ensure the nation's drug supply is safe and effective." *U.S. v. Sage Pharmaceuticals, Inc.*, 210 F.3d 475, 479 (5th Cir. 2000) (citation omitted). Similarly, "the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, and in what manner." *Gonzales v. Raich*, 545 U.S. 1, 27, 125 S. Ct. 2195, 2211 (2005). The Food and Drug Administration ("FDA"), this nation's preeminent drug regulatory body, supports the federal scheme through its mission to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect the public health." 21 U.S.C. § 393.

The federal system identifies drugs with a potential for abuse and labels them "controlled substances." 21 U.S.C. §§ 811–812. The system categorizes drugs into five "schedules" based on their potential for abuse and other factors. *Id.* § 812. Schedule I drugs have "high potential for abuse," lack "currently accepted medical use in treatment in the United States" and "lack accepted safety for use of the drug or other substance under medical supervision." *Id.* § 812 (b)(1). The other schedules of drugs have lesser potential for abuse and greater medical value. *Id.* § 812.

Schedule I drugs are not approved for medical use. Schedule II – IV drugs can be dispensed only with a physician's prescription; Schedule V drugs are over-

the-counter. 21 U.S.C. § 829. Further, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04.

The list of controlled substances is provided in 21 U.S.C. § 812 and 21 C.F.R. §§ 1308.11-15. Marijuana and its active ingredients in most forms are Schedule I drugs, and thus banned from any medical use. 21 U.S.C. § 812. The CSA provides an ongoing process to reevaluate controlled substances and determine whether to transfer them among schedules or decontrol them by removing them from all schedules. 21 U.S.C. § 811(a). The CSA also provides for the scheduling of new substances. *Id.*

A drug's scheduling is determined through rigorous medical and scientific evaluation. 21 U.S.C. §§ 811–12. All persons who handle controlled substances, such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies and scientific researchers, must register with the Drug Enforcement Administration ("DEA"). 21 U.S.C. § 823. Registrants must maintain detailed records of their respective controlled substance inventories, as well as establish adequate security controls to minimize theft and diversion. 21 C.F.R. § 1304.11(a).

A manufacturer intending to market a new drug must also go through a rigorous process. 21 U.S.C. § 355. The sale of drugs before they have been

approved through the above process is prohibited. *Id.* A drug application can be rejected if the evaluation of the drug does not show "whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* § 355(d).

**2. Marijuana's Place in Federal Law**

As noted, marijuana is a Schedule I drug, meaning that it "may be obtained and used lawfully only by doctors who submit a detailed research protocol for approval by the Food and Drug Administration and who agree to abide by strict recordkeeping and storage rules." *Americans for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438, 441 (D.C. Cir. 2013) (quoting *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1133 (D.C. Cir. 1994)).

"When it enacted the CSA in 1970, Congress placed marijuana in Schedule I. From that time, petitioners have indefatigably sought to obtain a change in marijuana's classification." *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 930 F.2d 936, 937 (D.C. Cir. 1991). But the DEA, FDA and NIDA [National Institute on Drug Abuse] have, in study after study, reached the same conclusion: marijuana continues to meet the criteria for Schedule I control under the CSA because "(1) Marijuana has a high potential for abuse. (2) Marijuana has no currently accepted medical use in treatment in the United States. (3) Marijuana lacks accepted safety for use under medical supervision." Drug

Enforcement Administration, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552, 40567 (July 8, 2011); *see also Raich, supra,* 545 U.S. at 15 n.23, 125 S. Ct. 2195, 2204 n.23 (describing efforts to reschedule marijuana).

### C. The AMMA

The AMMA is profoundly different from and incompatible with the carefully crafted federal scheme for safe delivery of medicine. The AMMA authorizes "qualifying patients" with "debilitating medical conditions" to possess marijuana for "medical use" pursuant to a state-issued card. A.R.S. §§ 36-2801 (9), (13), 36-2804.02. The term "medical use" is broadly defined:

> "Medical use" means the acquisition, possession, cultivation, manufacture, use, administration, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered qualifying patient's debilitating medical condition or symptoms associated with the patient's debilitating medical condition.

A.R.S. § 36-2801(9). The AMMA also includes broad "findings" that marijuana is medically useful. A.R.S. § 36-2801, Historical and Statutory Notes Sec. 2 ("findings" portion of 2010 Proposition 203).

The AMMA creates "a presumption that a qualifying patient or designated caregiver is engaged in the medical use of marijuana pursuant to [Title 36, Chapter 28.1]." A.R.S. § 36-2811(A). Qualifying patients, designated caregivers, and others who participate in the distribution of marijuana under the AMMA are

protected from arrest and other penalties, both civil and criminal. A.R.S. § 36-2811. Many of the records relating to cardholders and dispensaries are deemed confidential. A.R.S. § 36-2810.

The AMMA specifies a procedure for qualifying patients to obtain marijuana. The prospective qualifying patient must first apply to the Department of Health Services for a registry identification card. A.R.S. § 36-2804.02. That application includes a "written certification issued by a physician," as well as an application fee and personal information about the applicant. *Id.* The "written certification" must include a physician's opinion that "the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition." A.R.S. § 36-2801(18).

Physicians may only issue a written certification "in the course of a physician-patient relationship after the physician has completed a full assessment of the qualifying patient's medical history." *Id.* Notably, however, the written certification does not purport to be and is not a prescription under federal law. The term "physician" under the AMMA is also broadly used to include naturopathic and homeopathic physicians. A.R.S. § 36-2801.

The AMMA also provides for registration of dispensaries and their agents. A.R.S. §§ 36-2804, 36-2804.01. Dispensaries are subject to a number of statutory

requirements, including only being allowed to transfer marijuana to qualifying patients and having certain security requirements. A.R.S. § 36-2806. Dispensaries may cultivate unlimited amounts of marijuana "to assist registered qualifying patients with the medical use of marijuana directly or through the registered qualifying patients' designated caregivers." A.R.S. § 36-2806(D). Under certain circumstances, qualifying patients and designated caregivers can also grow up to twelve marijuana plants each. A.R.S. § 36-2801(1).

### D. Preemption

#### 1. Preemption Law

Congress has the power to preempt state law under a variety of circumstances. *See Arizona v. United States*, 567 U.S. ___, 132 S. Ct. 2492, 2500–01 (2012). Most relevant to this case are "those instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 2501 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 404 (1941)).

"What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373, 120 S. Ct. 2288, 2294 (2000). "'If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be

refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.'" *Id.* (citations omitted).

The CSA contains the following preemption clause:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, *unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.*

21 U.S.C.A. § 903 (emphasis added). The FDCA similarly provides that: "a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S. Ct. 1187, 1196 (2009) (citation omitted). When measured against the federal framework, the AMMA cannot survive.

**2. The AMMA Is Preempted**

Fundamentally, the AMMA decrees that marijuana is "medicine" and sets up an Arizona procedure for its cultivation, distribution and use. Both that fundamental determination and the accompanying procedures are in complete conflict with the federal laws and regulations that govern the classification, production, distribution, marketing and use of drugs and medicine in the United States. Accordingly, the AMMA is preempted.

The conflict can be highlighted through several examples: