NOVEL PSYCHOACTIVE SUBSTANCES : TIANEPTINE (UPDATE)

DECEMBER 2025

The Legislative Analysis and Public Policy Association (LAPPA) is continuing to monitor the emergence of various novel psychoactive substances (NPS) appearing on the illicit drug market in the United States. The term "novel" does not denote a new, never-before-seen substance but rather a substance that is newly available in the drug market. This fact sheet is just one in a series highlighting these potentially dangerous drugs and examines tianeptine, an unapproved drug commonly sold in gas stations and on the internet as a dietary supplement and causes opioid-like withdrawals.

Discovered and patented in the 1960s, tianeptine is an antidepressant drug structurally similar to tricyclic antidepressants that is sold as a prescription medication under the brand names Coaxil and Stablon in some European, Asian, and Latin American countries.[1] In the United States, however, tianeptine is not a drug approved by the U.S. Food and Drug Administration (FDA). Despite not being an FDA approved drug, tianeptine is available for purchase in the U.S. as a dietary supplement under brand names such as "Neptune's Fix," "Zaza Red," "TD Red," and "Tianna." Dietary supplements containing tianeptine can be purchased in gas stations, head shops, and on the internet and can be in pill, liquid, or powder form. Ads for supplements containing tianeptine claim that the product reduces pain and provides stress relief.

Animal and human studies show that tianeptine is a mu-opioid receptor agonist.[2] For this reason, experts believe that individuals who ingest tianeptine may develop a dependance and addiction to the substance. This risk increases for individuals with a history of opioid misuse and addiction, and FDA reports suggest that adverse events may occur when an individual takes tianeptine at high doses. Medical journals and reports to the FDA have indicated that U.S. consumers take daily doses of tianeptine between 1.3 and 250 times the daily dose typically recommended for tianeptine products approved in other countries.[3] Several case studies show that tianeptine toxicity mimics opioid toxicity and that individuals experience tianeptine withdrawal symptoms similar to those of opioid withdrawal. There are also reports of infants experiencing withdrawal from tianeptine, with symptoms that mimic those of infants withdrawing from opioid dependence, after tianeptine use during pregnancy. The parallels between opioids and tianeptine, coupled with tianeptine's availability at gas stations, led to the media nicknaming the substance "gas station heroin." Similar to heroin, naloxone reverses the effects of an overdose from tianeptine.

Tianeptine use in the U.S. has been on the rise in recent years. A 2018 study published in the *Morbidity and Mortality Weekly Report* issued by the U.S. Centers for Disease Control and Prevention (CDC) examined calls to U.S. poison control centers between 2000 and 2017 for tianeptine exposure.[4] The study found that in the 14 years between 2000 and 2013, the National Poison Data System (NPDS) received a total of 11 tianeptine exposure

[1] Tricyclic antidepressants are a class of medications used in the management and treatment of major depressive disorder. They are second-line treatments, usually considered after trying selective serotonin reuptake inhibitors (SSRIs). Jordan Moraczewski and Kapil K. Aedma, "Tricyclic Antidepressants," National Institutes of Health, National Library of Medicine (Nov. 21, 2022), https://www.ncbi.nlm.nih.gov/books/NBK557791/.

[2] Mu-opioid receptors are a type of receptor in the brain that is responsible for pain control, drug reward, and addictive behaviors. Mu-opioid receptor agonists, such as morphine and heroin, effectively bind to mu-opioid receptors and produce a physiological response in the body. Gavril W. Pasternak and Ying-Xian Pan, "Mu-opioids and Their Receptors: Evolution of a Concept," *Pharmacological Reviews* 64, no. 4 (October 2013): 1257-1317, https://doi.org/10.1124/pr.112.007138.

[3] "Tianeptine Products Linked to Serious Harm, Overdoses, Death," U.S. Food and Drug Administration, last modified May 9, 2025, https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death.

[4] Tharwat El Zahran, et al., "Characteristics of Tianeptine Exposures Reported to the National Poison Data System- United States, 2000-2017," *Morbidity and Mortality Weekly Report* 67, no. 30 (August 2018): 815-818, https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6730a2-H.pdf.

calls.[5] Starting in 2014, however, the number of tianeptine exposure calls increased exponentially, with five calls in 2014, 38 in 2015, 83 in 2016, and 81 in 2017.[6] The researchers hypothesized that the increase in calls starting in 2014 might be due to individuals learning of the 2014 study finding tianeptine to be an effective mu-opioid receptor agonist and thus reasoning that it could be a viable opioid alternative. Of the 218 calls that the NPDS received related to tianeptine exposure between 2000 and 2017, tianeptine-only exposures accounted for 114 calls.[7] In the remaining polysubstance calls, the most often reported substances in addition to tianeptine included phenibut (a central nervous system depressant), ethanol, benzodiazepines, and opioids.[8] Among the 114 tianeptine-only exposures, the most commonly reported clinical effects were neurologic, cardiovascular, and gastrointestinal.[9] The NPDS data also showed 29 tianeptine associated withdrawal calls between 2000 and 2017, with tianeptine being the only substance reported in 21 of those calls.[10] Among those 21 calls, the most frequently reported signs and symptoms included agitation, nausea, increased heart rate, and high blood pressure.[11] The number of reports have only continued to increase, with America's Poison Centers, which represents the country's 53 poison centers in partnership with the CDC and FDA, recording 389 calls about tianeptine to U.S. poison centers in 2023.[12]

Beyond the nonfatal tianeptine poisonings reported in the U.S. and internationally, prior to 2018, scientific literature contained reports of only two fatal overdoses, both occurring outside of the U.S.[13] In 2018, an article published in the *Journal of Analytical Toxicology* reported two fatalities involving tianeptine in Texas.[14] These two fatalities may be the first known tianeptine fatalities in the U.S.[15] While the current number of overdose deaths attributed to tianeptine in the U.S. is unclear, the number of deaths is rising. Families of decedents have begun filing wrongful death lawsuits against tianeptine manufacturers and retailers, arguing that the companies knew, or should have known, that these products posed a substantial and unreasonable risk of serious injury to users.[16]

In November 2018, the FDA published an alert for consumers about tianeptine in dietary supplements.[17] The alert stated that "tianeptine is a substance that does not meet the statutory definition of a dietary ingredient and is an unsafe food additive," and as a result, dietary supplements containing tianeptine are "adulterated" under the Federal Food, Drug, and Cosmetic Act.[18] The FDA advised consumers to avoid all products containing tianeptine, especially any claiming to treat opioid use disorder.[19] The FDA released another alert about tianeptine in February
2022, stating that companies continue to illegally market and sell products containing tianeptine to consumers and continue to make "dangerous and unproven claims that tianeptine can improve brain function and treat anxiety,

[5] *Id.* at 815.
[6] *Id.* at 816.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] David D. Gummin, et al., "2023 Annual Report of the National Poison Data System® (NPDS) from America's Poison Centers®: 41st Annual Report," *Clinical Toxicology* 62, no. 12 (Dec. 2024): 793-1027, pg. 27 digitally, https://doi.org/10.1080/15563650.2024.2412423.
[13] Erica L. Bakota, et al., "Case Reports of Fatalities Involving Tianeptine in the United States," *Journal of Analytical Toxicology* 42, no. 7 (September 2018): 503-509, https://doi.org/10.1093/jat/bky023.
[14] *Id.*
[15] *Id.*
[16] *See* Karen Haggarty v. Neptune Resources LLC, et al., No. 24CV212590 (Ohio Ct. Common Pleas, Lorain Cty. filed June 4, 2024); *see also* Angela Roos v. MRSS Inc., et al., No. 250802433 (Pa. Ct. Common Pleas, Phila. Cty. filed Aug. 21, 2025).
[17] "FDA Takes Action on Products Marketed as Dietary Supplements Containing Tianeptine and Warns Consumers," U.S. Food and Drug Administration, last modified November 20, 2018, https://www.fda.gov/food/hfp-constituent-updates/fda-takes-action-products-marketed-dietary-supplements-containing-tianeptine-and-warns-consumers.
[18] *Id.*; 21 U.S.C. § 342.
[19] "FDA Takes Action on Products Marketed as Dietary Supplements Containing Tianeptine and Warns Consumers," *supra* note 17.

depression, pain, opioid use disorder, and other conditions."[20] The FDA has also issued several warning letters to tianeptine manufacturers and retailers about the potential dangers of the substance, including a letter in January 2024 that urged retailers to stop selling the tianeptine supplement brand "Neptune's Fix" and any other tianeptine containing products.[21] Furthermore, the FDA has issued import alerts for tianeptine to help detain shipments of the products at U.S. borders.[22]

Despite the FDA-issued alerts, tianeptine is not a controlled substance under the federal Controlled Substances Act (CSA).[23] In May 2025, Representatives Jimmy Panetta (D-CA) and August Pfluger (R-TX) introduced a bill to make tianeptine a Schedule III controlled substance under the CSA, but as of this writing, there has not been any further action on the bill.[24] While tianeptine remains unscheduled on the federal level, a number of states have taken action to control the substance. As of December 2025, 14 states (Alabama,[25] Delaware,[26] Florida,[27] Georgia,[28] Indiana,[29] Kansas,[30] Kentucky,[31] Louisiana,[32] Minnesota,[33] Nebraska,[34] Nevada,[35] Ohio,[36] Utah,[37] and Virginia[38]) list tianeptine as a Schedule I controlled substance; five states (Arkansas,[39] Michigan,[40] North Carolina,[41] Oklahoma,[42] and Tennessee[43]) list tianeptine as a Schedule II controlled substance; and one state (Mississippi[44]) lists tianeptine as a Schedule III controlled substance. In June 2025, Connecticut enacted a law requiring the state Commissioner of the Department of Consumer Protection (CDCP) to schedule tianeptine.[45] In October 2025, the CDCP held a public hearing about the scheduling requirement but has not yet announced what schedule it will assign to tianeptine.[46] Maryland has chosen not to schedule tianeptine but has enacted a law prohibiting retailers from distributing, selling, exposing for sale, or advertising tianeptine products.[47] Retailers who violate Maryland's tianeptine prohibition are guilty of a misdemeanor.[48] The range in scheduling classifications among states that have chosen to schedule the substance suggests that there is no universal conclusion about the risk of abuse and medical usefulness (or lack thereof) of tianeptine.[49]

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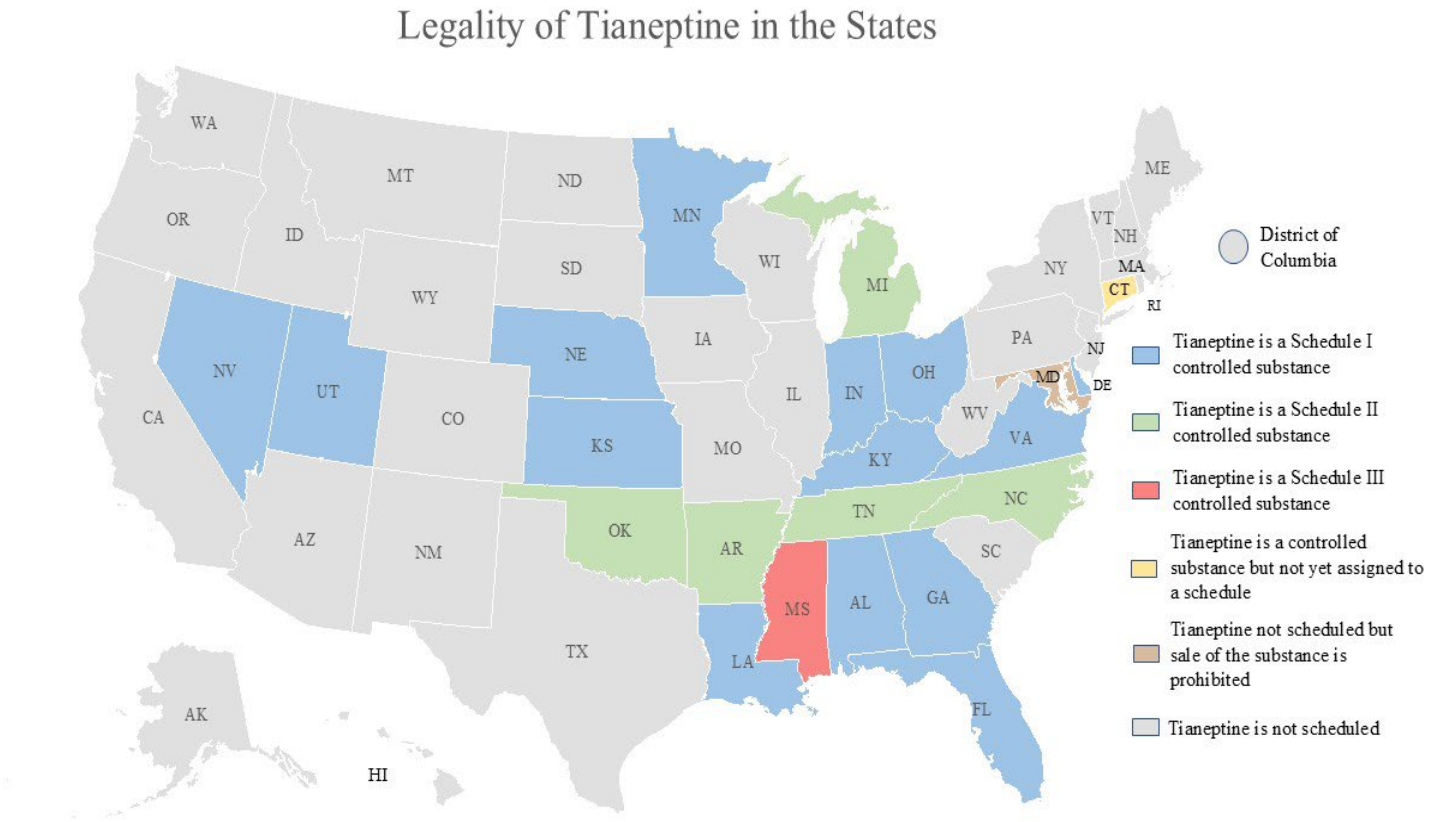
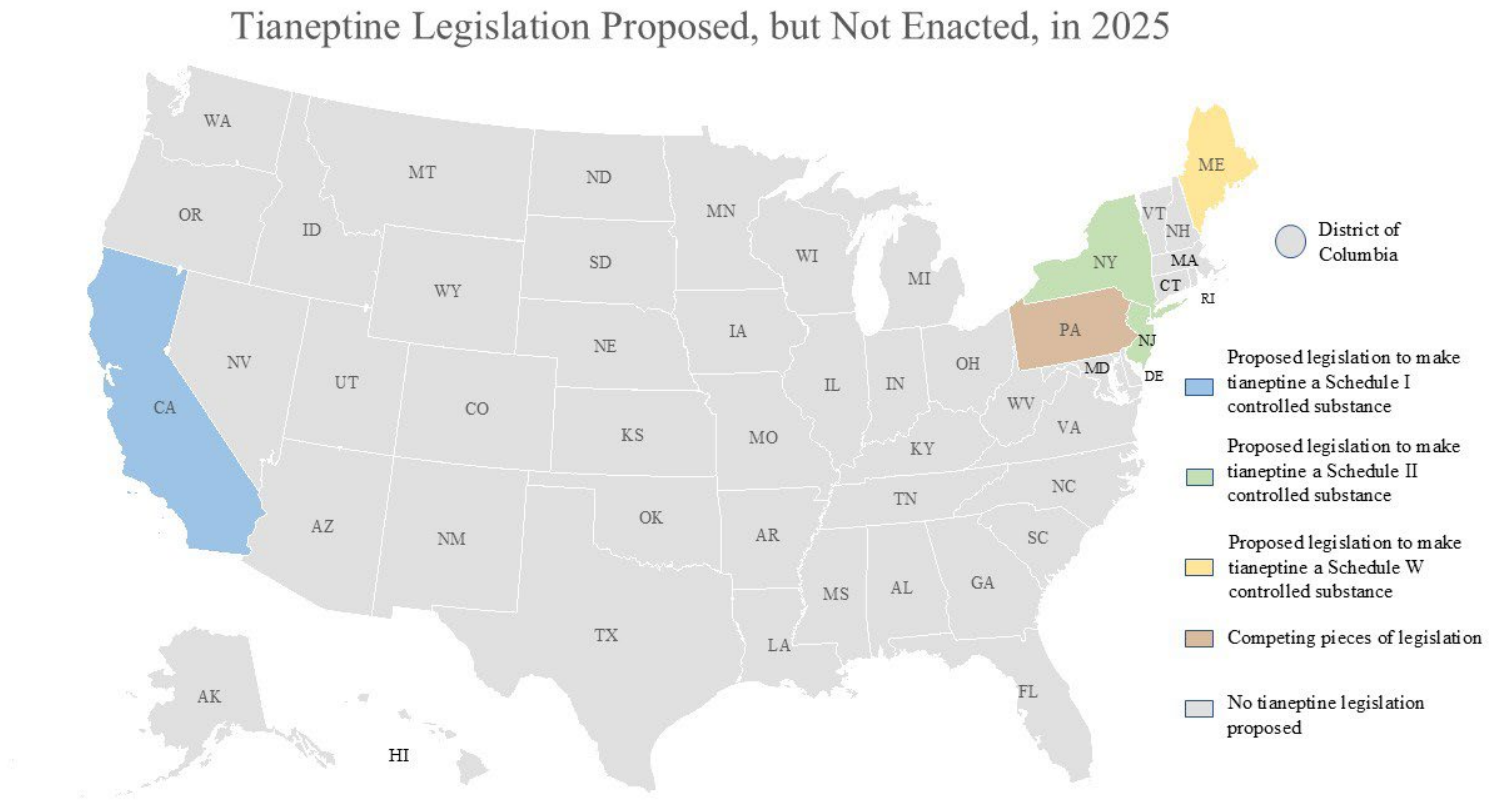
[20] "Tianeptine Products Linked to Serious Harm, Overdoses, Death," *supra* note 3.
[21] "FDA Warns Consumers Not to Purchase or Use Any Tianeptine Product Due to Serious Risks," U.S. Food and Drug Administration, last modified May 8, 2025, https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-any-tianeptine-product-due-serious-risks.
[22] "Tianeptine Products Linked to Serious Harm, Overdoses, Death," *supra* note 3.
[23] 21 U.S.C. § 801, *et seq*.
[24] STAND Against Emerging Opioids Act, H.R. 3520, 119th Cong. (1st Sess. 2025).
[25] ALA. CODE § 20-2-23 (2025). Tianeptine scheduled effective May 1, 2021.
[26] DEL. CODE ANN. tit. 16, § 4714 (West 2025). Tianeptine scheduled effective July 21, 2025.
[27] FLA. STAT. ANN. § 893.03 (West 2025). Tianeptine scheduled effective July 1, 2024.
[28] GA. CODE ANN. § 16-13-25 (West 2025). Tianeptine scheduled effective May 13, 2022.
[29] IND. CODE ANN. § 35-48-2-4 (West 2025). Tianeptine scheduled effective June 30, 2024.
[30] KAN. STAT. ANN. § 65-4105 (West 2025). Tianeptine scheduled effective July 1, 2024.
[31] 902 KY. ADMIN. REGS. 55:015E (2025). Tianeptine scheduled effective March 23, 2023.
[32] LA. STAT. ANN. § 40:964 (2025). Tianeptine scheduled effective August 1, 2025.
[33] MINN. STAT. ANN. § 152.02 (West 2025). Tianeptine scheduled effective August 1, 2018.
[34] NEB. REV. STAT. ANN. § 28-405 (West 2025). Tianeptine scheduled effective July 1, 2025.
[35] NEV. ADMIN. CODE § 453.510 (2025). Tianeptine scheduled effective June 20, 2024.
[36] OHIO ADMIN. CODE 4729:9-1-01 (West 2025). Tianeptine scheduled effective December 22, 2022.
[37] UTAH CODE ANN. § 58-37-4 (West 2025). Tianeptine scheduled effective May 7, 2025.
[38] VA. CODE ANN. § 54.1-3446 (West 2025). Tianeptine scheduled effective July 1, 2025.
[39] 007.07.2 ARK. CODE R. § 2 (West 2025). Tianeptine scheduled effective May 2, 2022.
[40] MICH. COMP. LAWS ANN. § 333.7214 (West 2025). Tianeptine scheduled effective July 4, 2018.
[41] N.C. GEN. STAT. ANN. § 90-90 (West 2025). Tianeptine scheduled effective December 1, 2024.
[42] OKLA. STAT. ANN. tit. 63 § 2-206 (West 2025). Tianeptine scheduled effective November 1, 2019.
[43] TENN. CODE ANN. § 39-17-408 (West 2025). Tianeptine scheduled effective July 1, 2022.
[44] MISS. CODE ANN. § 41-29-117 (West 2025). Tianeptine scheduled effective July 1, 2023.
[45] CONN. GEN. STAT. § 21a-243 (West 2025). Tianeptine required to be scheduled effective June 24, 2025.
[46] *Public Hearing on Regulation 2025-018*, CONN. DEPT. OF CONSUMER PROTECTION (Oct. 9, 2025), https://portal.ct.gov/dcp/knowledge-base/articles/public-hearing-on-regulation-2025-018?language=en_US.
[47] MD. CODE ANN., HEALTH-GEN. § 21-2D-02 (West 2025). Law enacted April 25, 2024.
[48] *Id.*
[49] Schedule I drugs are drugs with high abuse risk that have no safe, accepted medical uses. Schedule II drugs are drugs with a high abuse risk, but with safe and accepted medical uses. Schedule III drugs have a moderate to low potential for abuse with a safe and accepted medical use.

In 2025, five states introduced legislation related to tianeptine that has yet to be enacted. California[50] proposed legislation to make tianeptine a Schedule I controlled substance, while New Jersey,[51] New York,[52] and Pennsylvania[53] proposed legislation to make tianeptine a Schedule II controlled substance. Pennsylvania's proposed Schedule II legislation would also require the commonwealth's Department of Health to monitor adverse health events associated with tianeptine and issue public advisories regarding the dangers of tianeptine exposure when adverse health events or usage trends present a significant threat to public safety.[54] Additionally, Pennsylvania has a competing bill that would keep tianeptine unscheduled but would make the manufacture, delivery, or possession with intent to manufacture or deliver tianeptine a felony.[55] Maine[56] has introduced legislation to make tianeptine a schedule W drug.[57] The maps below detail the legality of tianeptine in the states.



[50] A.B. 634, 2025-2026 Leg., Reg. Sess. (Cal. 2025).
[51] A. 4814/S. 729, 221st Leg., 2024-2025 Sess. (N.J. 2025).
[52] A. 7501/S. 3351, 2025-2026 Leg., Reg. Sess. (N.Y. 2025).
[53] S.B. 946, 2025 Gen. Assemb., Reg. Sess. (Pa. 2025).
[54] *Id.*
[55] H.B. 377, 2025 Gen. Assemb., Reg. Sess. (Pa. 2025).
[56] H.P. 23, 132nd Leg., 1st Spec. Sess. (Me. 2025).
[57] Unlike the federal government and most states, which categorize controlled substances into Schedules I-V, Maine categorizes its drugs into Schedules W, X, Y, and Z. Maine's Schedule W category is akin to the federal Schedule I category.



While tianeptine is not as dangerous as other NPS, it remains a concern to states and to the FDA due to its opioid-like properties and its potential for dependence, withdrawal, and overdose in individuals taking the substance in high doses. Despite FDA warnings and state-level scheduling efforts, tianeptine remains largely unregulated on the federal level, resulting in a patchwork of laws and enforcement. Continued monitoring and public education are necessary to mitigate the potential harms associated with tianeptine use. LAPPA will continue to monitor its spread and any new regulatory responses at the state and federal level.

RESOURCES

"Tianeptine," U.S. Drug Enforcement Administration, last modified April 2025, https://www.deadiversion.usdoj.gov/drug_chem_info/tianeptine.pdf.

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ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to model laws and policies that can be used by national, state, and local criminal justice and substance use disorder practitioners who want the latest comprehensive information on law and policy. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, law enforcement/community engagement, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

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