

## 2013-2014 Federal Bills Table

## Research current through April 10, 2014

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	HOUSE	
HR 315	Synthetic Cathinones Control Act of 2013  Official Title: To provide for the placement of certain synthetic	2/28/13 - Referred to the Subcommittee on Crime, Terrorism,
	drugs on Schedule I under the Controlled Substances Act.	Homeland Security & Investigations
	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	1/18/13 - Referred to the House Judiciary Committee
	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	1/18/13 - Referred to the Subcommittee on Health
	21 of the Code of Federal Regulations.	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	2/8/13 - Referred to the Subcommittee on
	Official Title: To amend the Federal Food, Drug and Cosmetic Act to incentivize the development of abuse-deterrent drugs.	Health
	Introduced by: William Keating (D-MA-9) (14 Co-sponsors)	2/4/13 - Referred to the House Energy and Commerce Committee
	Amends the Federal Food, Drug and Cosmetic Act to prescribe new drug application requirements for abuse-deterrent drugs: (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	

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IID 400	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.	2/14/12 Survey?
HR 498	Sober Truth on Preventing Underage Drinking Reauthorization Act	2/14/13 - Sponsor's introductory remarks on measure
	Official Title: To provide for programs and activities with respect to the prevention of underage drinking  Introduced by: Lucille Roybal-Allard (D-CA-40) (64 Co-	2/8/13 - Referred to the House Subcommittee on Health
	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 adolescents for alcohol use, to reduce the prevalence of alcohol use among individuals under the age of 21, including college	2/5/13 - Referred to the House Energy and Commerce Committee

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	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	2/28/13 - Referred to
	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.	the Subcommittee on Crime, Terrorism, Homeland Security & Investigations
	purposes.	2/25/13 - Referred to
	Introduced by: Jared Polis (D-CO-2) (16 Co-sponsors)	the Subcommittee on Conservation, Energy
	Directs the Attorney General to issue a final order that removes marijuana in any form from all schedules of controlled	and Forestry
	substances under the Controlled Substances Act. Amends such	2/14/13 - Referred to
	Act to: (1) provide that Schedules I, II, III, IV, and V shall	the Subcommittee on
	consist of the drugs and other substances that are set forth in the	Public Lands and
	respective Schedules in part 1308 of title 21 of the CFR; (2)	Environmental
	exempt marijuana from such Act except as provided in this Act;	Regulation
	(3) revise the definition of "felony drug offense" to exclude	
	conduct relating to marijuana; and (4) eliminate marijuana from	2/8/13 - Referred to the
	provisions setting forth penalties applicable to prohibited	Subcommittee on
	conduct under such Act. Prohibits shipping or transporting	Health
	marijuana from any place outside a jurisdiction of the United	2/5/13 - Referred to the
	States into such a jurisdiction in which its possession, use, or sale is prohibited. Eliminates marijuana as: (1) a controlled	House Agriculture
	substance for purposes of the Controlled Substances Import and	Committee
	Export Act or the National Forest System Drug Control Act of	Committee
	1986, (2) a dangerous drug for purposes of federal criminal	2/5/13 - Referred to the
	code provisions authorizing interception of communications,	House Natural
	and (3) a targeted drug for purposes of provisions of the	Resources Committee
	national youth anti-drug media campaign under the ONDCP	
	Reauthorization Act of 1998. Amends the Federal Alcohol	2/5/13 - Referred to the
	Administration Act to set forth procedures for the issuance and	House Ways and
	revocation by the Secretary of the Treasury of permits for	Means Committee
	importing, shipping or selling in interstate or foreign commerce,	
	purchasing for resale, producing, packaging, or warehousing	2/5/13 - Referred to the
	marijuana. Prohibits any person from engaging in such conduct	House Energy and
	without a permit, subject to a \$1,000 fine and/or a \$500	Commerce Committee
	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 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  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	2/5/13 - Referred to the House Ways and Means Committee
	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.	
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.	4/8/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations
	Introduced by: Earl Blumenauer (D-OR-3) (23 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	2/15/13 - Referred to the Subcommittee on Health

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	Controlled Substances Act (CSA) and to recommend listing it	2/14/13 - Referred to
	as other than a schedule I or schedule II substance. Requires the	the House Judiciary
	Administrator of DEA, within one year of enactment of this	Committee
	Act, based upon such recommendation, to issue a notice of	2/14/12 7 2
	proposed rulemaking for the rescheduling of marijuana within	2/14/13 - Referred to
	the CSA, which shall include a recommendation to list	the House Energy and
	marijuana as other than a schedule I or schedule II substance.	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	2/14/13 - Referred to
	use of marijuana is legal under state law, prohibit or otherwise	the Committee on
	restrict: (1) the prescription or recommendation of marijuana	Energy and Commerce
	for medical use by a medical professional or the certification by	and to the Committee
	a medical professional that a patient has a condition for which	on the Judiciary, in
	marijuana may have therapeutic benefit; (2) an individual from	each case for
	obtaining, manufacturing, possessing, or transporting within his	consideration of such
	or her state marijuana for medical purposes, provided the	provisions as fall
	activities are authorized under state law; (3) a pharmacy or	within the jurisdiction
	other entity authorized to distribute medical marijuana from	of the committee
	obtaining, possessing or distributing marijuana to authorized	concerned.
	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.	
HR 672	Prescription Drug Abuse Prevention and Treatment Act of 2013	4/8/13 - Referred to the
		Subcommittee on
	Official Title: To provide for increased federal oversight of	Crime, Terrorism,
	prescription opioid treatment and assistance to states in	Homeland Security &
	reducing opioid abuse, diversion and deaths.	Investigations
		0/15/12 D C 14
	Introduced by: Nick Rahall (D-WV-3) (No Co-sponsors)	2/15/13 - Referred to
		the Subcommittee on
	Amends the Public Health Service Act to direct the	Health
	Administrator of SAMHSA to award grants to states and	2/12/12 B C 14
	nonprofit entities for consumer education about opioid abuse,	2/13/13 - Referred to
	including methadone abuse. Amends the Controlled Substances	the House Judiciary
	Act to: (1) set forth training requirements for practitioners	Committee
	registered to prescribe or dispense methadone or other opioids,	2/12/12 D.C. 14
	and (2) require each registered opioid treatment clinic to make	2/13/13 - Referred to
	acceptable arrangements for each patient who is restricted from	House Energy and
	having a take-home dose of a controlled substance related to	Commerce Committee
	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, 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. Truth in Trials Act

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 of the committee concerned.

HR 710

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) (15 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)

4/8/13 - Referred to the Subcommittee on Crime, Terrorism. Homeland Security & **Investigations** 

2/14/13 - Referred to the House Judiciary Committee

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	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.	
HR 752	Methamphetamine Education, Treatment, and Hope Act of 2013	2/15/13 - Referred to
		the Subcommittee on
	Official Title: To amend the Public Health Service Act to	Health
	provide for the establishment of a drug-free workplace	
	information clearinghouse, to support residential	2/15/13 - Referred to
	methamphetamine treatment programs for pregnant and	the House Energy and
	parenting women, to improve the prevention and treatment of	Commerce Committee
	methamphetamine addiction, and for other purposes.	
	menumphetamine addresson, and for other purposes.	
	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)	
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	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	4/8/13 - Referred to the
	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.	Subcommittee on Crime, Terrorism, Homeland Security & Investigations
	Introduced by: Barbara Lee (D-CA-13) (11Co-sponsors)	2/15/13 - Referred to the Subcommittee on
	Exempts real property from civil forfeiture under the Controlled Substances Act due to medical marijuana-related conduct that is	Health
	authorized by state law.	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	2/28/13 - Referred to the House Ways and
	Official Title: To amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs.	Means Committee
	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.	
HR 964	Respect States' and Citizens' Rights Act of 2013	4/8/2013 - Referred to the Subcommittee on
	Official Title: To amend the Controlled Substances Act to provide that federal law shall not preempt state law.	Crime, Terrorism, Homeland Security & Investigations
	Introduced by: Diana DeGette (D-CO-1) (9 Co-sponsors)	Č

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	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.	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 House Judiciary 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	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	3/12/13 - Referred to the House Ways and Means Committee
HR 1285 (See also S 621)	the use of illegal drugs.  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.	4/15/13 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security & Investigations

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	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.	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 House Energy and Commerce and 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	3/22/13 - Referred to the Subcommittee on
	Official Title: To direct the Commissioner of Food and Drugs to modify the approval of any drug containing controlled-	Health
	release oxycodone hydrochloride to limit such approval to use	3/21/13 - Referred to
	for the relief of severe-only instead of moderate-to-severe pain, and for other purposes.	the House Energy and Commerce Committee
	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.	
HR 1523	Respect State Marijuana Laws Act of 2013	4/30/13 - Referred to
	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.	the Subcommittee on Crime, Terrorism, Homeland Security & Investigations

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	Introduced by Dana Rohrabacher (R-CA-38) (26 Co-sponsors)  Amends the Controlled Substances Act to provide that provisions of such Act related to marihuana shall not apply to	4/12/13 - Referred to the Subcommittee on Health
	any person acting in compliance with state laws relating to the production, possession, distribution, dispensation, administration or delivery of marijuana.	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	4/30/13 - Referred to the Subcommittee on
	Official Title: To establish the National Commission on Federal Marijuana Policy.	Crime, Terrorism, Homeland Security & Investigations
	Introduced by Steve Cohen (D-TN-9) (10 Co-sponsors)	4/19/13 - Referred to
	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	the Subcommittee on Health
	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	4/18/13 - Referred to the House Foreign Affairs Committee
	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	4/18/13 - Referred to the Subcommittee on Financial Services
	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	4/18/13 - Referred to the House Ways and Means Committee
	collateral consequences of prosecution for marijuana possession; (7) recommendations for the appropriate placement	

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	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.	4/18/13 - 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	6/4/13 - Received in
	Official Title: To amend the Federal Food, Drug and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes.	the Senate and read twice and referred to the House Health, Education, Labor and Pensions Committee
	Introduced by Robert Latta (R-OH-5) (20 Co-sponsors)	6/3/13 - Passed in
	Establishes national standards for the FDA to monitor the distribution of prescription drugs. Imposes new regulatory	House
	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.	6/3/13 - On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.
	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.	6/3/13 - DEBATE: The House proceeded with forty minutes of debate
	Pharmaceutical tracing requirements for drug lots would be established for makers, wholesale distributors, pharmacies and re-packagers.	6/3/13 - Considered under suspension of the rules
	Drug suppliers, including third-party logistics providers, would be required to do business only with registered or licensed	6/3/13 - Mr. Latta moved to suspend the

	entities. Makers would have to serialize prescription drugs at the unit level.	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	5/10/13 - Referred to the Subcommittee on
	Official Title: To prohibit the manufacture, marketing, sale or shipment in interstate commerce of products designed to assist in defrauding a drug test.	Commerce, Manufacturing and Trade
	Introduced by Eliot Engel (D-NY-16) (1 Co-sponsor)	5/9/13 - Referred to the House Energy and
	Makes it unlawful to knowingly manufacture, market, sell, ship or otherwise provide to another individual any product with the 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.	Commerce Committee
HR 2130	Access to Substance Abuse Treatment Act of 2013	5/24/13 - Referred to
	Official Title: To amend the Public Health Service Act to provide grants for treatment of heroin, cocaine,	the Subcommittee on Health
	methamphetamine, 3,4-methylenedioxymethamphetamine (ecstasy), and phencyclidine (PCP) abuse and for other purposes.	5/23/13 - Referred to the House Energy and Commerce Committee
	Introduced by Matthew Cartwright (D-PA-17) (28 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,	

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	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 reentering 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 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 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.	2/14/14 - The Treasury Department announced that it would allow banks to accept

	Introduced by Ed Perlmutter (D-CO-7) (29 Co-Sponsors)	accounts from legal
	·	marijuana businesses
	Prohibits a federal banking regulator from: (1) terminating or	-
	limiting the deposit insurance of a depository institution solely	The Treasury
	because it either provides or has provided financial services to a	Department's new
	marijuana-related legitimate business; or (2) prohibiting,	policy would allow an
	penalizing or otherwise discouraging a depository institution	industry that is illegal
	from providing financial services to a marijuana-related	in a majority of U.S.
	legitimate business. Prohibits a federal banking regulator, in	states to open business-
	addition, from recommending, motivating, providing incentives	checking accounts and
	or encouraging a depository institution not to offer financial	accept credit cards.
	services to an individual, or to downgrade or cancel financial	-
	services offered to an individual, solely because the individual:	To contain the dangers
	(1) is or later becomes a manufacturer, producer, owner or	of operating an all-cash
	operator of a marijuana-related legitimate business; or (2) the	business, the Treasury's
	depository institution was not aware that the individual is the	FinCen issued
	owner or operator of a marijuana-related legitimate business.	guidelines for banks.
	Prohibits a federal banking regulator from taking any action on	The guidelines were
	a loan to an owner or operator of: (1) a marijuana-related	sought by marijuana
	legitimate business, or (2) real estate or equipment that is leased	businesses and the
	to a marijuana-related legitimate business. Grants immunity	governors of Colorado
	from federal criminal prosecution or investigation to a	and Washington state,
	depository institution providing financial services to a	whose voters in 2012
	marijuana-related legitimate business. Prohibits the Secretary of	approved ballot
	the Treasury from requiring a depository institution, and any	measures allowing
	director, officer, employee or agent of a depository institution,	marijuana sales and use
	to report a transaction as suspicious solely because a party to	for recreation.
	the transaction is a marijuana-related legitimate business.	9/13/13 - Referred to
		the Subcommittee on
		Crime, Terrorism,
		Homeland Security &
		Investigations
		, <b>0</b> 501540115
		7/10/13 - Referred to
		House Financial
		Services and House
		Judiciary
HR 3204	Drug Quality and Security Act	11/27/13 - Became
	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Public Law No: 113-54
Public	Official Title: To amend the Federal Food, Drug and Cosmetic	
Law No:	Act with respect to human drug compounding and drug supply	11/27/13 - Signed by
113-54	chain security and for other purposes.	President
	Introduced by Fred Upton (R-MI-06) (10 Co-sponsors)	

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	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.	
HR 3528	National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act of 2013	11/22/13 - Referred to the Subcommittee on Health
	Official Title: To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.	11/18/13 - Referred to the House Committee on Energy and
	Introduced by Ed Whitfield (R-KY-01) (2 Co-sponsors)	Commerce
	Provides grants to states to enhance their prescription monitoring programs (PMPs).	
HR 3717	Helping Families in Mental Health Crisis Act of 2013	4/3/14 - Subcommittee Hearings held
	Official Title: To make available needed psychiatric, psychological and supportive services for individuals diagnosed with mental illness and families in mental health crisis, and for other purposes	1/27/14 - Referred to the Subcommittee on Crime, Terrorism, Homeland Security &
	Introduced by Tim Murphy (R-PA-18) (70 Co-sponsors)	Investigations.
	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;

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		Referred to House Education and the Workforce; Referred to House Judiciary; Referred to House Energy and Commerce
HR 4069	Ensuring Patient Access and Effective Drug Enforcement Act of 2013	4/7/14 - Subcommittee hearings held
	Official Title: To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes	3/20/14 - Referred to the House Subcommittee on
	Introduced by Tom Marino (R-PA-10) (3 Co-sponsor)	Crime, Terrorism, Homeland Security,
	Amends the Controlled Substances Act by requiring that companies registered with the DEA ensure employees with	and Investigations
	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.	2/18/14 - Referred to the House Energy and Commerce Committee
	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.	2/18/14 - Referred to the House Judiciary Committee
	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 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 4169	Stop Overdose Stat Act or the S.O.S. Act	3/6/14 - Referred to the
	Official Title: To prevent deaths occurring from drug overdoses.	House Energy and Commerce Committee
	Introduced by Donna Edwards (D-MD-04) (20 Co-sponsors)	
	Awards grants or cooperative agreements, through the CDC, to eligible entities to enable them to reduce deaths occurring from overdoses of drugs. Conditions receipt of a grant or cooperative agreement under this section, on agreement to use the grant or cooperative agreement to purchase and distribute the drug naloxone.	
	Requires the Secretary of HHS, in consultation with a task force comprised of stakeholders, to develop a plan to reduce the number of deaths occurring from overdoses of drugs and submit the plan to Congress.	
HR 4241	An Act to Ban Zohydro	3/13/14 - Referred to the House Committee
	Official Title: To withdraw approval for the drug Zohydro ER and prohibit the Food and Drug Administration from approving such drug unless it is reformulated to prevent abuse	on Energy and Commerce
	Introduced by Stephen Lynch (D-MA-08) (17 Co-sponsors)	
HR 4288	Opioid Overdose Reduction Act of 2014  Official Title: To provide certain protections from civil liability with respect to the emergency administration of opioid overdose drugs.	3/24/14 - Referred to the House Committee on the Judiciary
	Introduced by Richard Neal (D-MA-01) (No Co-sponsors)	
	Limits civil liability for (1) healthcare professionals; (2) individuals working for, or volunteering at, a state or local agency opioid overdose program; or (3) other individuals who provide or administer opioid overdose drugs, unless the individuals cause harm by the gross negligence or reckless misconduct of the individual who administers the drug.	
H Res 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	4/19/13 - Referred to the Subcommittee on Health
	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.	4/15/13 - Referred to the House Energy and Commerce Committee

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	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.  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 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	2/14/13 - Read twice and referred to the Health, Education, Labor and Pensions Committee
	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	Safe Prescribing Act of 2013	3/20/13 - Read twice
(See also HR 1285)	Official Title: A bill to amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug.	and referred to the Senate Judiciary Committee
	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.	
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.	3/21/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee
	Introduced by: Robert Casey (D-PA) (5 Co-sponsors)	
	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	

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	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	4/11/13 - Placed on
		Senate Legislative
	Official Title: A bill to reauthorize and improve programs	Calendar
	related to mental health and substance use disorders.	
		4/11/13 - Placed on
	Introduced by: Tom Harkin (D-IA) (23 Co-sponsors)	Senate Legislative Calendar
	Title I: Education Programs - Achievement Through Prevention	
	Act - (Sec. 103) Amends part A of title I of the Elementary and	4/11/13 - Committee on
	Secondary Education Act of 1965 (ESEA) to allow states, local	Health, Education,
	educational agencies (LEAs), and schools to use school	Labor and Pensions.
	improvement funds to implement school-wide positive	
	behavioral interventions and supports and early intervening	4/10/13 - Reported by
	services and coordinate them with similar activities carried out	Senator Harkin (with
	under the Individuals with Disabilities Education Act. (Early	an amendment) in the
	intervening services are a set of coordinated services for	and ordered to be
	students in kindergarten through grade 12 who are not currently	reported to the Senate
	identified as needing special education or related services, but	Health, Education,
	who need additional academic and behavioral support to	Labor and Pensions
	succeed in a general education environment.)Revises	Committee
	requirements for state educational agency (SEA) reports and	4/9/13 - Read twice and
	LEA plans to include information relating to such interventions	referred to the Senate
	and services. Requires school-wide programs to implement such interventions and services, and LEAs to ensure the	Health, Education,
	provision of technical assistance to schools for that	Labor and Pensions
	implementation. Requires school improvement plans to specify	Committee
	whether the LEA or school will adopt and implement related	Committee
	policies or practices. Allows LEA improvement plans to	
	poneres of practices. Allows LLA improvement plans to	1

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

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	(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	4/11/13 - Read twice
5 700	Transmitted Ding Trafficking file of 2013	and referred to the
	Official Title: A bill to provide the Department of Justice with	Senate Judiciary
	additional tools to target extraterritorial drug trafficking	Committee
	1	Commute
	activity, and for other purposes.	
	Introduced by Dienna Faingtoin (D.CA) (6 Co. gnangers)	
	Introduced by: Dianne Feinstein (D-CA) (6 Co-sponsors)	

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	Amends the Controlled Substances Import and Export Act to prohibit the manufacture or distribution of a controlled 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	6/19/13 - Placed on
	2 3, ,	Senate Legislative
	Official Title: A bill to amend the Federal Food, Drug, and	Calendar
	Cosmetic Act with respect to compounding drugs.	
		6/19/13 - Reported by
	Introduced by: Tom Harkin (D-IA) (5 Co-sponsors)	Senator Harkin (with
	Amends the Federal Food, Drug and Cosmetic Act (FFDCA) to	two amendments) to the Senate Health,
	expand the regulation of compounded drugs. Subjects a	Education, Labor and
	compounded drug to all FFDCA requirements applicable to	Pensions Committee
	new drugs. Sets forth exceptions from new drug requirements,	T Chipronis Committee
	biological product requirements, labeling requirements, and	5/22/13 - Ordered to be
	good manufacturing practice requirements for a drug that: (1) is	reported to the Senate
	compounded by a traditional compounder, and (2) meets	Health, Education,
	applicable requirements. Defines & Idquo; traditional	Labor and Pensions
	compounder & rdquo; as a facility operating pursuant to state	Committee
	law that meets certain criteria, including that a drug is	5/15/12 P 1:
	compounded by a licensed pharmacist or licensed physician	5/15/13 - Read twice
	pursuant to a prescription order for an identified individual	and referred to the
	patient or compounded in limited qualities before a prescription order based on history of receiving such prescription orders.	Senate Health, Education, Labor and
	Includes as a traditional compounder hospitals and health	Pensions Committee
	systems (collection of hospitals) that compound drugs only to	1 chistoris Committee
	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 & Idquo; 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 (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 repackager 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, repackager, or third-party logistics provider to maintain the transaction documentation for each transaction (or, for a thirdparty 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 repackager 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 repackagers 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) guarantine 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 repackager 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

S 1277	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.  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) (2 Co-sponsors)  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 pharmacy, prescribers, hospitals, wholesalers, dispensers, manufacturers and other health care groups; (6) public policy experts; (7) representatives of state attorneys general; and (8)	7/16/13 - Sponsor introductory remarks on measure 7/10/13 - Read twice and referred to the Senate Health, Education, Labor and Pensions Committee
	representatives of state attorneys general, and (6) representatives of law enforcement officials, including local law enforcement officials.	
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.	9/25/13 - Hearing by the Senate Caucus on International Narcotics Control
	Introduced by: Amy Klobuchar (D-MN) (5 Co-sponsors)	7/18/13 - Read twice and referred to the

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	Amends the Controlled Substances Act to consider certain	Committee on the Judiciary
	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."	Judiciary
S 1323	Protecting our Youth from Dangerous Synthetic Drugs Act of 2013  Official Title: A bill to address the continued threat posed by	9/25/13 - Hearing by the Senate Caucus on International Narcotics Control
	dangerous synthetic drugs by amending the Controlled	Control
	Substances Act relating to controlled substance analogues.	7/18/13 - Read twice and referred to the
	Introduced by: Dianne Feinstein (D-CA) (7 Co-sponsors)	Senate Judiciary Committee
	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	
	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	
Q 1657	Attorney General, in consultation with the Secretary of HHS.	11/6/12 Dand
S 1657	Increasing the Safety of Prescription Drug Use Act of 2013  Official Title: A bill to reduce prescription drug misuse and	11/6/13 - Read twice and referred to the Senate Health,
	abuse	Education, Labor and Pensions Committee
	Introduced by: Tom Udall (D-NM) (1 Co-sponsor)	

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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).

S 1675 Recidivism Reduction and Public Safety Act of 2014

Official Title: A bill to reduce recidivism and increase public safety, and for other purposes.

Introduced by: Sheldon Whitehouse (D-RI) (6 Co-sponsors)

Amends the federal criminal code to direct the Bureau of Prisons to offer evidence-based recidivism reduction programs to prisoners who have been assessed to need to participate in such programs. Permits a reduction in the period a prisoner remains in custody after successfully participating in such a program, at the Bureau's discretion, by no more than 60 days per year of participation. Prohibits the combined credit awarded for successful completion of such a program and a program of residential substance abuse treatment from exceeding 15% of the prisoner's total sentence.

Directs the Attorney General to develop, and the Bureau to use, a methodology and procedures to assess the recidivism risk factors of all prisoners committed to the Bureau's custody for a term of imprisonment other than life imprisonment and to identify programming to reduce the risk factors. Requires United States Probation and Pretrial Services (USPPS) to report annually on rates of recidivism among individuals who have

3/11/14 - Amendment in the Senate Judiciary Committee; Placed on the Senate Legislative Calendar under General Orders

3/6/14 - Reported to the Senate Judiciary Committee

11/17/13 - Referred to the Senate Judiciary Committee

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	been released from federal prison and who are under USPPS supervision.	
	Requires: (1) the Administrative Office of the Courts to evaluate best practices used for the reentry into society of individuals released from the custody of the Bureau, (2) the Attorney General to select an appropriate number of federal judicial districts to conduct federal reentry demonstration projects using such best practices, (3) such Office to evaluate the results from each district selected, and (4) the Attorney General to report on the impact of reentry of prisoners on communities in which a disproportionate number of individuals reside upon release from incarceration.	
	Requires a probation officer's pre-sentence report to include: (1) information about the defendant's history of substance abuse and addiction; and (2) a detailed plan to reduce the likelihood the defendant will abuse drugs or alcohol, to reduce the likelihood of recidivism by addressing the defendant's specific risk factors, and to assist the defendant preparing for reentry into the community.	
	Requires the Bureau to ensure that each eligible prisoner has an opportunity to commence participation in a substance abuse treatment program by the date necessary to ensure that the prisoner completes such treatment not later than one year before the prisoner would otherwise be released from custody prior to any reduction in sentence for such participation. Directs USPPS to establish a five-year recidivism reduction and recovery enhancement pilot program in selected federal judicial districts.	
S 2092	Opioid Overdose Reduction Act of 2014	3/6/14 - Read twice and
	Official Title: A bill to provide certain protections from civil liability with respect to the emergency administration of opioid overdose drugs.	Referred to the Senate Committee on the Judiciary
	Introduced by Ed Markey (D-MA) (No Co-sponsors)	
	Limits civil liability for (1) healthcare professionals; (2) individuals working for, or volunteering at, a state or local agency opioid overdose program; or (3) other individuals who provide or administer opioid overdose drugs, unless the individuals cause harm by the gross negligence or reckless misconduct of the individual who administers the drug.	

S 2134	An Act to Ban Zohydro	3/13/14 - Read twice and referred to the
	Official Title: A bill to withdraw approval for the drug Zohydro	Senate Committee on
	ER and prohibit the Food and Drug Administration from	Health, Education,
	approving such drug unless it is reformulated to prevent abuse.	Labor, and Pensions
	Introduced by: Joe Manchin (D-WV) (No co-sponsors)	
	Withdraws approval of pure hydrocodone bitartrate extended-	
	release capsules (marketed as the drug Zohydro ER) under	
	section 505(c) of the Federal Food, Drug, and Cosmetic Act (21	
	U.S.C. 355(c)); orders the Commissioner of the FDA to NOT	
	approve any application under section 505 of the Federal Food,	
	Drug, and Cosmetic Act (21 U.S.C. 355) for pure hydrocodone bitartrate extended-release capsules unless the drug is	
	formulated to prevent abuse.	
S Res 389	A Resolution Designating the Week of March 9 -15, 2014, as	3/13/14 - Submitted in
	"National Youth Synthetic Drug Awareness Week."	the Senate, considered,
	, o	and agreed to without
	Official Title: A resolution designating the week of March 9,	amendment and with a
	2014, through March 15, 2014, as "National Youth Synthetic	preamble by
	Drug Awareness Week."	unanimous consent
	Introduced by: Amy Klobuchar (D-MN) (2 Co-sponsors)	
	Recognizes incidents of violent acts, some leading to serious injury and death, committed by people under the influence of synthetic drugs; focuses on deceptive marketing by sellers of, and easy access to, synthetic drugs; identifies that educating the	
	public, and especially youth, on the dangers of synthetic drugs	
	and promoting prevention of synthetic drug abuse are critical components of a multi-pronged effort to curb synthetic drug	
	abuse; designates the week of March 9 -15, 2014, as "National	
	Youth Synthetic Drug Awareness Week;" and urges	
	communities to carry out appropriate programs and activities to	
	educate parents and youth about the dangers associated with	
	synthetic drug abuse.	