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Center for U.S. Policy Files FDA Citizen Petition to Protect Marginalized Patients

Petition seeks to recall software that unfairly limits access to prescription drugs

April 28, 2023 – Washington, DC – The Center for U.S. Policy (CUSP) has filed a Citizen Petition with the U.S. Food and Drug Administration (FDA) aimed at protecting patients from being denied the prescription drugs they need. The petition asks the FDA to deem a widely used clinical decision support (CDS) software a misbranded medical device and to mandate a recall to prevent serious, adverse health consequences and death.

The CDS software is a substance use disorder (SUD) analytics tool that generates patients' "risk scores" using data from state prescription drug monitoring programs (PDMPs) and other sources. PDMPs are used by administrative and law enforcement agencies to surveil health care practitioners' prescribing, pharmacists' dispensing, and patients' receipt of controlled medications.

The CDS software influences prescribers' opioid, sedative, and stimulant prescribing decisions by calculating and reporting the likelihood that a patient will misuse substances, have or develop an SUD, or experience drug poisoning.

Data used to create the risk scores may include health records and insurance claims, criminal justice information, method of paying for medications, and distance traveled to obtain a prescription. It has even been suggested that the CDS software manufacturer incorporate data associated with banking, real estate, and other commercial transactions into the risk calculation data bank; it is unclear whether the manufacturer employs such data, however.

Health care providers have no credible way of evaluating the veracity of the CDS risk scores. Upon viewing patients' risk scores, health care providers may change their prescribing decisions, despite patients' needs for medications, to avoid criminal or administrative enforcement actions for "inappropriately" prescribing controlled substances.

“The CDS software integrated within PDMPs pressures prescribers to change their prescribing habits. The software has fundamentally altered the practice of medicine to the detriment of patients with pain or opioid use disorder and other marginalized groups,” said Lynn R. Webster, M.D., Senior Fellow at CUSP.

The unknown data and algorithms used in creating risk scores used in PDMPs may perpetuate or exacerbate disparities in health care. Black and Hispanic adults with pain are less likely to receive opioid pain relievers than White adults. When Black and Hispanic patients do receive opioids, they often receive lower doses than their White counterparts. Similarly, Black patients with opioid use disorder (OUD) are 77 percent less likely than White patients to be prescribed buprenorphine for OUD. Women with pain or OUD are less likely than corresponding men to access treatment with opioid medications.

According to a Centers for Disease Control and Prevention clinical guideline released in 2022, “Risk scores are reportedly generated by applying proprietary algorithms that are not publicly available to information from patient [health records] and other sources, such as court records and criminal and sexual trauma histories; these algorithms might disparately affect women, persons of color, and persons who live in poverty.”

“When patients with pain, OUD, anxiety, or insomnia, for example, have inadequate access to controlled medications their health care providers deem necessary, the resultant harms can include relegation to the illicit drug market, exposure to substances adulterated with illegal fentanyl, prosecution and incarceration, drug poisoning, suicide, and death,” said Michael C. Barnes, CUSP’s chairman.

CDS software that does not provide health care providers with enough information to independently review the CDS recommendations must be regulated as a medical device under the Food Drug & Cosmetic (FD&C) Act. The citizen petition alleges that the CDS software used in PDMPs meets the definition of a “device” under the FD&C Act and that the CDS manufacturer did not satisfy the regulatory requirements for devices, including a premarket notification enabling the FDA to substantiate the CDS software’s safety and effectiveness.

"The FDA has not substantiated the safety and effectiveness of this device," Dr. Webster said. "Nevertheless, the software has been integrated into PDMPs in up to 40 states, influencing the decision making of health care providers and harming patients."

CUSP petitioned the FDA to (1) deem the risk-score software a misbranded device; (2) issue a warning letter to the manufacturer; (3) commence mandatory recall procedures; and (4) take any other action appropriate to prevent adverse health consequences or death.

Read the full petition here.

For more information on risk scores, read "Dosing Discrimination: Regulating PDMP Risk Scores," written by Jennifer D. Oliva, Esq., and published in the *California Law Review*, available here.

For more information on disparities in controlled-medication prescribing, see:

- "Racial Inequality in Prescription Opioid Receipt — Role of Individual Health Systems," published in 2021 in *The New England Journal of Medicine*, available here;
- "Addiction Should Be Treated, Not Penalized," published in 2021 by the National Institute on Drug Abuse (NIDA), available here;
- "Buprenorphine Treatment Divide by Race/Ethnicity and Payment," published in 2019 in *JAMA Psychiatry*, available here*;* and
- "Access to Addiction Services Differs by Race and Gender," published in 2019 by NIDA, available here.

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About the Center for U.S. Policy (CUSP)

CUSP is a nonpartisan, 501(c)(3) not-for-profit research and education organization dedicated to enhancing Americans' health, safety, and economic opportunity. CUSP's 2023 priorities include preventing substance use disorder and drug poisonings, and supporting people affected by substance use.

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