



Greater Phoenix
Chamber of
Commerce

January 5, 2010

Director Will Humble
Arizona Department of Health Services
150 N 18th Avenue
Phoenix, AZ 85007

Re: Rule and Regulation of Medical Marijuana in the State of Arizona

Dear Director Humble:

Since 1888, the Greater Phoenix Chamber of Commerce has supported the growth and development of business. The Chamber continues to keep business connected to the community and serves as the collective voice of its more than 2,900 members at the local, county, state and federal levels of government. We believe providing input is critical to elected and non-elected government officials and agencies making public policy and regulatory decisions. These decisions can ultimately have either an adverse impact on the business community or benefit the overall business climate in metropolitan Phoenix. As such, we appreciate the opportunity to be part of the process in reviewing legislation and draft rules and providing our perspective to assist in shaping policy in Arizona. On behalf of the Chamber's membership, please accept and review this letter of comment related to the new medical marijuana rules for the state of Arizona.

Overview

Several members of the Greater Phoenix Chamber of Commerce with expertise in areas such as human resources, legal, transportation, insurance and agricultural, have reviewed and discussed the first proposed draft rule language to implement the medical marijuana policy in Arizona. Below please find suggestions for progressing toward a more well-rounded policy providing ample direction for employers, as well as, doctors, patients, dispensaries and others related to this Act. While this comment letter applies specifically to regulatory changes for the Act, the Greater Phoenix Chamber of Commerce also believes further legislation may be required to address issues beyond the authority of the Arizona Department of Health Services. We believe that without providing direction to employers and their employees, it is virtually impossible to ensure appropriate compliance with this Act. Our intent is to solidify ways to protect the public-at-large and ensure commerce can proceed safely within the parameters of this language. We hope these suggestions will lead toward the balance of treating the ill and debilitated while maintaining a productive and safe environment for commerce and the citizens of Arizona.

As the final part of this overview we would like to acknowledge and bring to your attention the 2005 US Supreme Court ruling of the case *Gonzales vs Raich*. The ruling on this case clearly articulated the federal government's right to ban and oppose medical marijuana as directly interfering with its larger overriding war on drugs, even though the marijuana in this case was privately grown for purely personal medical use. This case was also heard in the 9th Circuit for further consideration. Acknowledging the Arizona proposed legislation has already passed we thought it valuable to inform you of these cases in the event the federal government exercises their right to enforce this ban in Arizona. Despite these rulings, we present to you the comments that follow regarding medical marijuana in our state.

Rulemaking Authority

The Act as stated in ARS 36-2803 allows for the regulation of nonprofit medical marijuana dispensaries for the purpose of protection against theft and diversion, and the regulation of the process as related to registration and renewal of applications and fees, identification cards and dispensary registration certificates. Due to the way the Act is worded, the business community has additional concerns that ADHS and others cannot address because they have been denied the

necessary authority to provide protection for the citizens of Arizona and the fragile flow of commerce so desperately needed in the state. Therefore, additional legislation will be required to comply with this Act.

Definition of Terms

The Act, as crafted by medical marijuana interests and passed by the voters in 2010, uses terminology lacking structured definition which in some cases promote confusion to its current use in statute. Terms in the policy allow for a broad interpretation, provoking litigation for the courts to discern their meaning. Undoubtedly, this will result in costly endeavors to protect the general public and for employers to comply. Therefore, we encourage further definition of terms used throughout the Act to provide clarity to all of Arizona's citizens meanwhile acknowledging additional legislation may be required for this purpose. The following terms are examples of concern:

“Benefit under Federal Law or Regulation” (monetary or licensing) – as described in ARS § 36-2813(B), we suggest the definition of federal benefit to, at minimum, include any employers who receive federal funding and grants, obtain a federal license, and/or secure a federal contract of any kind. In compliance with the federal Drug-Free Workplace Act of 1988, any firm with a single (or more) federal contract of more than \$100,000 is subject to this Act. This would include any employee, full-time or temporary, who works on any activity under the grant or contract and is on payroll. Additionally, contractors or grantees performing work in federal facilities, involved in federal procurement of utility services, issued order contracts or grants to educational organizations are included in these provisions as covered by the Act.

Furthermore, the United States Department of Transportation (USDOT) has internal drug policy regulations under their Drug and Alcohol Testing Regulation – 49 CFR Part 40, at 40.151(e). These regulations do not authorize “medical marijuana” under a state law to be a valid medical explanation for a transportation employee's positive drug test result. USDOT has declared the following transportation positions as safety-sensitive and therefore, unacceptable for these employees to use medical marijuana based on these regulations: pilots, school bus drivers, truck drivers, train engineers, subway operators, aircraft maintenance personnel, transit fire-armed security personnel, ship captains and pipeline emergency response personnel. As an employer befitting the above definition, we suggest these occupations also be identified as positions of benefit under federal law or regulation.

Finally, a number of federal agencies (including the Department of Defense, Department of Energy, Nuclear Regulatory Commission and National Aeronautics and Space Administration) have issued regulations that require federal contractors, grantees and licensees to maintain fitness-for-duty requirements or drug-free workplace programs. For example, licensees for the Nuclear Regulatory Commission (NRC) are also held to similar regulations as under USDOT through the NRC Fitness-For-Duty program defined in 10 CFR Part 26. The NRC regulation addresses the concern of trustworthiness and reliability as related to use of medical marijuana and other hallucinogens. Their regulation is imperative to ensure individuals who are subject to Part 26 requirements are not impaired from using drugs when performing duties subject therein. As this prohibition has concurrence from the Department of Justice, Health and Human Services and the Office of National Drug Control Policy, we request this personnel and others of similar integrity also be identified in the definition of federal benefit under law or regulation.

“Impairment” – as described in ARS § 36-2802(D) the definition of impaired will need further characterization. A study done in 1993 at the University Of Iowa College Of Medicine showed chronic marijuana use with a frequency of 7 times or more per week for an extended period of time imposed deficits in mathematical skills and verbal expression as well as selective impairment in memory retrieval processes. Additionally, an article published by the University of North Carolina Charlotte in April 2010, noted frequent use of marijuana promotes amotivational syndrome which decreases the frequency of doing things that need to be done but individuals may not particularly like doing. Under the new Arizona initiative, the option for frequent use is permissible which may result in this type of behavior, undesirable to employers. Similarly, a study published in the American Journal of Psychiatry in 1985 noted that when experienced licensed private pilots smoked a cigarette containing 19 mg of delta 9-tetrahydrocannabinol (THC), their *“mean performance on the flight task showed trends toward impairment on all variables”* 24 hours later. It further stated, *“Despite these deficits, the pilots reported no awareness of impaired performance. These results may have implications for performance of complex tasks the day after smoking marijuana.”*

As administrators of the process, the Los Angeles Police Department (LAPD) and National Highway Traffic and Safety Administration (NHTSA) both utilize a number of field sobriety tests to determine impairment. LAPD uses one-leg stand, finger-to-nose, walk the line, standing steadiness, nystagmus, pupil reaction, pupil size and pulse rate. NHTSA's process includes a post-arrest investigative procedure called the Drug Evaluation and Classification program. It requires a controlled environment and cannot be executed at roadside. As part of the program Drug Recognition Experts observe and question suspects as they perform individual tests prior to chemical analysis. This program is based on the LAPD program and has been implemented in twenty-six states and the District of Columbia. We suggest these tests and behaviors or portions thereof become part of the definition of impairment to further provide structure around this term.

"Physician/Patient Relationship" - as it relates to medical marijuana initiative language R9-17-101, the physician-patient relationship is defined as the interaction between a physician and an individual in which the physician has ongoing responsibility for the assessment, care and treatment of the patient's debilitating medical condition. This language does not speak to the history of their relationship leading up to what may require treatment of medical marijuana. We would like to suggest parameters be established in regard to the relationship of these parties to identify a history of visits with a single doctor or doctors within a single office, appointments regarding the debilitating condition and information regarding the previous treatments which were proven ineffective.

"Health Benefit Plans" - as it relates to healthcare provided by public and private employers, we suggest further clarification of this term. Current language provides that neither a government medical assistance program nor private health insurer is responsible for reimbursement to a person for the costs associated with the medical use of marijuana. Worker's compensation is constitutionally mandated medical care provided by employers for employees who are injured during the course of employment. Provisions include wage replacement, compensation for economic loss, dependent benefits due to the death of an employee and reimbursement/payment of medical and like expenses. Therefore we believe the definition of Health Benefit Plan should include care provided pursuant to Article XVIII, Section 8 of the Constitution or any statutes enacted by the legislature relating to workers' compensation.

Security of inventory, storage and the transport of medical marijuana

For the safety of Arizona's citizenry, security of medical marijuana throughout the distribution process is critical. Every effort should be made to ensure product is not subject to theft, car-jacking, employee misconduct or any other misuse of medical marijuana. It is essential the distribution of medical marijuana be limited to qualifying patients and not illegally distributed to the general public.

Inventory Control and Storage

As it relates to the ability to track and store inventory, R9-17-313 and R9-17-315, it's important to have checks and balances within the inventory process to be sure all product is accounted for at dispensaries, caregivers, cultivation sites and food establishments. We suggest the development and implementation of a real-time comprehensive tracking and reporting system to log inventories to and from these establishments. As part of the security precaution, system enhancements should include medical marijuana inventories be stored only in secure locations and containers. This system should allow for oversight by DHS while increasing measures of control at the facilities. This system should also allow for a decrease in time-consuming efforts required by DHS to assist in monitoring inventory activities as well as provide them information pertinent to conducting audits or other necessary control processes.

Transport of Inventory

Security, as it relates to the transport of medical marijuana product, must be ensured throughout the entire distribution process. R9-17-315 addresses security related to dispensaries, however we suggest a broadening this focus to be include the supply chain. In an effort to provide further security and insurance that medical marijuana will be preserved for the ill and debilitated, tracking of product during the movement between facilities, caregivers, etc., is critical. We suggest a tracking process be established and implemented in the state of Arizona to further provide this safety net. For example, the state of Colorado has enacted rules requiring medical marijuana

be pre-packaged at the cultivation site in front of a video camera, logged into an inventory book, weighed at its departure and again at the arrival of the receiving licensed dispensary.

For additional security, we suggest routes from the cultivation sites to the dispensaries be identified and submitted to DHS for approval. Approved route information should be shared with law enforcement and the Arizona Department of Transportation (ADOT). Outside of these agencies, we suggest these routes remain confidential to limit risks which may occur while en route. Acknowledging the challenge and risks associated with security, this effort suggests further legislation should be implemented to preserve the medical product for patients and hinder distribution into illegal markets.

Unfortunately, the Act does not account for transport operators, therefore, additional legislation should be considered. Transport operators should be required to apply and be approved for a license to transport medical marijuana from any point within the supply chain and on any basis of frequency. As part of the process to obtain a license, drivers should be required to submit fingerprints and should not have a prior record consisting of a felony. As drivers may also be considered caregivers, they too should be required to adhere to these same provisions for obtaining a transport license.

Additionally, vehicles used to transport medical marijuana should be properly labeled and identified. We acknowledge the risks associated with labeling vehicles, however we suggest at minimum drivers of these vehicles should have demarcation on their registration form recognizing they are legal transporters of medical marijuana. Penalties should apply for violation or duplication of their medical marijuana transporter license and/or registration.

We also suggest medical marijuana transport vehicles should also have some method of identification for authorities and state agencies. For example, United States Department of Transportation (USDOT) requires commercial motor vehicles (CMV) travelling intrastate to mark their vehicles by displaying the name of the carrier and the USDOT assigned number followed by AZ. ADOT requires the company name, USDOT number, address of the business, telephone number and website, if available, be displayed on both sides of the vehicle. The USDOT number must be visible from a distance of 50 feet at all times. Penalties are applied if the number is not visible. Again recognizing there may be risks associated with labeling vehicles, these examples provide insight to existing processes in use by state and federal agencies which may be applicable in or whole or in part therein.

Protection from Fraudulent Behavior

As it relates to the ability to assist public safety officers and the general public in identifying medical marijuana licenses and ID cards appropriately, we submit the following suggestions:

- A legal example of a caregiver or patient ID card should be posted on the DHS website.
- Security provisions to protect legal identification cards should be established, similar to the Motor Vehicle Division standards.
- A process should be established by which employers can inquire about the legality of an ID card. As access to the database is not likely, an exception-based process for employer utilization is desired by the business community.
- The adoption of automated, robust and electronic procedures to address enrollment and provider fraud and to assist in enforcing the Act. Such a system should validate critical pieces of information such as licensure status, sanctions, certification, criminal record, death, LEIE and EPLS exclusion, DEA/NPI/TIN against authoritative sources at the time of enrollment or re-enrollment via a regular data transfer interface.
- An on-going screening of potential and enrolled users via a screening of recipients. This screen should be set against public records information to support program integrity functions to automatically flag individual beneficiaries for potential fraud, including both identity fraud and unreported location or residency changes.

- The implementation of currently available technology to assess the “actual” address of enrollees/applicants. This technology will provide warning notifications to ADHS and law enforcement when the enrollee is misrepresenting their address. This may minimize efforts from enrollees who register themselves as living outside of the 25 mile dispensary limit but are using that address in name only. The interface should also identify when an enrollee is deceased so appropriate action can be taken in relation to the enrollee’s file and prevent unauthorized use.

Network adequacy and access are always areas of critical importance in dispensary enrollment and on-going dispensary relations. We recommend that the ADHS implement an enhanced provider enrollment process that at a minimum, the solution should:

- Maintain and update a dynamic provider risk profile to be used for ongoing fraud and abuse that should examine associations to excluded providers or felons, ownership or corporate affiliations, and other derogatory indicators. Alert program staff or systems when critical changes to licensure, exclusion, address relocation, criminal record, etc occur.
- Maintain a system with national and state databases for licensure, death records, tax information, address identification and validate and identify physician specialties for provider’s upon enrollment and for ongoing monitoring when changes occur such as a provider’s license has expired, been suspended, or revoked.
- ADHS should develop provider profiles that assess physicians or providers with multiple regulatory sanctions whose records may indicate

Again, further clarification in statute relevant to the area of fraud will need to be provided.

Conclusion

As previously mentioned, we maintain the position additional enhancement to this policy may be required through the legislative process. We support any necessary legislation which may address the concerns of the business community and employers in relation to misuse of medical marijuana in the workplace and we invite further opportunity for dialogue with you on this issue. As previously noted, our intent is to strengthen this policy for the protection of the state of Arizona and preserve a safe and prosperous economic environment within the parameters of this Act. On behalf of the Greater Phoenix Chamber of Commerce, thank you for the opportunity to submit comment on this very important issue.

Sincerely,



Todd Sanders
President and CEO
Greater Phoenix Chamber of Commerce

certiorari to the united states court of appeals for the ninth circuit

No. 03-1454 Argued November 29, 2004--Decided June 6, 2005

California's Compassionate Use Act authorizes limited marijuana use for medicinal purposes. Respondents Raich and Monson are California residents who both use doctor-recommended marijuana for serious medical conditions. After federal Drug Enforcement Administration (DEA) agents seized and destroyed all six of Monson's cannabis plants, respondents brought this action seeking injunctive and declaratory relief prohibiting the enforcement of the federal Controlled Substances Act (CSA) to the extent it prevents them from possessing, obtaining, or manufacturing cannabis for their personal medical use. Respondents claim that enforcing the CSA against them would violate the Commerce Clause and other constitutional provisions. The District Court denied respondents' motion for a preliminary injunction, but the Ninth Circuit reversed, finding that they had demonstrated a strong likelihood of success on the claim that the CSA is an unconstitutional exercise of Congress' Commerce Clause authority as applied to the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law. The court relied heavily on *United States v. Lopez*, 514 U. S. 549, and *United States v. Morrison*, 529 U. S. 598, to hold that this separate class of purely local activities was beyond the reach of federal power.

Held. Congress' Commerce Clause authority includes the power to prohibit the local cultivation and use of marijuana in compliance with California law. Pp. 6-31.

(a) For the purposes of consolidating various drug laws into a comprehensive statute, providing meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthening law enforcement tools against international and interstate drug trafficking, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Title II of which is the CSA. To effectuate the statutory goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA. 21 U. S. C. §§841(a)(1), 844(a). All controlled substances are classified into five schedules, §812, based on their accepted medical uses, their potential for abuse, and their psychological and physical effects on the body, §§811, 812. Marijuana is classified as a Schedule I substance, §812(c), based on its high potential for abuse, no accepted medical use, and no accepted safety for use in medically supervised treatment, §812(b)(1). This classification renders the manufacture, distribution, or possession of marijuana a criminal offense. §§841(a)(1), 844(a). Pp. 6-11.

(b) Congress' power to regulate purely local activities that are part of an economic "class of activities" that have a substantial effect on interstate commerce is firmly established. See, *e.g.*, *Perez v. United States*, 402 U. S. 146, 151. If Congress decides that the "total incidence" of a practice poses a threat to a national market, it may regulate the entire class. See, *e.g.*, *id.*, at 154-155. Of particular relevance here is *Wickard v. Filburn*, 317 U. S. 111, 127-128, where, in rejecting the appellee farmer's contention that Congress' admitted power to regulate the production of wheat for commerce did not authorize federal regulation of wheat production intended wholly for the appellee's own consumption, the Court established that Congress can regulate purely intrastate activity that is not itself "commercial," *i.e.*, not produced for sale, if it concludes that failure to regulate that class of activity would undercut the regulation of the interstate market in that commodity. The similarities between this case and *Wickard* are striking. In both cases, the regulation is squarely within Congress' commerce power because production of the commodity meant for home consumption, be it wheat or marijuana, has a substantial effect on supply and demand in the national market for that commodity. In assessing the scope of Congress' Commerce Clause authority, the Court need not determine whether respondents' activities, taken in the aggregate, substantially affect interstate commerce in fact, but only whether a "rational basis" exists for so concluding. *E.g.*, *Lopez*, 514 U. S., at 557. Given the enforcement difficulties that attend distinguishing between marijuana cultivated locally and marijuana grown elsewhere, 21 U. S. C. §801(5), and concerns about diversion into illicit channels, the Court has no difficulty concluding that Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the CSA. Pp. 12-20.

(c) Respondents' heavy reliance on *Lopez* and *Morrison* overlooks the larger context of modern-era Commerce Clause jurisprudence preserved by those cases, while also reading those cases far too broadly. The statutory challenges at issue there were markedly different from the challenge here. Respondents ask the Court to excise individual applications of a concededly valid comprehensive statutory scheme. In contrast, in both *Lopez* and *Morrison*, the parties asserted that a particular statute or provision fell outside Congress' commerce power in its entirety. This distinction is pivotal for the Court has often reiterated that "[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." *Perez*, 402 U. S., at 154. Moreover, the Court emphasized that the laws at issue in *Lopez* and *Morrison* had nothing to do with "commerce" or any sort of economic enterprise. See *Lopez*, 514 U. S., at 561; *Morrison*, 529 U. S., at 610. In contrast, the CSA regulates

quintessentially economic activities: the production, distribution, and consumption of commodities for which there is an established, and lucrative, interstate market. Prohibiting the intrastate possession or manufacture of an article of commerce is a rational means of regulating commerce in that product. The Ninth Circuit cast doubt on the CSA's constitutionality by isolating a distinct class of activities that it held to be beyond the reach of federal power: the intrastate, noncommercial cultivation, possession, and use of marijuana for personal medical purposes on the advice of a physician and in accordance with state law. However, Congress clearly acted rationally in determining that this subdivided class of activities is an essential part of the larger regulatory scheme. The case comes down to the claim that a locally cultivated product that is used domestically rather than sold on the open market is not subject to federal regulation. Given the CSA's findings and the undisputed magnitude of the commercial market for marijuana, *Wickard* and its progeny foreclose that claim. Pp. 20-30.

352 F.3d 1222, vacated and remanded.

Stevens, J., delivered the opinion of the Court, in which *Kennedy, Souter, Ginsburg, and Breyer, JJ.*, joined. *Scalia, J.*, filed an opinion concurring in the judgment. *O'Connor, J.*, filed a dissenting opinion, in which *Rehnquist, C. J.*, and *Thomas, J.*, joined as to all but Part III. *Thomas, J.*, filed a dissenting opinion.

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al.*, PETITIONERS *v.* ANGEL McCLARY RAICH *et al.*

on writ of certiorari to the United States Court of Appeals for the Ninth Circuit

[June 6, 2005]

Justice Stevens delivered the opinion of the Court.

California is one of at least nine States that authorize the use of marijuana for medicinal purposes.¹ The question presented in this case is whether the power vested in Congress by Article I, §8, of the Constitution "[t]o make all Laws which shall be necessary and proper for carrying into Execution" its authority to "regulate Commerce with foreign Nations, and among the several States" includes the power to prohibit the local cultivation and use of marijuana in compliance with California law.

I

California has been a pioneer in the regulation of marijuana. In 1913, California was one of the first States to prohibit the sale and possession of marijuana,² and at the end of the century, California became the first State to authorize limited use of the drug for medicinal purposes. In 1996, California voters passed Proposition 215, now codified as the Compassionate Use Act of 1996.³ The proposition was designed to ensure that "seriously ill" residents of the State have access to marijuana for medical purposes, and to encourage Federal and State Governments to take steps towards ensuring the safe and affordable distribution of the drug to patients in need.⁴ The Act creates an exemption from criminal prosecution for physicians,⁵ as well as for patients and primary caregivers who possess or cultivate marijuana for medicinal purposes with the recommendation or approval of a physician.⁶ A "primary caregiver" is a person who has consistently assumed responsibility for the housing, health, or safety of the patient.⁷

Respondents Angel Raich and Diane Monson are California residents who suffer from a variety of serious medical conditions and have sought to avail themselves of medical marijuana pursuant to the terms of the Compassionate Use Act. They are being treated by licensed, board-certified family practitioners, who have concluded, after prescribing a host of conventional medicines to treat respondents' conditions and to alleviate their associated symptoms, that marijuana is the only drug available that provides effective treatment. Both women have been using marijuana as a medication for several years pursuant to their doctors' recommendation, and both rely heavily on cannabis to function on a daily basis. Indeed, Raich's physician believes that forgoing cannabis treatments would certainly cause Raich excruciating pain and could very well prove fatal.

Respondent Monson cultivates her own marijuana, and ingests the drug in a variety of ways including smoking and using a vaporizer. Respondent Raich, by contrast, is unable to cultivate her own, and thus relies on two caregivers,

litigating as "John Does," to provide her with locally grown marijuana at no charge. These caregivers also process the cannabis into hashish or keif, and Raich herself processes some of the marijuana into oils, balms, and foods for consumption.

On August 15, 2002, county deputy sheriffs and agents from the federal Drug Enforcement Administration (DEA) came to Monson's home. After a thorough investigation, the county officials concluded that her use of marijuana was entirely lawful as a matter of California law. Nevertheless, after a 3-hour standoff, the federal agents seized and destroyed all six of her cannabis plants.

Respondents thereafter brought this action against the Attorney General of the United States and the head of the DEA seeking injunctive and declaratory relief prohibiting the enforcement of the federal Controlled Substances Act (CSA), 84 Stat. 1242, 21 U. S. C. §801 *et seq.*, to the extent it prevents them from possessing, obtaining, or manufacturing cannabis for their personal medical use. In their complaint and supporting affidavits, Raich and Monson described the severity of their afflictions, their repeatedly futile attempts to obtain relief with conventional medications, and the opinions of their doctors concerning their need to use marijuana. Respondents claimed that enforcing the CSA against them would violate the Commerce Clause, the Due Process Clause of the Fifth Amendment, the Ninth and Tenth Amendments of the Constitution, and the doctrine of medical necessity.

The District Court denied respondents' motion for a preliminary injunction. *Raich v. Ashcroft*, 248 F. Supp. 2d 918 (ND Cal. 2003). Although the court found that the federal enforcement interests "wane[d]" when compared to the harm that California residents would suffer if denied access to medically necessary marijuana, it concluded that respondents could not demonstrate a likelihood of success on the merits of their legal claims. *Id.*, at 931.

A divided panel of the Court of Appeals for the Ninth Circuit reversed and ordered the District Court to enter a preliminary injunction.⁸ *Raich v. Ashcroft*, 352 F. 3d 1222 (2003). The court found that respondents had "demonstrated a strong likelihood of success on their claim that, as applied to them, the CSA is an unconstitutional exercise of Congress' Commerce Clause authority." *Id.*, at 1227. The Court of Appeals distinguished prior Circuit cases upholding the CSA in the face of Commerce Clause challenges by focusing on what it deemed to be the "*separate and distinct class of activities*" at issue in this case: "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law." *Id.*, at 1228. The court found the latter class of activities "different in kind from drug trafficking" because interposing a physician's recommendation raises different health and safety concerns, and because "this limited use is clearly distinct from the broader illicit drug market--as well as any broader commercial market for medicinal marijuana--insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce." *Ibid.*

The majority placed heavy reliance on our decisions in *United States v. Lopez*, 514 U. S. 549 (1995), and *United States v. Morrison*, 529 U. S. 598 (2000), as interpreted by recent Circuit precedent, to hold that this separate class of purely local activities was beyond the reach of federal power. In contrast, the dissenting judge concluded that the CSA, as applied to respondents, was clearly valid under *Lopez* and *Morrison*; moreover, he thought it "simply impossible to distinguish the relevant conduct surrounding the cultivation and use of the marijuana crop at issue in this case from the cultivation and use of the wheat crop that affected interstate commerce in *Wickard v. Filburn*." 352 F. 3d, at 1235 (Beam, J., dissenting) (citation omitted).

The obvious importance of the case prompted our grant of certiorari. 542 U. S. 936 (2004). The case is made difficult by respondents' strong arguments that they will suffer irreparable harm because, despite a congressional finding to the contrary, marijuana does have valid therapeutic purposes. The question before us, however, is not whether it is wise to enforce the statute in these circumstances; rather, it is whether Congress' power to regulate interstate markets for medicinal substances encompasses the portions of those markets that are supplied with drugs produced and consumed locally. Well-settled law controls our answer. The CSA is a valid exercise of federal power, even as applied to the troubling facts of this case. We accordingly vacate the judgment of the Court of Appeals.

II

Shortly after taking office in 1969, President Nixon declared a national "war on drugs."⁹ As the first campaign of that war, Congress set out to enact legislation that would consolidate various drug laws on the books into a comprehensive statute, provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthen law enforcement tools against the traffic in illicit drugs.¹⁰ That effort culminated in the passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236.

This was not, however, Congress' first attempt to regulate the national market in drugs. Rather, as early as 1906 Congress enacted federal legislation imposing labeling regulations on medications and prohibiting the manufacture or shipment of any adulterated or misbranded drug traveling in interstate commerce.¹¹ Aside from these labeling restrictions, most domestic drug regulations prior to 1970 generally came in the guise of revenue laws, with the Department of the Treasury serving as the Federal Government's primary enforcer.¹² For example, the primary drug control law, before being repealed by the passage of the CSA, was the Harrison Narcotics Act of 1914, 38 Stat. 785 (repealed 1970). The Harrison Act sought to exert control over the possession and sale of narcotics, specifically cocaine and opiates, by requiring producers, distributors, and purchasers to register with the Federal Government, by assessing taxes against parties so registered, and by regulating the issuance of prescriptions.¹³

Marijuana itself was not significantly regulated by the Federal Government until 1937 when accounts of marijuana's addictive qualities and physiological effects, paired with dissatisfaction with enforcement efforts at state and local levels, prompted Congress to pass the Marihuana Tax Act, Pub. L. 75-238, 50 Stat. 551 (repealed 1970).¹⁴ Like the Harrison Act, the Marihuana Tax Act did not outlaw the possession or sale of marijuana outright. Rather, it imposed registration and reporting requirements for all individuals importing, producing, selling, or dealing in marijuana, and required the payment of annual taxes in addition to transfer taxes whenever the drug changed hands.¹⁵ Moreover, doctors wishing to prescribe marijuana for medical purposes were required to comply with rather burdensome administrative requirements.¹⁶ Noncompliance exposed traffickers to severe federal penalties, whereas compliance would often subject them to prosecution under state law.¹⁷ Thus, while the Marihuana Tax Act did not declare the drug illegal *per se*, the onerous administrative requirements, the prohibitively expensive taxes, and the risks attendant on compliance practically curtailed the marijuana trade.

Then in 1970, after declaration of the national "war on drugs," federal drug policy underwent a significant transformation. A number of noteworthy events precipitated this policy shift. First, in *Leary v. United States*, 395 U.S. 6 (1969), this Court held certain provisions of the Marihuana Tax Act and other narcotics legislation unconstitutional. Second, at the end of his term, President Johnson fundamentally reorganized the federal drug control agencies. The Bureau of Narcotics, then housed in the Department of Treasury, merged with the Bureau of Drug Abuse Control, then housed in the Department of Health, Education, and Welfare (HEW), to create the Bureau of Narcotics and Dangerous Drugs, currently housed in the Department of Justice.¹⁸ Finally, prompted by a perceived need to consolidate the growing number of piecemeal drug laws and to enhance federal drug enforcement powers, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act.¹⁹

Title II of that Act, the CSA, repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs. The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.²⁰ Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.²¹

To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§841(a)(1), 844(a). The CSA categorizes all controlled substances into five schedules. §812. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. §§811, 812. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. §§821-830. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Ibid.* 21 CFR §1301 *et seq.* (2004).

In enacting the CSA, Congress classified marijuana as a Schedule I drug. 21 U.S.C. §812(c). This preliminary classification was based, in part, on the recommendation of the Assistant Secretary of HEW "that marihuana be retained within schedule I at least until the completion of certain studies now underway."²² Schedule I drugs are categorized as such because of their high potential for abuse, lack of any accepted medical use, and absence of any accepted safety for use in medically supervised treatment. §812(b)(1). These three factors, in varying gradations, are also used to categorize drugs in the other four schedules. For example, Schedule II substances also have a high potential for abuse which may lead to severe psychological or physical dependence, but unlike Schedule I drugs, they have a currently accepted medical use. §812(b)(2). By classifying marijuana as a Schedule I drug, as opposed to listing it on a lesser schedule, the manufacture, distribution, or possession of marijuana became a criminal offense, with the sole exception being use of the drug as part of a Food and Drug Administration pre-approved research study. §§823(f), 841(a)(1), 844(a); see also *United States v. Oakland Cannabis Buyer's Cooperative*, 532 U.S. 483, 490 (2001).

The CSA provides for the periodic updating of schedules and delegates authority to the Attorney General, after consultation with the Secretary of Health and Human Services, to add, remove, or transfer substances to, from, or between schedules. §811. Despite considerable efforts to reschedule marijuana, it remains a Schedule I drug.²³

III

Respondents in this case do not dispute that passage of the CSA, as part of the Comprehensive Drug Abuse Prevention and Control Act, was well within Congress' commerce power. Brief for Respondents 22, 38. Nor do they contend that any provision or section of the CSA amounts to an unconstitutional exercise of congressional authority. Rather, respondents' challenge is actually quite limited; they argue that the CSA's categorical prohibition of the manufacture and possession of marijuana as applied to the intrastate manufacture and possession of marijuana for medical purposes pursuant to California law exceeds Congress' authority under the Commerce Clause.

In assessing the validity of congressional regulation, none of our Commerce Clause cases can be viewed in isolation. As charted in considerable detail in *United States v. Lopez*, our understanding of the reach of the Commerce Clause, as well as Congress' assertion of authority thereunder, has evolved over time.²⁴ The Commerce Clause emerged as the Framers' response to the central problem giving rise to the Constitution itself: the absence of any federal commerce power under the Articles of Confederation.²⁵ For the first century of our history, the primary use of the Clause was to preclude the kind of discriminatory state legislation that had once been permissible.²⁶ Then, in response to rapid industrial development and an increasingly interdependent national economy, Congress "ushered in a new era of federal regulation under the commerce power," beginning with the enactment of the Interstate Commerce Act in 1887, 24 Stat. 379, and the Sherman Antitrust Act in 1890, 26 Stat. 209, as amended, 15 U. S. C. §2 *et seq.*²⁷

Cases decided during that "new era," which now spans more than a century, have identified three general categories of regulation in which Congress is authorized to engage under its commerce power. First, Congress can regulate the channels of interstate commerce. *Perez v. United States*, 402 U. S. 146, 150 (1971). Second, Congress has authority to regulate and protect the instrumentalities of interstate commerce, and persons or things in interstate commerce. *Ibid.* Third, Congress has the power to regulate activities that substantially affect interstate commerce. *Ibid.*; *NLRB v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 37 (1937). Only the third category is implicated in the case at hand.

Our case law firmly establishes Congress' power to regulate purely local activities that are part of an economic "class of activities" that have a substantial effect on interstate commerce. See, e.g., *Perez*, 402 U. S., at 151; *Wickard v. Filburn*, 317 U. S. 111, 128-129 (1942). As we stated in *Wickard*, "even if appellee's activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce." *Id.*, at 125. We have never required Congress to legislate with scientific exactitude. When Congress decides that the "'total incidence'" of a practice poses a threat to a national market, it may regulate the entire class. See *Perez*, 402 U. S., at 154-155 (quoting *Westfall v. United States*, 274 U. S. 256, 259 (1927) ("[W]hen it is necessary in order to prevent an evil to make the law embrace more than the precise thing to be prevented it may do so")). In this vein, we have reiterated that when "'a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence.'" E.g., *Lopez*, 514 U. S., at 558 (emphasis deleted) (quoting *Maryland v. Wirtz*, 392 U. S. 183, 196, n. 27 (1968)).

Our decision in *Wickard*, 317 U. S. 111, is of particular relevance. In *Wickard*, we upheld the application of regulations promulgated under the Agricultural Adjustment Act of 1938, 52 Stat. 31, which were designed to control the volume of wheat moving in interstate and foreign commerce in order to avoid surpluses and consequent abnormally low prices. The regulations established an allotment of 11.1 acres for Filburn's 1941 wheat crop, but he sowed 23 acres, intending to use the excess by consuming it on his own farm. Filburn argued that even though we had sustained Congress' power to regulate the production of goods for commerce, that power did not authorize "federal regulation [of] production not intended in any part for commerce but wholly for consumption on the farm." *Wickard*, 317 U. S., at 118. Justice Jackson's opinion for a unanimous Court rejected this submission. He wrote:

"The effect of the statute before us is to restrict the amount which may be produced for market and the extent as well to which one may forestall resort to the market by producing to meet his own needs. That appellee's own contribution to the demand for wheat may be trivial by itself is not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial." *Id.*, at 127-128

Wickard thus establishes that Congress can regulate purely intrastate activity that is not itself "commercial," in that it is not produced for sale, if it concludes that failure to regulate that class of activity would undercut the regulation of the interstate market in that commodity.

The similarities between this case and *Wickard* are striking. Like the farmer in *Wickard*, respondents are cultivating, for home consumption, a fungible commodity for which there is an established, albeit illegal, interstate market.²⁸ Just as the Agricultural Adjustment Act was designed "to control the volume [of wheat] moving in interstate and foreign commerce in order to avoid surpluses . . ." and consequently control the market price, *id.*, at 115, a primary purpose of the

CSA is to control the supply and demand of controlled substances in both lawful and unlawful drug markets. See nn. 20-21, *supra*. In *Wickard*, we had no difficulty concluding that Congress had a rational basis for believing that, when viewed in the aggregate, leaving home-consumed wheat outside the regulatory scheme would have a substantial influence on price and market conditions. Here too, Congress had a rational basis for concluding that leaving home-consumed marijuana outside federal control would similarly affect price and market conditions.

More concretely, one concern prompting inclusion of wheat grown for home consumption in the 1938 Act was that rising market prices could draw such wheat into the interstate market, resulting in lower market prices. *Wickard*, 317 U. S., at 128. The parallel concern making it appropriate to include marijuana grown for home consumption in the CSA is the likelihood that the high demand in the interstate market will draw such marijuana into that market. While the diversion of homegrown wheat tended to frustrate the federal interest in stabilizing prices by regulating the volume of commercial transactions in the interstate market, the diversion of homegrown marijuana tends to frustrate the federal interest in eliminating commercial transactions in the interstate market in their entirety. In both cases, the regulation is squarely within Congress' commerce power because production of the commodity meant for home consumption, be it wheat or marijuana, has a substantial effect on supply and demand in the national market for that commodity.²⁹

Nonetheless, respondents suggest that *Wickard* differs from this case in three respects: (1) the Agricultural Adjustment Act, unlike the CSA, exempted small farming operations; (2) *Wickard* involved a "quintessential economic activity"--a commercial farm--whereas respondents do not sell marijuana; and (3) the *Wickard* record made it clear that the aggregate production of wheat for use on farms had a significant impact on market prices. Those differences, though factually accurate, do not diminish the precedential force of this Court's reasoning.

The fact that *Wickard*'s own impact on the market was "trivial by itself" was not a sufficient reason for removing him from the scope of federal regulation. 317 U. S., at 127. That the Secretary of Agriculture elected to exempt even smaller farms from regulation does not speak to his power to regulate all those whose aggregated production was significant, nor did that fact play any role in the Court's analysis. Moreover, even though *Wickard* was indeed a commercial farmer, the activity he was engaged in--the cultivation of wheat for home consumption--was not treated by the Court as part of his commercial farming operation.³⁰ And while it is true that the record in the *Wickard* case itself established the causal connection between the production for local use and the national market, we have before us findings by Congress to the same effect.

Findings in the introductory sections of the CSA explain why Congress deemed it appropriate to encompass local activities within the scope of the CSA. See n. 20, *supra*. The submissions of the parties and the numerous *amici* all seem to agree that the national, and international, market for marijuana has dimensions that are fully comparable to those defining the class of activities regulated by the Secretary pursuant to the 1938 statute.³¹ Respondents nonetheless insist that the CSA cannot be constitutionally applied to their activities because Congress did not make a specific finding that the intrastate cultivation and possession of marijuana for medical purposes based on the recommendation of a physician would substantially affect the larger interstate marijuana market. Be that as it may, we have never required Congress to make particularized findings in order to legislate, see *Lopez*, 514 U. S., at 562; *Perez*, 402 U. S., at 156, absent a special concern such as the protection of free speech, see, e.g., *Turner Broadcasting System, Inc. v. FCC*, 512 U. S. 622, 664-668 (1994) (plurality opinion). While congressional findings are certainly helpful in reviewing the substance of a congressional statutory scheme, particularly when the connection to commerce is not self-evident, and while we will consider congressional findings in our analysis when they are available, the absence of particularized findings does not call into question Congress' authority to legislate.³²

In assessing the scope of Congress' authority under the Commerce Clause, we stress that the task before us is a modest one. We need not determine whether respondents' activities, taken in the aggregate, substantially affect interstate commerce in fact, but only whether a "rational basis" exists for so concluding. *Lopez*, 514 U. S., at 557; see also *Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U. S. 264, 276-280 (1981); *Perez*, 402 U. S., at 155-156; *Katzenbach v. McClung*, 379 U. S. 294, 299-301 (1964); *Heart of Atlanta Motel, Inc. v. United States*, 379 U. S. 241, 252-253 (1964). Given the enforcement difficulties that attend distinguishing between marijuana cultivated locally and marijuana grown elsewhere, 21 U. S. C. §801(5), and concerns about diversion into illicit channels,³³ we have no difficulty concluding that Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the CSA. Thus, as in *Wickard*, when it enacted comprehensive legislation to regulate the interstate market in a fungible commodity, Congress was acting well within its authority to "make all Laws which shall be necessary and proper" to "regulate Commerce ... among the several States." U. S. Const., Art. I, §8. That the regulation ensnares some purely intrastate activity is of no moment. As we have done many times before, we refuse to excise individual components of that larger scheme.

To support their contrary submission, respondents rely heavily on two of our more recent Commerce Clause cases. In their myopic focus, they overlook the larger context of modern-era Commerce Clause jurisprudence preserved by those cases. Moreover, even in the narrow prism of respondents' creation, they read those cases far too broadly. Those two cases, of course, are *Lopez*, 514 U. S. 549, and *Morrison*, 529 U. S. 598. As an initial matter, the statutory challenges at issue in those cases were markedly different from the challenge respondents pursue in the case at hand. Here, respondents ask us to excise individual applications of a concededly valid statutory scheme. In contrast, in both *Lopez* and *Morrison*, the parties asserted that a particular statute or provision fell outside Congress' commerce power in its entirety. This distinction is pivotal for we have often reiterated that "[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." *Perez*, 402 U. S., at 154 (emphasis deleted) (quoting *Wirtz*, 392 U. S., at 193); see also *Hodel*, 452 U. S., at 308.

At issue in *Lopez*, 514 U. S. 549, was the validity of the Gun-Free School Zones Act of 1990, which was a brief, single-subject statute making it a crime for an individual to possess a gun in a school zone. 104 Stat. 4844-4845, 18 U. S. C. §922(q)(1)(A). The Act did not regulate any economic activity and did not contain any requirement that the possession of a gun have any connection to past interstate activity or a predictable impact on future commercial activity. Distinguishing our earlier cases holding that comprehensive regulatory statutes may be validly applied to local conduct that does not, when viewed in isolation, have a significant impact on interstate commerce, we held the statute invalid. We explained:

"Section 922(q) is a criminal statute that by its terms has nothing to do with 'commerce' or any sort of economic enterprise, however broadly one might define those terms. Section 922(q) is not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated. It cannot, therefore, be sustained under our cases upholding regulations of activities that arise out of or are connected with a commercial transaction, which viewed in the aggregate, substantially affects interstate commerce." 514 U. S., at 561.

The statutory scheme that the Government is defending in this litigation is at the opposite end of the regulatory spectrum. As explained above, the CSA, enacted in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act, 84 Stat. 1242-1284, was a lengthy and detailed statute creating a comprehensive framework for regulating the production, distribution, and possession of five classes of "controlled substances." Most of those substances--those listed in Schedules II through V--"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). The regulatory scheme is designed to foster the beneficial use of those medications, to prevent their misuse, and to prohibit entirely the possession or use of substances listed in Schedule I, except as a part of a strictly controlled research project.

While the statute provided for the periodic updating of the five schedules, Congress itself made the initial classifications. It identified 42 opiates, 22 opium derivatives, and 17 hallucinogenic substances as Schedule I drugs. 84 Stat. 1248. Marijuana was listed as the 10th item in the third subcategory. That classification, unlike the discrete prohibition established by the Gun-Free School Zones Act of 1990, was merely one of many "essential part[s] of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Lopez*, 514 U. S., at 561.³⁴ Our opinion in *Lopez* casts no doubt on the validity of such a program.

Nor does this Court's holding in *Morrison*, 529 U. S. 598. The Violence Against Women Act of 1994, 108 Stat. 1902, created a federal civil remedy for the victims of gender-motivated crimes of violence. 42 U. S. C. §13981. The remedy was enforceable in both state and federal courts, and generally depended on proof of the violation of a state law. Despite congressional findings that such crimes had an adverse impact on interstate commerce, we held the statute unconstitutional because, like the statute in *Lopez*, it did not regulate economic activity. We concluded that "the noneconomic, criminal nature of the conduct at issue was central to our decision" in *Lopez*, and that our prior cases had identified a clear pattern of analysis: "Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained." ³⁵ *Morrison*, 529 U. S., at 610.

Unlike those at issue in *Lopez* and *Morrison*, the activities regulated by the CSA are quintessentially economic. "Economics" refers to "the production, distribution, and consumption of commodities." Webster's Third New International Dictionary 720 (1966). The CSA is a statute that regulates the production, distribution, and consumption of commodities for which there is an established, and lucrative, interstate market. Prohibiting the intrastate possession or manufacture of an article of commerce is a rational (and commonly utilized) means of regulating commerce in that product.³⁶ Such prohibitions include specific decisions requiring that a drug be withdrawn from the market as a result of the failure to comply with regulatory requirements as well as decisions excluding Schedule I drugs entirely from the market. Because the CSA is a statute that directly regulates economic, commercial activity, our opinion in *Morrison* casts no doubt on its constitutionality.

The Court of Appeals was able to conclude otherwise only by isolating a "separate and distinct" class of activities that it held to be beyond the reach of federal power, defined as "the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician and in accordance with state law." 352 F. 3d, at 1229. The court characterized this class as "different in kind from drug trafficking." *Id.*, at 1228. The differences between the members of a class so defined and the principal traffickers in Schedule I substances might be sufficient to justify a policy decision exempting the narrower class from the coverage of the CSA. The question, however, is whether Congress' contrary policy judgment, *i.e.*, its decision to include this narrower "class of activities" within the larger regulatory scheme, was constitutionally deficient. We have no difficulty concluding that Congress acted rationally in determining that none of the characteristics making up the purported class, whether viewed individually or in the aggregate, compelled an exemption from the CSA; rather, the subdivided class of activities defined by the Court of Appeals was an essential part of the larger regulatory scheme.

First, the fact that marijuana is used "for personal medical purposes on the advice of a physician" cannot itself serve as a distinguishing factor. 352 F. 3d, at 1229. The CSA designates marijuana as contraband for *any* purpose; in fact, by characterizing marijuana as a Schedule I drug, Congress expressly found that the drug has no acceptable medical uses. Moreover, the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, and in what manner. Indeed, most of the substances classified in the CSA "have a useful and legitimate medical purpose." 21 U. S. C. §801(1). Thus, even if respondents are correct that marijuana does have accepted medical uses and thus should be redesignated as a lesser schedule drug,³⁷ the CSA would still impose controls beyond what is required by California law. The CSA requires manufacturers, physicians, pharmacies, and other handlers of controlled substances to comply with statutory and regulatory provisions mandating registration with the DEA, compliance with specific production quotas, security controls to guard against diversion, recordkeeping and reporting obligations, and prescription requirements. See 21 U. S. C. §§821-830; 21 CFR §1301 *et seq.* (2004). Furthermore, the dispensing of new drugs, even when doctors approve their use, must await federal approval. *United States v. Rutherford*, 442 U. S. 544 (1979). Accordingly, the mere fact that marijuana--like virtually every other controlled substance regulated by the CSA--is used for medicinal purposes cannot possibly serve to distinguish it from the core activities regulated by the CSA.

Nor can it serve as an "objective marke[r]" or "objective facto[r]" to arbitrarily narrow the relevant class as the dissenters suggest, *post*, at 6 (O'Connor, J., dissenting); *post*, at 12 (Thomas, J., dissenting). More fundamentally, if, as the principal dissent contends, the personal cultivation, possession, and use of marijuana for medicinal purposes is beyond the "'outer limits' of Congress' Commerce Clause authority," *post*, at 1 (O'Connor, J., dissenting), it must also be true that such personal use of marijuana (or any other homegrown drug) for recreational purposes is also beyond those "'outer limits," "whether or not a State elects to authorize or even regulate such use. Justice Thomas' separate dissent suffers from the same sweeping implications. That is, the dissenters' rationale logically extends to place *any* federal regulation (including quality, prescription, or quantity controls) of *any* locally cultivated and possessed controlled substance for *any* purpose beyond the "'outer limits'" of Congress' Commerce Clause authority. One need not have a degree in economics to understand why a nationwide exemption for the vast quantity of marijuana (or other drugs) locally cultivated for personal use (which presumably would include use by friends, neighbors, and family members) may have a substantial impact on the interstate market for this extraordinarily popular substance. The congressional judgment that an exemption for such a significant segment of the total market would undermine the orderly enforcement of the entire regulatory scheme is entitled to a strong presumption of validity. Indeed, that judgment is not only rational, but "visible to the naked eye," *Lopez*, 514 U. S., at 563, under any commonsense appraisal of the probable consequences of such an open-ended exemption.

Second, limiting the activity to marijuana possession and cultivation "in accordance with state law" cannot serve to place respondents' activities beyond congressional reach. The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail. It is beyond peradventure that federal power over commerce is "superior to that of the States to provide for the welfare or necessities of their inhabitants," "however legitimate or dire those necessities may be." *Wirtz*, 392 U. S., at 196 (quoting *Sanitary Dist. of Chicago v. United States*, 266 U. S. 405, 426 (1925)). See also 392 U. S., at 195-196; *Wickard*, 317 U. S., at 124 ("[N]o form of state activity can constitutionally thwart the regulatory power granted by the commerce clause to Congress"). Just as state acquiescence to federal regulation cannot expand the bounds of the Commerce Clause, see, *e.g.*, *Morrison*, 529 U. S., at 661-662 (Breyer, J., dissenting) (noting that 38 States requested federal intervention), so too state action cannot circumscribe Congress' plenary commerce power. See *United States v. Darby*, 312 U. S. 100, 114 (1941) ("That power can neither be enlarged nor diminished by the exercise or non-exercise of state power").³⁸

Respondents acknowledge this proposition, but nonetheless contend that their activities were not "an essential part of a larger regulatory scheme" because they had been "isolated by the State of California, and [are] policed by the State of California," and thus remain "entirely separated from the market." Tr. of Oral Arg. 27. The dissenters fall prey to similar reasoning. See n. 38, *supra* this page. The notion that California law has surgically excised a discrete activity that is

hermetically sealed off from the larger interstate marijuana market is a dubious proposition, and, more importantly, one that Congress could have rationally rejected.

Indeed, that the California exemptions will have a significant impact on both the supply and demand sides of the market for marijuana is not just "plausible" as the principal dissent concedes, *post*, at 16 (*O'Connor, J*, dissenting), it is readily apparent. The exemption for physicians provides them with an economic incentive to grant their patients permission to use the drug. In contrast to most prescriptions for legal drugs, which limit the dosage and duration of the usage, under California law the doctor's permission to recommend marijuana use is open-ended. The authority to grant permission whenever the doctor determines that a patient is afflicted with "any other illness for which marijuana provides relief," Cal. Health & Safety Code Ann. §11362.5(b)(1)(A) (West Supp. 2005), is broad enough to allow even the most scrupulous doctor to conclude that some recreational uses would be therapeutic.³⁹ And our cases have taught us that there are some unscrupulous physicians who overprescribe when it is sufficiently profitable to do so.⁴⁰

The exemption for cultivation by patients and caregivers can only increase the supply of marijuana in the California market.⁴¹ The likelihood that all such production will promptly terminate when patients recover or will precisely match the patients' medical needs during their convalescence seems remote; whereas the danger that excesses will satisfy some of the admittedly enormous demand for recreational use seems obvious.⁴² Moreover, that the national and international narcotics trade has thrived in the face of vigorous criminal enforcement efforts suggests that no small number of unscrupulous people will make use of the California exemptions to serve their commercial ends whenever it is feasible to do so.⁴³ Taking into account the fact that California is only one of at least nine States to have authorized the medical use of marijuana, a fact *Justice O'Connor's* dissent conveniently disregards in arguing that the demonstrated effect on commerce while admittedly "plausible" is ultimately "unsubstantiated," *post*, at 14, 16, Congress could have rationally concluded that the aggregate impact on the national market of all the transactions exempted from federal supervision is unquestionably substantial.

So, from the "separate and distinct" class of activities identified by the Court of Appeals (and adopted by the dissenters), we are left with "the intrastate, noncommercial cultivation, possession and use of marijuana." 352 F. 3d, at 1229. Thus the case for the exemption comes down to the claim that a locally cultivated product that is used domestically rather than sold on the open market is not subject to federal regulation. Given the findings in the CSA and the undisputed magnitude of the commercial market for marijuana, our decisions in *Wickard v. Filburn* and the later cases endorsing its reasoning foreclose that claim.

V

Respondents also raise a substantive due process claim and seek to avail themselves of the medical necessity defense. These theories of relief were set forth in their complaint but were not reached by the Court of Appeals. We therefore do not address the question whether judicial relief is available to respondents on these alternative bases. We do note, however, the presence of another avenue of relief. As the Solicitor General confirmed during oral argument, the statute authorizes procedures for the reclassification of Schedule I drugs. But perhaps even more important than these legal avenues is the democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress. Under the present state of the law, however, the judgment of the Court of Appeals must be vacated. The case is remanded for further proceedings consistent with this opinion.

It is so ordered.

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al*, PETITIONERS *v.* ANGEL McCLARY RAICH *et al*

on writ of certiorari to the united states court of
appeals for the ninth circuit

[June 6, 2005]

Justice Scalia, concurring in the judgment.

I agree with the Court's holding that the Controlled Substances Act (CSA) may validly be applied to respondents' cultivation, distribution, and possession of marijuana for personal, medicinal use. I write separately because my understanding of the doctrinal foundation on which that holding rests is, if not inconsistent with that of the Court, at least more nuanced

Since *Perez v. United States*, 402 U.S. 146 (1971), our cases have mechanically recited that the Commerce Clause permits congressional regulation of three categories: (1) the channels of interstate commerce; (2) the instrumentalities of interstate commerce, and persons or things in interstate commerce; and (3) activities that "substantially affect" interstate commerce. *Id.*, at 150; see *United States v. Morrison*, 529 U.S. 598, 608-609 (2000); *United States v. Lopez*, 514 U.S. 549, 558-559 (1995); *Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264, 276-277 (1981). The first two categories are self-evident, since they are the ingredients of interstate commerce itself. See *Gibbons v. Ogden*, 9 Wheat. 1, 189-190 (1824). The third category, however, is different in kind, and its recitation without explanation is misleading and incomplete.

It is *misleading* because, unlike the channels, instrumentalities, and agents of interstate commerce, activities that substantially affect interstate commerce are not themselves part of interstate commerce, and thus the power to regulate them cannot come from the Commerce Clause alone. Rather, as this Court has acknowledged since at least *United States v. Coombs*, 12 Pet. 72 (1838), Congress's regulatory authority over intrastate activities that are not themselves part of interstate commerce (including activities that have a substantial effect on interstate commerce) derives from the Necessary and Proper Clause. *Id.*, at 78; *Katzenbach v. McClung*, 379 U.S. 294, 301-302 (1964); *United States v. Wrightwood Dairy Co.*, 315 U.S. 110, 119 (1942); *Shreveport Rate Cases*, 234 U.S. 342, 353 (1914); *United States v. E. C. Knight Co.*, 156 U.S. 1, 39-40 (1895) (Harlan, J., dissenting). And the category of "activities that substantially affect interstate commerce," *Lopez*, *supra*, at 559, is *incomplete* because the authority to enact laws necessary and proper for the regulation of interstate commerce is not limited to laws governing intrastate activities that substantially affect interstate commerce. Where necessary to make a regulation of interstate commerce effective, Congress may regulate even those intrastate activities that do not themselves substantially affect interstate commerce.

I

Our cases show that the regulation of intrastate activities may be necessary to and proper for the regulation of interstate commerce in two general circumstances. Most directly, the commerce power permits Congress not only to devise rules for the governance of commerce between States but also to facilitate interstate commerce by eliminating potential obstructions, and to restrict it by eliminating potential stimulants. See *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 36-37 (1937). That is why the Court has repeatedly sustained congressional legislation on the ground that the regulated activities had a substantial effect on interstate commerce. See, e.g., *Hodel*, *supra*, at 281 (surface coal mining); *Katzenbach*, *supra*, at 300 (discrimination by restaurants); *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 258 (1964) (discrimination by hotels); *Mandeville Island Farms v. American Crystal Sugar Co.*, 334 U.S. 219, 237 (1948) (intrastate price-fixing); *Board of Trade of Chicago v. Olsen*, 262 U.S. 1, 40 (1923) (activities of a local grain exchange); *Stafford v. Wallace*, 258 U.S. 495, 517, 524-525 (1922) (intrastate transactions at stockyard). *Lopez* and *Morrison* recognized the expansive scope of Congress's authority in this regard: "[T]he pattern is clear. Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained." *Lopez*, *supra*, at 560; *Morrison*, *supra*, at 610 (same).

This principle is not without limitation. In *Lopez* and *Morrison*, the Court--conscious of the potential of the "substantially affects" test to "obliterate the distinction between what is national and what is local," *Lopez*, *supra*, at 566-567 (quoting *A. L. A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 554 (1935)); see also *Morrison*, *supra*, at 615-616--rejected the argument that Congress may regulate *noneconomic* activity based solely on the effect that it may have on interstate commerce through a remote chain of inferences. *Lopez*, *supra*, at 564-566; *Morrison*, *supra*, at 617-618. "[I]f we were to accept [such] arguments," the Court reasoned in *Lopez*, "we are hard pressed to posit any activity by an individual that Congress is without power to regulate." *Lopez*, *supra*, at 564; see also *Morrison*, *supra*, at 615-616. Thus, although Congress's authority to regulate intrastate activity that substantially affects interstate commerce is broad, it does not permit the Court to "pile inference upon inference," *Lopez*, *supra*, at 567, in order to establish that noneconomic activity has a substantial effect on interstate commerce.

As we implicitly acknowledged in *Lopez*, however, Congress's authority to enact laws necessary and proper for the regulation of interstate commerce is not limited to laws directed against economic activities that have a substantial effect on interstate commerce. Though the conduct in *Lopez* was not economic, the Court nevertheless recognized that it could be regulated as "an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." 514 U.S. , at 561. This statement referred to those cases permitting the regulation of intrastate activities "which in a substantial way interfere with or obstruct the exercise of the granted

power " *Wrightwood Dairy Co.*, 315 U. S., at 119; see also *United States v. Darby*, 312 U. S. 100, 118-119 (1941); *Shreveport Rate Cases*, 234 U. S., at 353. As the Court put it in *Wrightwood Dairy*, where Congress has the authority to enact a regulation of interstate commerce, "it possesses every power needed to make that regulation effective " 315 U. S., at 118-119

Although this power "to make ... regulation effective" commonly overlaps with the authority to regulate economic activities that substantially affect interstate commerce,² and may in some cases have been confused with that authority, the two are distinct. The regulation of an intrastate activity may be essential to a comprehensive regulation of interstate commerce even though the intrastate activity does not itself "substantially affect" interstate commerce. Moreover, as the passage from *Lopez* quoted above suggests, Congress may regulate even noneconomic local activity if that regulation is a necessary part of a more general regulation of interstate commerce. See *Lopez, supra*, at 561. The relevant question is simply whether the means chosen are "reasonably adapted" to the attainment of a legitimate end under the commerce power. See *Darby, supra*, at 121.

In *Darby*, for instance, the Court explained that "Congress, having ... adopted the policy of excluding from interstate commerce all goods produced for the commerce which do not conform to the specified labor standards," 312 U. S., at 121, could not only require employers engaged in the production of goods for interstate commerce to conform to wage and hour standards, *id.*, at 119-121, but could also require those employers to keep employment records in order to demonstrate compliance with the regulatory scheme, *id.*, at 125. While the Court sustained the former regulation on the alternative ground that the activity it regulated could have a "great effect" on interstate commerce, *id.*, at 122-123, it affirmed the latter on the sole ground that "[t]he requirement for records even of the intrastate transaction is an appropriate means to a legitimate end," *id.*, at 125.

As the Court said in the *Shreveport Rate Cases*, the Necessary and Proper Clause does not give "Congress ... the authority to regulate the internal commerce of a State, as such," but it does allow Congress "to take all measures necessary or appropriate to" the effective regulation of the interstate market, "although intrastate transactions ... may thereby be controlled " 234 U. S., at 353; see also *Jones & Laughlin Steel Corp.*, 301 U. S., at 38 (the logic of the *Shreveport Rate Cases* is not limited to instrumentalities of commerce).

II

Today's principal dissent objects that, by permitting Congress to regulate activities necessary to effective interstate regulation, the Court reduces *Lopez* and *Morrison* to "little more than a drafting guide." *Post*, at 5 (opinion of *O'Connor, J.*). I think that criticism unjustified. Unlike the power to regulate activities that have a substantial effect on interstate commerce, the power to enact laws enabling effective regulation of interstate commerce can only be exercised in conjunction with congressional regulation of an interstate market, and it extends only to those measures necessary to make the interstate regulation effective. As *Lopez* itself states, and the Court affirms today, Congress may regulate noneconomic intrastate activities only where the failure to do so "could ... undercut" its regulation of interstate commerce. See *Lopez, supra*, at 561; *ante*, at 15, 21, 22. This is not a power that threatens to obliterate the line between "what is truly national and what is truly local." *Lopez, supra*, at 567-568.

Lopez and *Morrison* affirm that Congress may not regulate certain "purely local" activity within the States based solely on the attenuated effect that such activity may have in the interstate market. But those decisions do not declare noneconomic intrastate activities to be categorically beyond the reach of the Federal Government. Neither case involved the power of Congress to exert control over intrastate activities in connection with a more comprehensive scheme of regulation; *Lopez* expressly disclaimed that it was such a case, 514 U. S., at 561, and *Morrison* did not even discuss the possibility that it was. (The Court of Appeals in *Morrison* made clear that it was not. See *Brzonkala v. Virginia Polytechnic Inst.*, 169 F. 3d 820, 834-835 (CA4 1999) (en banc).) To dismiss this distinction as "superficial and formalistic," see *post*, at 6 (*O'Connor, J.*, dissenting), is to misunderstand the nature of the Necessary and Proper Clause, which empowers Congress to enact laws in effectuation of its enumerated powers that are not within its authority to enact in isolation. See *McCulloch v. Maryland*, 4 Wheat. 316, 421-422 (1819).

And there are other restraints upon the Necessary and Proper Clause authority. As Chief Justice Marshall wrote in *McCulloch v. Maryland*, even when the end is constitutional and legitimate, the means must be "appropriate" and "plainly adapted" to that end. *Id.*, at 421. Moreover, they may not be otherwise "prohibited" and must be "consistent with the letter and spirit of the constitution." *Ibid.* These phrases are not merely hortatory. For example, cases such as *Printz v. United States*, 521 U. S. 898 (1997), and *New York v. United States*, 505 U. S. 144 (1992), affirm that a law is not "'proper for carrying into Execution the Commerce Clause' " "[w]hen [it] violates [a constitutional] principle of state sovereignty " *Printz, supra*, at 923-924; see also *New York, supra*, at 166.

III

The application of these principles to the case before us is straightforward. In the CSA, Congress has undertaken to extinguish the interstate market in Schedule I controlled substances, including marijuana. The Commerce Clause unquestionably permits this. The power to regulate interstate commerce "extends not only to those regulations which aid, foster and protect the commerce, but embraces those which prohibit it." *Darby*, 312 U. S., at 113. See also *Hipolite Egg Co v. United States*, 220 U. S. 45, 58 (1911); *Lottery Case*, 188 U. S. 321, 354 (1903). To effectuate its objective, Congress has prohibited almost all intrastate activities related to Schedule I substances--both economic activities (manufacture, distribution, possession with the intent to distribute) and noneconomic activities (simple possession). See 21 U. S. C §§841(a), 844(a). That simple possession is a noneconomic activity is immaterial to whether it can be prohibited as a necessary part of a larger regulation. Rather, Congress's authority to enact all of these prohibitions of intrastate controlled-substance activities depends only upon whether they are appropriate means of achieving the legitimate end of eradicating Schedule I substances from interstate commerce.

By this measure, I think the regulation must be sustained. Not only is it impossible to distinguish "controlled substances manufactured and distributed intrastate" from "controlled substances manufactured and distributed interstate," but it hardly makes sense to speak in such terms. Drugs like marijuana are fungible commodities. As the Court explains, marijuana that is grown at home and possessed for personal use is never more than an instant from the interstate market--and this is so whether or not the possession is for medicinal use or lawful use under the laws of a particular State.³ See *ante*, at 23-30. Congress need not accept on faith that state law will be effective in maintaining a strict division between a lawful market for "medical" marijuana and the more general marijuana market. See *id.*, at 26-27, and n. 38. "To impose on [Congress] the necessity of resorting to means which it cannot control, which another government may furnish or withhold, would render its course precarious, the result of its measures uncertain, and create a dependence on other governments, which might disappoint its most important designs, and is incompatible with the language of the constitution." *McCulloch*, *supra*, at 424.

Finally, neither respondents nor the dissenters suggest any violation of state sovereignty of the sort that would render this regulation "inappropriate," *id.*, at 421--except to argue that the CSA regulates an area typically left to state regulation. See *post*, at 6-7, 11 (opinion of *O'Connor*, J.); *post*, at 8-9 (opinion of *Thomas*, J.); Brief for Respondents 39-42. That is not enough to render federal regulation an inappropriate means. The Court has repeatedly recognized that, if authorized by the commerce power, Congress may regulate private endeavors "even when [that regulation] may pre-empt express state-law determinations contrary to the result which has commended itself to the collective wisdom of Congress." *National League of Cities v. Usery*, 426 U. S. 833, 840 (1976); see *Cleveland v. United States*, 329 U. S. 14, 19 (1946); *McCulloch*, *supra*, at 424. At bottom, respondents' state-sovereignty argument reduces to the contention that federal regulation of the activities permitted by California's Compassionate Use Act is not sufficiently necessary to be "necessary and proper" to Congress's regulation of the interstate market. For the reasons given above and in the Court's opinion, I cannot agree.

I thus agree with the Court that, however the class of regulated activities is subdivided, Congress could reasonably conclude that its objective of prohibiting marijuana from the interstate market "could be undercut" if those activities were excepted from its general scheme of regulation. See *Lopez*, 514 U. S., at 561. That is sufficient to authorize the application of the CSA to respondents.

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al.*, PETITIONERS *v.* ANGEL McCLARY RAICH *et al.*

on writ of certiorari to the united states court of
appeals for the ninth circuit

[June 6, 2005]

Justice O'Connor, with whom *The Chief Justice* and *Justice Thomas* join as to all but Part III, dissenting.

We enforce the "outer limits" of Congress' Commerce Clause authority not for their own sake, but to protect historic spheres of state sovereignty from excessive federal encroachment and thereby to maintain the distribution of power

fundamental to our federalist system of government *United States v. Lopez*, 514 U. S. 549, 557 (1995); *NLRB v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 37 (1937). One of federalism's chief virtues, of course, is that it promotes innovation by allowing for the possibility that "a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U. S. 262, 311 (1932) (Brandeis, J., dissenting)

This case exemplifies the role of States as laboratories. The States' core police powers have always included authority to define criminal law and to protect the health, safety, and welfare of their citizens. *Brecht v. Abrahamson*, 507 U. S. 619, 635 (1993); *Whalen v. Roe*, 429 U. S. 589, 603, n. 30 (1977). Exercising those powers, California (by ballot initiative and then by legislative codification) has come to its own conclusion about the difficult and sensitive question of whether marijuana should be available to relieve severe pain and suffering. Today the Court sanctions an application of the federal Controlled Substances Act that extinguishes that experiment, without any proof that the personal cultivation, possession, and use of marijuana for medicinal purposes, if economic activity in the first place, has a substantial effect on interstate commerce and is therefore an appropriate subject of federal regulation. In so doing, the Court announces a rule that gives Congress a perverse incentive to legislate broadly pursuant to the Commerce Clause--nestling questionable assertions of its authority into comprehensive regulatory schemes--rather than with precision. That rule and the result it produces in this case are irreconcilable with our decisions in *Lopez*, *supra*, and *United States v. Morrison*, 529 U. S. 598 (2000). Accordingly I dissent.

I

In *Lopez*, we considered the constitutionality of the Gun-Free School Zones Act of 1990, which made it a federal offense "for any individual knowingly to possess a firearm ... at a place the individual knows, or has reasonable cause to believe, is a school zone," 18 U. S. C. §922(q)(2)(A). We explained that "Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce ... , i.e., those activities that substantially affect interstate commerce." 514 U. S., at 558-559 (citation omitted). This power derives from the conjunction of the Commerce Clause and the Necessary and Proper Clause. *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U. S. 528, 585-586 (1985) (*O'Connor*, J., dissenting) (explaining that *United States v. Darby*, 312 U. S. 100 (1941), *United States v. Wrightwood Dairy Co.*, 315 U. S. 110 (1942), and *Wickard v. Filburn*, 317 U. S. 111 (1942), based their expansion of the commerce power on the Necessary and Proper Clause, and that "the reasoning of these cases underlies every recent decision concerning the reach of Congress to activities affecting interstate commerce"); *ante*, at 2 (*Scalia*, J., concurring in judgment). We held in *Lopez* that the Gun-Free School Zones Act could not be sustained as an exercise of that power.

Our decision about whether gun possession in school zones substantially affected interstate commerce turned on four considerations. *Lopez*, *supra*, at 559-567; see also *Morrison*, *supra*, at 609-613. First, we observed that our "substantial effects" cases generally have upheld federal regulation of economic activity that affected interstate commerce, but that §922(q) was a criminal statute having "nothing to do with 'commerce' or any sort of economic enterprise." *Lopez*, 514 U. S., at 561. In this regard, we also noted that "[s]ection 922(q) is not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated. It cannot, therefore, be sustained under our cases upholding regulations of activities that arise out of or are connected with a commercial transaction, which viewed in the aggregate, substantially affects interstate commerce." *Ibid.* Second, we noted that the statute contained no express jurisdictional requirement establishing its connection to interstate commerce. *Ibid.*

Third, we found telling the absence of legislative findings about the regulated conduct's impact on interstate commerce. We explained that while express legislative findings are neither required nor, when provided, dispositive, findings "enable us to evaluate the legislative judgment that the activity in question substantially affect[s] interstate commerce, even though no such substantial effect [is] visible to the naked eye." *Id.*, at 563. Finally, we rejected as too attenuated the Government's argument that firearm possession in school zones could result in violent crime which in turn could adversely affect the national economy. *Id.*, at 563-567. The Constitution, we said, does not tolerate reasoning that would "convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States." *Id.*, at 567. Later in *Morrison*, *supra*, we relied on the same four considerations to hold that §40302 of the Violence Against Women Act of 1994, 42 U. S. C. §13981, exceeded Congress' authority under the Commerce Clause.

In my view, the case before us is materially indistinguishable from *Lopez* and *Morrison* when the same considerations are taken into account.

II

A

What is the relevant conduct subject to Commerce Clause analysis in this case? The Court takes its cues from Congress, applying the above considerations to the activity regulated by the Controlled Substances Act (CSA) in general. The Court's decision rests on two facts about the CSA: (1) Congress chose to enact a single statute providing a comprehensive prohibition on the production, distribution, and possession of all controlled substances, and (2) Congress did not distinguish between various forms of intrastate noncommercial cultivation, possession, and use of marijuana. See 21 U. S. C. §§841(a)(1), 844(a). Today's decision suggests that the federal regulation of local activity is immune to Commerce Clause challenge because Congress chose to act with an ambitious, all-encompassing statute, rather than piecemeal. In my view, allowing Congress to set the terms of the constitutional debate in this way, *i.e.*, by packaging regulation of local activity in broader schemes, is tantamount to removing meaningful limits on the Commerce Clause.

The Court's principal means of distinguishing *Lopez* from this case is to observe that the Gun-Free School Zones Act of 1990 was a "brief, single-subject statute," *ante*, at 20, see also *ante*, at 19, whereas the CSA is "a lengthy and detailed statute creating a comprehensive framework for regulating the production, distribution, and possession of five classes of 'controlled substances,'" *ibid*. Thus, according to the Court, it was possible in *Lopez* to evaluate in isolation the constitutionality of criminalizing local activity (there gun possession in school zones), whereas the local activity that the CSA targets (in this case cultivation and possession of marijuana for personal medicinal use) cannot be separated from the general drug control scheme of which it is a part.

Today's decision allows Congress to regulate intrastate activity without check, so long as there is some implication by legislative design that regulating intrastate activity is essential (and the Court appears to equate "essential" with "necessary") to the interstate regulatory scheme. Seizing upon our language in *Lopez* that the statute prohibiting gun possession in school zones was "not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated," 514 U. S., at 561, the Court appears to reason that the placement of local activity in a comprehensive scheme confirms that it is essential to that scheme. *Ante*, at 21-22. If the Court is right, then *Lopez* stands for nothing more than a drafting guide: Congress should have described the relevant crime as "transfer or possession of a firearm anywhere in the nation"--thus including commercial and noncommercial activity, and clearly encompassing some activity with assuredly substantial effect on interstate commerce. Had it done so, the majority hints, we would have sustained its authority to regulate possession of firearms in school zones. Furthermore, today's decision suggests we would readily sustain a congressional decision to attach the regulation of intrastate activity to a pre-existing comprehensive (or even not-so-comprehensive) scheme. If so, the Court invites increased federal regulation of local activity even if, as it suggests, Congress would not enact a *new* interstate scheme exclusively for the sake of reaching intrastate activity, see *ante*, at 22, n. 33; *ante*, at 6 (*Scalia, J.*, concurring in judgment).

I cannot agree that our decision in *Lopez* contemplated such evasive or overbroad legislative strategies with approval. Until today, such arguments have been made only in dissent. See *Morrison*, 529 U. S., at 657 (*Breyer, J.*, dissenting) (given that Congress can regulate "an essential part of a larger regulation of economic activity," "can Congress save the present law by including it, or much of it, in a broader 'Safe Transport' or 'Worker Safety' act?"). *Lopez* and *Morrison* did not indicate that the constitutionality of federal regulation depends on superficial and formalistic distinctions. Likewise I did not understand our discussion of the role of courts in enforcing outer limits of the Commerce Clause for the sake of maintaining the federalist balance our Constitution requires, see *Lopez*, 514 U. S., at 557; *id.*, at 578 (*Kennedy, J.*, concurring), as a signal to Congress to enact legislation that is more extensive and more intrusive into the domain of state power. If the Court always defers to Congress as it does today, little may be left to the notion of enumerated powers.

The hard work for courts, then, is to identify objective markers for confining the analysis in Commerce Clause cases. Here, respondents challenge the constitutionality of the CSA as applied to them and those similarly situated. I agree with the Court that we must look beyond respondents' own activities. Otherwise, individual litigants could always exempt themselves from Commerce Clause regulation merely by pointing to the obvious--that their personal activities do not have a substantial effect on interstate commerce. See *Maryland v. Wirtz*, 392 U. S. 183, 193 (1968); *Wickard*, 317 U. S., at 127-128. The task is to identify a mode of analysis that allows Congress to regulate more than nothing (by declining to reduce each case to its litigants) and less than everything (by declining to let Congress set the terms of analysis). The analysis may not be the same in every case, for it depends on the regulatory scheme at issue and the federalism concerns implicated. See generally *Lopez*, 514 U. S., at 567; *id.*, at 579 (*Kennedy, J.*, concurring).

A number of objective markers are available to confine the scope of constitutional review here. Both federal and state legislation--including the CSA itself, the California Compassionate Use Act, and other state medical marijuana legislation--recognize that medical and nonmedical (*i.e.*, recreational) uses of drugs are realistically distinct and can be segregated,

and regulate them differently. See 21 U.S.C. §812; Cal. Health & Safety Code Ann. §11362.5 (West Supp. 2005); *ante*, at 1 (opinion of the Court). Respondents challenge only the application of the CSA to medicinal use of marijuana. Cf. *United States v. Raines*, 362 U.S. 17, 20-22 (1960) (describing our preference for as-applied rather than facial challenges). Moreover, because fundamental structural concerns about dual sovereignty animate our Commerce Clause cases, it is relevant that this case involves the interplay of federal and state regulation in areas of criminal law and social policy, where "States lay claim by right of history and expertise." *Lopez, supra*, at 583 (Kennedy, J., concurring); see also *Morrison, supra*, at 617-619; *Lopez, supra*, at 580 (Kennedy, J., concurring) ("The statute before us upsets the federal balance to a degree that renders it an unconstitutional assertion of the commerce power, and our intervention is required"); cf. *Garcia*, 469 U.S., at 586 (O'Connor, J., dissenting) ("[S]tate autonomy is a relevant factor in assessing the means by which Congress exercises its powers" under the Commerce Clause). California, like other States, has drawn on its reserved powers to distinguish the regulation of medicinal marijuana. To ascertain whether Congress' encroachment is constitutionally justified in this case, then, I would focus here on the personal cultivation, possession, and use of marijuana for medicinal purposes.

B

Having thus defined the relevant conduct, we must determine whether, under our precedents, the conduct is economic and, in the aggregate, substantially affects interstate commerce. Even if intrastate cultivation and possession of marijuana for one's own medicinal use can properly be characterized as economic, and I question whether it can, it has not been shown that such activity substantially affects interstate commerce. Similarly, it is neither self-evident nor demonstrated that regulating such activity is necessary to the interstate drug control scheme.

The Court's definition of economic activity is breathtaking. It defines as economic any activity involving the production, distribution, and consumption of commodities. And it appears to reason that when an interstate market for a commodity exists, regulating the intrastate manufacture or possession of that commodity is constitutional either because that intrastate activity is itself economic, or because regulating it is a rational part of regulating its market. Putting to one side the problem endemic to the Court's opinion--the shift in focus from the activity at issue in this case to the entirety of what the CSA regulates, see *Lopez, supra*, at 565 ("depending on the level of generality, any activity can be looked upon as commercial")--the Court's definition of economic activity for purposes of Commerce Clause jurisprudence threatens to sweep all of productive human activity into federal regulatory reach.

The Court uses a dictionary definition of economics to skirt the real problem of drawing a meaningful line between "what is national and what is local," *Jones & Laughlin Steel*, 301 U.S., at 37. It will not do to say that Congress may regulate noncommercial activity simply because it may have an effect on the demand for commercial goods, or because the noncommercial endeavor can, in some sense, substitute for commercial activity. Most commercial goods or services have some sort of privately producible analogue. Home care substitutes for daycare. Charades games substitute for movie tickets. Backyard or windowsill gardening substitutes for going to the supermarket. To draw the line wherever private activity affects the demand for market goods is to draw no line at all, and to declare everything economic. We have already rejected the result that would follow--a federal police power. *Lopez, supra*, at 564.

In *Lopez* and *Morrison*, we suggested that economic activity usually relates directly to commercial activity. See *Morrison*, 529 U.S., at 611, n. 4 (intrastate activities that have been within Congress' power to regulate have been "of an apparent commercial character"); *Lopez*, 514 U.S., at 561 (distinguishing the Gun-Free School Zones Act of 1990 from "activities that arise out of or are connected with a commercial transaction"). The homegrown cultivation and personal possession and use of marijuana for medicinal purposes has no apparent commercial character. Everyone agrees that the marijuana at issue in this case was never in the stream of commerce, and neither were the supplies for growing it. (Marijuana is highly unusual among the substances subject to the CSA in that it can be cultivated without any materials that have traveled in interstate commerce.) *Lopez* makes clear that possession is not itself commercial activity. *Ibid*. And respondents have not come into possession by means of any commercial transaction; they have simply grown, in their own homes, marijuana for their own use, without acquiring, buying, selling, or bartering a thing of value. Cf. *id.*, at 583 (Kennedy, J., concurring) ("The statute now before us forecloses the States from experimenting ... and it does so by regulating an activity beyond the realm of commerce in the ordinary and usual sense of that term").

The Court suggests that *Wickard*, which we have identified as "perhaps the most far reaching example of Commerce Clause authority over intrastate activity," *Lopez, supra*, at 560, established federal regulatory power over any home consumption of a commodity for which a national market exists. I disagree. *Wickard* involved a challenge to the Agricultural Adjustment Act of 1938 (AAA), which directed the Secretary of Agriculture to set national quotas on wheat production, and penalties for excess production. 317 U.S., at 115-116. The AAA itself confirmed that Congress made an explicit choice not to reach--and thus the Court could not possibly have approved of federal control over--small-scale, noncommercial wheat farming. In contrast to the CSA's limitless assertion of power, Congress provided an exemption

within the AAA for small producers. When Filburn planted the wheat at issue in *Wickard*, the statute exempted plantings less than 200 bushels (about six tons), and when he harvested his wheat it exempted plantings less than six acres. *Id.*, at 130, n. 30. *Wickard*, then, did not extend Commerce Clause authority to something as modest as the home cook's herb garden. This is not to say that Congress may never regulate small quantities of commodities possessed or produced for personal use, or to deny that it sometimes needs to enact a zero tolerance regime for such commodities. It is merely to say that *Wickard* did not hold or imply that small-scale production of commodities is always economic, and automatically within Congress' reach.

Even assuming that economic activity is at issue in this case, the Government has made no showing in fact that the possession and use of homegrown marijuana for medical purposes, in California or elsewhere, has a substantial effect on interstate commerce. Similarly, the Government has not shown that regulating such activity is necessary to an interstate regulatory scheme. Whatever the specific theory of "substantial effects" at issue (*i.e.*, whether the activity substantially affects interstate commerce, whether its regulation is necessary to an interstate regulatory scheme, or both), a concern for dual sovereignty requires that Congress' excursion into the traditional domain of States be justified.

That is why characterizing this as a case about the Necessary and Proper Clause does not change the analysis significantly. Congress must exercise its authority under the Necessary and Proper Clause in a manner consistent with basic constitutional principles. *Garcia*, 469 U. S. , at 585 (*O'Connor*, J., dissenting) ("It is not enough that the 'end be legitimate'; the means to that end chosen by Congress must not contravene the spirit of the Constitution"). As *Justice Scalia* recognizes, see *ante*, at 7 (opinion concurring in judgment), Congress cannot use its authority under the Clause to contravene the principle of state sovereignty embodied in the Tenth Amendment. *Ibid.* Likewise, that authority must be used in a manner consistent with the notion of enumerated powers--a structural principle that is as much part of the Constitution as the Tenth Amendment's explicit textual command. Accordingly, something more than mere assertion is required when Congress purports to have power over local activity whose connection to an intrastate market is not self-evident. Otherwise, the Necessary and Proper Clause will always be a back door for unconstitutional federal regulation. Cf. *Printz v. United States*, 521 U. S. 898, 923 (1997) (the Necessary and Proper Clause is "the last, best hope of those who defend ultra vires congressional action"). Indeed, if it were enough in "substantial effects" cases for the Court to supply conceivable justifications for intrastate regulation related to an interstate market, then we could have surmised in *Lopez* that guns in school zones are "never more than an instant from the interstate market" in guns already subject to extensive federal regulation, *ante*, at 8 (*Scalia*, J., concurring in judgment), recast *Lopez* as a Necessary and Proper Clause case, and thereby upheld the Gun-Free School Zones Act of 1990. (According to the Court's and the concurrence's logic, for example, the *Lopez* court should have reasoned that the prohibition on gun possession in school zones could be an appropriate means of effectuating a related prohibition on "sell[ing]" or "deliver[ing]" firearms or ammunition to "any individual who the licensee knows or has reasonable cause to believe is less than eighteen years of age." 18 U. S. C. §922(b)(1) (1988 ed., Supp. II).)

There is simply no evidence that homegrown medicinal marijuana users constitute, in the aggregate, a sizable enough class to have a discernable, let alone substantial, impact on the national illicit drug market--or otherwise to threaten the CSA regime. Explicit evidence is helpful when substantial effect is not "visible to the naked eye." See *Lopez*, 514 U. S. , at 563. And here, in part because common sense suggests that medical marijuana users may be limited in number and that California's Compassionate Use Act and similar state legislation may well isolate activities relating to medicinal marijuana from the illicit market, the effect of those activities on interstate drug traffic is not self-evidently substantial.

In this regard, again, this case is readily distinguishable from *Wickard*. To decide whether the Secretary could regulate local wheat farming, the Court looked to "the actual effects of the activity in question upon interstate commerce." 317 U. S. , at 120. Critically, the Court was able to consider "actual effects" because the parties had "stipulated a summary of the economics of the wheat industry." *Id.*, at 125. After reviewing in detail the picture of the industry provided in that summary, the Court explained that consumption of homegrown wheat was the most variable factor in the size of the national wheat crop, and that on-site consumption could have the effect of varying the amount of wheat sent to market by as much as 20 percent. *Id.*, at 127. With real numbers at hand, the *Wickard* Court could easily conclude that "a factor of such volume and variability as home-consumed wheat would have a substantial influence on price and market conditions" nationwide. *Id.*, at 128; see also *id.*, at 128-129 ("This record leaves us in no doubt" about substantial effects).

The Court recognizes that "the record in the *Wickard* case itself established the causal connection between the production for local use and the national market" and argues that "we have before us findings by Congress to the same effect." *Ante*, at 17 (emphasis added). The Court refers to a series of declarations in the introduction to the CSA saying that (1) local distribution and possession of controlled substances causes "swelling" in interstate traffic; (2) local production and distribution cannot be distinguished from interstate production and distribution; (3) federal control over intrastate incidents "is essential to effective control" over interstate drug trafficking. 21 U. S. C. §§801(1)-(6). These bare declarations cannot be compared to the record before the Court in *Wickard*.

They amount to nothing more than a legislative insistence that the regulation of controlled substances must be absolute. They are asserted without any supporting evidence--descriptive, statistical, or otherwise. "[S]imply because Congress may conclude a particular activity substantially affects interstate commerce does not necessarily make it so" *Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U. S. 264, 311 (1981) (*Rehnquist, J.*, concurring in judgment). Indeed, if declarations like these suffice to justify federal regulation, and if the Court today is right about what passes rationality review before us, then our decision in *Morrison* should have come out the other way. In that case, Congress had supplied numerous findings regarding the impact gender-motivated violence had on the national economy 529 U. S., at 614; *id.*, at 628-636 (*Souter, J.*, dissenting) (chronicling findings) But, recognizing that "[w]hether particular operations affect interstate commerce sufficiently to come under the constitutional power of Congress to regulate them is ultimately a judicial rather than a legislative question," "we found Congress' detailed findings inadequate. *Id.*, at 614 (quoting *Lopez, supra*, at 557, n. 2, in turn quoting *Heart of Atlanta Motel, Inc. v. United States*, 379 U. S. 241, 273 (1964) (*Black, J.*, concurring)). If, as the Court claims, today's decision does not break with precedent, how can it be that voluminous findings, documenting extensive hearings about the specific topic of violence against women, did not pass constitutional muster in *Morrison*, while the CSA's abstract, unsubstantiated, generalized findings about controlled substances do?

In particular, the CSA's introductory declarations are too vague and unspecific to demonstrate that the federal statutory scheme will be undermined if Congress cannot exert power over individuals like respondents. The declarations are not even specific to marijuana (Facts about substantial effects may be developed in litigation to compensate for the inadequacy of Congress' findings; in part because this case comes to us from the grant of a preliminary injunction, there has been no such development) Because here California, like other States, has carved out a limited class of activity for distinct regulation, the inadequacy of the CSA's findings is especially glaring. The California Compassionate Use Act exempts from other state drug laws patients and their caregivers "who possess or cultivat[e] marijuana for the personal medical purposes of the patient upon the written or oral recommendation of a physician" to treat a list of serious medical conditions. Cal. Health & Safety Code Ann. §§11362.5(d), 11362.7(h) (West Supp. 2005) (emphasis added). Compare *ibid.* with, e.g., §11357(b) (West 1991) (criminalizing marijuana possession in excess of 28.5 grams); §11358 (criminalizing marijuana cultivation). The Act specifies that it should not be construed to supersede legislation prohibiting persons from engaging in acts dangerous to others, or to condone the diversion of marijuana for nonmedical purposes §11362.5(b)(2) (West Supp. 2005). To promote the Act's operation and to facilitate law enforcement, California recently enacted an identification card system for qualified patients §§11362.7-11362.83. We generally assume States enforce their laws, see *Riley v. National Federation of Blind of N. C., Inc.*, 487 U. S. 781, 795 (1988), and have no reason to think otherwise here.

The Government has not overcome empirical doubt that the number of Californians engaged in personal cultivation, possession, and use of medical marijuana, or the amount of marijuana they produce, is enough to threaten the federal regime. Nor has it shown that Compassionate Use Act marijuana users have been or are realistically likely to be responsible for the drug's seeping into the market in a significant way. The Government does cite one estimate that there were over 100,000 Compassionate Use Act users in California in 2004, Reply Brief for Petitioners 16, but does not explain, in terms of proportions, what their presence means for the national illicit drug market. See generally *Wirtz*, 392 U. S., at 196, n. 27 (Congress cannot use "a relatively trivial impact on commerce as an excuse for broad general regulation of state or private activities"); cf. General Accounting Office, *Marijuana: Early Experience with Four States' Laws That Allow Use for Medical Purposes* 21-23 (Rep. No. 03-189, Nov. 2002), <http://www.gao.gov/new.items/d03189.pdf> (as visited June 3, 2005 and available in Clerk of Court's case file) (in four California counties before the identification card system was enacted, voluntarily registered medical marijuana patients were less than 0.5 percent of the population; in Alaska, Hawaii, and Oregon, statewide medical marijuana registrants represented less than 0.05 percent of the States' populations). It also provides anecdotal evidence about the CSA's enforcement. See Reply Brief for Petitioners 17-18. The Court also offers some arguments about the effect of the Compassionate Use Act on the national market. It says that the California statute might be vulnerable to exploitation by unscrupulous physicians, that Compassionate Use Act patients may overproduce, and that the history of the narcotics trade shows the difficulty of cordoning off any drug use from the rest of the market. These arguments are plausible; if borne out in fact they could justify prosecuting Compassionate Use Act patients under the federal CSA. But, without substantiation, they add little to the CSA's conclusory statements about diversion, essentiality, and market effect. Piling assertion upon assertion does not, in my view, satisfy the substantiality test of *Lopez* and *Morrison*.

III

We would do well to recall how James Madison, the father of the Constitution, described our system of joint sovereignty to the people of New York: "The powers delegated by the proposed constitution to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite.... The powers reserved to the several States will extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State." *The Federalist* No. 45, pp. 292-293 (C. Rossiter ed. 1961)

Relying on Congress' abstract assertions, the Court has endorsed making it a federal crime to grow small amounts of marijuana in one's own home for one's own medicinal use. This overreaching stifles an express choice by some States, concerned for the lives and liberties of their people, to regulate medical marijuana differently. If I were a California citizen, I would not have voted for the medical marijuana ballot initiative; if I were a California legislator I would not have supported the Compassionate Use Act. But whatever the wisdom of California's experiment with medical marijuana, the federalism principles that have driven our Commerce Clause cases require that room for experiment be protected in this case. For these reasons I dissent.

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al.*, PETITIONERS *v.* ANGEL McCLARY RAICH *et al.*

on writ of certiorari to the united states court of
appeals for the ninth circuit

[June 6, 2005]

Justice Thomas, dissenting

Respondents Diane Monson and Angel Raich use marijuana that has never been bought or sold, that has never crossed state lines, and that has had no demonstrable effect on the national market for marijuana. If Congress can regulate this under the Commerce Clause, then it can regulate virtually anything--and the Federal Government is no longer one of limited and enumerated powers

I

Respondents' local cultivation and consumption of marijuana is not "Commerce . . . among the several States." U. S. Const., Art. I, §8, cl. 3. By holding that Congress may regulate activity that is neither interstate nor commerce under the Interstate Commerce Clause, the Court abandons any attempt to enforce the Constitution's limits on federal power. The majority supports this conclusion by invoking, without explanation, the Necessary and Proper Clause. Regulating respondents' conduct, however, is not "necessary and proper for carrying into Execution" Congress' restrictions on the interstate drug trade. Art. I, §8, cl. 18. Thus, neither the Commerce Clause nor the Necessary and Proper Clause grants Congress the power to regulate respondents' conduct.

A

As I explained at length in *United States v. Lopez*, 514 U. S. 549 (1995), the Commerce Clause empowers Congress to regulate the buying and selling of goods and services trafficked across state lines. *Id.*, at 586-589 (concurring opinion). The Clause's text, structure, and history all indicate that, at the time of the founding, the term "commerce" consisted of selling, buying, and bartering, as well as transporting for these purposes. *Id.*, at 585 (*Thomas, J.*, concurring). Commerce, or trade, stood in contrast to productive activities like manufacturing and agriculture. *Id.*, at 586-587 (*Thomas, J.*, concurring). Throughout founding-era dictionaries, Madison's notes from the Constitutional Convention, The Federalist Papers, and the ratification debates, the term "commerce" is consistently used to mean trade or exchange--not all economic or gainful activity that has some attenuated connection to trade or exchange. *Ibid.* (*Thomas, J.*, concurring); Barnett, The Original Meaning of the Commerce Clause, 68 U. Chi. L. Rev. 101, 112-125 (2001). The term "commerce" commonly meant trade or exchange (and shipping for these purposes) not simply to those involved in the drafting and ratification processes, but also to the general public. Barnett, New Evidence of the Original Meaning of the Commerce Clause, 55 Ark. L. Rev. 847, 857-862 (2003).

Even the majority does not argue that respondents' conduct is itself "Commerce among the several States." Art. I, §8, cl. 3. *Ante*, at 19. Monson and Raich neither buy nor sell the marijuana that they consume. They cultivate their cannabis entirely in the State of California--it never crosses state lines, much less as part of a commercial transaction. Certainly no evidence from the founding suggests that "commerce" included the mere possession of a good or some purely personal activity that did not involve trade or exchange for value. In the early days of the Republic, it would have been unthinkable that Congress could prohibit the local cultivation, possession, and consumption of marijuana.

On this traditional understanding of "commerce," the Controlled Substances Act (CSA), 21 U. S. C. §801 *et seq.*, regulates a great deal of marijuana trafficking that is interstate and commercial in character. The CSA does not, however, criminalize only the interstate buying and selling of marijuana. Instead, it bans the entire market--intrastate or interstate, noncommercial or commercial--for marijuana. Respondents are correct that the CSA exceeds Congress' commerce power as applied to their conduct, which is purely intrastate and noncommercial.

B

More difficult, however, is whether the CSA is a valid exercise of Congress' power to enact laws that are "necessary and proper for carrying into Execution" its power to regulate interstate commerce. Art. I, §8, cl. 18. The Necessary and Proper Clause is not a warrant to Congress to enact any law that bears some conceivable connection to the exercise of an enumerated power.¹ Nor is it, however, a command to Congress to enact only laws that are absolutely indispensable to the exercise of an enumerated power.²

In *McCulloch v. Maryland*, 4 Wheat 316 (1819), this Court, speaking through Chief Justice Marshall, set forth a test for determining when an Act of Congress is permissible under the Necessary and Proper Clause:

"Let the end be legitimate, let it be within the scope of the constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but consist with the letter and spirit of the constitution, are constitutional." *Id.*, at 421.

To act under the Necessary and Proper Clause, then, Congress must select a means that is "appropriate" and "plainly adapted" to executing an enumerated power; the means cannot be otherwise "prohibited" by the Constitution; and the means cannot be inconsistent with "the letter and spirit of the [C]onstitution." *Ibid*; D. Currie, *The Constitution in the Supreme Court: The First Hundred Years 1789-1888*, pp. 163-164 (1985). The CSA, as applied to respondents' conduct, is not a valid exercise of Congress' power under the Necessary and Proper Clause.

1

Congress has exercised its power over interstate commerce to criminalize trafficking in marijuana across state lines. The Government contends that banning Monson and Raich's intrastate drug activity is "necessary and proper for carrying into Execution" its regulation of interstate drug trafficking. Art. I, §8, cl. 18. See 21 U. S. C. §801(6). However, in order to be "necessary," the intrastate ban must be more than "a reasonable means [of] effectuat[ing] the regulation of interstate commerce." Brief for Petitioners 14; see *ante*, at 19 (majority opinion) (employing rational-basis review). It must be "plainly adapted" to regulating interstate marijuana trafficking--in other words, there must be an "obvious, simple, and direct relation" between the intrastate ban and the regulation of interstate commerce. *Sabri v. United States*, 541 U. S. 600, 613 (2004) (*Thomas, J.*, concurring in judgment); see also *United States v. Dewitt*, 9 Wall. 41, 44 (1870) (finding ban on intrastate sale of lighting oils not "appropriate and plainly adapted means for carrying into execution" Congress' taxing power).

On its face, a ban on the intrastate cultivation, possession and distribution of marijuana may be plainly adapted to stopping the interstate flow of marijuana. Unregulated local growers and users could swell both the supply and the demand sides of the interstate marijuana market, making the market more difficult to regulate. *Ante*, at 9-10, 19 (majority opinion). But respondents do not challenge the CSA on its face. Instead, they challenge it as applied to their conduct. The question is thus whether the intrastate ban is "necessary and proper" as applied to medical marijuana users like respondents.³

Respondents are not regulable simply because they belong to a large class (local growers and users of marijuana) that Congress might need to reach, if they also belong to a distinct and separable subclass (local growers and users of state-authorized, medical marijuana) that does not undermine the CSA's interstate ban. *Ante*, at 6-7 (*O'Connor, J.*, dissenting). The Court of Appeals found that respondents' "limited use is distinct from the broader illicit drug market," because "th[eir] medicinal marijuana ... is not intended for, nor does it enter, the stream of commerce." *Raich v. Ashcroft*, 352 F. 3d 1222, 1228 (CA9 2003). If that is generally true of individuals who grow and use marijuana for medical purposes under state law, then even assuming Congress has "obvious" and "plain" reasons why regulating intrastate cultivation and possession is necessary to regulating the interstate drug trade, none of those reasons applies to medical marijuana patients like Monson and Raich.

California's Compassionate Use Act sets respondents' conduct apart from other intrastate producers and users of marijuana. The Act channels marijuana use to "seriously ill Californians," Cal. Health & Safety Code Ann.

§11362 5(b)(1)(A) (West Supp. 2005), and prohibits "the diversion of marijuana for nonmedical purposes," §11362 5(b)(2).⁴ California strictly controls the cultivation and possession of marijuana for medical purposes. To be eligible for its program, California requires that a patient have an illness that cannabis can relieve, such as cancer, AIDS, or arthritis, §11362.5(b)(1)(A), and that he obtain a physician's recommendation or approval, §11362 5(d). Qualified patients must provide personal and medical information to obtain medical identification cards, and there is a statewide registry of cardholders. §§11362.715- 76 Moreover, the Medical Board of California has issued guidelines for physicians' cannabis recommendations, and it sanctions physicians who do not comply with the guidelines. See, e.g., *People v Spark*, 121 Cal App 4th 259, 263, 16 Cal. Rptr. 3d 840, 843 (2004)

This class of intrastate users is therefore distinguishable from others. We normally presume that States enforce their own laws, *Riley v. National Federation of Blind of N. C., Inc.*, 487 U.S. 781, 795 (1988), and there is no reason to depart from that presumption here: Nothing suggests that California's controls are ineffective. The scant evidence that exists suggests that few people--the vast majority of whom are aged 40 or older--register to use medical marijuana. General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes* 22-23 (Rep. No. 03-189, Nov. 2002), <http://www.gao.gov/new.items/d01389.pdf> (all Internet materials as visited on June 3, 2005, and available in Clerk of Court's case file). In part because of the low incidence of medical marijuana use, many law enforcement officials report that the introduction of medical marijuana laws has not affected their law enforcement efforts. *Id.*, at 32.

These controls belie the Government's assertion that placing medical marijuana outside the CSA's reach "would prevent effective enforcement of the interstate ban on drug trafficking." Brief for Petitioners 33. Enforcement of the CSA can continue as it did prior to the Compassionate Use Act. Only now, a qualified patient could avoid arrest or prosecution by presenting his identification card to law enforcement officers. In the event that a qualified patient is arrested for possession or his cannabis is seized, he could seek to prove as an affirmative defense that, in conformity with state law, he possessed or cultivated small quantities of marijuana intrastate solely for personal medical use. *People v. Mower*, 28 Cal. 4th 457, 469-470, 49 P. 3d 1067, 1073-1075 (2002); *People v. Trippet*, 56 Cal. App. 4th 1532, 1549 (1997). Moreover, under the CSA, certain drugs that present a high risk of abuse and addiction but that nevertheless have an accepted medical use--drugs like morphine and amphetamines--are available by prescription. 21 U.S.C. §§812(b)(2)(A)-(B); 21 CFR §1308.12 (2004). No one argues that permitting use of these drugs under medical supervision has undermined the CSA's restrictions.

But even assuming that States' controls allow some seepage of medical marijuana into the illicit drug market, there is a multibillion-dollar interstate market for marijuana. Executive Office of the President, Office of Nat. Drug Control Policy, *Marijuana Fact Sheet* 5 (Feb. 2004), <http://www.whitehousedrugpolicy.gov/publications/factsht/marijuana/index.html>. It is difficult to see how this vast market could be affected by diverted medical cannabis, let alone in a way that makes regulating intrastate medical marijuana obviously essential to controlling the interstate drug market.

To be sure, Congress declared that state policy would disrupt federal law enforcement. It believed the across-the-board ban essential to policing interstate drug trafficking. 21 U.S.C. §801(6). But as *Justice O'Connor* points out, Congress presented no evidence in support of its conclusions, which are not so much findings of fact as assertions of power. *Ante*, at 13-14 (dissenting opinion). Congress cannot define the scope of its own power merely by declaring the necessity of its enactments.

In sum, neither in enacting the CSA nor in defending its application to respondents has the Government offered any obvious reason why banning medical marijuana use is necessary to stem the tide of interstate drug trafficking. Congress' goal of curtailing the interstate drug trade would not plainly be thwarted if it could not apply the CSA to patients like Monson and Raich. That is, unless Congress' aim is really to exercise police power of the sort reserved to the States in order to eliminate even the intrastate possession and use of marijuana.

2

Even assuming the CSA's ban on locally cultivated and consumed marijuana is "necessary," that does not mean it is also "proper." The means selected by Congress to regulate interstate commerce cannot be "prohibited" by, or inconsistent with the "letter and spirit" of, the Constitution. *McCulloch*, 4 Wheat., at 421.

In *Lopez*, I argued that allowing Congress to regulate intrastate, noncommercial activity under the Commerce Clause would confer on Congress a general "police power" over the Nation. 514 U.S., at 584, 600 (concurring opinion). This is no less the case if Congress ties its power to the Necessary and Proper Clause rather than the Commerce Clause. When agents from the Drug Enforcement Administration raided Monson's home, they seized six cannabis plants. If the Federal Government can regulate growing a half-dozen cannabis plants for personal consumption (not because it is interstate

commerce, but because it is inextricably bound up with interstate commerce), then Congress' Article I powers--as expanded by the Necessary and Proper Clause--have no meaningful limits. Whether Congress aims at the possession of drugs, guns, or any number of other items, it may continue to "appropria[te] state police powers under the guise of regulating commerce." *United States v. Morrison*, 529 U. S. 598, 627 (2000) (*Thomas, J.*, concurring).

Even if Congress may regulate purely intrastate activity when essential to exercising some enumerated power, see *Dewitt*, 9 Wall., at 44; but see Barnett, *The Original Meaning of the Necessary and Proper Clause*, 6 U. Pa. J. Const. L. 183, 186 (2003) (detailing statements by Founders that the Necessary and Proper Clause was not intended to expand the scope of Congress' enumerated powers), Congress may not use its incidental authority to subvert basic principles of federalism and dual sovereignty. *Printz v. United States*, 521 U. S. 898, 923-924 (1997); *Alden v. Maine*, 527 U. S. 706, 732-733 (1999); *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U. S. 528, 585 (1985) (*O'Connor, J.*, dissenting); *The Federalist* No. 33, pp. 204-205 (J. Cooke ed. 1961) (A. Hamilton) (hereinafter *The Federalist*).

Here, Congress has encroached on States' traditional police powers to define the criminal law and to protect the health, safety, and welfare of their citizens. *Brecht v. Abrahamson*, 507 U. S. 619, 635 (1993); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707, 719 (1985). Further, the Government's rationale--that it may regulate the production or possession of any commodity for which there is an interstate market--threatens to remove the remaining vestiges of States' traditional police powers. See Brief for Petitioners 21-22; cf. Ehrlich, *The Increasing Federalization of Crime*, 32 *Ariz. St. L. J.* 825, 826, 841 (2000) (describing both the relative recency of a large percentage of federal crimes and the lack of a relationship between some of these crimes and interstate commerce). This would convert the Necessary and Proper Clause into precisely what Chief Justice Marshall did not envision, a "pretext . . . for the accomplishment of objects not intrusted to the government." *McCulloch, supra*, at 423.

II

The majority advances three reasons why the CSA is a legitimate exercise of Congress' authority under the Commerce Clause: First, respondents' conduct, taken in the aggregate, may substantially affect interstate commerce, *ante*, at 19; second, regulation of respondents' conduct is essential to regulating the interstate marijuana market, *ante*, at 21-22; and, third, regulation of respondents' conduct is incidental to regulating the interstate marijuana market, *ante*, at 19-20. Justice *O'Connor* explains why the majority's reasons cannot be reconciled with our recent Commerce Clause jurisprudence. The majority's justifications, however, suffer from even more fundamental flaws.

A

The majority holds that Congress may regulate intrastate cultivation and possession of medical marijuana under the Commerce Clause, because such conduct arguably has a substantial effect on interstate commerce. The majority's decision is further proof that the "substantial effects" test is a "rootless and malleable standard" at odds with the constitutional design. *Morrison, supra*, at 627 (*Thomas, J.*, concurring).

The majority's treatment of the substantial effects test is rootless, because it is not tethered to either the Commerce Clause or the Necessary and Proper Clause. Under the Commerce Clause, Congress may regulate interstate commerce, not activities that substantially affect interstate commerce--any more than Congress may regulate activities that do not fall within, but that affect, the subjects of its other Article I powers. *Lopez, supra*, at 589 (*Thomas, J.*, concurring). Whatever additional latitude the Necessary and Proper Clause affords, *supra*, at 9-10, the question is whether Congress' legislation is essential to the regulation of interstate commerce itself--not whether the legislation extends only to economic activities that substantially affect interstate commerce. *Supra*, at 4; *ante*, at 5 (*Scalia, J.*, concurring in judgment).

The majority's treatment of the substantial effects test is malleable, because the majority expands the relevant conduct. By defining the class at a high level of generality (as the intrastate manufacture and possession of marijuana), the majority overlooks that individuals authorized by state law to manufacture and possess medical marijuana exert no demonstrable effect on the interstate drug market. *Supra*, at 7-8. The majority ignores that whether a particular activity substantially affects interstate commerce--and thus comes within Congress' reach on the majority's approach--can turn on a number of objective factors, like state action or features of the regulated activity itself. *Ante*, at 6-7 (*O'Connor, J.*, dissenting). For instance, here, if California and other States are effectively regulating medical marijuana users, then these users have little effect on the interstate drug trade.⁶

The substantial effects test is easily manipulated for another reason. This Court has never held that Congress can regulate noneconomic activity that substantially affects interstate commerce. *Morrison*, 529 U. S., at 613 ("[T]hus far in our Nation's history our cases have upheld Commerce Clause regulation of intrastate activity only where that activity is economic in nature" (emphasis added)); *Lopez, supra*, at 560. To evade even that modest restriction on federal power, the

majority defines economic activity in the broadest possible terms as the "the production, distribution, and consumption of commodities" *Ante*, at 23 (quoting Webster's Third New International Dictionary 720 (1966) (hereinafter Webster's 3d). This carves out a vast swath of activities that are subject to federal regulation. See *ante*, at 8-9 (*O'Connor, J.*, dissenting). If the majority is to be taken seriously, the Federal Government may now regulate quilting bees, clothes drives, and potluck suppers throughout the 50 States. This makes a mockery of Madison's assurance to the people of New York that the "powers delegated" to the Federal Government are "few and defined," while those of the States are "numerous and indefinite." *The Federalist No. 45*, at 313 (J. Madison).

Moreover, even a Court interested more in the modern than the original understanding of the Constitution ought to resolve cases based on the meaning of words that are actually in the document. Congress is authorized to regulate "Commerce," and respondents' conduct does not qualify under any definition of that term.⁸ The majority's opinion only illustrates the steady drift away from the text of the Commerce Clause. There is an inexorable expansion from "'commerce,'" *ante*, at 1, to "commercial" and "economic" activity, *ante*, at 20, and finally to all "production, distribution, and consumption" of goods or services for which there is an "established interstate market," *ante*, at 23. Federal power expands, but never contracts, with each new locution. The majority is not interpreting the Commerce Clause, but rewriting it.

The majority's rewriting of the Commerce Clause seems to be rooted in the belief that, unless the Commerce Clause covers the entire web of human activity, Congress will be left powerless to regulate the national economy effectively. *Ante*, at 15-16; *Lopez*, 514 U.S., at 573-574 (*Kennedy, J.*, concurring). The interconnectedness of economic activity is not a modern phenomenon unfamiliar to the Framers. *Id.*, at 590-593 (*Thomas, J.*, concurring); Letter from J. Madison to S. Roane (Sept. 2, 1819), in 3 *The Founders' Constitution* 259-260 (P. Kurland & R. Lerner eds. 1987). Moreover, the Framers understood what the majority does not appear to fully appreciate: There is a danger to concentrating too much, as well as too little, power in the Federal Government. This Court has carefully avoided stripping Congress of its ability to regulate interstate commerce, but it has casually allowed the Federal Government to strip States of their ability to regulate intrastate commerce--not to mention a host of local activities, like mere drug possession, that are not commercial.

One searches the Court's opinion in vain for any hint of what aspect of American life is reserved to the States. Yet this Court knows that "[t]he Constitution created a Federal Government of limited powers." *New York v. United States*, 505 U.S. 144, 155 (1992) (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991)). That is why today's decision will add no measure of stability to our Commerce Clause jurisprudence: This Court is willing neither to enforce limits on federal power, nor to declare the Tenth Amendment a dead letter. If stability is possible, it is only by discarding the stand-alone substantial effects test and revisiting our definition of "Commerce among the several States." Congress may regulate interstate commerce--not things that affect it, even when summed together, unless truly "necessary and proper" to regulating interstate commerce.

B

The majority also inconsistently contends that regulating respondents' conduct is both incidental and essential to a comprehensive legislative scheme. *Ante*, at 19-20, 21-22. I have already explained why the CSA's ban on local activity is not essential. *Supra*, at 7-8. However, the majority further claims that, because the CSA covers a great deal of interstate commerce, it "is of no moment" if it also "ensnares some purely intrastate activity." *Ante*, at 19. So long as Congress casts its net broadly over an interstate market, according to the majority, it is free to regulate interstate and intrastate activity alike. This cannot be justified under either the Commerce Clause or the Necessary and Proper Clause. If the activity is purely intrastate, then it may not be regulated under the Commerce Clause. And if the regulation of the intrastate activity is purely incidental, then it may not be regulated under the Necessary and Proper Clause.

Nevertheless, the majority terms this the "pivotal" distinction between the present case and *Lopez* and *Morrison*. *Ante*, at 20. In *Lopez* and *Morrison*, the parties asserted facial challenges, claiming "that a particular statute or provision fell outside Congress' commerce power in its entirety." *Ante*, at 20. Here, by contrast, respondents claim only that the CSA falls outside Congress' commerce power as applied to their individual conduct. According to the majority, while courts may set aside whole statutes or provisions, they may not "excise individual applications of a concededly valid statutory scheme." *Ante*, at 20-21; see also *Perez v. United States*, 402 U.S. 146, 154 (1971); *Maryland v. Wirtz*, 392 U.S. 183, 192-193 (1968).

It is true that if respondents' conduct is part of a "class of activities ... and that class is within the reach of federal power," *Perez, supra*, at 154 (emphases deleted), then respondents may not point to the *de minimis* effect of their own personal conduct on the interstate drug market, *Wirtz, supra*, at 196, n. 27. *Ante*, at 6 (*O'Connor, J.*, dissenting). But that begs the question at issue: whether respondents' "class of activities" is "within the reach of federal power," which depends in turn on whether the class is defined at a low or a high level of generality. *Supra*, at 5. If medical marijuana patients like

Monson and Raich largely stand outside the interstate drug market, then courts must excise them from the CSA's coverage. Congress expressly provided that if "a provision [of the CSA] is held invalid in one of more of its *applications*, the provision shall remain in effect in all its valid applications that are severable." 21 U. S. C. §901 (emphasis added); see also *United States v Booker*, 543 U. S. ____, ____ (2005) (slip op., at 9, and n. 9) (*Thomas, J.*, dissenting in part).

Even in the absence of an express severability provision, it is implausible that this Court could set aside entire portions of the United States Code as outside Congress' power in *Lopez* and *Morrison*, but it cannot engage in the more restrained practice of invalidating particular applications of the CSA that are beyond Congress' power. This Court has regularly entertained as-applied challenges under constitutional provisions, see *United States v Raines*, 362 U. S. 17, 20-21 (1960), including the Commerce Clause, see *Katzenbach v. McClung*, 379 U. S. 294, 295 (1964); *Heart of Atlanta Motel, Inc. v. United States*, 379 U. S. 241, 249 (1964); *Wickard v. Filburn*, 317 U. S. 111, 113-114 (1942). There is no reason why, when Congress exceeds the scope of its commerce power, courts may not invalidate Congress' overreaching on a case-by-case basis. The CSA undoubtedly regulates a great deal of interstate commerce, but that is no license to regulate conduct that is neither interstate nor commercial, however minor or incidental.

If the majority is correct that *Lopez* and *Morrison* are distinct because they were facial challenges to "particular statute[s] or provision[s]," *ante*, at 20, then congressional power turns on the manner in which Congress packages legislation. Under the majority's reasoning, Congress could not enact--either as a single-subject statute or as a separate provision in the CSA--a prohibition on the intrastate possession or cultivation of marijuana. Nor could it enact an intrastate ban simply to supplement existing drug regulations. However, that same prohibition is perfectly constitutional when integrated into a piece of legislation that reaches other regulable conduct. *Lopez*, 514 U. S. , at 600-601 (*Thomas, J.*, concurring).

Finally, the majority's view--that because *some* of the CSA's applications are constitutional, they must *all* be constitutional--undermines its reliance on the substantial effects test. The intrastate conduct swept within a general regulatory scheme may or may not have a substantial effect on the relevant interstate market. "[O]ne *always* can draw the circle broadly enough to cover an activity that, when taken in isolation, would not have substantial effects on commerce." *Id.*, at 600 (*Thomas, J.*, concurring). The breadth of legislation that Congress enacts says nothing about whether the intrastate activity substantially affects interstate commerce, let alone whether it is necessary to the scheme. Because medical marijuana users in California and elsewhere are not placing substantial amounts of cannabis into the stream of interstate commerce, Congress may not regulate them under the substantial effects test, no matter how broadly it drafts the CSA.

The majority prevents States like California from devising drug policies that they have concluded provide much-needed respite to the seriously ill. It does so without any serious inquiry into the necessity for federal regulation or the propriety of "displac[ing] state regulation in areas of traditional state concern," *id.*, at 583 (*Kennedy, J.*, concurring). The majority's rush to embrace federal power "is especially unfortunate given the importance of showing respect for the sovereign States that comprise our Federal Union." *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U. S. 483, 502 (2001) (*Stevens, J.*, concurring in judgment). Our federalist system, properly understood, allows California and a growing number of other States to decide for themselves how to safeguard the health and welfare of their citizens. I would affirm the judgment of the Court of Appeals. I respectfully dissent.

FOOTNOTES

Footnote 1

See Alaska Stat. §§11.71.090, 17.37.010-17.37.080 (Lexis 2004); Colo. Const., Art. XVIII, §14, Colo. Rev. Stat. §18-18-406.3 (Lexis 2004); Haw. Rev. Stat. §§329-121 to 329-128 (2004 Cum. Supp.); Me. Rev. Stat. Ann., Tit. 22, §2383-B(5) (West 2004); Nev. Const., Art. 4, §38, Nev. Rev. Stat. §§453A.010-453A.810 (2003); Ore. Rev. Stat. §§475.300-475.346 (2003); Vt. Stat. Ann., Tit. 18, §§4472-4474d (Supp. 2004); Wash. Rev. Code §§69.51.010-69.51.080 (2004); see also Ariz. Rev. Stat. Ann. §13-3412.01 (West Supp. 2004) (voter initiative permitting physicians to prescribe Schedule I substances for medical purposes that was purportedly repealed in 1997, but the repeal was rejected by voters in 1998). In November 2004, Montana voters approved Initiative 148, adding to the number of States authorizing the use of marijuana for medical purposes.

Footnote 2

1913 Cal. Stats. ch. 324, §8a; see also Gieringer, The Origins of Cannabis Prohibition in California, Contemporary Drug Problems, 21-23 (rev. 2005)

Footnote 3

Cal. Health & Safety Code Ann. §11362.5 (West Supp. 2005). The California Legislature recently enacted additional legislation supplementing the Compassionate Use Act §§11362.7-11362.9 (West Supp. 2005)

Footnote 4

"The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:

"(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief

"(B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction

"(C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana " §11362.5(b)(1) (West Supp. 2005)

Footnote 5

"Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes." §11362.5(c) (West Supp. 2005).

Footnote 6

"Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician " §11362.5(d) (West Supp. 2005)

Footnote 7

§11362.5(e) (West Supp. 2005)

Footnote 8

On remand, the District Court entered a preliminary injunction enjoining petitioners " 'from arresting or prosecuting Plaintiffs Angel McClary Raich and Diane Monson, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them with respect to the intrastate, non-commercial cultivation, possession, use, and obtaining without charge of cannabis for personal medical purposes on the advice of a physician and in accordance with state law, and which is not used for distribution, sale, or exchange.' " Brief for Petitioners 9.

Footnote 9

See D. Musto & P. Korsmeyer, *The Quest for Drug Control* 60 (2002) (hereinafter Musto & Korsmeyer).

Footnote 10

H. R. Rep. No. 91-1444, pt. 2, p. 22 (1970) (hereinafter H. R. Rep.); 26 *Congressional Quarterly Almanac* 531 (1970) (hereinafter *Almanac*); Musto & Korsmeyer 56-57.

Footnote 11

Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, repealed by Act of June 25, 1938, ch. 675, §902(a), 52 Stat. 1059.

Footnote 12

See *United States v. Doremus*, 249 U.S. 86 (1919); *Leary v. United States*, 395 U.S. 6, 14-16 (1969).

Footnote 13

See *Doremus*, 249 U.S. at 90-93.

Footnote 14

R. Bonnie & C. Whitebread, *The Marijuana Conviction* 154-174 (1999); L. Grinspoon & J. Bakalar, *Marihuana, the Forbidden Medicine* 7-8 (rev. ed. 1997) (hereinafter Grinspoon & Bakalar). Although this was the Federal Government's first attempt to regulate the marijuana trade, by this time all States had in place some form of legislation regulating the sale, use, or possession of marijuana. R. Isralowitz, *Drug Use, Policy, and Management* 134 (2d ed. 2002).

Footnote 15

Leary, 395 U.S. at 14-16.

Footnote 16

Grinspoon & Bakalar 8.

Footnote 17

Leary, 395 U.S. at 16-18.

Footnote 18

Musto & Korsmeyer 32-35; 26 *Almanac* 533. In 1973, the Bureau of Narcotics and Dangerous Drugs became the Drug Enforcement Administration (DEA). See Reorg. Plan No. 2 of 1973, §1, 28 CFR §0.100 (1973).

Footnote 19

The Comprehensive Drug Abuse Prevention and Control Act of 1970 consists of three titles. Title I relates to the prevention and treatment of narcotic addicts through HEW (now the Department of Health and Human Services). 84 Stat. 1238. Title II, as discussed in more detail above, addresses drug control and enforcement as administered by the Attorney General and the DEA. *Id.*, at 1242. Title III concerns the import and export of controlled substances. *Id.*, at 1285.

Footnote 20

In particular, Congress made the following findings:

"(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people

"(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

"(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because--

"(A) after manufacture, many controlled substances are transported in interstate commerce,

"(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

"(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

"(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

"(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

"(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic " 21 U. S. C. §§801(1)-(6).

Footnote 21

See *United States v Moore*, 423 U. S. 122, 135 (1975); see also H. R. Rep., at 22

Footnote 22

H. R. Rep., at 61 (quoting letter from Roger E. Egeberg, M. D. to Hon. Harley O. Staggers (Aug. 14, 1970))

Footnote 23

Starting in 1972, the National Organization for the Reform of Marijuana Laws (NORML) began its campaign to reclassify marijuana. Grinspoon & Bakalar 13-17 After some fleeting success in 1988 when an Administrative Law Judge (ALJ) declared that the DEA would be acting in an "unreasonable, arbitrary, and capricious" manner if it continued to deny marijuana access to seriously ill patients, and concluded that it should be reclassified as a Schedule III substance, *Grinspoon v. DEA*, 828 F. 2d 881, 883-884 (CA1 1987), the campaign has proved unsuccessful. The DEA Administrator did not endorse the ALJ's findings, 54 Fed. Reg. 53767 (1989), and since that time has routinely denied petitions to reschedule the drug, most recently in 2001. 66 Fed. Reg. 20038 (2001). The Court of Appeals for the District of Columbia Circuit has reviewed the petition to reschedule marijuana on five separate occasions over the course of 30 years, ultimately upholding the Administrator's final order. See *Alliance for Cannabis Therapeutics v. DEA*, 15 F. 3d 1131, 1133 (1994).

Footnote 24

United States v Lopez, 514 U. S. 549, 552-558 (1995); *id.*, at 568-574 (*Kennedy, J.*, concurring); *id.*, at 604-607 (*Souter, J.*, dissenting)

Footnote 25

See *Gibbons v Ogden*, 9 Wheat 1, 224 (1824) (opinion of Johnson, J.); Stern, That Commerce Which Concerns More States Than One, 47 Harv. L. Rev. 1335, 1337, 1340-1341 (1934); G. Gunther, Constitutional Law 127 (9th ed. 1975).

Footnote 26

See *Lopez*, 514 U. S., at 553-554; *id.*, at 568-569 (*Kennedy, J.*, concurring); see also *Granholtz v Heald*, 544 U. S. ___, ___ (2005) (slip op., at 8-9).

Footnote 27

Lopez, 514 U. S., at 554; see also *Wickard v Filburn*, 317 U. S. 111, 121 (1942) ("It was not until 1887, with the enactment of the Interstate Commerce Act, that the interstate commerce power began to exert positive influence in American law and life. This first important federal resort to the commerce power was followed in 1890 by the Sherman Anti-Trust Act and, thereafter, mainly after 1903, by many others. These statutes ushered in new phases of adjudication, which required the Court to approach the interpretation of the Commerce Clause in the light of an actual exercise by Congress of its power thereunder" (footnotes omitted)).

Footnote 28

Even respondents acknowledge the existence of an illicit market in marijuana; indeed, Raich has personally participated in that market, and Monson expresses a willingness to do so in the future. App. 59, 74, 87. See also *Department of Revenue of Mont. v Kurth Ranch*, 511 U. S. 767, 770, 774, n. 12, and 780, n. 17 (1994) (discussing the "market value" of marijuana); *id.*, at 790 (*Rehnquist, C. J.*, dissenting); *id.*, at 792 (*O'Connor, J.*, dissenting); *Whalen v. Roe*, 429 U. S. 589, 591 (1977) (addressing prescription drugs "for which there is both a lawful and an unlawful market"); *Turner v. United States*, 396 U. S. 398, 417, n. 33 (1970) (referring to the purchase of drugs on the "retail market").

Footnote 29

To be sure, the wheat market is a lawful market that Congress sought to protect and stabilize, whereas the marijuana market is an unlawful market that Congress sought to eradicate. This difference, however, is of no constitutional import. It has long been settled that Congress' power to regulate commerce includes the power to prohibit commerce in a particular commodity. *Lopez*, 514 U. S., at 571 (*Kennedy, J.*, concurring) ("In the *Lottery Case*, 188 U. S. 321 (1903), the Court rejected the argument that Congress lacked [the] power to prohibit the interstate movement of lottery tickets because it had power only to regulate, not to prohibit"); see also *Wickard*, 317 U. S., at 128 ("The stimulation of commerce is a use of the regulatory function quite as definitely as prohibitions or restrictions thereon").

Footnote 30

See *Wickard*, 317 U. S., at 125 (recognizing that Wickard's activity "may not be regarded as commerce").

Footnote 31

The Executive Office of the President has estimated that in 2000 American users spent \$10.5 billion on the purchase of marijuana. Office of Nat. Drug Control Policy, Marijuana Fact Sheet 5 (Feb. 2004), available at <http://www.whitehousedrugpolicy.gov/publications/factsht/marijuana/index.html> (all Internet materials as visited June 2, 2005, and available in Clerk of Court's case file).

Footnote 32

Moreover, as discussed in more detail above, Congress did make findings regarding the effects of intrastate drug activity on interstate commerce. See n. 20, *supra*. Indeed, even the Court of Appeals found that those findings "weigh[ed] in favor" of upholding the constitutionality of the CSA. 352 F. 3d 1222, 1232 (CA9 2003) (case below). The dissenters, however, would impose a new and heightened burden on Congress (unless the litigants can garner evidence sufficient to cure Congress' perceived "inadequa[cies]")--that legislation must contain detailed findings proving that each activity regulated within a comprehensive statute is essential to the statutory scheme. *Post*, at 13-15 (O'Connor, J., dissenting); *post*, at 8 (Thomas, J., dissenting). Such an exacting requirement is not only unprecedented, it is also impractical. Indeed, the principal dissent's critique of Congress for "not even" including "declarations" specific to marijuana is particularly unpersuasive given that the CSA initially identified 80 other substances subject to regulation as Schedule I drugs, not to mention those categorized in Schedules II-V. *Post*, at 14 (O'Connor, J., dissenting). Surely, Congress cannot be expected (and certainly should not be required) to include specific findings on each and every substance contained therein in order to satisfy the dissenters' unfounded skepticism.

Footnote 33

See n. 21, *supra* (citing sources that evince Congress' particular concern with the diversion of drugs from legitimate to illicit channels).

Footnote 34

The principal dissent asserts that by "[s]eizing upon our language in *Lopez*," *post*, at 5 (opinion of O'Connor, J.), *i.e.*, giving effect to our well-established case law, Congress will now have an incentive to legislate broadly. Even putting aside the political checks that would generally curb Congress' power to enact a broad and comprehensive scheme for the purpose of targeting purely local activity, there is no suggestion that the CSA constitutes the type of "evasive" legislation the dissent fears, nor could such an argument plausibly be made. *Post*, at 6 (O'Connor, J., dissenting).

Footnote 35

Lopez, 514 U. S., at 560; see also *id.*, at 573-574 (Kennedy, J., concurring) (stating that *Lopez* did not alter our "practical conception of commercial regulation" and that Congress may "regulate in the commercial sphere on the assumption that we have a single market and a unified purpose to build a stable national economy")

Footnote 36

See 16 U. S. C. §668(a) (bald and golden eagles); 18 U. S. C. §175(a) (biological weapons); §831(a) (nuclear material); §842(n)(1) (certain plastic explosives); §2342(a) (contraband cigarettes)

Footnote 37

We acknowledge that evidence proffered by respondents in this case regarding the effective medical uses for marijuana, if found credible after trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I. See, *e.g.*, Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* 179 (J. Joy, S. Watson, & J. Benson eds. 1999) (recognizing that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC [Tetrahydrocannabinol] for pain relief, control of nausea and vomiting, and appetite stimulation"); see also *Conant v. Walters*, 309 F. 3d 629, 640-643 (CA9 2002) (Kozinski, J., concurring) (chronicling medical studies recognizing valid medical uses for marijuana and its derivatives). But the possibility that the drug may be reclassified in the future has no relevance to the question whether Congress now has the power to regulate its production and distribution. Respondents' submission, if accepted, would place all homegrown medical substances beyond the reach of Congress' regulatory jurisdiction.

Footnote 38

That is so even if California's current controls (enacted eight years after the Compassionate Use Act was passed) are "[e]ffective," as the dissenters would have us blindly presume, *post*, at 15 (*O'Connor, J.*, dissenting); *post*, at 6, 12 (*Thomas, J.*, dissenting). California's decision (made 34 years after the CSA was enacted) to impose "stric[t] controls" on the "cultivation and possession of marijuana for medical purposes," *post*, at 6 (*Thomas, J.*, dissenting), cannot retroactively divest Congress of its authority under the Commerce Clause. Indeed, *Justice Thomas'* urgings to the contrary would turn the Supremacy Clause on its head, and would resurrect limits on congressional power that have long since been rejected. See *post*, at 8 (*Scalia, J.*, concurring in judgment) (quoting *McCulloch v. Maryland*, 4 Wheat. 316, 424 (1819)) ("To impose on [Congress] the necessity of resorting to means which it cannot control, which another government may furnish or withhold, would render its course precarious, the result of its measures uncertain, and create a dependence on other governments, which might disappoint its most important designs, and is incompatible with the language of the constitution' ")

Moreover, in addition to casting aside more than a century of this Court's Commerce Clause jurisprudence, it is noteworthy that *Justice Thomas'* suggestion that States possess the power to dictate the extent of Congress' commerce power would have far-reaching implications beyond the facts of this case. For example, under his reasoning, Congress would be equally powerless to regulate, let alone prohibit, the intrastate possession, cultivation, and use of marijuana for recreational purposes, an activity which all States "strictly contro[l]" Indeed, his rationale seemingly would require Congress to cede its constitutional power to regulate commerce whenever a State opts to exercise its "traditional police powers to define the criminal law and to protect the health, safety, and welfare of their citizens." *Post*, at 9-10 (dissenting opinion).

Footnote 39

California's Compassionate Use Act has since been amended, limiting the catchall category to "[a]ny other chronic or persistent medical symptom that either: ... [s]ubstantially limits the ability of the person to conduct one or more major life activities as defined" in the Americans with Disabilities Act of 1990, or "[i]f not alleviated, may cause serious harm to the patient's safety or physical or mental health." Cal. Health & Safety Code Ann. §§11362.7(h)(12)(A) to (12)(B) (West Supp. 2005).

Footnote 40

See, e.g., *United States v. Moore*, 423 U.S. 122 (1975); *United States v. Doremus*, 249 U.S. 86 (1919)

Footnote 41

The state policy allows patients to possess up to eight ounces of dried marijuana, and to cultivate up to 6 mature or 12 immature plants. Cal. Health & Safety Code Ann. §11362.77(a) (West Supp. 2005). However, the quantity limitations serve only as a floor. Based on a doctor's recommendation, a patient can possess whatever quantity is necessary to satisfy his medical needs, and cities and counties are given *carte blanche* to establish more generous limits. Indeed, several cities and counties have done just that. For example, patients residing in the cities of Oakland and Santa Cruz and in the counties of Sonoma and Tehama are permitted to possess up to 3 pounds of processed marijuana. Reply Brief for United States 19 (citing Proposition 215 Enforcement Guidelines). Putting that quantity in perspective, 3 pounds of marijuana yields roughly 3,000 joints or cigarettes. Executive Office of the President, Office of National Drug Control Policy, What America's Users Spend on Illegal Drugs 24 (Dec. 2001), http://www.whitehousedrugpolicy.gov/publications/pdf/american_users_spend_2002.pdf And the street price for that amount can range anywhere from \$900 to \$24,000. DEA, Illegal Drug Price and Purity Report (Apr. 2003) (DEA-02058)

Footnote 42

For example, respondent Raich attests that she uses 2.5 ounces of cannabis a week. App. 82. Yet as a resident of Oakland, she is entitled to possess up to 3 pounds of processed marijuana at any given time, nearly 20 times more than she uses on a weekly basis.

Footnote 43

See, e.g., *People ex rel Lungren v. Peron*, 59 Cal. App. 4th 1383, 1386-1387 (1997) (recounting how a Cannabis Buyers' Club engaged in an "indiscriminate and uncontrolled pattern of sale to thousands of persons among the general public, including persons who had not demonstrated any recommendation or approval of a physician and, in fact, some of whom were not under the care of a physician, such as undercover officers," and noting that "some persons who had purchased marijuana on respondents' premises were reselling it unlawfully on the street")

FOOTNOTES

Footnote 1

See also *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 584-585 (1985) (O'Connor, J., dissenting) (explaining that it is through the Necessary and Proper Clause that "an intrastate activity 'affecting' interstate commerce can be reached through the commerce power").

Footnote 2

Wickard v. Filburn, 317 U.S. 111 (1942), presented such a case. Because the unregulated production of wheat for personal consumption diminished demand in the regulated wheat market, the Court said, it carried with it the potential to disrupt Congress's price regulation by driving down prices in the market. *Id.*, at 127-129. This potential disruption of Congress's interstate regulation, and not only the effect that personal consumption of wheat had on interstate commerce, justified Congress's regulation of that conduct. *Id.*, at 128-129.

Footnote 3

The principal dissent claims that, if this is sufficient to sustain the regulation at issue in this case, then it should also have been sufficient to sustain the regulation at issue in *United States v. Lopez*, 514 U.S. 549 (1995). See *post*, at 11-12 (arguing that "we could have surmised in *Lopez* that guns in school zones are 'never more than an instant from the interstate market' in guns already subject to federal regulation, recast *Lopez* as a Necessary and Proper Clause case, and thereby upheld the Gun-Free School Zones Act"). This claim founders upon the shoals of *Lopez* itself, which made clear that the statute there at issue was "not an essential part of a larger regulation of economic activity." *Lopez, supra*, at 561 (emphasis added). On the dissent's view of things, that statement is inexplicable. Of course it is in addition difficult to imagine what intelligible scheme of regulation of the interstate market in guns could have as an appropriate means of effectuation the prohibition of guns within 1000 feet of schools (and nowhere else). The dissent points to a federal law, 18 U.S.C. §922(b)(1), barring licensed dealers from selling guns to minors, see *post*, at 12, but the relationship between the regulatory scheme of which §922(b)(1) is a part (requiring all dealers in firearms that have traveled in interstate commerce to be licensed, see §922(a)) and the statute at issue in *Lopez* approaches the nonexistent--which is doubtless why the Government did not attempt to justify the statute on the basis of that relationship.

FOOTNOTES

Footnote 1

McCulloch v. Maryland, 4 Wheat. 316, 419-421 (1819); Madison, The Bank Bill, House of Representatives (Feb. 2, 1791), in 3 The Founders' Constitution 244 (P. Kurland & R. Lerner eds. 1987) (requiring "direct" rather than "remote" means-end fit); Hamilton, Opinion on the Constitutionality of the Bank (Feb. 23, 1791), in *id.*, at 248, 250 (requiring "obvious" means-end fit, where the end was "clearly comprehended within any of the specified powers" of Congress).

Footnote 2

McCulloch, supra, at 413-415; D. Currie, The Constitution in the Supreme Court: The First Hundred Years 1789-1888, p. 162 (1985).

Footnote 3

Because respondents do not challenge on its face the CSA's ban on marijuana, 21 U. S. C. §§841(a)(1), 844(a), our adjudication of their as-applied challenge casts no doubt on this Court's practice in *United States v. Lopez*, 514 U. S. 549 (1995), and *United States v. Morrison*, 529 U. S. 598 (2000). In those cases, we held that Congress, in enacting the statutes at issue, had exceeded its Article I powers.

Footnote 4

Other States likewise prohibit diversion of marijuana for nonmedical purposes. See, e.g., Colo. Const., Art. XVIII, §14(2)(d); Nev. Rev. Stat. §§453A.300(1)(e)-(f) (2003); Ore. Rev. Stat. §§475.316(1)(c)-(d) (2003).

Footnote 5

In fact, the Anti-Federalists objected that the Necessary and Proper Clause would allow Congress, *inter alia*, to "constitute new Crimes, ... and extend [its] Power as far as [it] shall think proper; so that the State Legislatures have no Security for the Powers now presumed to remain to them; or the People for their Rights." Mason, *Objections to the Constitution Formed by the Convention* (1787), in 2 *The Complete Anti-Federalist* 11, 12-13 (H. Storing ed. 1981) (emphasis added). Hamilton responded that these objections were gross "misrepresentation[s]." *The Federalist* No. 33, at 204. He termed the Clause "perfectly harmless," for it merely confirmed Congress' implied authority to enact laws in exercising its enumerated powers. *Id.*, at 205; see also *Lopez*, 514 U. S., at 597, n. 6 (Thomas, J., concurring) (discussing Congress' limited ability to establish nationwide criminal prohibitions); *Cohens v. Virginia*, 6 Wheat. 264, 426-428 (1821) (finding it "clear that [C]ongress cannot punish felonies generally," except in areas over which it possesses plenary power). According to Hamilton, the Clause was needed only "to guard against cavilling refinements" by those seeking to cripple federal power. *The Federalist* No. 33, at 205; *id.*, No. 44, at 303-304 (J. Madison).

Footnote 6

Remarkably, the majority goes so far as to declare this question irrelevant. It asserts that the CSA is constitutional even if California's current controls are effective, because state action can neither expand nor contract Congress' powers. *Ante*, at 27, n. 38. The majority's assertion is misleading. Regardless of state action, Congress has the power to regulate intrastate economic activities that substantially affect interstate commerce (on the majority's view) or activities that are necessary and proper to effectuating its commerce power (on my view). But on either approach, whether an intrastate activity falls within the scope of Congress' powers turns on factors that the majority is unwilling to confront. The majority apparently believes that even if States prevented any medical marijuana from entering the illicit drug market, and thus even if there were no need for the CSA to govern medical marijuana users, we should uphold the CSA under the *Commerce* Clause and the *Necessary* and *Proper* Clause. Finally, to invoke the *Supremacy* Clause, as the majority does, *ibid.*, is to beg the question. The CSA displaces California's *Compassionate Use Act* if the CSA is constitutional as applied to respondents' conduct, but that is the very question at issue.

Footnote 7

Other dictionaries do not define the term "economic" as broadly as the majority does. See, e.g., *The American Heritage Dictionary of the English Language* 583 (3d ed. 1992) (defining "economic" as "[o]f or relating to the production, development, and management of *material wealth*, as of a country, household, or business enterprise" (emphasis added)). The majority does not explain why it selects a remarkably expansive 40-year-old definition.

Footnote 8

See, e.g., *id.*, at 380 ("[t]he buying and selling of goods, especially on a large scale, as between cities or nations"); *The Random House Dictionary of the English Language* 411 (2d ed. 1987) ("an interchange of goods or commodities, esp. on a large scale between different countries ... or between different parts of the same country"); Webster's 3d 456 ("the exchange or buying and selling of commodities esp. on a large scale and involving transportation from place to place")

500 F.3d 850

Angel McClary RAICH; John Doe, Number One; John Doe, Number Two, Plaintiffs-Appellants,
v.
Alberto R. GONZALES, Attorney General, as United States Attorney General;

[500 F.3d 851]

Karen Tandy, as Administrator of the Drug Enforcement Administration, Defendants-Appellees.
No. 03-15481.

United States Court of Appeals, Ninth Circuit.

Argued and Submitted March 27, 2006.

Filed March 14, 2007.

[500 F.3d 854]

Robert A. Raich, (briefed) Oakland, CA and Randy E. Barnett, (argued) Boston University School of Law, Boston, MA, for the plaintiffs-appellants

Mark T. Quinlivan, Assistant United States Attorney, Boston, MA, for the defendants-appellees

Appeal from the United States District Court for the Northern District of California; Martin J. Jenkins, District Judge, Presiding D C No CV-02-04872-MJJ

Before PREGERSON, C. ARLEN BEAM, and PAEZ, Circuit Judges

PREGERSON, Circuit Judge

Plaintiff-Appellant Angel McClary Raich ("Raich") is a seriously ill individual who uses marijuana for medical purposes on the recommendation of her physician. Such use is permitted under California law. The remaining plaintiffs-appellants assist Raich by growing marijuana for her treatment.

Appellants seek declaratory and injunctive relief based on the alleged unconstitutionality of the Controlled Substances Act, and a declaration that medical necessity precludes enforcement of the Controlled Substances Act against them. On March 5, 2003, the district court denied appellants' motion for a preliminary injunction. We hear this matter on remand following the Supreme Court's decision in Gonzales v. Raich, 545 U.S. 1, 125 S.Ct. 2195, 162 L.Ed.2d 1 (2005). For the reasons set forth below, we affirm the district court.

STATUTORY SCHEMES

I. *The Controlled Substances Act*

Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, to create a comprehensive drug enforcement regime it called the Controlled Substances Act, 21 U.S.C. § 801-971. Congress established five "schedules" of "controlled substances." See 21 U.S.C. § 802(6). Controlled substances are placed on a particular schedule based on their potential for abuse, their accepted medical use in treatment, and the physical and psychological consequences of abuse of the substance. See 21 U.S.C. § 812(b). Marijuana is a Schedule I controlled substance. 21 U.S.C. § 812(c), Sched. I(c)(10). For a substance to be designated a Schedule I controlled substance, it must be found: (1) that the substance "has a high potential for abuse"; (2) that the substance "has no currently accepted medical use in treatment in the United States"; and (3) that "[t]here is a lack of accepted safety for

use of the drug or other substance under medical supervision " 21 U.S.C. § 812(b)(1). The Controlled Substances Act sets forth

[500 F.3d 855]

procedures by which the schedules may be modified. See 21 U.S.C. § 811(a)

Under the Controlled Substances Act, it is unlawful to knowingly or intentionally "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance," except as otherwise provided in the statute. 21 U.S.C. § 841(a)(1). Possession of a controlled substance, except as authorized under the Controlled Substances Act, is also unlawful. See 21 U.S.C. § 844(a)

II California's Compassionate Use Act of 1996

California voters passed Proposition 215 in 1996, which is codified as the Compassionate Use Act of 1996 ("Compassionate Use Act"). See Cal. Health & Safety Code § 11362.5. The Compassionate Use Act is intended to permit Californians to use marijuana for medical purposes by exempting patients, primary caregivers, and physicians from liability under California's drug laws. The Act explicitly states that its purpose is to

ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

Id. § 11362.5(b)(1)(A). Another purpose of the Compassionate Use Act is "[t]o ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction." *Id.* § 11362.5(b)(1)(B). The Compassionate Use Act strives "[t]o encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana." *Id.* § 11362.5(b)(1)(C).

To achieve its goal, the Compassionate Use Act exempts from liability under California's drug laws "a patient, or . . . a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician." *Id.* § 11362.5(d).

FACTUAL & PROCEDURAL HISTORY

Appellant Angel McClary Raich is a Californian who uses marijuana for medical treatment. Raich has been diagnosed with more than ten serious medical conditions, including an inoperable brain tumor, a seizure disorder, life-threatening weight loss, nausea, and several chronic pain disorders. Raich's doctor, Dr. Frank Henry Lucido, testified that he had explored virtually every legal treatment alternative, and that all were either ineffective or resulted in intolerable side effects. Dr. Lucido provided a list of thirty-five medications that were unworkable because of their side effects.

Marijuana, on the other hand, has proven to be of great medical value for Raich. Raich has been using marijuana as a medication for nearly eight years, every two waking hours of every day. Dr. Lucido states that, for Raich, foregoing marijuana treatment may be fatal. As the district court put it, "[t]raditional medicine has utterly failed[Raich]." *Raich v. Ashcroft*, 248 F.Supp.2d 918, 921 (N.D. Cal. 2003).

Raich is unable to cultivate marijuana for her own use. Instead, Raich's caregivers, John Doe Number One and John Doe Number Two, cultivate it for her. They

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provide marijuana to Raich free of charge. They have joined this action as plaintiffs anonymously in order to protect Raich's access to medical marijuana.

This action arose in response to a law enforcement raid on the home of another medical marijuana user, former plaintiff-appellant Diane Monson.¹ On August 15, 2002, Butte County Sheriff's Department deputies, the Butte County District Attorney, and agents from the federal Drug Enforcement Agency ("DEA") came to Monson's home. After DEA agents took control of Monson's six marijuana plants, a three-hour standoff between state and federal authorities ensued. The Butte County deputies and district attorney concluded that Monson's use of marijuana was legal under the Compassionate Use Act. The DEA agents, after conferring with the U.S. Attorney for the Eastern District of California, concluded that Monson possessed the plants in violation of federal law. The DEA agents seized and destroyed Monson's six marijuana plants.

Fearing raids in the future and the prospect of being deprived of their medicinal marijuana, Raich, Monson, and the John Doe plaintiffs sued the United States Attorney General and the Administrator of the DEA in federal district court on October 9, 2002. The suit sought declaratory and injunctive relief. Specifically, plaintiffs-appellants argued: (1) that the Controlled Substances Act was unconstitutional as applied to them because the legislation exceeded Congress's Commerce Clause authority; (2) that through the Controlled Substances Act, Congress impermissibly exercised a police power that is reserved to the State of California under the Tenth Amendment; (3) that the Controlled Substances Act unconstitutionally infringed their fundamental rights protected by the Fifth and Ninth Amendments; and (4) that the Controlled Substances Act could not be enforced against them because their allegedly unlawful conduct was justified under the common law doctrine of necessity.

On October 30, 2002, the plaintiffs-appellants moved for a preliminary injunction. On March 4, 2003, the district court denied the motion by a published order. See Raich v. Ashcroft, 248 F.Supp.2d 918. The district court found that, "despite the gravity of plaintiffs' need for medical cannabis, and despite the concrete interest of California to provide it for individuals like them," the appellants had not established the required "'irreducible minimum' of a likelihood of success on the merits under the law of this Circuit." *Id.* at 931.

On December 16, 2003, we reversed and remanded this matter to the district court to enter a preliminary injunction. See Raich v. Ashcroft, 352 F.3d 1222, 1235 (9th Cir.2003). We held that the plaintiffs-appellants had demonstrated a strong likelihood of success on the merits of their claim that the Controlled Substances Act, as applied to them, exceeded Congress's Commerce Clause authority. *See id.* at 1234. We did not reach plaintiffs-appellants' remaining arguments in favor of the preliminary injunction. *See id.* at 1227. The Government timely petitioned the Supreme Court for a writ of certiorari. The Supreme Court granted certiorari on June 28, 2004. See Ashcroft v. Raich, 542 U.S. 936, 124 S.Ct. 2909, 159 L.Ed.2d 811 (2004).

On June 6, 2005, the Supreme Court vacated our opinion and held that Congress's Commerce Clause authority includes the power to prohibit purely intrastate cultivation and use of marijuana. See Gonzales v. Raich, 125 S.Ct. at 2215. The Court remanded the case to us to address plaintiffs-appellants's remaining

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legal theories in support of a preliminary injunction. *See id.* On remand, Raich renews her claims based on common law necessity, fundamental rights protected by the Fifth and Ninth Amendments, and rights

reserved to the states under the Tenth Amendment. She also argues for the first time that the Controlled Substances Act, by its terms, does not prohibit her from possessing and using marijuana if permitted to do so under state law. We have jurisdiction over this interlocutory appeal under 28 U.S.C. § 1292(a)(1).

STANDING & STANDARD OF REVIEW

To satisfy the requirements of constitutional standing, "the plaintiff must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision." Mujahid v. Daniels, 413 F.3d 991, 994 (9th Cir. 2005) (citing Spencer v. Kemna, 523 U.S. 1, 7, 118 S.Ct. 978, 140 L.Ed.2d 43 (1998)). Furthermore, the injury must be: (1) concrete and particularized, and (2) actual or imminent, not conjectural or hypothetical. See United States v. Antelope, 395 F.3d 1128, 1132 (9th Cir. 2005).

We are convinced that the requirements of constitutional standing have been met here.² Although Raich has not suffered any past injury, she is faced with the threat that the Government will seize her medical marijuana and prosecute her for violations of federal drug law. The threat posed by deprivation of her medical treatment is serious and concrete: Raich's doctor testified that foregoing medical marijuana treatment might be fatal. The threat is not speculative or conjectural: DEA agents previously seized and destroyed the medical marijuana of former plaintiff-appellant Diane Monson. Monson's withdrawal from this action does not change the fact that DEA agents have—and may again—seize and destroy medical marijuana possessed by gravely ill Californians, including Raich. Finally, it is clear that Raich's threatened injury may be fairly traced to the defendants, and that a favorable injunction from this court would redress Raich's threatened injury.

A district court's decision regarding preliminary injunctive relief is subject to limited review. See Harris v. Bd. of Supervisors, 366 F.3d 754, 760 (9th Cir. 2004). The court should be reversed only if it abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact. See id. A preliminary injunction must be supported by findings of fact, reviewed for clear error. See Hawkins v. Comparet-Cassani, 251 F.3d 1230, 1239 (9th Cir. 2001). The district court's conclusions of law are reviewed de novo. See Brown v. Cal. Dep't of Transp., 321 F.3d 1217, 1221 (9th Cir. 2003).

DISCUSSION

"The standard for granting a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties." Clear Channel Outdoor, Inc. v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir. 2003). We have two different criteria for determining whether preliminary injunctive relief is warranted. "Under the traditional criteria, a plaintiff must show (1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to [the] plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases)." See Save Our Sonoran, Inc. v. Flowers, 408 F.3d 1113, 1120 (9th Cir. 2005) (internal quotations omitted). We

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also use an alternative test whereby a court may grant the injunction if the plaintiff demonstrates either: (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that serious questions are raised and the balance of hardships tips sharply in his favor. See id.

The two alternative formulations "represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. They are not separate tests but rather outer reaches of a single continuum." Baby Tam & Co. v. City of Las Vegas, 154 F.3d 1097, 1100 (9th Cir. 1998) (internal quotation marks and citations omitted).

I Common Law Necessity

Raich first argues that she has a likelihood of success on the merits of her claim that the common law doctrine of necessity bars the federal government from enforcing the Controlled Substances Act against her medically-necessary use of marijuana.³ Raich avers that she is faced with a choice of evils: to either obey the Controlled Substances Act and endure excruciating pain and possibly death, or violate the terms of the Controlled Substances Act and obtain relief from her physical suffering.

The necessity defense "traditionally covered the situation where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils" and the actor had no "reasonable, legal alternative to violating the law." United States v. Bailey, 444 U.S. 394, 410, 100 S.Ct. 624, 62 L.Ed.2d 575 (1980); see also 2 Wayne R. LaFare, *Substantive Criminal Law* § 10.1 at 116 (2d ed. 2003 & Supp. 2005). As we have recognized,

In some sense, the necessity defense allows us to act as individual legislatures, amending a particular criminal provision or crafting a one-time exception to it, subject to court review, when a real legislature would formally do the same under those circumstances. For example, by allowing prisoners who escape a burning jail to claim the justification of necessity, we assume the lawmaker, confronting this problem, would have allowed for an exception to the law proscribing prison escapes.

United States v. Schoon, 971 F.2d 193, 196-97 (9th Cir. 1991)

The Supreme Court has recognized that a common law necessity defense exists even when a statute does not explicitly include the defense. See Bailey, 444 U.S. at 425, 100 S.Ct. 624 (Blackmun, J., dissenting) (having "no difficulty in concluding that Congress intended the defenses of duress and necessity to be available" to prison escape defendant); *id.* at 415 n. 11, 100 S.Ct. 624 (Rehnquist, J., majority opinion) (noting that the majority's "principal difference with the dissent, therefore, is not as to the existence of [the necessity] defense but as to the importance of surrender as an element of it").⁴

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A. Whether Raich Satisfies the Requirements of the Common Law Necessity Defense⁵

Here, although we ultimately conclude that Raich is not entitled to injunctive relief on the basis of her common law necessity claim, we briefly note that, in light of the compelling facts before the district court, Raich appears to satisfy the threshold requirements for asserting a necessity defense under our case law. We have set forth the following general standards for a necessity defense:

As a matter of law, a defendant must establish the existence of four elements to be entitled to a necessity defense: (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relation between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law.

United States v. Aguilar, 883 F.2d 662, 693 (9th Cir. 1989).

We first ask whether Raich was faced with a choice of evils and whether she chose the lesser evil. Raich's physician presented uncontroverted evidence that Raich "cannot be without cannabis as medicine" because she would quickly suffer "precipitous medical deterioration" and "could very well" die. If Raich obeys the Controlled Substances Act she will have to endure intolerable pain including severe chronic pain in her face and jaw muscles due to temporomandibular joint dysfunction and bruxism, severe chronic pain and chronic burning from fibromyalgia that forces her to be flat on her back for days, excruciating pain from non-epileptic seizures, heavy bleeding and severely painful menstrual periods due to a uterine fibroid tumor, and acute weight loss resulting possibly in death due to a life-threatening wasting disorder.⁶

Alternatively, Raich can violate the Controlled Substances Act and avoid the bulk of those debilitating

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pains by using marijuana. The evidence persuasively demonstrates that, in light of her medical condition, Raich satisfies the first prong of the necessity defense.

We next ask whether Raich is acting to prevent imminent harm. All medical evidence in the record suggests that, if Raich were to stop using marijuana, the acute chronic pain and wasting disorders would immediately resume. The Government does not dispute the severity of her conditions or the likelihood that her pain would recur if she is deprived of marijuana. Raich has therefore established that the harm she faces is imminent.

Prong three asks whether Raich reasonably anticipated a causal connection between her unlawful conduct and the harm to be avoided. We believe that Raich's belief in the causal connection is reasonable. Here, Raich's licensed physician testified to the causal connection between her physical condition and her need to use marijuana. The Government did not dispute this medical evidence. Because Raich has clearly demonstrated the medical correlation, she has satisfied prong three.⁷

Finally, we ask whether Raich had any legal alternatives to violating the law. Dr. Lucido's testimony makes clear that Raich had no legal alternatives: Raich "has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects." Raich's physician explained that the intolerable side effects included violent nausea, shakes, itching, rapid heart palpitations, and insomnia. We agree that Raich does not appear to have any legal alternative to marijuana use.⁸

Although Raich appears to satisfy the factual predicate for a necessity defense, it is not clear whether the Supreme Court's decision in *United States v. Oakland Cannabis Buyers' Cooperative* forecloses a necessity defense to a prosecution of a seriously ill defendant under the Controlled Substances Act. 532 U.S. 483, 484 n. 7, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001). Similarly, whether the Controlled Substances Act encompasses a legislative "determination of values," *id.* at 491, 121 S.Ct. 1711, that would preclude a necessity defense is also an unanswered question. These are difficult issues, and in light of our conclusion below that Raich's necessity claim is best resolved within the context of a specific prosecution under the Controlled Substances Act, where the issue would be fully joined, we do not attempt to answer them here.

B. Whether a Viable Necessity Defense Gives Raich a Likelihood of Success on the Merits on this Action for Injunctive Relief

Irrespective of the compelling factual basis for Raich's necessity claim, whether Raich has a likelihood of success on the merits in this action for injunctive relief is a different question. We conclude

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that Raich has not demonstrated that she will likely succeed in obtaining injunctive relief on the necessity ground.

The necessity defense is an affirmative defense that removes criminal liability for violation of a criminal statute. See 2 LaFare, *Substantive Criminal Law* § 9.1(a) (2d ed. 2003 & Supp. 2005). Necessity is essentially a justification for the prohibited conduct: the "harm caused by the justified behavior remains a legally recognized harm that is to be avoided whenever possible." Paul H. Robinson, *Criminal Law Defenses* § 24(a) (1984 & Supp. 2006-2007). A common law necessity defense thus singles out conduct that is "otherwise criminal, which under the circumstances is socially acceptable and which deserves neither criminal liability nor even censure." LaFare, *Substantive Criminal Law* § 9.1(a)(3) (2d ed. 2003 & Supp. 2005) (quotation omitted). The necessity defense serves to protect the defendant from criminal

liability.

Though a necessity defense may be available in the context of a criminal prosecution, it does not follow that a court should prospectively enjoin enforcement of a statute. Raich's violation of the Controlled Substances Act is a legally recognized harm, but the necessity defense shields Raich from liability for criminal prosecution during such time as she satisfies the defense. Thus, if Raich were to make a miraculous recovery that obviated her need for medical marijuana, her necessity-based justification defense would no longer exist. Similarly, if Dr. Lucido found an alternative treatment that did not violate the law—a legal alternative to violating the Controlled Substances Act—Raich could no longer assert a necessity defense. That is to say, a necessity defense is best considered in the context of a concrete case where a statute is allegedly violated, and a specific prosecution results from the violation. Indeed, oversight and enforcement of a necessity defense-based injunction would prove impracticable: the ongoing vitality of the injunction could hinge on factors including Raich's medical condition or advances in lawful medical technology. Nothing in the common law or our cases suggests that the existence of a necessity defense empowers this court to enjoin the enforcement of the Controlled Substances Act as to one defendant.

Because common law necessity prevents criminal liability, but does not permit us to enjoin prosecution for what remains a legally recognized harm, we hold that Raich has not shown a likelihood of success on the merits on her medical necessity claim for an injunction.⁹

II. Substantive Due Process

Raich contends that the district court erred by failing to protect her fundamental rights. Her argument focuses on unenumerated rights protected by the Fifth and Ninth Amendments to the Constitution under a theory of substantive due process.¹⁰

A. Substantive Due Process, Generally

Although the Fifth Amendment's Due Process Clause states only that "[n]o

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person shall be deprived of life, liberty, or property, without due process of law," see U.S. Const. amend. V, it unquestionably provides substantive protections for certain unenumerated fundamental rights.¹¹ "The Due Process Clause guarantees more than fair process, and the 'liberty' it protects includes more than the absence of physical restraint." Washington v. Glucksberg, 521 U.S. 702, 719, 117 S.Ct. 2258, 138 L.Ed.2d 772 (1997); see also Planned Parenthood of S.E. Penn. v. Casey, 505 U.S. 833, 847, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992) ("It is tempting, as a means of curbing the discretion of federal judges, to suppose that liberty encompasses no more than those rights already guaranteed to the individual against federal interference by the express provisions of the first eight Amendments to the Constitution. But of course this Court has never accepted that view" (internal citation omitted)). As Justice Harlan put it over forty years ago:

[T]he full scope of the liberty guaranteed by the Due Process Clause cannot be found in or limited by the precise terms of the specific guarantees elsewhere provided in the Constitution. This 'liberty' is not a series of isolated points pricked out in terms of the taking of property; the freedom of speech, press, and religion; the right to keep and bear arms; the freedom from unreasonable searches and seizures; and so on. It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment.

Poe v. Ullman, 367 U.S. 497, 543, 81 S.Ct. 1752, 6 L.Ed.2d 989 (1961) (Harlan, J., dissenting)

(citations omitted); see also *Casey*, 505 U.S. at 849, 112 S.Ct. 2791 (noting that Justice Harlan's position was adopted by the Court in *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed 2d 510 (1965)) These contentions find support in the Ninth Amendment, which provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people " U.S. Const. amend IX

In *Glucksberg*, the Supreme Court set forth the two elements of the substantive due process analysis

First, we have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, "deeply rooted in this Nation's history and tradition," and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." Second, we have required in substantive-due-process cases a "careful description" of the asserted fundamental liberty interest

Glucksberg, 521 U.S. at 720-21, 117 S.Ct. 2258 (citations omitted)

The Supreme Court has a long history of recognizing unenumerated fundamental rights as protected by substantive due process,

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even before the term evolved into its modern usage. See, e.g., *Casey*, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed 2d 674 (to have an abortion); *Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed 2d 147 (1973) (same); *Eisenstadt v. Baird*, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed 2d 349 (1972) (to use contraception); *Griswold*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed 2d 510 (to use contraception, to marital privacy); *Loving v. Virginia*, 388 U.S. 1, 87 S.Ct. 1817, 18 L.Ed 2d 1010 (1967) (to marry); *Rochin v. California*, 342 U.S. 165, 72 S.Ct. 205, 96 L.Ed. 183 (1952) (to bodily integrity); *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 62 S.Ct. 1110, 86 L.Ed. 1655 (1942) (to have children); *Pierce v. Society of Sisters*, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925) (to direct the education and upbringing of one's children); *Meyer v. Nebraska*, 262 U.S. 390, 43 S.Ct. 625, 67 L.Ed. 1042 (1923) (same) But the Court has cautioned against the doctrine's expansion. See *Glucksberg*, 521 U.S. at 720, 117 S.Ct. 2258 (stating that the Court must restrain the expansion of substantive due process "because guideposts for responsible decisionmaking in this uncharted area are scarce and open-ended" and because judicial extension of constitutional protection for an asserted substantive due process right "place[s] the matter outside the arena of public debate and legislative action" (citations omitted)); *Reno v. Flores*, 507 U.S. 292, 302, 113 S.Ct. 1439, 123 L.Ed 2d 1 (1993) (noting that "[t]he doctrine of judicial self-restraint requires us to exercise the utmost care whenever we are asked to break new ground in this field" (quoting *Collins v. Harker Heights*, 503 U.S. 115, 125, 112 S.Ct. 1061, 117 L.Ed 2d 261 (1992))).

Bearing that rubric in mind, we consider Raich's substantive due process claim. In the present case, it is helpful to begin with the second step—the description of the asserted fundamental right—before determining whether the right is deeply rooted in this nation's history and traditions and implicit in the concept of ordered liberty

B. Breadth of the Fundamental Right

Glucksberg instructs courts to adopt a narrow definition of the interest at stake. See 521 U.S. at 722, 117 S.Ct. 2258 ("[W]e have a tradition of carefully formulating the interest at stake in substantive-due-process cases"); see also *Flores*, 507 U.S. at 302[, 113 S.Ct. 1439] (noting that the asserted liberty interest must be construed narrowly to avoid unintended consequences). Substantive due process requires a "careful description of the asserted fundamental liberty interest." *Glucksberg*, 521 U.S. at 721, 117 S.Ct. 2258 (quotation and citations omitted)

Glucksberg involved a substantive due process challenge to Washington state's ban on assisted suicide. See *id.* at 705-06, 117 S. Ct. 2258. The Court in *Glucksberg* rejected the suggestion that the interest at stake was the "right to die" or "the right to choose a humane, dignified death," and instead held that the narrow question before the Court was "whether the 'liberty' specially protected by the Due Process Clause includes a right to commit suicide which itself includes a right to assistance in doing so." *Id.* at 722-23, 117 S. Ct. 2258.

Another case that considered and rejected several asserted fundamental rights involved unaccompanied alien juveniles who are in the custody of immigration authorities. See *Flores*, 507 U.S. at 294[, 113 S. Ct. 1439]. The *Flores* Court rejected the proposed fundamental right of "freedom from physical restraint" because it was not an accurate depiction of the true issue in the case. See *Flores*, 507 U.S. at 302[, 113 S. Ct. 1439]. The Court also rejected the formulation of the "right of a child to be released from all other custody into the custody of its parents, legal guardian, or even close relatives." *Id.* Instead,

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the *Flores* Court examined the narrow "right of a child who has no available parent, close relative, or legal guardian, and for whom the government is responsible, to be placed in the custody of a willing-and-able private custodian rather than of a government-operated or government-selected child-care institution." *Id.*; see also *Lawrence v. Texas*, 539 U.S. 558, 578, 123 S.Ct. 2472, 156 L.Ed.2d 508 (2003) (recognizing narrowly defined fundamental right to engage in consensual sexual activity, including homosexual sodomy, in the home without government intrusion).

C. Raich's Asserted Fundamental Interest

Raich asserts that she has a fundamental right to "mak[e] life-shaping medical decisions that are necessary to preserve the integrity of her body, avoid intolerable physical pain, and preserve her life." We note that Raich's carefully crafted interest comprises several fundamental rights that have been recognized at least in part by the Supreme Court. See *Lawrence*, 539 U.S. at 574, 123 S.Ct. 2472 (recognizing that "the Constitution demands [respect] for the autonomy of the person in making [personal] choices"); *Casey*, 505 U.S. at 849, 112 S.Ct. 2791 (noting importance of protecting "bodily integrity"); *id.* at 852, 112 S.Ct. 2791 (observing that a woman's "suffering is too intimate and personal" for government to compel such suffering by requiring woman to carry a pregnancy to term).

Yet, Raich's careful statement does not narrowly and accurately reflect the right that she seeks to vindicate. Conspicuously missing from Raich's asserted fundamental right is its centerpiece: that she seeks the right to use *marijuana* to preserve bodily integrity, avoid pain, and preserve her life.¹² As in *Glucksberg*, *Flores*, and *Cruzan*, the right must be carefully stated and narrowly identified before the ensuing analysis can proceed. Accordingly, we will add the centerpiece—the use of marijuana—to Raich's proposed right.¹³

Accordingly, the question becomes whether the liberty interest specially protected by the Due Process Clause embraces a right to make a life-shaping decision on a physician's advice to use medical marijuana to preserve bodily integrity, avoid intolerable pain, and preserve life, when all other prescribed medications and remedies have failed.

D. Whether the Asserted Right is "Deeply Rooted in This Nation's History and Tradition" and "Implicit in the Concept of Ordered Liberty"

We turn to whether the asserted right is "deeply rooted in this Nation's history and tradition," and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." *Glucksberg*, 521 U.S. at 720-21, 117 S.Ct. 2258.

It is beyond dispute that marijuana has a long history of use—medically and otherwise

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—in this country. Marijuana was not regulated under federal law until Congress passed the Marihuana Tax Act of 1937, Pub L. No. 75-348, 50 Stat. 551 (repealed 1970), and marijuana was not prohibited under federal law until Congress passed the Controlled Substances Act in 1970. See Gonzales v. Raich, 125 S.Ct. at 2202. There is considerable evidence that efforts to regulate marijuana use in the early-twentieth century targeted recreational use, but permitted medical use. See Richard J. Bonnie & Charles H. Whitebread, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition*, 56 Va. L. Rev. 971, 1010, 1027, 1167 (1970) (noting that all twenty-two states that had prohibited marijuana by the 1930s created exceptions for medical purposes). By 1965, although possession of marijuana was a crime in all fifty states, almost all states had created exceptions for "persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person." Leary v. United States, 395 U.S. 6, 16-17, 89 S.Ct. 1532, 23 L.Ed.2d 57 (1969).

The history of medical marijuana use in this country took an about-face with the passage of the Controlled Substances Act in 1970. Congress placed marijuana on Schedule I of the Controlled Substances Act, taking it outside of the realm of all uses, including medical, under federal law. As the Supreme Court noted in Gonzales v. Raich, 125 S.Ct. at 2199, no state permitted medical marijuana usage until California's Compassionate Use Act of 1996. Thus, from 1970 to 1996, the possession or use of marijuana—medically or otherwise—was proscribed under state and federal law.¹⁴

Raich argues that the last ten years have been characterized by an emerging awareness of marijuana's medical value. She contends that the rising number of states that have passed laws that permit medical use of marijuana or recognize its therapeutic value is additional evidence that the right is fundamental. Raich avers that the asserted right in this case should be protected on the "emerging awareness" model that the Supreme Court used in Lawrence v. Texas, 539 U.S. at 571, 123 S.Ct. 2472.

The Lawrence Court noted that, when the Court had decided Bowers v. Hardwick, 478 U.S. 186, 106 S.Ct. 2841, 92 L.Ed.2d 140 (1986), "[twenty-four] States and the District of Columbia had sodomy laws." Lawrence, 539 U.S. at 572, 123 S.Ct. 2472. By the time a similar challenge to sodomy laws arose in Lawrence in 2004, only thirteen states had maintained their sodomy laws, and there was a noted "pattern of nonenforcement." *Id.* at 573, 123 S.Ct. 2472. The Court observed that "times can blind us to certain truths and later generations can see that laws once thought necessary and proper in fact serve only to oppress." *Id.* at 579, 123 S.Ct. 2472.

Though the Lawrence framework might certainly apply to the instant case, the use of medical marijuana has not obtained the degree of recognition today that private sexual conduct had obtained by 2004 in Lawrence. Since 1996, ten states other than California have passed laws decriminalizing in varying degrees the use, possession, manufacture, and distribution of marijuana for the seriously ill. See Alaska Stat. § 11.71.090; Colo. Rev. Stat. § 18-18-406.3; Haw. Rev. Stat. § 329-125; Me. Rev.

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Stat. Ann. tit. 22, § 2383-B; Mont. Code Ann. § 50-46-201; Nev. Rev. Stat. § 453A.200; Or. Rev. Stat. § 475.319; R.I. Gen. Laws § 21-28.6-4; Vt. Stat. Ann. tit. 18, § 4474b; Wash. Rev. Code § 69.51A.040. Other states have passed resolutions recognizing that marijuana may have therapeutic value, and yet others have permitted limited use through closely monitored experimental treatment programs.¹⁵

We agree with Raich that medical and conventional wisdom that recognizes the use of marijuana for medical purposes is gaining traction in the law as well. But that legal recognition has not yet reached the point where a conclusion can be drawn that the right to use medical marijuana is "fundamental" and

"implicit in the concept of ordered liberty " See *Glucksberg*, 521 U.S. at 720-21, 117 S.Ct. 2258 (citations omitted). For the time being, this issue remains in "the arena of public debate and legislative action " *Id* at 720, 117 S.Ct. 2258; see also *Gonzales v Raich*, 125 S.Ct. at 2215

As stated above, Justice Anthony Kennedy told us that "times can blind us to certain truths and later generations can see that laws once thought necessary and proper in fact serve only to oppress." *Lawrence*, 539 U.S. at 579, 123 S.Ct. 2472 For now, federal law is blind to the wisdom of a future day when the right to use medical marijuana to alleviate excruciating pain may be deemed fundamental. Although that day has not yet dawned, considering that during the last ten years eleven states have legalized the use of medical marijuana, that day may be upon us sooner than expected. Until that day arrives, federal law does not recognize a fundamental right to use medical marijuana prescribed by a licensed physician to alleviate excruciating pain and human suffering ¹⁶

III Tenth Amendment

Third, Raich contends that the Controlled Substances Act infringes upon the sovereign powers of the State of California, most notably the police powers, as conferred by the Tenth Amendment. The district court found that, as a valid exercise of Congress's Commerce Clause powers, the Controlled Substances Act could curtail the states' exercise of their police powers without violating the Tenth Amendment. See *Raich v. Ashcroft*, 248 F.Supp.2d at 927. The district court further held that the Controlled Substances Act regulates individual behavior and does not force the state to take any action. *Id*

The Tenth Amendment reads, in its entirety: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to

[500 F 3d 867]

the States respectively, or to the people " U.S. Const. amend. X. Police power is unquestionably an area of traditional state control.

Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are primarily, and historically, . . . matter[s] of local concern, the States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (internal citations and quotation marks omitted). The Compassionate Use Act, aimed at providing for the health of the state's citizens, appears to fall squarely within the general rubric of the state's police powers.

Generally speaking, however, a power granted to Congress trumps a competing claim based on a state's police powers. "The Court long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers." *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291 (1981); see also *United States v. Jones*, 231 F.3d 508, 515 (9th Cir.2000) ("We have held that if Congress acts under one of its enumerated powers, there can be no violation of the Tenth Amendment").

The Supreme Court held in *Gonzales v Raich* that Congress acted within the bounds of its Commerce Clause authority when it criminalized the purely intrastate manufacture, distribution, or possession of marijuana in the Controlled Substances Act. See 125 S.Ct. at 2215. Thus, after *Gonzales v. Raich*, it would seem that there can be no Tenth Amendment violation in this case. Raich concedes that recent Supreme Court decisions have largely foreclosed her Tenth Amendment claim, and she also concedes that this case

does not implicate the "commandeering" line of cases¹⁷

The Supreme Court's recent decision in Gonzales v. Oregon, 546 U.S. 243, 126 S.Ct. 904, 163 L.Ed 2d 748 (Jan. 17, 2006) is not to the contrary. In that case, the Court invalidated an Interpretive Rule issued by the Attorney General on the basis of statutory construction, not on the basis of constitutional invalidity under the Tenth Amendment. See *id.* at 925. Because the Attorney General's Rule was "incongruous with the *statutory* purposes and design" of the Controlled Substances Act, the Rule had to be nullified. *Id.* at 921 (emphasis added). Although Gonzales v. Oregon undoubtedly implicates federalism issues, its holding is inapposite to Raich's Tenth Amendment claim.

We hold that Raich failed to demonstrate a likelihood of success on her claim that the Controlled Substances Act violates the Tenth Amendment. Accordingly, the district court did not abuse its discretion in denying Raich's motion for preliminary injunction on that basis.

[500 F.3d 868]

IV *The Controlled Substances Act, By Its Terms*

Finally, Raich argues that the plain text of the Controlled Substances Act does not prohibit her from possessing marijuana pursuant to a doctor's order. She observes that the Controlled Substances Act prohibits possession of a controlled substance "unless such substance was obtained . . . pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice." 21 U.S.C. § 844(a). The Controlled Substances Act defines "practitioner" as "a physician licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." *Id.* § 802(21). Raich contends that her doctor is a licensed physician who may, in the jurisdiction in which he practices, administer controlled substances, including marijuana under the Compassionate Use Act, pursuant to a valid prescription. Accordingly, she argues that her possession of marijuana is legal under the Controlled Substances Act.

Raich raises this argument for the first time in her opening brief to our second review of her case. It is a long-standing rule in the Ninth Circuit that, generally, "we will not consider arguments that are raised for the first time on appeal." Smith v. Marsh, 194 F.3d 1045, 1052 (9th Cir. 1999). That rule is subject to the exceptions that we may consider a new issue if: (1) there are exceptional circumstances why the issue was not raised in the trial court; (2) the new issue arises while the appeal is pending because of a change in the law; or (3) the issue presented is a pure question of law and the opposing party will suffer no prejudice as a result of the failure to raise the issue in the trial court. See United States v. Carlson, 900 F.2d 1346, 1349 (9th Cir. 1990).

Raich does not address the waiver issue in her opening brief, nor does she cite any relevant exception that might apply to her argument. We observe that there do not appear to be any exceptional circumstances concerning why Raich did not raise the argument below, and that there has been no change in the law relevant to this argument. Thus, Raich's only argument against waiver of this claim is that it is a purely legal question, and that the Government will suffer no prejudice as a result of Raich's failure to raise the issue below.¹⁸

Even if a case falls within one of the exceptions to waiver enunciated in Carlson, we must "still decide whether the particular circumstances of the case overcome our presumption against hearing new arguments." Dream Palace, 384 F.3d at 1005. Although Raich's Controlled Substances Act claim appears to fall within the third exception, we conclude that this claim is waived because of the "particular circumstances" surrounding the claim.

Raich failed to raise this claim before the district court and before this court in her appeal in Raich v.

Ashcroft,

[500 F 3d 869]

352 F 3d 1222. Furthermore, when we requested renewed briefing for this appeal by our order of September 6, 2005, we directed the parties to brief the "remaining claims for declaratory and injunctive relief on the basis of the Tenth Amendment, the Fifth and Ninth Amendments, and the doctrine of medical necessity, as set forth in their complaint " *Raich v Gonzales*, No 03-15481 (9th Cir. Sept 6, 2005) (order directing renewed briefing) Because Raich did not raise this issue below, and because our order instructed the parties to brief only the three claims set forth above, we hold that Raich's claim based on the plain language of the Controlled Substances Act is waived We express no opinion as to the merits of that claim

CONCLUSION

We conclude that Raich has not demonstrated a likelihood of success on the merits of her action for injunctive relief First, we hold that Raich's common law necessity defense is not foreclosed by *Oakland Cannabis* or the Controlled Substances Act, but that the necessity defense does not provide a proper basis for injunctive relief. Second, although changes in state law reveal a clear trend towards the protection of medical marijuana use, we hold that the asserted right has not yet gained the traction on a national scale to be deemed fundamental. Third, we hold that the Controlled Substances Act, a valid exercise of Congress's commerce power, does not violate the Tenth Amendment Finally, we decline to reach Raich's argument that the Controlled Substances Act, by its terms, does not prohibit her possession and use of marijuana because this argument was not raised below.

Accordingly, the judgment of the district court is **AFFIRMED**.

Notes:

* Karen Tandy is substituted for her predecessor, Asa Hutchinson, as Administrator of the Drug Enforcement Administration, pursuant to Fed R App. P. 43(c)(2)

** The Honorable C Arlen Beam, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation

1 Plaintiff-Appellant Monson withdrew from this action on December 12, 2005.

2 We also note that the Supreme Court did not question constitutional standing in this case *See Gonzales v. Raich*, 545 U.S. 1, 125 S.Ct. 2195, 162 L.Ed.2d 1

3. We address Raich's necessity claim before her constitutional substantive due process claim because "an Act of Congress ought not be construed to violate the Constitution if any other possible construction remains available " *Gilmore v. California*, 220 F.3d 987, 998 (9th Cir.2000) (quoting *NLRB v. Catholic Bishop*, 440 U.S. 490, 500, 99 S.Ct. 1313, 59 L.Ed.2d 533 (1979)).

4. Dicta in a recent Supreme Court decision questioned the ongoing vitality of common law necessity defense The majority in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 490, 121 S.Ct. 1711, 149 L.Ed 2d 722 (2001) ("*Oakland Cannabis*"), stated that "it is an open question whether federal courts ever have authority to recognize a necessity defense not provided by statute " But the majority ultimately conceded that the "Court ha[d] discussed the possibility of a necessity defense without altogether rejecting it." *Id* (citing *Bailey*, 444 U.S. at 415, 100 S Ct 624) Three Justices filed a separate concurrence in *Oakland Cannabis*, noting that "the Court gratuitously casts doubt on 'whether necessity can ever be a defense' to any federal statute that does not explicitly provide for it, calling such a defense

into question by a misleading reference to its existence as an "open question" *Id.* at 501, 121 S.Ct. 1711 (Stevens, J., concurring) (quoting majority opinion) (emphasis in original) "[O]ur precedent has expressed no doubt about the viability of the common-law defense, even in the context of federal criminal statutes that do not provide for it in so many words" *Id.* (citing *Bailey*, 444 U.S. at 415, 100 S.Ct. 624).

We do not believe that the *Oakland Cannabis* dicta abolishes more than a century of common law necessity jurisprudence. *See, e.g., Regina v. Dudley & Stephens*, 14 Q.B.D. 273 (1884)

5. As the Supreme Court did in *Oakland Cannabis*, we first address the underlying principles of the common law necessity defense, and then turn to the defense's relationship to the Controlled Substances Act and the relief sought. *See, e.g., Oakland Cannabis*, 532 U.S. at 490-95, 121 S.Ct. 1711

6. This litany of ailments makes no mention of the fact that Raich was confined to a wheelchair before she found effective pain management in marijuana, which restored her ability to walk. The seriousness of her conditions cannot be overemphasized: in 1997, the extreme physical and psychological pain led Raich to attempt suicide. We are mindful that "extreme pain totally occupies the psychic world" and that "in serious pain the claims of the body utterly nullify the claims of the world." Seth F. Kreimer, *The Second Time as Tragedy: The Assisted Suicide Cases and the Heritage of Roe v. Wade*, 24 *Hastings Const. L.Q.* 863, 895 & n. 157 (1997) (citations omitted). Raich has shown remarkable fortitude in pursuing this action to vindicate the rights of the infirm despite her precarious physical condition.

7. The causal connection prong limits the danger that a medical necessity exception could open the floodgates to widespread exceptions to the Controlled Substances Act. A marijuana "necessity" claimant absolutely must present, as Raich has, testimony that the allegedly unlawful action was taken at the direction of a doctor.

8. The Government suggests that certain federal programs exist which might allow Raich to obtain marijuana lawfully. *See, e.g.,* 21 U.S.C. § 823(f) (authorizing the Secretary of Health and Human Services to permit medical practitioners to design and implement research protocols using Schedule I substances, including marijuana, on a case-by-case basis). Amici curiae American Civil Liberties Union Foundation and Marijuana Policy Project and Rick Doblin, Ph.D. make abundantly clear that this is not a tenable "alternative." The program is highly restricted and has not accepted new medical marijuana patients since 1992.

9. We cannot ignore that the unusual circumstances of this case raise the danger of acute preconviction harms. The arrest of Raich or her suppliers, or the confiscation of her medical marijuana would cause Raich severe physical trauma. Under the right circumstances, Raich might obtain relief from the courts for preconviction harm based on common law necessity. *See generally Jones v. City of Los Angeles*, 444 F.3d 1118, 1129-31 (9th Cir. 2006) (noting that constitutionally cognizable harm can occur "at arrest, at citation, or even earlier," and criticizing the government's position that "would allow the state to criminalize a protected behavior or condition and cite, arrest, jail, and even prosecute individuals for violations, so long as no conviction resulted").

10. We refer to these claims together as the substantive due process claim.

11. Although the Fifth Amendment's Due Process Clause is applicable here, cases finding substantive rights under the Fourteenth Amendment's Due Process Clause are equally relevant. *See Troxel v. Granville*, 530 U.S. 57, 65, 120 S.Ct. 2054, 147 L.Ed.2d 49 (2000) ("We have long recognized that the Amendment's Due Process Clause, like its Fifth Amendment counterpart, guarantees more than fair process. The Clause also includes a substantive component that provides heightened protection against government interference with certain fundamental rights and liberty interests" (emphasis added) (internal citation and quotation marks omitted)).

12. This degree of specificity is required. In Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990), the Court declined to frame the right as an unqualified right to die, and instead specifically construed the right as a "constitutionally protected right to refuse lifesaving hydration and nutrition." *Id.* at 279, 110 S.Ct. 2841

13. We also find persuasive the suggestion of amicus curiae California Medical Association and California Nurses Association: that the definition incorporate reference to the fact that Raich seeks to establish this right "on a physician's advice." We also think that resort to a Schedule I substance should be a last resort, and therefore narrow the right by limiting it to circumstances "when all other prescribed medications have failed."

14. The mere enactment of a law, state or federal, that prohibits certain behavior does not necessarily mean that the behavior is not deeply rooted in this country's history and traditions. It is noteworthy, however, that over twenty-five years went by before any state enacted a law to protect the alleged right

15. While these lesser endorsements of medical marijuana are relevant, they cannot carry the same weight as legislative enactments that fully decriminalize the use of medical marijuana. As the *Lawrence* Court considered the number of states that retained laws that prohibited sodomy, so too must we consider the number of states that continue to prohibit medical marijuana.

16. Because we find no fundamental right here, we do not address whether any law that limits that right is narrowly drawn to serve a compelling state interest. See *Flores*, 507 U.S. at 301-02, 113 S.Ct. 1439. We note, however, that a recent Supreme Court case suggests that the Controlled Substances Act is not narrowly drawn when fundamental rights are concerned. See *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 126 S.Ct. 1211, 1221-23, 163 L.Ed.2d 1017 (Feb. 21, 2006) (observing that "mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day," and that the government had presented no evidence that narrow exceptions to the Schedule I prohibitions would undercut the government's ability to effectively enforce the Controlled Substances Act)

17. The commandeering cases involve attempts by Congress to direct states to perform certain functions, command state officers to administer federal regulatory programs, or to compel states to adopt specific legislation. See, e.g., *Printz v. United States*, 521 U.S. 898, 935, 117 S.Ct. 2365, 138 L.Ed.2d 914 (1997); *New York v. United States*, 505 U.S. 144, 166, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992). The Controlled Substances Act, by contrast, "does not require the [state legislature] to enact any laws or regulations, and it does not require state officials to assist in the enforcement of federal statutes regulating private individuals." *Reno v. Condon*, 528 U.S. 141, 151, 120 S.Ct. 666, 145 L.Ed.2d 587 (2000)

18. We assess prejudice to a party by asking whether the party is in a different position than it would have been absent the alleged deficiency. See *Zhang v. Am. Gem Seafoods, Inc.*, 339 F.3d 1020, 1035 (9th Cir. 2003). The rule "serves to ensure that legal arguments are considered with the benefit of a fully developed factual record, offers appellate courts the benefit of the district court's prior analysis, and prevents parties from sand-bagging their opponents with new arguments on appeal." *Dream Palace v. County of Maricopa*, 384 F.3d 990, 1005 (9th Cir. 2004). It does not appear that the Government has suffered any prejudice from Raich's failure to raise this claim below: the Government is in the same position that it would have otherwise been

BEAM, Circuit Judge, concurring and dissenting:

I concur in the result reached by the court in this case, more particularly its holding that "Raich has not demonstrated a likelihood of success on the merits of her action for injunctive relief" and that the district

court's denial of an injunction should be affirmed. I dissent from the court's expansive consideration of the doctrine of common law necessity as well as from several of the factual findings and legal conclusions applied to this issue and other claims before the court

DISCUSSION

We should decide only the case that is properly before us, not any other, and we should leave for another day any claim or issue not ripe for consideration. When we do otherwise, we simply create obituary dictum. See, e.g., Carey v. Musladin, ___ U.S. ___, 127 S.Ct. 649, 655, 166 L.Ed.2d 482 (2006) (Stevens, J., concurring) (citing Sheet Metal Workers' v. EEOC, 478 U.S. 421, 490, 106 S.Ct. 3019, 92 L.Ed.2d 344 (1986))

This case returns to us on remand from the Supreme Court. But, the party that earlier supplied jurisdiction to the Supreme Court and to this court, Diane Monson, has withdrawn. *Ante* at 856 n. 1. Thus, the facts concerning Ms. Monson generously recited by the court are in no way relevant or material to the issues now raised by Raich. Accordingly, the court likely has no jurisdiction over any claim asserted by the plaintiffs in this appeal but most certainly no jurisdiction to decide whether Raich may assert the doctrine of common law necessity in a future criminal prosecution.

At oral argument, counsel for the parties conceded that there is not now pending nor has there ever been pending a prosecution or even a threatened prosecution of

[500 F.3d 870]

Raich for possession or use of personal amounts of medicinal marijuana. Indeed, counsel for Raich acknowledged at oral argument that, to his knowledge, there has never been a federal criminal prosecution for simple possession or use of medicinal marijuana against anyone anywhere in California. Counsel for the government likewise indicated a lack of knowledge of any such prosecution and stated that it would be "incredibly unlikely" that any such federal prosecution would ensue in the future. So, the court's statement, *ante* at 857, that "[a]lthough Raich has not suffered any past injury, she is faced with the threat that the Government will seize her medical marijuana and prosecute her for violations of federal drug law" is plainly not supported by the record.

Accordingly, I return to the issues of standing, ripeness and justiciability advanced in my earlier dissent in this case. With specific regard to the court's lengthy discussion of and rulings upon the doctrine of common law necessity, it is clear that

"[W]here it is impossible to know whether a party will ever be found to have violated a statute, or how, if such a violation is found, those charged with enforcing the statute will respond, any challenge to that statute is premature." Alaska Airlines, Inc. v. City of Long Beach, 951 F.2d 977, 986 (9th Cir. 1991). To satisfy Article III's standing requirements, a plaintiff must show that she has suffered a concrete and particularized injury in fact that is actual or imminent (not conjectural or hypothetical). Plaintiff must also show that the injury is fairly traceable to the challenged action of the defendant and that it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Citizens for Better Forestry v. United States Dep't of Agric., 341 F.3d 961, 969 (9th Cir. 2003).

Raich v. Ashcroft, 352 F.3d 1222, 1235-36 (9th Cir. 2003) (Beam, J., dissenting)

Here, as to Raich, there is no discrete, challenged action from which an injury can fairly be traced. San Diego County Gun Rights Committee v. Reno, 98 F.3d 1121, 1127 (9th Cir. 1996), requires Raich to show a specific threat of prosecution, and she bears the burden of establishing that the statute in question is actually being enforced. A specific warning of prosecution may suffice, but "a general threat of prosecution is not enough to confer standing." *Id.* Accordingly, the applicability, or not, of the doctrine of common law

necessity is not a justiciable issue on this record and Raich currently has no standing to ask the court to consider the matter

Assuming for purposes of discussion that the bare question of the viability of the doctrine is before us, I nonetheless respectfully disagree with substantial portions of the court's analysis of the matter

The doctrine of common law (medical) necessity is an affirmative defense assertable only in a criminal prosecution *E.g., United States v. Arellano-Rivera*, 244 F.3d 1119, 1125-26 (9th Cir.2001) (holding that "before a *defendant* may present evidence of a necessity defense, his offer of proof must establish that a reasonable jury could" ascertain all the elements of the defense) (emphasis added) After reference to several measures of potential injury and harm to Raich almost totally unrelated to a reasonably foreseeable criminal prosecution, the court ultimately recognizes the legal limitations of the defense, but only after issuing what amounts to a lengthy advisory opinion

Here we are engaged in the review of a civil proceeding seeking declaratory relief and injunction, not a criminal adjudication It is important to note that, contrary to the inference of the court in its factual dissertation, there has been no "testimony"

[500 F 3d 871]

in this case directly addressing the elements of this defense The evidentiary record, such as it is, was developed in the district court through a request for a preliminary injunction under Rule 65 of the Federal Rules of *Civil Procedure*. All facts recited by the court, some of which are admittedly testimonial in nature, arise from written "declarations" provided by Raich, Monson, Dr Lucido and Dr Rose, Monson's physician, in support of the injunction request Yet, every case cited by the court concerning the viability of the doctrine and its elements involves a criminal prosecution ¹ The burden of proof of such a defense lies with the defendant and involves the following elements:

As a matter of law, a defendant must establish the existence of four elements to be entitled to a necessity defense: (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relation between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law.

United States v. Aguilar, 883 F.2d 662, 693 (9th Cir.1989)

In this civil action, Raich is not presently in a posture to address elements one, two and three and cannot establish element four She has not been faced with a "choice of evils," one of which could lead to a criminal prosecution Nor has she acted to prevent "imminent harm " She has presented no evidence of a tested, adversarial nature sufficient to establish the causal relationship required by element three And, she has not established and probably cannot establish that she has no legal alternative to violating the law

The court states that "Raich's physician [Dr Frank Lucido] presented uncontroverted evidence that Raich 'cannot be without *cannabis* as medicine' because she would quickly suffer 'precipitous medical deterioration' and 'could very well' die " *Ante* at 859 (emphasis added). This opinion evidence is, of course, gleaned from a written declaration seeking declaratory and injunctive relief while positing a very speculative happenstance The opinion is not the fruit of an adversarial hearing involving the assertion of an affirmative defense by a criminal defendant in a criminal prosecution designed to test the admissibility and credibility of the proposed evidence But even if Raich "cannot be without cannabis as medicine," as Dr Lucido opines, cannabis (or its synthetic equivalent) as medicine is lawfully available to Raich through the prescription-dispensed drug Marinol ² And, newly crafted or presently existing drugs as yet untested by Raich may become known or available prior to any prosecution So Raich may well have a legal alternative to the violation of the drug control laws

I also cannot fully join the court's analysis of United States v. Oakland Cannabis Buyers Cooperative, 532 U.S. 483, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001), as set forth in its footnote 4. *Ante* at 858-59. Although I do not concede that the Supreme Court's discussion in *Oakland Cannabis* is dicta, I do agree with the court's

[500 F.3d 872]

conclusion that the case does not abolish "common law necessity jurisprudence."

Thus, while I do not concur in the court's statement that "Raich appears to satisfy the threshold requirements for asserting a necessity defense under our case law," *ante* at 859, I do acknowledge that she certainly *may* be eligible to advance such a defense to criminal liability in the context of an actual prosecution

Finally, if I fully understand the majority's approach, the most troubling aspect of its opinion is that it purports to let this court determine, on the evidence presented to the district court at the Rule 65 hearing, that Raich, and anyone similarly situated, is entitled to a medical necessity defense if criminally prosecuted in the future. I respectfully believe that this turns applicable federal criminal procedure on its head. The viability and applicability of this affirmative defense is a mixed question of law and fact. *Arellano-Rivera*, 244 F.3d at 1125. In a criminal prosecution of Raich for possession and use of marijuana for medicinal purposes, if it ever occurs, the issue of the sufficiency of the evidence to submit this particular defense to a jury is a question of law for the federal trial court. *Id.* The establishment of the factual elements of the defense, if submitted, is for the jury (or other trier of fact) *Id.* Imposition of this court's rulings into a later prosecution would improperly pretermitt established criminal procedure. Thus, the court's medical necessity discussion is a wholly speculative and possibly unconstitutional jurisprudential exercise

CONCLUSION

Accordingly, for the above-stated reasons, I dissent from portions of the court's factual findings and legal conclusions but concur in the denial of Raich's request for injunction and in the court's affirmance of the district court

Notes:

1 See, e.g., United States v. Bailey, 444 U.S. 394, 100 S.Ct. 624, 62 L.Ed.2d 575 (1980) (discussing the choice of two evils doctrine); United States v. Schoon, 971 F.2d 193 (9th Cir.1991) (giving the burning jail example); United States v. Aquilar, 883 F.2d 662 (9th Cir.1989) (explaining the standards and elements of the necessity defense).

2 The active ingredient in Marinol is synthetic delta-9-tetrahydrocannabinol, a naturally occurring component of *Cannabis sativa L*, the marijuana Raich says she now consumes. Physicians' Desk Reference, 61st ed., 2007 at 3333.



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January 7, 2011

Via Electronic Delivery and US Mail

Mr. Will Humble
Director, Arizona Department of Health Services
150 North 18th Avenue
Phoenix, AZ 85007

A handwritten signature in black ink that reads 'Tom Edlow'.

RECEIVED
ADHS
DIRECTORS OFFICE
11 JAN 11 PM 2:44

Re: ADHS Informal Draft Rules for the Arizona Medical Marijuana Act

Dear Director Humble:

Thank you for the opportunity to comment on the Informal Draft Rules proposed by the Arizona Department of Health Services (the "Department") for implementation of the Arizona Medical Marijuana Act (the "Act"). We applaud the Department's efforts in drafting rules governing the safe and responsible administration of the Act. We commend staff and agree with many of the proposed rules, however we are concerned about a number of provisions that are inconsistent with the Act or contrary to the intent of the law.

70% Cultivation Rule

Proposed rule R9-17-307(C) requires a dispensary to "cultivate at least 70% of the medical marijuana the dispensary provides to qualifying patients or designated caregivers" and limits the amount it can provide to other dispensaries. This provision is similar to the Colorado legislation (House Bill 1284) passed in May 2010 which was intended to bring greater oversight to an inadequate cultivation environment that was not sufficiently addressed in the original Colorado legislation. In contrast, the Arizona Act already provides for strict oversight and control of all cultivation facilities in the state such that any limit on cultivation and sales to other dispensaries is unnecessary. As it exists today, this provision is unreasonable, over-burdensome, against public policy, and may lead to adverse unintended consequences.

Many medical professionals and other highly-qualified dispensary applicants may be dissuaded from operating a dispensary if it requires the technical knowledge, experience, and prohibitive costs of owning and operating a cultivation facility. We agree that the Act should allow a dispensary the right to operate its own cultivation facility, however, the Act does not prohibit a dispensary from obtaining medical marijuana from the cultivation facilities of other dispensaries. To impose a 70% requirement is over-burdensome on dispensary owners. It may also lead to unintended consequences such as waste, under-qualified cultivation operators, and the possible creation of a secondary, illegal market of oversupply product.

There are a number of benefits in allowing greater product exchange among dispensaries and cultivation facilities. Unit costs will decrease if there is more commerce among the registered dispensaries and cultivation facilities. Decreased unit costs are essential for qualified patients who are already struggling to afford the otherwise prohibitive cost of medication. Lower unit costs also ensure greater regulation by discouraging the purchase of cheaper, inferior-quality marijuana that may be obtained illegally.

The inter-commerce among dispensaries and cultivation facilities will lead to more responsible, qualified and superior facilities as purchasing dispensaries will support only the best quality suppliers. Fewer, larger and more efficient cultivation facilities decrease the potential for public nuisance and oversaturation, reduce regulatory costs and oversight, and are less burdensome on the state. Ultimately, an unrestricted market among the registered dispensaries will result in a more responsible and superior cultivation facility with lower unit costs.

Medical Director

We are supportive of proposed rule R9-17-310(C) which requires a medical director to oversee the development and dissemination of education, systems, policies and procedures of dispensaries. However, we disagree with provision (D) which prohibits a physician-patient relationship with the medical director and which also restricts its ability to write medical marijuana recommendations for a qualifying patient.

The medical director requirement will likely absorb a large number of primary care physicians which regularly treat patients who already have an existing physician-patient relationship. In many cases, longstanding patients would need to find a new primary care physician to write medical marijuana recommendations for a qualifying patient. A more reasonable approach should allow a medical director to write a medical marijuana recommendation for a qualifying patient where there is an existing physician-patient relationship of at least 5 years. This approach would allow the continued physician-patient relationship and encourage credible physicians to apply as medical directors. It would also discourage less credible and under-qualified individuals from becoming dispensary medical directors.

Bonding

Proposed rule R9-17-302 sets forth the criteria for applying for a dispensary registration certificate, including (B)(15)(d) which asks the applicant to state, among other things, "whether the dispensary has a surety bond and, if so, how much." This provision is one of the criteria used in evaluating an application, however, it is unclear if this is a mandatory requirement.

In order to ensure that future dispensary owners are the most qualified, capable, and responsible, we propose a \$200,000 cash bond requirement to remain on deposit with the Department for the initial first year of operation of a qualified dispensary, as part of the dispensary registration application process. Such a provision would require an immediate investment that would effectively sift out unsuitable potential applicants. It

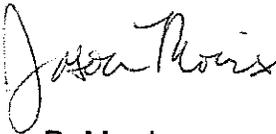
would also ensure that only the most responsible, capable, and committed applicants apply for a dispensary registration certificate. The cash bond would be refunded to the dispensary after the first annual renewal. The bond may be forfeited if a state-approved dispensary does not open for business within 12 months of state-approval (subject to force majeure), or makes a fraudulent statement in the dispensary registration certificate application.

Conclusion

We commend the Department and recognize their exhaustive efforts in drafting rules implementing the Act. While we are grateful for the opportunity to comment, we will continue to analyze the proposed rules in greater detail, and reserve the right to make further comments about the initial rules as necessary.

Thank you for the opportunity to comment on the proposed text amendment, and we look forward to working with you on this matter. If you have any questions, please feel free to contact me at jason@witheymorris.com or 602-230-0600.

Sincerely yours,
WITHEY MORRIS, P.L.C.

By 
Jason B. Morris