I or II (a) which has a stimulant, depressant or hallucinogenic effect on the central nervous	9/25/13 - Hearing by the Senate Caucus on International Narcotics Control 7/18/13 - Read twice and referred to the Senate Judiciary Committee

	system that is substantially similar to or greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (b) with respect to a particular person, which such person represents or intends to have a stimulant, depressant or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (2) a substance designated as a controlled substance analogue by the Controlled Substance Analogue Committee . . . and the Attorney General, in consultation with the Secretary of HHS. The Committee will be (1) headed by the Administrator of the DEA; and (2) comprised of scientific experts in the fields of chemistry and pharmacology from (a) the DEA; (b) NIDA; (c) CDC; and (d) any other federal agency determined by the Attorney General, in consultation with the Secretary of HHS.	
S 1657	*A Bill to Reduce Prescription Drug Misuse and Abuse* Official Title: A bill to reduce prescription drug misuse and abuse Introduced by: Tom Udall (D-NM) (1 Co-sponsor) Amends section 399O of the Public Health Service Act (42 U.S.C. 243g-3) and ensures that states create PDMPs that (1) are interoperable with those in other states, federal agencies and across appropriate state agencies, including health agencies, as determined by the Secretary; (2) are interoperable with electronic health records and e-prescribing, where appropriate; and (3) provide automatic, real-time or daily information about a patient when a practitioner requests information about such patient, among other things. Awards five-year grants to eligible entities to facilitate training in order to increase the capacity of health care providers to conduct patient screening and brief interventions to prevent the abuse of prescription drugs and other controlled substances. Also awards grants to states to develop continuing education criteria and review processes that allow state health profession boards or state agencies to certify appropriate education and training for informed and safe prescribing of opioids and other drugs on Schedules II and III under section 202 of the Controlled Substances Act (21 U.S.C. 812).	11/6/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee