No. 03-1454

In the Supreme Court of the United States

JOHN D. ASHCROFT, ET AL.,
PETITIONERS,

v.

ANGEL MCCLARY RAICH, ET AL.,
RESPONDENTS.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF *AMICI CURIAE* FOR THE CALIFORNIA NURSES ASSOCIATION AND THE DKT LIBERTY PROJECT IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

The California Nurses Association (CNA) is a professional nursing association of more than 50,000 professional nurses practicing in the State of California. The CNA's primary goals are to promote patient advocacy that protects patients and ensures a single standard of quality healthcare for all. The CNA also seeks to develop the professional and educational advancement of professional nurses, and to foster high standards of nursing practice.

The DKT Liberty Project is a non-profit organization founded to protect the liberties fundamental to a free society. It advocates vigilance over regulation of all kinds, especially restrictions of civil and economic liberties that threaten the reservation of power to the citizenry that underlies our constitutional system.

CNA participated as *amicus curiae* in this case at the Court of Appeals, based on its firm conviction that the District Court's failure to grant a preliminary injunction to protect seriously ill patients whose doctors have recommended cannabis as a last-resort medical treatment seriously infringed upon the constitutional rights of the patients whose well-being both *amici* are committed to preserve. The federal government's actions in this case threatens these (and other) patients' constitutional rights to make autonomous decisions regarding their own bodies, and to seek medical treatment for alleviation of pain and suffering and preservation of life. Likewise, the federal government's actions here attempt to constrain and regulate the purely intrastate practice of medicine, an area historically within the sovereign power of the States. Accordingly, CNA

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[1] This brief is filed with the written consent of both parties, as indicated by letters filed with the Court. No party authored this brief in whole or in part and no one, other than the *amici curiae* or its counsel, monetarily contributed to the preparation or submission of this brief.

and the DKT Liberty Project strongly urge this Court to uphold the Court of Appeals' decision that respects the authority of individual States to exercise their sovereign authority with regard to what medications patients in their states may legally possess and use.

SUMMARY OF ARGUMENT

The history of federal legislation about drugs that Congress believed to be harmful and about pharmaceuticals in interstate commerce demonstrates clearly that the 1970 Controlled Substances Act plowed thoroughly new ground. In attempting to ban the wholly intrastate, non-economic possession and use of cannabis for medical purposes, on the advice and recommendation of a licensed medical practitioner, when the state has authorized such possession and use, Congress has exceeded its enumerated and delegated commerce power.

ARGUMENT

THE FEDERAL POWER TO REGULATE NATIONAL COMMERCE DOES NOT ALLOW CONGRESS TO BAN THE LOCAL, WHOLLY INTRASTATE, NON-ECONOMIC POSSESSION OF CANNABIS FOR MEDICAL PURPOSES SPECIFICALLY ALLOWED BY LOCAL STATE LAW.

While the history of Congress' constitutional authority to "regulate Commerce . . . among the several States," has been largely one of expansion, this Court has recently reiterated one core principle of federalism that limits that authority: "The Constitution requires a distinction between what is truly national and what is truly local." *United States v. Morrison*,

529 U.S. 598, 617-18 (2000); *see also United States v. Lopez,* 514 U.S. 549, 567-68 (1995).

One factor in determining whether a particular activity is local is whether it falls within an area of regulation in which the states are traditionally sovereign. Indeed, in *Lopez*, this Court invalidated a gun-possession statute whose connection to interstate commerce—guns near school threaten education which leads to less productive citizens—would also justify federal statutes "in areas such as criminal law enforcement or education where States historically have been sovereign." *Lopez,* 514 U.S. at 564. Similarly, noting that "we can think of no better example of the police power, which the Founders denied the National Government and reposed in the States, than the suppression of violent crime and vindication of its victims," this Court held that Congress lacked commerce clause authority to prohibit violent crimes based on gender, even when Congress found that such crimes affected interstate commerce. *Morrison,* 529 U.S. at 618.

Here, the Government argues that "neither the purported medical use of marijuana nor the role of a physician in approving it provides the slightest basis for excluding it from the comprehensive coverage of the CSA." Gov't Brief at 41. But, as *Lopez* and *Morrison* teach, the medical context of this case *is critical*, because the activity—intrastate, noncommercial possession of cannabis for medical purposes at a doctor's recommendation—is squarely within the local context of states' reserved powers in the area of public health and welfare. This is so despite the fact that cannabis could be a product in interstate commerce, just as in *Lopez,* a gun could be a product in interstate commerce. A patient's decision, based on her and her doctor's best judgment, to pursue particular medical treatment options to alleviate pain and suffering and to preserve her life, is the opposite of a truly national, and the paradigm of a truly local, indeed, a

private matter. This local medical context, in an area of historical state sovereignty, marks the limits of Congress' interstate commerce authority.[2]

Congress' blanket ban on *any* use, in the face of a state law specifically allowing the medical use at issue here, does in fact obliterate the distinction between what is local and what is truly national. Although Congress has a significant role to play in ensuring that the interstate market for pharmaceuticals insures safe products that are efficacious for their claimed purpose, and that interstate commerce channels are not misused to promote the abuse of dangerous products, Congress cannot appropriate to itself the historical state police power to ban the private, intrastate, non-economic activity of possessing medicine that Congress believes may be harmful but that the State believes to be helpful.

A. Although Congress Has Long Protected Consumers from Adulterated Or Misbranded Drugs In Interstate Commerce, It Has Not Historically Attempted To Prohibit Patients From Possessing Medicine Their Doctors Recommend Or Prescribe.

The history of how Congress has approached the social issue of narcotic and other drug abuse is instructive.[3]

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[2] Of course, a state's power to legislate in the area of public health and welfare is not unlimited by any means. It is bounded by constitutional requirements that legislation be, for example, rationally related to *public* health, not discriminatory, and not invasive of its citizens' privacy. *Amici* strongly believe that patients have a fundamental right to make autonomous decisions regarding their own bodies, and to seek medical treatment for alleviating pain and suffering, and to preserve their own lives. Thus, either a state or federal ban on the private, intrastate, non-economic possession of medical cannabis would still be subject to constitutional challenge.

Indeed, some *amici curiae* suggest that this history demonstrates that Congress has been exercising the powers at issue here for nearly a century. Brief of *Amici Curiae* Robert L. DuPont, M.D., *et al.* at 15 ("DuPont *Amici* Brief"). But those *amici* ignore the critical issue of what constitutional powers Congress used and how it used them.

1. Congress Has Long Used Its Interstate Commerce Authority To Protect Consumers Against Unscrupulous Manufacturers.

In 1906, in response to concern about the growing use of "patent" medicines that, unknown to consumers, contained significant quantities of opium, cocaine, and alcohol, Congress enacted the first Pure Food & Drug Act, which required drug manufacturers whose products were in interstate commerce to label those products accurately with the ingredients of the drug. The Act applied, on its face, only to products "introduce[d] into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia." Pure Food Act, Pub. L. No. 59-384, § 2, 34 Stat. 768 (1906).

Consumer protection from manufacturers trying to cut costs was again Congress' goal in the 1938 Food, Drug & Cosmetic Act. That statute was enacted after a manufacturer distributed a new "elixir sulfanilamide" they had tested for flavor and fragrance, but not for safety. More than 75 people died. James T. O'Reilly, *Food and Drug Administration*

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[3] As one historian of pharmacy has noted, "[T]here is no better illustration of the encroachment of the power of the federal government into activities that were previously entirely within the province of the states, than what goes on daily behind the prescription counter." David L. Cowan, The Development of State Pharmaceutical Law, 37 Pharmacy in History 49, 56 (1995).

§ 3.04, at 3-13 (2d ed. 1993 & 2004 Supp.) That Act, like the 1906 Act, was enacted under Congress' Commerce Clause authority, and it applied, on its face, only to items in interstate commerce. 21 U.S.C. §§ 321(b), 331(a)-(d) (prohibiting adulteration of drugs while "in interstate commerce," introducing adulterated or misbranded drug "in interstate commerce," and receipt of adulterated or misbranded drugs "in interstate commerce").[4]

Until 1970, Congress continued to tie its regulations related to drugs and medicines to interstate commerce. And even when it stretched in 1965 to suggest it could use its interstate commerce power to reach *intrastate* commerce in some drugs, Congress excepted personal or household use from that law (since personal possession was not "commerce"), and it specifically noted that it was trying to reach the sale of those drugs "when not under the supervision of a licensed practitioner." Drug Control Abuse Amendments of 1965, Pub. L. No. 89-74, § 2, 79 Stat. 226 (1965).

2. But Congress' Efforts To Prohibit Or Suppress Substances On Public Health Grounds Were Sustained Only Under Congress' Taxing Power.

From the formation of the union, states—and states alone—were responsible for laws directly regulating the

[4] Nor was this a *pro forma* requirement. In 1946, the FDA seized cartons of spaghetti and macaroni on grounds of adulteration as they sat in a warehouse. But the federal seizure was invalidated because the statute required that the product be adulterated when introduced into, or while in, interstate commerce. *United States v. Phelps Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946). Where the FDA could only show that the food was adulterated after sitting for two years in a warehouse after traveling in interstate commerce, the case was outside the FDA's jurisdiction. *Id.*

public health and welfare.[5] In the earliest opinion addressing the divergence of federal and state authority, Chief Justice Marshall defined state power as including "that immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government; all of which can be most advantageously exercised by the States themselves. Inspection laws, quarantine laws, health laws of every description . . . are components of this mass." *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824). To the extent public health might justify banning or controlling any substance because of its harmful effects on public health, such a ban would have been clearly within the inherent authority of the states, and outside the limits of federal authority.

Indeed, when Congress first became concerned with the social and public health effects of narcotic drugs at the turn of the 19th century, it acted quite consciously within those widely accepted limits on its delegated power. Rather than assert any authority under the Commerce Clause, Congress enacted the first federal narcotics statute solely under its *taxing* authority. The Harrison Act, enacted in 1914, required registration and payment of an occupational tax of $1.00 per year by all persons who imported, produced, dealt in, sold, or gave away opium, cocaine, or their derivatives. *United States v. Jin Fuey Moy*, 241 U.S. 394, 399-400 (1916). Further, the Act made it unlawful for any unregistered person (except patients with a prescription) who had not paid the tax to possess such products. *Id*.

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[5] The early colonists were vigilant. When one Nicholas Knopp sold a "worthless concoction" as a scurvy remedy, the Massachusetts Bay Colony fined him five pounds, and threatened a whipping if the payment were delayed. Wallace F. Janssen, America's First Food and Drug Laws, 30 Food Drug Cosm. L. J. 665, 669 (1975).

When the Act was challenged, as it immediately was, the government tried to argue that "Congress gave [the Act] the appearance of a taxing measure in order to give it a coating of constitutionality, but that it really was a police measure that strained all powers of the legislature, and that [section] 8 means all that it says, taking its words in their plain, literal sense." 241 U.S. at 401. Not surprisingly, the Court rejected that argument and upheld the statute *only* insofar as it was a revenue statute.[6] Although Congress might have a moral end in mind when enacting a revenue statute, the Court held it could accomplish its ends only insofar as they were "within the limits of a revenue measure." *Id.* at 402. Accordingly, the Court held the ban on possession in the tax revenue statute could not apply to a patient, who, not being a seller or a dealer, was not required to register and pay the tax.

In later challenges, the Court continued to uphold the Harrison Act *only* as a revenue-raising measure within Congress' taxing authority:

> In interpreting the [Harrison] Act, we must assume that it is a taxing measure, for otherwise it would be no law at all. If it is a mere act for the purpose of regulating and restraining the purchase of the opiate and other drugs, it is beyond the power of Congress and must be regarded as invalid.

Nigro v. United States, 276 U.S. 332, 341 (1928); *see also United States v. Doremus*, 249 U.S. 86, 93 (1919) ("[o]f course Congress may not in the exercise of federal power exert authority wholly reserved to the states").

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[6] The Court noted that if opium were produced in any state (as opposed being imported through foreign commerce) "obviously the gravest question of power would be raised by an attempt of Congress to make possession of such opium a crime." *Id.* at 401.

And when the government attempted to use the Harrison Act to prosecute doctors for prescribing opiates to particular patients in ways the government disagreed with, the Court strongly rejected that effort. Thus, in *Linder v. United States*, 268 U.S. 5 (1925), the Bureau of Narcotic Affairs—the office at Treasury responsible for enforcing this revenue law—prosecuted a duly registered and tax-paying physician who had given four tablets of morphine and cocaine to a patient who was a known addict, without filing the IRS form. The statute exempted a physician from the form requirement if he distributed the substances directly to the patient "in the course of his professional practice." 268 U.S. at 17. In response to the government's argument that distributing the opiates to an addict was not within the course of the professional practice of medicine, the Court stated unequivocally:

> Obviously, direct control of medical practice in the states is beyond the power of the federal government. Incidental regulation of such practice by Congress through a taxing act cannot extend to matters plainly inappropriate and unnecessary to reasonable enforcement of a revenue measure.

Id. at 18.[7] The Court continued, "Federal power is delegated, and its prescribed limits must not be transcended even though

[7] The Court clarified two earlier cases, *United States v. Doremus*, 249 U.S. 86 (1919) and *Webb v. United States*, 249 U.S. 96 (1919), on which the government relied to argue that doctors could not provide opiates to addicted patients. Noting that in those earlier cases, the facts involved distribution of large amounts of opiates that could be diverted, thus frustrating the revenue purposes of the Act, the Court concluded:

the end seems desirable. . . . [W]e cannot say that by so dispensing [the drugs here] the doctor necessarily transcended the limits of that professional conduct with which Congress never intended to interfere." 268 U.S. at 22-23.

Following its success with the Harrison Act, and alarmed by lurid newspaper accounts of marijuana brought into the country by Mexican laborers, Congress sought to deter non-medical marijuana use by enacting the 1937 Marihuana Tax Act. It did so despite the fact that in the five years preceding that Act, every state had enacted some legislation relating to controlling marijuana, and thirty-five states had enacted some form of the Uniform Narcotic Drug Act, which included an optional provision that would include cannabis in the list of covered narcotics. *See* Richard J. Bonnie & Charles H. Whitebread, II, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry Into the Legal History of American Marijuana Prohibition*, 56 Va. Law. Rev. 971, 1034 (1970).

Like the Harrison Act, the Marijuana Tax Act did *not* prohibit the possession or purchase of cannabis. Rather, as a revenue measure, it required persons importing, producing, selling, or otherwise dealing with cannabis to register with

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> The opinion[s] cannot be accepted as authority for holding that a physician, who acts bona fide and according to fair medical standards, may never give an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction. Enforcement of the tax demands no such drastic rule, *and if the act had such scope it would certainly encounter grave constitutional difficulties*.

Lindner, 268 U.S. at 22 (emphasis added).

the IRS and pay an occupational tax. It also taxed the transfer of cannabis by requiring all transferees of cannabis to file a written order form and to pay a transfer tax of $1.00 per ounce if registered, and $100 per ounce if not registered. *Id.* at 1062-63. Thus, Congress simply taxed cannabis under its taxing authority, making it more expensive in order to deter its use and creating a record for state prosecution uses. And, like the Harrison Act, the Supreme Court upheld this exercise of the federal taxing authority. *United States v. Sanchez,* 340 U.S. 42, 44 (1950) ("Nor does a tax statute necessarily fall because it touches on activities which Congress might not otherwise regulate.").

These narcotics tax laws, enacted and sustained *only* under Congress' taxing power, stand in sharp contrast to the laws Congress enacted during the same period relating to pharmaceuticals in interstate commerce.

3. Under Neither The Taxing Laws Nor The Consumer Protection Laws Did Congress Attempt To Control What Medications Doctors Could Prescribe.

In none of the Acts discussed above did Congress ever attempt to regulate what substances doctors could prescribe for specific patients or conditions. In the tax acts, medical uses were exempted from coverage. And the drug purity laws were to protect consumers in the interstate market so that manufacturers could not market unsafe medicines, or medicines that were useless for the purposes the manufacturers claimed. Those laws were not a list of medicines doctors could or could not use.

Indeed, even under its commerce powers, Congress historically had *never* tried to legislate how individual doctors can medically use the substances available in interstate commerce. Historically and today, physicians can, and frequently do, prescribe and use pharmaceuticals for

"off-label" uses. Although controlled clinical trials have contributed greatly to scientific knowledge, they are not the only means of obtaining useful information about a potential treatment modality. Anecdotal cases, particularly if they are meaningful in number, may offer critically important guidance to physicians and patients. Consequently, it is well-accepted that patients may take, on prescription, an approved medication for an unapproved medical use, i.e. "off-label" prescriptions. The American Medical Association takes the position that "a physician may lawfully use an FDA approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion." Policy 120.988, AMA Policy Compendium 1996.[8] The AMA Council on Scientific Affairs has reviewed the issue of off-label prescription use and concluded that the prevalence and clinical importance of unapproved indications are substantial, especially in the areas of oncology, rare diseases, and pediatrics. Report of the Council on Scientific Affairs 3-A-97, *Unlabeled Indications of Food and Drug Administration-Approved Drugs*. Similarly, the California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops. Cal. Atty. Gen. 192 (1978).

And just as federal law does not prohibit doctors from trying off-label uses, it does not prohibit persons (other than

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[8] This is also true of medical devices. In fact, the FDA Modernization Act (FDAMA) explicitly prohibits FDA intrusion into medical practice with regard to the off-label use of devices: "Nothing in this [Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396.

manufacturers) from spreading the word about off-label uses, so long as they derive no direct commercial interest from the sale or distribution of the product. Likewise, federal law does not prohibit a physician from prescribing or dispensing an unapproved drug outside the bounds of an approved investigational drug study. And federal law *explicitly* preserves the longstanding ability of both doctors and pharmacists to compound—mix up on their own—a drug product for an identified patient, without obtaining the approval the FDCA would otherwise require for a "new drug." 21 U.S.C. § 353a. All of these examples demonstrate that federal law has consistently left to doctors, and to the states that regulate them, the decisions as to which medicines should be used for particular patients.

Finally, despite the government's insistence that the law relating to medicines must be uniform to control potential problems, federal law is *not* the exclusive source of regulation of pharmaceuticals and medicines. States like California have enacted their own food and drug acts, and manufacturers may (and sometimes must) go through the California process to sell and distribute a drug in California. *See Cal. Health & Safety Code* 109875 *et seq.* (West Supp. 2004). Similarly, most states have their own laws relating to controlled substances, and many of the states classify substances differently than the federal government does. For example, Minnesota includes cannabis on Schedule II when it is used in conjunction with a doctor's research program. And although Georgia classifies cannabis as a Schedule I drug, it provides immunity from state prosecution for patients participating in Georgia's therapeutic research program. Ga. Code Ann. § 43-34-126 (2004).[9] Thus, both federal and state

[9] Indeed, 30 states currently have either classified cannabis to recognize its therapeutic potential, or they have immunized patients from prosecution if they are participating in a statutorily-authorized therapeutic research program, although a few of those programs must be approved by

law have long recognized that the issue of what medications are appropriate for particular patients is an issue for doctors and patients, within the broad outlines of state regulation of the practice of medicine.

B. The Controlled Substances Act Plowed New Ground By Making Noncommercial Intrastate Possession Of Cannabis For Medical Use A Federal Crime, Regardless Of What States Decided About Its Medical Use.

In 1970, Congress abandoned its 194-year-old position that it lacked authority to ban the wholly intrastate non-economic possession of medical substances. For the first time ever, Congress claimed the power, based solely on its interstate commerce authority, to decide for every state what substances could be used by doctors to treat patients, and what could not. Indeed, this approach "'plow[ed] thoroughly new ground and represents a sharp break with the long-standing pattern of federal . . . legislation.'" *Lopez*, 514 U.S. at 563 (citation omitted). Repealing the revenue laws such as the Harrison Tax Act and the Marijuana Tax Act, as well as fifty other laws, Congress set up what it called a "closed system" in which all substances that posed any danger were classified into five categories, whether in interstate commerce (or intrastate commerce) or not.

Deciding that cannabis had "no currently accepted medical use" Congress banned it (among other substances) outright. 21 U.S.C. § 812. For other substances it decided had medical uses, Congress placed them under more severe or less severe restraints, depending on how likely they were to be illegally diverted and used for non-medical purposes.

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the federal government, which has not yet happened. *E.g.* Ala. Code 20-2-110 *et seq.* (2004) (therapeutic research program); 720 ILCS 550/11, 550/15 (West 2004) (same); Mass. Gen. Laws ch. 94D § 1 *et seq*. (2004) (same).

When Congress enacted the CSA, most states agreed with Congress; their own state statutes reflected their own assumptions that cannabis, for example, lacked medical usefulness. Thus, for some time, Congress's encroachment into state authority caused no friction since many, if not all, state laws paralleled the federal law. However, in the 1980's, medical research began to resurface, suggesting that in fact, cannabis did have some specific therapeutic usefulness, and that for some patients, it gave relief when other medications did not. *See* 1999 Institute of Medicine Report*, Marijuana and Medicine, Assessing the Science Base* (summarizing research from 1980's and 1990's) (available at http://books.nap.edu/books/0309071550/html). In response to this emerging research, states began to reconsider their conclusions about the medical uses for cannabis, and between 1978 and 1983, thirty-five states passed some form of medical research or medical use legislation. More recently, nine states—Alaska, California, Hawaii, Maine, Nevada, Oregon, Vermont, and Washington—have established laws specifically allowing the use of medical cannabis when in consultation with a doctor.[10] Thus, based on *medical research*, many doctors have developed the view that medical cannabis appears to work better for some patients than other medicines, and, under their traditional public health authority, several states have responded to allow doctors and patients to seek the best treatment options for those patients. These states and their citizens have exercised their authority, within our federalist system, to "serve as a laboratory; and try novel social and economic

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[10] *See* Alaska Stat. §§ 11.71.090, 17.37.010 *et seq*. (Michie 2003); Cal. Health & Safety Code § 11362.5 (West Supp. 2004); Colo. Const. art. 18, § 4; Haw. Rev. Stat. Ann. § 329-121 *et seq*. (Michie Supp. 2003); Me. Rev. Stat. Ann. tit. 22, § 2383-B (West 2004); Nev. Rev. Stat. Ann. § 453A.200 (Michie Supp. 2003); Or. Rev. Stat. §§ 475.300-.346 (2003); Vt. Stat. Ann. tit. 18 § 4472 *et seq*. (2004); Wash. Rev. Code Ann. §§ 69.51.010-.080 (West 2004).

experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). And it is not just a few states who understand this principle. In response to questions about his position on states allowing the use of medical cannabis, President Bush has declared, "I believe each state can choose that decision as they so choose." *Justices Rule Against Medical Use of Marijuana*, Pittsburgh Post-Gazette, May 15, 2001, at A1.

The government and its *amici* argue at length that the entire CSA will collapse if Congress does not have the commerce power to ban instrastate possession of medical cannabis that has never been, and is not intended to be, in commerce. But this argument proves far too much. First, this decision will not lead, as *amici* claim, to some vague "underground 'medical' system." DuPont *Amici* Brief at 22. In fact, confirming that Congress lacks commerce clause power over intrastate medical, non-commercial possession and use of cannabis will allow exactly the same system of federal regulation of all medications *in interstate commerce* to continue. And for those therapeutic substances that Congress has prohibited in interstate commerce—such as medical cannabis—limiting Congress' reach to *commerce* simply ensure that *states* regulate whether those medical substances may be possessed or used outside the context of commerce.

The DuPont *Amici's* contention that the Court of Appeals' holding would allow anyone to cultivate any narcotic locally is also misplaced. Unlike Congress, states have the inherent authority (within constitutional limits) to make rational laws relating to public health, including the authority to reasonably and rationally ban or regulate dangerous products, whether in commerce or not. And the states have exercised that authority as their legislatures,

executives, and citizens see fit. Neither this Court nor the Congress can presume that states will exercise that authority badly, or not at all, as a premise for expanding Congress' delegated power. California, as well as eight other states, specifically allows the possession and use of cannabis *as medicine*, in consultation with a doctor. There is no reason to believe that these (or any other) states will suddenly decide that other dangerous substances can be homegrown in any circumstances.

C. To The Extent The CSA Regulates The Intrastate, Noncommercial Cultivation And Possession Of Cannabis For Personal Medical Purposes As Recommended By A Physician Under Valid State Law, It Is Beyond Congress' Interstate Commerce Power.

Congress' attempt to extend its reach beyond the commerce inherent in buying, selling, and manufacturing to the simple non-economic cultivation and possession, for medical purposes, of a substance that has demonstrably never been part of any commercial exchange exceeds its constitutional authority. *Amici* do not contend that Congress may not regulate medical drugs, like other products, in interstate commerce, subject to other constitutional limitations. But "the State has the sovereign right . . . to protect the . . . general welfare of the people . . . . Once we are in the domain of the reserve power of a State we must respect the wide discretion on the part of the [state] legislature in determining what is and what is not necessary." *City of El Paso v. Simmons*, 379 U.S. 497, 508-09 (1965) (quoting *East New York Savings Bank v. Hahn*, 326 U.S. 230, 232-23 (1945)) (alteration in original). Here, recognizing that intrastate cultivation, possession, and use of medical cannabis on a physician's advice under valid state law is an

activity quite distinct from the recreational use creating the interstate market about which Congress was concerned is one way to respect that state discretion, without imperiling the rest of the Controlled Substances Act. And Congress cannot bootstrap a general police power into its delegated authority simply by asserting that all instances of possession necessarily substantially impact interstate commerce.

Nor can Congress derive an undelegated power from its dissatisfaction with the way a state has exercised its reserved power. The DuPont *Amici* Brief argues that California's medical cannabis system creates "chaos" and so must be reigned in by Congress whereas another system that did not create "chaos" would presumably be allowed. DuPont *Amici* Brief at 19. But even if this assertion were true—and it is not—there is no "rescue" clause in the Constitution authorizing Congress to exceed its delegated powers when the states make "mistakes." Indeed, the power to try novel social experiments must include the power to fail. Because this experiment is confined within a state, and because it does *not* involve transactions that are economic or commercial that could truly affect interstate commerce, it is not within Congress' power to regulate.

The DuPont *Amici* Brief also argues that allowing states to determine whether patients or caregivers may grow their own non-commercial cannabis for medical purposes would lead to "widespread use" across a state. DuPont *Amici* Brief at 25. But this argument does not follow: if state law authorizes sick patients to use it with their doctor's approval, the universe of potential users is already defined. That universe will not grow (or shrink) based on a decision by this Court. Nor could the non-commercial medical cannabis distribution system—wholly within the state—hypothesized by the DuPont *Amici* in any way "disrupt" a federal system

for all other medical products that are *in interstate commerce.* The two simply do not intersect.

Finally, even good policy reasons cannot create a power in Congress that was not delegated by the Constitution. And the ones suggested here would be insufficient, even if they could. First, if there is any disincentive to the commercial research and development of medical cannabis, it is not that some states allow patients to grow their own. DuPont *Amici* Brief at 25-26. Instead, that disincentive is created by the federal ban on any use of (and much research about) cannabis. Were the federal government to lift the ban and allow medical uses, market mechanisms would certainly ensure that pharmaceutical companies would quickly solve whatever problems of purity and potency exist. And if doctors have the opportunity to prescribe a commercially available product with more predictable characteristics, it is unlikely they would prescribe home grown remedies. Second, health care professionals *have* been put in an untenable position, as the DuPont *Amici* argue, *id.* at 27, but not by the states who have enacted state laws protecting the right of patients to seek medical treatment that works for them. They have been put in that position by a Congress who concluded, for every patient in every state, that cannabis has no medical use, when many doctors and at least nine states believe otherwise Thus, as a result of federal law, doctors are forced to either withhold potentially life-saving, and certainly life-enhancing treatment, or to risk violating federal law. Limiting Congress' reach to interstate commerce, and not beyond, resolves that tension.

CONCLUSION

Because Congress' authority to regulate interstate commerce does not extend to banning intrastate, non-commercial possession of medical cannabis at a doctor's

recommendation under valid state law, this Court should conclude that the Controlled Substances Act does not preclude such possession, and should affirm the Court of Appeals' decision.

Respectfully submitted,

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