Congressional Research Service

Memorandum

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SUBJECT: Possible Legal Effects of the Medical Marijuana Amendment to S. 1082

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In response to several inquiries, this memorandum provides a preliminary impression of the legal effect of a medical marijuana amendment to S. 1082 that was recently approved by the Senate Committee on Health, Education, Labor, and Pensions. As approved, the amendment provides:

> The Secretary shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements and penalties of the Federal Food, Drug, and Cosmetic Act regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

The effect of the amendment appears unclear. Although lacking in details, the amendment may contain significant implications for existing regulatory schemes under the Federal Food, Drug, and Cosmetic Act (FFDCA),[1] the Controlled Substances Act (CSA),[2] and state law. As a result, the amendment raises numerous questions regarding its implementation and effect, but the statutory language does not provide much guidance on these points. This memorandum is not exhaustive in its analysis because of the time constraints due to the vote scheduled on S. 1082 next week; it is intended only to explore potential legal questions and issues that might arise if the legislation were enacted.

Before turning to an analysis of the amendment, a brief examination of existing federal and state law regarding medical marijuana may be instructive.[3] Currently, several states have laws that permit the medical use of marijuana. At the same time, federal agents can investigate, arrest, and prosecute medical marijuana patients, caregivers, and providers in accordance with the CSA, which classifies marijuana as a Schedule I drug — a classification

[1] 21 U.S.C. §§ 301 et seq.

[2] *Id.* at §§ 801 et seq.

[3] For more information on medical marijuana, see CRS Report RL33211, *Medical Marijuana: Review and Analysis of Federal and State Policies*, by Mark Eddy.

reserved for those substances that have no currently accepted medical use in treatment in the United States. It therefore prohibits the cultivation, distribution, or possession of marijuana.[4] Meanwhile, the Food and Drug Administration (FDA), which is responsible for regulating drug safety and efficacy, has previously concluded that there is no scientific data to support the safe and effective medical use of marijuana.[5]

Overall Effect and Intent of the Amendment. The ultimate effect of the amendment is not clear. On one hand, the plain language of the amendment could have the effect of curtailing state medical marijuana policies by placing additional regulatory hurdles on activities conducted pursuant to state policies. On the other hand, because the amendment would make State-legalized medical marijuana subject to FDA review and approval, the plain language of the amendment also appears to provide a potential pathway to federal legalization of medical marijuana.

Since it is not clear from the statutory language whether the amendment is intended to curtail or expand the availability and use of medical marijuana, a reviewing court may turn to the amendment's legislative history to determine congressional intent.[6] As expressed at the mark-up conducted by the full committee, the intent of the amendment is "to squelch the medical use of cannabis products that has been approved by the voters or legislatures of 12 states since 1996."[7] However, given that the amendment clearly establishes a mechanism for federal approval of medical marijuana, a reviewing court might not view the expressed intent as determinative.

The FDA's Ability to Regulate Medical Marijuana. As noted above, this amendment appears to grant the FDA explicit statutory authority under the FFDCA to regulate medical marijuana. Although the amendment does not specify the category under which the FDA could regulate medical marijuana, the FDA could find that medical marijuana is a drug under the statutory definition below, which provides that a drug is an

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[4] 21 U.S.C. §§ 812(b)(1)(B), 812(c). The U.S. Supreme Court has previously stated:

> It is clear from the text of the [CSA] that Congress has made a determination that marijuana has no medical benefits... The statute expressly contemplates that many drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," 21 U.S.C. § 801(1), but it includes no exception at all for any medical use of marijuana.

United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 493 (2001).

[5] Press Release, U.S. Food and Drug Administration, *Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine* (April 20, 2006), at [http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html].

[6] To determine Congress's intent, a court may also examine the statutory context of the statute; look for motivating events, such as the passage of state medical marijuana laws; and review documents such as committee reports. Richard K. Neumann, Jr., Legal Reasoning and Writing: Structure, Strategy, and Style, § 16.1 (2005), at 185.

[7] CRS Report RL33211, *Medical Marijuana: Review and Analysis of Federal and State Policies*, by Mark Eddy, at 1; *see also* Fawn Johnson, *Kennedy: Generic Biotech will be in PDUFA Legislation*, Congress Daily (Apr. 19, 2007).

article that "affect[s] the structure or any function of the body."[8] Under the FFDCA, "drugs" fall into three categories or an inclusive fourth category comprised of articles intended to become a component of any of the other three categories. These three categories are: (1) "articles recognized in the official United States Pharmacopoeia" or a similar standard-setting body for prescriptions and over-the-counter medications; (2) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and (3) "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[9] When determining whether an article is a drug under the second or third categories, the agency takes the intent of the vendor into account. However, even if a vendor does not intend to sell an item as a drug, the FDA can still govern it as a drug.[10]

The Current System of FDA Approval of New Drugs. By necessitating, among other requirements, FDA approval of state-legalized medical marijuana under the FFDCA, the amendment could have the effect of restricting or terminating state medical marijuana programs,[11] in part because the FDA does not seem likely to approve medical marijuana as safe and effective, given the agency's past statements. In contrast, however, the amendment could provide a pathway to legalization of state-legalized medical marijuana under the FFDCA, if an applicant for marijuana as an investigational new drug was able to meet FDA approval requirements. A drug cannot be marketed in the United States without FDA approval, for which the manufacturer must demonstrate the drug's safety and effectiveness to FDA's satisfaction, see its manufacturing plant pass FDA inspection, and obtain FDA approval for the drug's labeling — a term that includes all written and electronic material about the drug, including packaging, prescribing information for physicians, and patient brochures. There are four steps leading to FDA approval of a drug for marketing in the United States: an investigational new drug (IND) application, clinical trials, a new drug application(NDA), and FDA review.

As a practical matter, the FDA approval process would likely prevent a small grower of individual plants from submitting an IND application. However, an applicant (usually the drug's sponsor or manufacturer) with greater resources could file an IND application with the FDA.[12] For more information on subsequent steps in the FDA approval process (clinical

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[8] 21 U.S.C. § 321(g)(1).

[9] *Id.*

[10] James T. O'Reilly, Food and Drug Administration, § 13.3 (2005). Sunscreen is one example of such a product. *Id.*

[11] Fawn Johnson, *Kennedy: Generic Biotech will be in PDUFA Legislation*, Congress Daily (Apr. 19, 2007).

[12] The IND must be filed before testing in humans, referred to as *clinical* testing, begins. It includes information about the proposed study protocol, completed animal test data, the lead investigator's qualifications, and the written approval of an Institutional Review Board based on its determination that the study participants will be made aware of the drug's investigative status and that any risk of harm will be necessary, explained, and minimized. The manufacturer will meet with the FDA to discuss whether the clinical study design has sufficient statistical power to enable the manufacturer to draw valid estimates of the safety and effectiveness of the drug. The application must include an *Indication for Use* section that describes what the drug does and the clinical condition and population for which drug use is intended. Trial subjects should be representative of those who would receive the drug if it is approved. The FDA has 30 days to review an IND. If there is no

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trials, new drug application, and FDA review), see pages 5-7 of CRS report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by Susan Thaul.

Intrastate versus Interstate Activities. The amendment may also raise questions regarding its effect on intrastate activities related to medical marijuana. Under the amendment, "State-legalized medical marijuana," which presumably refers to intrastate but not interstate medical marijuana-related activities, would "be subject to the full regulatory requirements" of the FFDCA. However, many, although not all, of the activities currently regulated and/or prohibited by the FFDCA apply only to activities occurring in interstate commerce. For example, the statute prohibits the introduction or delivery for introduction into interstate commerce of any drug that is unapproved.[13] As a result, although the amendment requires "State-legalized medical marijuana" to comply with FDA drug approval requirements, it is not clear that a failure to do so would result in a violation of the FFDCA. In other words, it is possible that the amendment is intended to make certain provisions of the FFDCA applicable to intrastate as well as interstate activities related to medical marijuana. However, because the amendment references existing FFDCA requirements that arguably do not apply to intrastate activities, another possible interpretation suggests that purely intrastate medical marijuana activities would not be affected by some of the requirements set forth in the amendments.

Possible FFDCA Violations and Penalties. In addition to penalties under the CSA for the cultivation, distribution, or possession of marijuana, the amendment may subject medical marijuana patients, caregivers, and providers to a second set of violations under the FFDCA if the FDA approved medical marijuana as a drug. Generally speaking, if a person[14] violates a prohibited act of the FFDCA,[15] the person may be liable under the penalties section[16] of the Act. For example, if an approved drug is adulterated or misbranded, then it will violate the FFDCA, and, as a practical matter, marijuana sold by an individual grower would be unlikely to comply with the complicated adulteration and misbranding provisions of the statute. However, violations of the FFDCA apply only to adulteration or misbranding of a drug that has been introduced, delivered for introduction into, received in, or held for sale after shipment in interstate commerce. As a result, purely intrastate medical marijuana activities may not be affected by some of the penalties set forth in the FFDCA. Additionally, it is not clear that the FDA would still have the authority under FFDCA § 304 to seize any adulterated or misbranded drugs "when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce." Presumably, however, FFDCA provisions that do not require a connection to interstate commerce would apply to intrastate activities.[17]

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[12] (...continued)
objection, a manufacturer may begin clinical testing after that time.

[13] 21 U.S.C. §§ 331(d), 355(a).

[14] The FFDCA defines "person" to include individuals, partnerships, corporations, and associations. FFDCA § 201(e).

[15] FFDCA § 301.

[16] FFDCA § 303(a).

[17] Some penalties do not reference interstate commerce, such as FFDCA § 301(g), which prohibits "[t]he manufacture within any Territory of any . . . drug . . . that is adulterated or misbranded."
(continued...)

Effect of the Amendment on the Controlled Substances Act. It is also unclear what effect the medical marijuana amendment to S. 1082 would have on the CSA regulatory regime. The CSA outlaws manufacture, distribution, dispensation, or possession of marijuana "except as authorized".[18] Although the amendment, which appears to provide a mechanism for federal approval of medical marijuana, could be viewed as an exception to the CSA's categorical prohibitions, it is uncertain whether the medical marijuana amendment to the FFDCA would be considered an "authorization" exempting such activity from scrutiny under the CSA. To resolve the apparent conflict between these two statutes should the medical marijuana amendment be enacted, the courts would likely follow principles of statutory construction.[19] The medical marijuana amendment does not explicitly state Congress' intentions to override the CSA regarding its marijuana prohibitions. However, this apparent conflict could complicate enforcement and regulatory efforts conducted by the two agencies.

Furthermore, although the amendment would subject State-legalized medical marijuana to FDA regulations, the amendment does not change the classification status of marijuana in the CSA schedules; marijuana would still remain a Schedule I drug, a category that statutorily excludes substances that have currently accepted medical uses.[20] However, the CSA expressly notes that Schedule I includes "any material, compound, mixture, or preparation, which contains any quantity of" marijuana, "unless specifically excepted or unless listed in another schedule."[21] It is possible that the medical marijuana amendment could be viewed as a "specific exception" for purposes of the Schedule I designation (though other uses of marijuana would still be considered to meet the Schedule I classification criteria). However, rescheduling a substance may only be accomplished through an act of Congress or a rule by the Attorney General,[22] and the medical marijuana amendment does not provide for this change to the CSA Schedules.

Federal Preemption of State Legislation. The amendment also raises many questions about its potential preemptive effect on state law. This section provides an overview of federal preemption standards but does not reach a conclusion, due to the lack of clearly defined terms, whether the amendment would preempt state laws and bring intrastate activities under FDA authority.

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[17] (...continued)
Likewise, FFDCA § 301(p) prohibits "[t]he failure to register in accordance with section 510," which requires persons "engaging in the manufacture, preparation, propagation, compounding, or processing of a drug" to register with the Secretary of Health and Human Services.

[18] *Id.* at § 841(a).

[19] *See, e.g.*, United States v. Estate of Romani, 523 U.S. 517, 532 (1998) (a later, more specific statute governs); *see also* Morton v. Mancari, 417 U.S. 535, 550-51 (1974) (a general statute will not be held to have been repealed by implication by a more specific one unless there is "clear intention otherwise").

[20] Indeed, 21 U.S.C. § 829 provides that drugs in Schedules II-V may be dispensed under a prescription, but fails to provide such allowance for Schedule I substances.

[21] 21 U.S.C. § 812(c). The only express statutory exception for drugs that have been classified as Schedule I controlled substances (including marijuana) is government-approved, "bona-fide" research projects. Id. at § 823(f).

[22] Id. at § 811(a).

The Supremacy Clause of the Constitution, Article VI, clause 2, states:

> This Constitution, and the Laws of the United States . . . and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, and Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Courts often encounter difficulty in applying the Supremacy Clause, especially when federal law is silent as to a statute's preemptive effect. A preemption analysis usually begins "with the assumption that the historic police powers of the States were not to be superseded by [a federal law] unless that was the clear and manifest purpose of Congress."[23] If the statute in question contains an explicit statement of preemptive scope, therefore, either preempting state law or disclaiming intent to do so, that is usually the end of the matter.[24] The Court also, however, recognizes three categories of implied preemption of state law, various formulations of which are that state law must give way to federal law (1) if there is a direct conflict between them, (2) if implementation of state law "would frustrate congressional purpose," or (3) if federal law has "occupied the field" of regulation. The latter two categories are not as precise, and the courts may find it easier to analyze a statute's preemptive effect if such effect is clearly delineated. A state may create its own laws if Congress did not intend to occupy the field.[25]

Neither the amendment nor the FFDCA contain an explicit statement of preemptive scope.[26] However, the amendment's subjection of state-legalized medical marijuana to federal FDA regulatory requirements could raise questions under the second and/or third categories of implied preemption — frustration of congressional purpose and a federally occupied field. On one hand, the amendment could potentially result in conflicts between FDA requirements and state laws, and a reviewing court could therefore find "implied conflict pre-emption where it is 'impossible for a private party to comply with both state and federal requirements,' or where state law 'stands as an obstacle to the accomplishment and

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[23] Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605 (1991). "[F]or the purposes of the Supremacy Clause, the constitutionality of local ordinances is analyzed in the same way as that of statewide laws." Hillsborough County v. Automated Med. Labs, Inc., 471 U.S. 707, 713 (1985).

[24] A statement asserting preemption or disclaiming intent to preempt must be clear not only as to preemptive intent, but also as to scope. In *International Paper Co. v. Ouellette*, 479 U.S. 481 (1987), for example, the Court ruled that some aspects of state law were preempted in spite of a savings clause in the citizens suit provision of the Clean Water Act declaring that "nothing in this section" should be read as affecting an injured party's right to seek relief under any statute or common law. Other parts of the Act outside the citizens suit section were read as implying preemption. "Because we do not believe Congress intended to undermine this carefully drawn statute [leaving a source state responsible for control of point-source discharges within its boundaries] through a general savings clause, we conclude that the CWA precludes a court from applying the law of an affected state against an out-of-state source." *Id.* at 484.

[25] Colorado Anti-Discrimination Commission v. Continental Air Lines, Inc., 372 U.S. 714 (1963); Huron Portland Cement Co. v. Detroit, 362 U.S. 440 (1960).

[26] The FFDCA contains an explicit preemption provision with respect to over-the-counter drugs but not with respect to prescription drugs.

execution of the full purposes and objectives of Congress.' "[27] On the other hand, the federal and state laws may not conflict because the FFDCA applies to interstate activities. State medical marijuana laws generally apply only to intrastate activities. A reviewing court could find that Congress's intent to supersede state laws "is not to be implied unless the act of Congress fairly interpreted is in actual conflict with the law of the State."[28] Ultimately, the highly fact-dependent and subjective nature of preemption analysis make it difficult to predict the outcome of a preemption challenge to such state medical marijuana laws.

A comparison of each state's medical marijuana laws to the FFDCA to determine if a reviewing court would find implied conflict preemption is beyond the scope of this memorandum. Generally, state laws tend to address the amount of medical marijuana a patient may legally possess in that state and may create a state registry or system of identification cards for medical marijuana patients. While the FFDCA does not currently address these topics, this amendment could be interpreted as granting the agency authority to conduct rulemakings on these subjects. The Supreme Court has "held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes."[29] However, the amendment only subjects state-legalized medical marijuana to the full regulatory requirements of the FDA and does not require the FDA to undertake a rulemaking on the matter.

Conclusion. Ultimately, it is unclear what legal effect the amendment to S. 1082 would have on existing federal or state statutes. Furthermore, due to time constraints, this memorandum does not address congressional authority under the commerce clause to regulate intrastate activity.[30] Rather, the discussion above is intended to highlight just a few of the possible issues or questions that may emerge if the amendment were enacted.

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[27] Sprietsma v. Mercury Marine, 537 U.S. 51, 64-65 (2002) (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)) (internal citations omitted).

[28] Huron Portland Cement Co. v. Detroit, 362 U.S. 440, 443 (1960) (quoting Savage v. Jones, 225 U.S. 501, 533 (1912)).

[29] Hillsborough County, 471 U.S. at 713.

[30] The Supreme Court has rejected challenges to the CSA's prohibition of the manufacture and possession of marijuana as applied to the *intrastate* manufacture and possession of marijuana for medical purposes pursuant to state law. The Court ruled in *Gonzales v. Raich*, 125 S. Ct. 2195 (2005) that the CSA's prohibition was within Congress' authority under the Commerce Clause. For more information on this decision, *see* CRS Report RS22167, Gonzales v. Raich: *Congress's Power Under the Commerce Clause to Regulate Medical Marijuana*, by Todd B. Tatelman. In addition, the Court held in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S.483 (2001), that there is no medical necessity defense to the CSA's marijuana prohibitions, not even in states that have created a medical marijuana exception to a comparable ban under state law. For more information about this decision, *see* CRS Report RL31100, *Marijuana for Medical Purposes: The Supreme Court's Decision in* United States v. Oakland Cannabis Buyers' Cooperative *and Related Legal Issues*, by Charles Doyle. Because the statutory language and purpose of the FFDCA differs from the CSA, the current scope of the FDA's authority to regulate intrastate drug marketing appears to be somewhat less extensive.