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# Legitimate Medicine in the Age of Consumerism

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*From the opioid epidemic and medical marijuana to abortion restrictions and physician-assisted suicide, disputes over the proper uses of medicine loom large in American life. Nowhere is this conflict more apparent than in federal drug control policy, which is premised on a clear distinction between legitimate “medical” uses and illicit “abuse.” Yet the Controlled Substances Act defines neither of these foundational concepts. While it is tempting to imagine medicine’s scope is limited to treating or preventing disease — rendering nontherapeutic drug use “abuse” — in fact medical practice has always included interventions that are not aimed at healing. This trend has only accelerated as medical practice has become increasingly consumer-oriented. From Adderall to Xanax, patients now routinely seek prescriptions not to treat diagnosable illnesses, but to relieve stress, improve productivity, and otherwise enhance quality of life.*

*As physicians increasingly prescribe psychoactive drugs to help healthy people obtain desirable mental states, distinguishing legitimate drug use from recreational abuse becomes ever more difficult. Having failed to acknowledge this challenge, the DEA, courts, and scholars have not offered a principled way to make this distinction, rendering drug control policy increasingly incoherent. As a result, doctors face criminal prosecution without clear standards governing prescribing, potentially valuable interventions are arbitrarily barred from the market, and millions seek the benefits of drugs without professional medical guidance to mitigate their risks.*

*Rather than being limited to therapeutic aims, medicine is better understood as the application of a loosely-defined set of knowledge and interventions that the law entrusts to specific professionals, with*

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accompanying duties to use these tools to benefit patients. Medical practice includes treating and preventing illnesses, but can also include enhancing social and cognitive functioning and promoting the well-being of people whose challenges do not rise to the level of disorders. Discarding a narrow conception of medicine does not require abandoning the enforcement of drug laws or the policing of doctors. But acknowledging the expansiveness of medicine's domain does argue for clarifying the scope of physicians' criminal liability and pursuing new strategies for harnessing drugs' benefits while mitigating their risks.

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## INTRODUCTION

The world's most voracious consumer of drugs is awash in controversies over their legitimate uses.<sup>1</sup> Amid a devastating opioid epidemic, physicians are targeted for excessively prescribing painkillers even as patient advocates insist that pain is under-treated.<sup>2</sup> Dozens of states are in open rebellion against the federal government's insistence that cannabis has no medical value.<sup>3</sup> Even as skyrocketing prescriptions to treat Attention-Deficit/Hyperactivity Disorder ("ADHD") fuel concerns about the "medicalization" of a normal childhood, people from all walks of life seek out these same drugs to increase energy, lose weight, and enhance their competitiveness in school and the workplace.<sup>4</sup>

Common to all of these controversies is confusion regarding the scope of legitimate medicine and the nature of drug abuse. Federal drug control policies are premised on a sharp divide between these two

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<sup>1</sup> See UNITED NATIONS OFFICE ON DRUGS & CRIME, WORLD DRUG REPORT 2017, EXECUTIVE SUMMARY 10 (Joseph Boyle & Jonathan Gibbons eds., 2017), [https://www.unodc.org/wdr2017/field/Booklet\\_1\\_EXSUM.pdf](https://www.unodc.org/wdr2017/field/Booklet_1_EXSUM.pdf) ("The United States accounts for approximately one quarter of the estimated number of drug-related deaths worldwide."); WORLD HEALTH ORGANIZATION, THE WORLD MEDICINES SITUATION 31 (Sheila Davey ed., 2004) ("The [pharmaceutical] market share of the USA alone rose from 18.4% of the world total in 1976 to over 52% in 2000."); U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, HEALTH, UNITED STATES, 2016 WITH CHARTBOOK ON LONG-TERM TRENDS IN HEALTH 293, tbl.79 (2016), <https://www.cdc.gov/nchs/data/abus/abus16.pdf#079> (observing that 48.9% of Americans reported consuming at least one prescription drug within the past thirty days); Louisa Degenhardt et al., *Toward a Global View of Alcohol, Tobacco, Cannabis, and Cocaine Use: Findings from the WHO World Mental Health Surveys*, 5 PLOS MED. 1053, 1056 (2008) ("Lifetime tobacco use was most common in the [United States] (74%) . . . . The proportions of respondents who ever used cannabis were highest in the [United States] (42%) . . . . The [United States] was an outlier in lifetime cocaine use, with 16% of respondents reporting that they had tried cocaine at least once compared to 4.0%–4.3% in Colombia, Mexico, Spain, and New Zealand, and extremely low proportions in countries in the Middle East, Africa, and Asia."); Keith Humphreys, *Americans Use Far More Opioids Than Anyone Else in the World*, WASH. POST (Mar. 15, 2017), <https://www.washingtonpost.com/news/wonk/wp/2017/03/15/americans-use-far-more-opioids-than-anyone-else-in-the-world/>.

<sup>2</sup> See Christopher Zara, *Chronic Pain Patients Say the Crackdown on Opioids Means They're Now Treated Like Addicts*, VICE NEWS (Oct. 24, 2016, 1:31 AM), [https://news.vice.com/en\\_us/article/yw5zjj/opioids-chronic-pain](https://news.vice.com/en_us/article/yw5zjj/opioids-chronic-pain).

<sup>3</sup> See *State Medical Marijuana Laws*, NAT'L CONF. OF STATE LEGISLATURES (Oct. 16, 2019), <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>.

<sup>4</sup> See Matt Lamkin, *Regulating Identity: Medical Regulation as Social Control*, 2016 BYU L. REV. 501, 512 n.41 (2016). See generally Peter Conrad & Meredith R. Bergey, *The Impending Globalization of ADHD: Notes on the Expansion and Growth of a Medicalized Disorder*, 122 SOC. SCI. & MED. 31 (2014).

concepts. Under the Controlled Substances Act (“CSA” or the “Act”) drugs are banned entirely if they lack a “currently accepted medical use” and have a “high potential for abuse.”<sup>5</sup> Other lawfully available drugs can only be prescribed for a “legitimate medical purpose.”<sup>6</sup> Yet neither Congress, nor courts, nor scholars have adequately explained which purposes qualify as “medical,” and therefore are legitimate, and which uses fall outside that scope, and thus constitute “abuse.”

At first blush, the most tempting answer — the one often advanced by defenders of the drug enforcement regime — is that medicine encompasses the use of drugs for treating and preventing illnesses, while uses that lack a therapeutic purpose constitute abuse. But a moment’s reflection reveals the line cannot be drawn in this way — at least not without radically redefining the scope of medicine as it has existed since the dawn of the Western tradition.

Medicine has always included practices that are not aimed at healing, and these nontherapeutic practices have only proliferated as medicine has increasingly become a consumer product. The people formerly known as “doctors” and “patients” have been rebranded as health care “providers” and “consumers.”<sup>7</sup> Pharmaceutical companies advertise their wares directly to potential customers, alongside ads for air-freshening sprays and robotic vacuum cleaners, as though drugs were just another product that can make life easier and more enjoyable.<sup>8</sup> For their part, consumers have shown a seemingly insatiable demand for biomedical interventions aimed not at addressing serious illnesses, but simply enhancing quality of life — by relieving stress, boosting work performance, improving appearance, and otherwise enhancing social functioning.<sup>9</sup>

The medical industry has adapted to accommodate — and profit from — this growing medical consumerism. Medical experts have endorsed

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<sup>5</sup> 21 U.S.C. § 812(b)(1) (2019).

<sup>6</sup> 21 C.F.R. § 1306.04(a) (2019).

<sup>7</sup> See Peter Conrad & Valerie Leiter, *Medicalization, Markets and Consumers*, 45 J. HEALTH & SOC. BEHAV. 158, 160 (2004).

<sup>8</sup> *Id.* (“The use of advertising, the development of specific medical markets, and the standardization of medical services into product lines have contributed to an increased commodification of medical goods and services.”); Laura Mamo & Jennifer R. Fishman, *Potency in All the Right Places: Viagra as a Technology of the Gendered Body*, 7 BODY & SOC’Y 13, 17 (2001) (“Drugs, therefore, are becoming much more akin to other consumer products for the body, like cosmetics or other over-the-counter health products that promise quick detectable results. Prescription drugs are fast becoming a capitalist fetish, where one is encouraged to think of such drugs as a means through which to improve one’s life, which can *always* be improved.”) (citation omitted).

<sup>9</sup> See Lamkin, *supra* note 4, at 506-19.

ever-broader definitions of illness that have transformed ordinary social challenges into legitimate targets for “treatment.”<sup>10</sup> As the medical profession has created new disorders and expanded diagnostic criteria for existing ailments, an increasing number of Americans find themselves with medical diagnoses — from “social anxiety disorder” to “idiopathic short stature” — that warrant drug therapy.<sup>11</sup> In other cases, the profession has simply expanded the scope of medical practice to encompass using biomedical interventions for patently nontherapeutic purposes, such as performing some 17 million cosmetic surgeries in 2016 alone.<sup>12</sup>

As doctors prescribe medications to help healthy people modify their moods and personalities in the ways they desire, it becomes increasingly difficult to distinguish these practices from drug uses that have long been considered forms of abuse.<sup>13</sup> At the same time, many drugs that have been dismissed as merely “recreational” are gaining legitimacy as treatments for serious health conditions. Thirty states and the District of Columbia have legalized the use of cannabis for medical purposes, even as proposals percolate in Congress to lift the federal ban on prescribing it.<sup>14</sup> The U.S. Food and Drug Administration (“FDA”) recently approved its first psychedelic compound, esketamine,<sup>15</sup> and has granted “breakthrough therapy” status to two banned psychedelic

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<sup>10</sup> See Conrad & Leiter, *supra* note 7, at 158.

<sup>11</sup> *Id.* at 163-66.

<sup>12</sup> AM. SOC'Y OF PLASTIC SURGEONS, 2016 PLASTIC SURGERY STATISTICS REPORT 5 (2016).

<sup>13</sup> As the Director of the National Institute of Drug Abuse testified before Congress, “[t]he recent increase in the extent of prescription drug abuse in this country” can be attributed in part to “a greater social acceptability for medicating a growing number of conditions.” *Efforts of the National Institute on Drug Abuse to Prevent and Treat Prescription Drug Abuse: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Res. of the H. Comm. on Gov't Reform*, 109th Cong. (2006) (statement of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse), <https://archives.drugabuse.gov/testimonies/2006/efforts-national-institute-drug-abuse-to-prevent-treat-prescription-drug-abuse>.

<sup>14</sup> Christopher Ingraham, *The Senate Marijuana Reform Bill Would Bring Federal Policy in Line With Medical Research*, WASH. POST (Mar. 10, 2015, 8:42 AM), <https://www.washingtonpost.com/news/wonk/wp/2015/03/10/the-senate-marijuana-reform-bill-would-bring-federal-policy-in-line-with-medical-research/>; *State Medical Marijuana Laws*, *supra* note 3.

<sup>15</sup> Press Release, U.S. Food & Drug Admin., FDA Approves New Nasal Spray Medication for Treatment-Resistant Depression; Available Only at a Certified Doctor's Office or Clinic (Mar. 5, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>.

compounds — MDMA and psilocybin — as potential treatments for post-traumatic stress disorder (“PTSD”) and depression.<sup>16</sup>

These shifts have destabilized our understanding of the legitimate role of medicine. If, for example, these ostensibly recreational drugs were approved as treatments for specific illnesses, doctors could legally prescribe them for other purposes as well — a common practice called “off-label” prescribing.<sup>17</sup> Yet these off-label uses would be subject to the CSA’s injunction that a prescription must be written for a “legitimate medical purpose.”<sup>18</sup> But it is entirely unclear which purposes would fall within that scope. For example, would it be legitimate to prescribe cannabis simply to help a stressed-out patient relax? If not, how can this be distinguished from the commonplace prescribing of drugs like Xanax to help healthy patients cope with sub-diagnostic levels of anxiety?<sup>19</sup> Would it be legitimate to prescribe cannabis to enhance a patient’s

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<sup>16</sup> Tom Jackman, *As Legal Marijuana Booms, Denver Votes on Decriminalizing Hallucinogenic Mushrooms*, WASH. POST (May 6, 2019, 3:00 AM), <https://www.washingtonpost.com/crime-law/2019/05/06/legal-marijuana-booms-denver-votes-decriminalizing-hallucinogenic-mushrooms/>; Press Release, Multidisciplinary Ass’n for Psychedelic Studies, *FDA Grants Breakthrough Therapy Designation for MDMA-Assisted Psychotherapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials* (Aug. 26, 2017) [hereinafter *FDA Grants Breakthrough Therapy Designation*] <http://www.maps.org/news/media/6786-press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials>. See generally *Breakthrough Therapy*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy> (last updated Jan. 4, 2018) (“Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).”).

<sup>17</sup> As Scott Gast notes, “[o]nce the FDA approves a drug or device for one particular use, however, a physician may legitimately prescribe it for uses other than those identified in the FDA approval — so-called ‘off-label’ uses — according to the physician’s professional judgment regarding the best course of treatment. Therefore, while FDA approval of the specific use of a drug may support a conclusion that such a use constitutes the legitimate practice of medicine, the lack of approval for a specific use does not necessarily mean that use falls outside the scope of legitimate medical practice.” Scott Gast, *Who Defines “Legitimate Medical Practice?” Lessons Learned From the Controlled Substances Act, Physician-Assisted Suicide, & Oregon v. Ashcroft*, 10 VA. J. SOC. POL’Y & L. 261, 268-69 (2002). As described *infra* Part IV.C, however, the FDA can place limits on off-label prescribing of drugs by requiring implementation of Risk Evaluation and Mitigation Strategies (“REMS”). See Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO ST. L.J. 1053, 1081-82 (2017).

<sup>18</sup> 21 C.F.R. § 1306.04(a) (2019).

<sup>19</sup> See *infra* notes 184–99.

sexual desire?<sup>20</sup> If not, how could this prohibition be reconciled with the FDA's recent approval of another drug for precisely this purpose?<sup>21</sup> If, on the other hand, prescriptions for these purposes are within the scope of legitimate medicine, it is not clear what is left of the concept of recreational drug use.

The reason it is so difficult to distinguish legitimate medical purposes from their illicit cousins is that medicine is not best defined by a narrow set of purposes. Whether an intervention qualifies as "medical" does not hinge primarily on the purpose for which it is prescribed, such as the treatment or prevention of a disease, but rather on the type of means being employed. Medicine is better understood as the application of certain kinds of interventions — especially technologies rooted in biology and biochemistry — to promote patients' well-being, broadly conceived.<sup>22</sup> Medical practice includes treating and preventing illnesses, but can also include enhancing social and cognitive functioning and improving the well-being of people whose challenges do not rise to the level of disorders.

Discarding a narrow conception of medicine does not require abandoning the enforcement of drug laws or policing of doctors. Even under a broad conception of medicine's scope, physicians retain legal and ethical obligations to meet professional standards of conduct and to use their prescribing powers to benefit patients. Biological interventions pose special risks to individuals and to public health, which the state has an interest in mitigating. Having deputized medical professionals to serve as gatekeepers for access to many interventions, it is important to ensure that doctors do not abuse this authority.

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<sup>20</sup> See Bob Green, David Kavanagh & Ross Young, *Being Stoned: A Review of Self-Reported Cannabis Effects*, 22 *DRUG & ALCOHOL REV.* 453, 456, tbl.2 (2003) (in meta-analysis of studies of cannabis users' self-reports regarding the drug's effects, more than half of users reported the drug caused increased sexual arousal); see also Christopher Ingraham, *Marijuana Users Have More Sex, Researchers Find*, *WASH. POST* (Oct. 27, 2017, 10:05 AM), <https://www.washingtonpost.com/news/wonk/wp/2017/10/27/marijuana-users-have-more-sex-researchers-find/> (reporting multiple studies suggesting cannabis use may boost libido).

<sup>21</sup> See, e.g., *Addyi (flibanserin) Information for Healthcare Professionals*, *SPROUT PHARM.*, <https://addyi.com/hcp> (last visited May 6, 2018) [<https://perma.cc/B7LM-3FE3>] [hereinafter *Addyi*] ("Addyi is the [first and] only FDA-approved . . . treatment for acquired, generalized Hypoactive Sexual Desire Disorder (HSDD) in premenopausal women. Symptoms of HSDD include chronically low sexual desire, which your patients may call low libido, and associated personal distress . . . . Addyi has been shown to increase sexual desire and satisfying sexual events . . . .").

<sup>22</sup> See Christopher Boorse, *Goals of Medicine*, in *NATURALISM IN THE PHILOSOPHY OF HEALTH* 145, 163 (Élodie Giroux ed., 2016).

Acknowledging that medicine's scope extends beyond treating illnesses requires adapting drug enforcement policy to the realities of today's medical marketplace. Rather than prosecuting doctors for prescribing drugs without a "legitimate medical purpose," physicians should face criminal liability under the CSA only when they have abandoned their role as physicians in favor of acting as traffickers — i.e., by using their prescribing power not to benefit patients, but for personal profit.<sup>23</sup> Drugs that have been banned for lacking an "accepted medical use" should be reevaluated under standards that construe medical benefits broadly and policymakers should deploy a more sophisticated set of strategies to ensure that drugs are used in ways that harness their benefits while minimizing risks.

### I. THE DRUG WAR'S DICHOTOMIES

The federal government polices the uses of drugs through the Controlled Substances Act,<sup>24</sup> a statute enacted "with the main objectives of combating drug abuse and controlling the legitimate and illegitimate [drug] traffic."<sup>25</sup> As described below, the Act restricts the availability of certain drugs — "controlled substances" — ostensibly on the basis of their therapeutic potential and their risk of abuse. In practice, however, the distinction between therapeutic and nontherapeutic uses has proved to be a poor foundation for defining medicine's legitimate scope. As a result, neither the CSA, drug enforcers, nor courts have demarcated legitimate drug uses from abuse in a principled way that withstands scrutiny.

#### A. Medical Use vs. Drug Abuse

Federal law bans certain drugs based on a conclusion that they have no "medical" use. Accordingly, any use of such a substance is deemed a form of "abuse" that confirms the dangerousness of the drug.

The CSA criminalizes the "manufacture, distribution, dispensing, and possession" of certain substances except as provided for in the Act.<sup>26</sup> Each substance controlled under the Act is assigned to one of five schedules, reflecting different levels of restrictions.<sup>27</sup> Schedule I is the

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<sup>23</sup> See Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U.J. HEALTH L. & POL'Y 231, 235 (2008).

<sup>24</sup> 21 U.S.C. § 801 (2019).

<sup>25</sup> *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006).

<sup>26</sup> *Id.*

<sup>27</sup> 21 U.S.C. § 812(a) (2019).



highest level of control. With very narrow exceptions, it is a crime to distribute or possess substances assigned to Schedule I.<sup>28</sup> Substances in Schedules II through V can be lawfully prescribed and possessed, subject to certain requirements.<sup>29</sup> Drugs in Schedule II can be lawfully dispensed and possessed only with a doctor's prescription, and those prescriptions are subject to tight controls, such as limitations on refills and the issuance of multiple prescriptions.<sup>30</sup> At the low end, Schedule V is comprised of drugs that are deemed to have low potential for abuse, but may contain limited quantities of narcotics or stimulants, including many "over-the-counter" (non-prescription) cough syrups.<sup>31</sup>

Through the CSA, Congress empowered the U.S. Attorney General to assign substances to schedules. The Attorney General has delegated this authority to the Drug Enforcement Administration ("DEA").<sup>32</sup> In order to place a drug in Schedule I, the DEA must issue findings that the drug has "no currently accepted medical use *in treatment*," has a "high potential for abuse," and cannot be used safely even under medical supervision.<sup>33</sup> According to the Act, all three of these criteria must be met in order for a drug to be banned.<sup>34</sup> In practice, however, the DEA

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<sup>28</sup> See *id.* at § 841(a).

<sup>29</sup> See 21 C.F.R. § 1306.07 (2019); Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 336 (2013); Hoffmann, *supra* note 23, at 309 n.259 ("For example, prescriptions may not be written for Schedule I substances. Prescribing regulations for the drugs in the other groups specify requirements for refilling prescriptions, oral prescriptions, partial filling of prescriptions, and labeling of substances prescribed.").

<sup>30</sup> 21 U.S.C. § 829(a); U.S. DEP'T OF JUSTICE, DRUG ENF'T ADMIN., PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 19-21 (2006), [https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf).

<sup>31</sup> *Drug Scheduling*, U.S. DEP'T OF JUSTICE, DRUG ENF'T ADMIN., <https://www.dea.gov/drug-scheduling> [<https://perma.cc/66ZS-L3GT>] (last visited Sept. 27, 2019).

<sup>32</sup> Kreit, *supra* note 29, at 336-37. However, the DEA cannot assign alcohol or tobacco to a schedule because Congress exempted these substances from the CSA. *Id.*

<sup>33</sup> 21 U.S.C. § 812(b)(1) (emphasis added).

<sup>34</sup> See *id.* Elsewhere, the CSA lists eight additional "[f]actors determinative of control or removal from schedules" which emphasize such considerations as the drug's "actual or relative potential for abuse" and "[i]ts history and current pattern of abuse." *Id.* at § 811(c). "The exact relationship between these eight 'factors' and the three 'findings required for each of the schedules' remains somewhat mysterious." Kreit, *supra* note 29, at 345. Kreit notes that the Department of Health, Education, and Welfare "observed that the 'eight factors . . . unfortunately are for the most part vague and redundant. The list exhibits circular reasoning and lack of parallelism, particularly when viewed together with the definitions of the schedules.'" *Id.* (quoting *United States v. Pastor*, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975)).

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has assigned drugs to Schedule I based solely on determinations that they have no currently accepted medical use.<sup>35</sup>

Since a drug must satisfy all three criteria to be assigned to Schedule I, drugs that have “a high potential for abuse,” such as opioids, are not banned because they have accepted medical uses. In theory, the same should be true of drugs that lack accepted medical uses, but do not pose serious safety risks to users; since such drugs do not meet all three criteria for Schedule I, they should not be banned under the Act. Curiously, however, the DEA has never encountered a substance that lacks an accepted medical use, but has a low potential for abuse.<sup>36</sup> Each time the DEA has concluded that a substance lacks an accepted medical use, the agency has also determined that the substance also has a high potential for abuse and poses serious risks to users.<sup>37</sup>

Accordingly, although scheduling decisions under the CSA ostensibly hinge on three criteria, in practice the decision to ban a drug currently rests entirely on whether it has an accepted medical use in treatment. However, neither the Act nor the DEA has adequately defined which uses qualify as “medical” or which aims count as “treatment.”<sup>38</sup> As discussed in Part III below, the intuitively appealing answers to these questions do not reflect the realities of medical practice.

#### B. *Legitimate Prescribing vs. Trafficking*

In addition to banning certain drugs altogether, the CSA restricts how legal substances may be prescribed. As with scheduling, the Act’s provisions regarding prescriptions center around a distinction between legitimate and illegitimate uses of drugs.<sup>39</sup>

The CSA seeks to combat “the diversion of drugs from legitimate to illicit channels” by controlling who may prescribe controlled substances and for which purposes.<sup>40</sup> The Act provides that drugs in Schedules II through IV can only be dispensed pursuant to a prescription issued by a “practitioner” — i.e., a doctor or other person who is legally permitted to dispense a controlled substance “in the course of professional

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<sup>35</sup> See Kreit, *supra* note 29 at 342-43.

<sup>36</sup> *Id.* at 343.

<sup>37</sup> *Id.*

<sup>38</sup> Neither the Controlled Substances Act nor DEA regulations define these terms. See 21 U.S.C. § 802; 21 C.F.R. § 1300.01 (2019).

<sup>39</sup> See *Gonzales v. Raich*, 545 U.S. 1, 12-13 (2005).

<sup>40</sup> *Id.*

practice or research.”<sup>41</sup> To be exempt from the law’s general prohibitions on dispensing controlled substances, physicians must register with the Attorney General.<sup>42</sup>

DEA regulations provide that in order to be “effective,” “[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”<sup>43</sup> Courts have interpreted the phrases “legitimate medical purpose” and “in the usual course of his professional practice” as redundant, finding no distinctions between the two.<sup>44</sup> A doctor who prescribes drugs without a legitimate medical purpose is deemed not to be acting as a “practitioner” under the Act, and therefore violates the CSA’s provisions barring the dispensing of controlled substances.<sup>45</sup>

In practice, however, it has proved difficult to define the scope of conduct that will support a criminal conviction for prescribing drugs without a legitimate medical purpose.<sup>46</sup> “Neither the CSA nor its implementing regulations define ‘legitimate medical purpose’; nor do they set standards as to what constitutes ‘the usual course of professional practice.’”<sup>47</sup> In construing this language, courts and the DEA have vacillated between asserting that the meaning of these phrases is so obvious that no elaboration is necessary and insisting that the terms are impossible to define with any particularity.

The DEA has taken both of these positions. In 2004, the agency issued a document answering frequently asked questions (“FAQ”) regarding how doctors could avoid violating the CSA while prescribing opioids

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<sup>41</sup> 21 U.S.C. § 802(21) (defining “practitioner”); *id.* § 829(a)-(b) (authorizing “practitioner[s]” to prescribe controlled substances); *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975). *See* 21 U.S.C. § 841(a)(1) (criminalizing distribution of controlled substances “[e]xcept as authorized by this subchapter”).

<sup>42</sup> “Because these substances are necessary for treatment of many patients, virtually all practicing physicians register with the DEA.” Hoffmann, *supra* note 23, at 265. *See* 21 U.S.C. § 823.

<sup>43</sup> 21 C.F.R. § 1306.04(a) (2019).

<sup>44</sup> *United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978); *United States v. Plesons*, 560 F.2d 890, 897 n.6 (8th Cir. 1977); *see also* *Dispensing of Controlled Substances to Assist Suicide*, 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001) (to be codified at 7 C.F.R. pt. 1306).

<sup>45</sup> *Rosenberg*, 515 F.2d at 193 (“[A] doctor who acts other than in the course of professional practice is not a practitioner under the Act and is therefore not authorized to prescribe controlled substances. Such a physician is therefore subject to the criminal provisions of the Act contained in section 841(a)(1).”).

<sup>46</sup> Hoffmann, *supra* note 23, at 265 (“Since the CSA was enacted, courts, in numerous cases, have struggled with applying this language.”).

<sup>47</sup> *Id.* at 274.

for treating pain.<sup>48</sup> The Agency declared that the FAQ “provides clear answers to common questions” about conforming opioid prescribing practices to the CSA’s requirements.<sup>49</sup> While the DEA referred to the FAQ as “a consensus document” designed to help doctors clearly understand which conduct is prohibited by the CSA,<sup>50</sup> just three months later the agency withdrew the document and disavowed its contents.<sup>51</sup> In 2006, the Agency released a new policy statement that reversed course entirely, insisting that it was not possible to provide definitive guidance on this subject. This time the Agency insisted that “it is not possible to expand on the phrase ‘legitimate medical purpose in the usual course of professional practice,’ in a way that will provide definitive guidelines that address all the varied situations physicians might encounter” and that “one cannot provide an exhaustive and foolproof list of ‘dos and don’ts’ when it comes to prescribing controlled substances for pain or any other medical purpose.”<sup>52</sup>

Doctors have understandably lamented this lack of “definitive guidelines” — particularly when they find themselves charged as drug traffickers.<sup>53</sup> Physician defendants have repeatedly argued that the phrases “legitimate medical purpose” and “usual course of professional practice” are unconstitutionally vague because they “do not warn the physician of what conduct is proscribed,” lack “objective standards,” and are “subject to diverse interpretation.”<sup>54</sup>

To date courts have uniformly rejected this argument — typically in cursory opinions that have themselves suffered from considerable vagueness. In an early case, the Ninth Circuit disposed of a defendant’s vagueness challenge by arguing that the phrase “in the course of

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<sup>48</sup> U.S. Dep’t of Justice, Drug Enft Admin., U.S. Dep’t of Justice Last Acts Partnership & Univ. Wis. Med. Sch. Pain & Policies Study Grp., *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel*, 19 J. Pain & Palliative Care Pharmacotherapy 71 (2005) [hereinafter DEA 2004 FAQ].

<sup>49</sup> *Id.* at 71.

<sup>50</sup> *Id.*

<sup>51</sup> Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170, 67,170 (Nov. 16, 2004).

<sup>52</sup> Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,717, 52,719 (Sept. 6, 2006).

<sup>53</sup> See, e.g., *No Safe Harbors for Doctors: Response to DEA Pamphlet on Prescription Pain Medications*, ASS’N OF AM. PHYSICIANS & SURGEONS (2004), <http://www.aapsonline.org/painman/paindocs2/nosafeharbors.pdf> (“There is no safe harbor for the treatment of chronic pain as long as doctors are subject to criminal prosecution and the draconian penalties reserved for drug dealers, when the case hinges on a disagreement between practitioners as to what is proper treatment for a patient.”).

<sup>54</sup> *United States v. Collier*, 478 F.2d 268, 270-71 (5th Cir. 1973).

professional practice' . . . clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes."<sup>55</sup> Notwithstanding the court's confidence that these terms are easily construed and applied, it never elaborated on their meaning. Instead, the court simply opined that "it is difficult to see how the language can be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress intended to make illegal and subject to sanctions."<sup>56</sup>

More recently, the Tenth Circuit dismissed a vagueness challenge by concluding that no "specific set of facts had to be present in order to find that a physician stepped outside of his role and issued prescriptions without a legitimate medical purpose."<sup>57</sup> The court offered no explanation of the meaning of the contested phrases. Instead, it responded to the vagueness challenge by noting that courts simply "looked to the facts in the record to conclude enough facts existed for a fact finder to affirmatively determine that the physician issued the drugs for an improper purpose."<sup>58</sup> A doctor (or attorney) looking for insight into how to avoid violating the CSA will not find it here.

Nor have legal scholars stepped in to fill this gap — a surprising omission given the range of high-profile controversies that hinge on the legitimate uses of drugs, such as the opioid epidemic, medical marijuana, and assisted suicide, to name just a few. While philosophers have debated whether medicine has an "internal morality" that constrains its legitimate scope,<sup>59</sup> legal scholars have not applied these

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<sup>55</sup> *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975).

<sup>56</sup> *Id.* at 198. A dissenting opinion concluded that "Congress has, without doubt, used language that is 'so vague that men of common intelligence must necessarily guess as to its meaning and differ as to its application.'" *Id.* at 204 (Ely, J., dissenting).

<sup>57</sup> *United States v. MacKay*, 715 F.3d 807, 823 (10th Cir. 2013).

<sup>58</sup> *Id.* See also *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992) ("There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.").

<sup>59</sup> See, e.g., Boorse, *supra* note 22; Peter H. Schwartz, *Broadening and Balancing the Goals of Medicine: Battling Disease and Treating the Healthy*, in *NATURALISM IN THE PHILOSOPHY OF HEALTH* 199 (Élodie Giroux, ed., 2016); Leon R. Kass, *Regarding the End of Medicine and the Pursuit of Health*, 40 *PUBLIC INTEREST* 11 (1975); John Ladd, *The Internal Morality of Medicine: An Essential Dimension of the Patient-Physician Relationship*, in *THE CLINICAL ENCOUNTER: THE MORAL FABRIC OF THE PHYSICIAN-PATIENT RELATIONSHIP* 209 (Earl E. Shelp, ed., 1983); ALASDAIR MACINTYRE, *AFTER VIRTUE: A STUDY IN MORAL THEORY* (3d ed. 2007); Edmund D. Pellegrino, *The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Healing Professions*, 26 *J. MED. & PHIL.* 559 (2001).

insights to analyses of the CSA's purview. For example, both Zettler<sup>60</sup> and Gast<sup>61</sup> have explored the extent to which the Act grants federal law enforcement authority to regulate medical practice and the balance of power between states and the federal government in this area. Similarly, Noah has suggested that defining the legitimate scope of medicine may not merely be a scientific question, but "a contested political and social question" that the federal government should play a role in deciding.<sup>62</sup> But these arguments have not grappled with the nebulosity of standards for determining medical legitimacy. Hoffmann highlights the inherent indeterminacy of the phrase "legitimate medical purpose" in the context of treating pain with opioids, but does not analyze the broader question of which objectives are within medicine's legitimate purview.<sup>63</sup>

In sum, under the CSA, whether a prescription is issued for a legitimate medical purpose carries enormous weight — it is the difference between a prison sentence or an insurance check. Yet notwithstanding these high stakes, few have sought to define the scope of legitimate practices and sporadic attempts to do so have floundered.

## II. PATIENT MOTIVES AS THE TEST OF MEDICAL LEGITIMACY

A key source of confusion in determining which practices qualify as legitimate is a failure to specify whether the "purpose" at issue is the *physician's* purpose in prescribing the drug (e.g., helping the patient versus profiting from drug trafficking) or the *patient's* purpose in using the drug (for an accepted purpose versus to satisfy a craving). Courts have failed to identify these as distinct inquiries that may often overlap, but do not always. Sometimes courts have insisted that the central question is whether, in prescribing controlled substances, the physician was acting as a "trafficker" by using her prescribing authority not to benefit patients, but for personal profit.<sup>64</sup> But in many cases courts have instead focused on how patients used the drugs they were prescribed,

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<sup>60</sup> See Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 454-77 (2015).

<sup>61</sup> See Gast, *supra* note 17, at 269-73. Gast also correctly predicted both the ultimate outcome in a subsequent Supreme Court case addressing this issue (*Gonzales v. Oregon*, 546 U.S. 243 (2006)) as well as much of the majority's reasoning in that case. *See id.*

<sup>62</sup> Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 185-86 (2004).

<sup>63</sup> See Hoffmann, *supra* note 23, at 235.

<sup>64</sup> See, e.g., *United States v. Moore*, 423 U.S. 122, 135-37 (1975); *United States v. Katz*, 445 F.3d 1023, 1028 (8th Cir. 2006); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994).

allowing doctors to be convicted for prescribing drugs to patients who then sold the drugs to others or consumed them to feed their addictions.<sup>65</sup>

Using this latter sense of “purpose” — that is, focusing on a patient’s aims for using a drug — raises two serious problems. As an initial matter, physicians may be deceived about patients’ reasons for drug-taking. More fundamentally, it is not clear which patient goals are within the bounds of legitimate medicine and which fall outside that scope.

#### A. *Physicians as Guarantors of Patients’ Good Faith*

Courts have frequently upheld convictions of doctors without requiring evidence that the defendant sought to profit from trafficking drugs.<sup>66</sup> Instead, doctors have been convicted under the CSA based on evidence that their patients were using their prescribed drugs for illicit purposes.<sup>67</sup> For example, Dr. Ronald McIver was convicted based on the testimony of patients who were “either drug addicts or drug diverters who lied to McIver about their use of the drugs.”<sup>68</sup> In another case, Dr. Jeri Hassman avoided a lengthy prison term by pleading guilty to “knowingly comforting or assisting four patients who possessed controlled drugs obtained through misrepresentation, deception, or fraud.”<sup>69</sup> Dr. Hassman knew or had reason to suspect that each of these four patients had diverted their prescribed drugs to others, but she did not report them to the police.<sup>70</sup>

Prosecuting doctors for patients’ drug diversion or misuse is problematic because doctors do not always know their patients’ motives for drug-taking. In the case of opioids for example, there is no objective test doctors can use to determine whether a patient is truly in pain. Rather, as the DEA itself has acknowledged, patients’ “[s]elf-report is the ‘gold standard’ for pain management.”<sup>71</sup> Detecting when a patient is

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<sup>65</sup> See Hoffmann, *supra* note 23, at 239-56. Granted, these two purposes can be related. If a doctor prescribes a narcotic to a person whom the doctor knows is selling the drugs to others, that can help support an inference that the doctor is writing prescriptions for profit, rather than acting as a physician. But clearly there can also be situations in which doctors write prescriptions with no illicit motive, but patients abuse the drugs they have been prescribed. See *infra* Part II.A.

<sup>66</sup> See Hoffmann, *supra* note 23, at 239-56.

<sup>67</sup> See *id.*

<sup>68</sup> *Id.* at 255.

<sup>69</sup> *Id.* at 252.

<sup>70</sup> See *id.*

<sup>71</sup> DEA 2004 FAQ, *supra* note 48, at 80.

lying about pain may be particularly difficult for doctors, who “must develop a trusting relationship with their patients” in order to succeed as physicians.<sup>72</sup> In one study that tested doctors’ ability to determine whether a patient was lying, physicians correctly identified lying patients only 10% of the time.<sup>73</sup> Moreover, patients’ reasons for taking opioids can be complex. It is not uncommon for people who are addicted to narcotics to also suffer from serious pain that warrants treatment with opioids.<sup>74</sup>

These challenges argue for granting doctors a wide range of deference. Particularly given that doctors can face civil liability and sanctions from state medical boards for *under-treating* a patient’s pain, the criminal law should give doctors a wide berth.<sup>75</sup> Both courts and the DEA have given lip service to this idea. In its FAQ for physicians regarding the proper prescribing of pain medications, the DEA insisted that a physician cannot be arrested — let alone convicted — “unless he or she can be shown to have *knowingly and intentionally* distributed or prescribed controlled substances to a person outside the scope of legitimate

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<sup>72</sup> See Hoffmann, *supra* note 23, at 303.

<sup>73</sup> Beth Jung & Marcus M. Reidenberg, *Physicians Being Deceived*, 8 PAIN MED. 433, 433 (2007).

<sup>74</sup> Hoffmann, *supra* note 23, at 286. In its 2004 “consensus document,” the DEA frankly acknowledged that “even patients with severe pain can develop patterns of abuse or addiction, or engage in criminal activity,” including selling medications and “[m]ultiple episodes of ‘lost’ or ‘stolen’ prescriptions.” DEA 2004 FAQ, *supra* note 48, at 77, 96. Nevertheless, the DEA averred “[t]hese behaviors should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated.” *Id.* at 96. Rather, the DEA’s “consensus document” concluded “if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred.” *Id.* at 97. However, the DEA later reversed itself, issuing an interim policy statement that characterized these conclusions as “misstatements” and warning that “[u]nder no circumstances may a physician dispense controlled substances with the knowledge that they will be used for a nonmedical purpose or that they will be resold by the patient.” Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (Nov. 16, 2004).

<sup>75</sup> “Physicians who ignore their patient’s pain accounts would be arguably negligent.” Hoffmann, *supra* note 23, at 303 (citing Ben A. Rich, *Physicians’ Legal Duty to Relieve Suffering*, 175 WEST J. MED. 151, 152 (2001) (discussing the jury verdict against a doctor for undertreating his elderly patient’s pain in *Bergman v. Wing Chin, MD & Eden Med. Ctr.*, No. H205732-1 (Cal. App. Dep’t Super. Ct. 1999))). Hoffmann further notes that “[b]etween 1999 and 2004 . . . two state medical boards disciplined physicians for failure to adequately prescribe pain medication for their patients.” *Id.* at 269.



practice.”<sup>76</sup> However, just three months later the DEA retracted that document and disavowed its contents.<sup>77</sup>

While courts have likewise insisted that physicians can only be convicted under the CSA for knowingly and intentionally prescribing drugs without a legitimate medical purpose,<sup>78</sup> in practice they have used a much lower standard. As Diane Hoffmann has detailed, rather than requiring the prosecution to prove that the physician actually knew a patient was abusing or diverting the drugs he prescribed, “courts permit a willful blindness standard that, in effect, allows a jury to convict based on an ex post facto ‘he should have been more careful’ theory or to convict on mere negligence.”<sup>79</sup> In fact in criminal cases under the CSA, courts have repeatedly applied a standard that is easier to satisfy than the liability standard in a civil negligence action, affirming convictions of physicians even in the absence of any established standard of care and even when their prescribing practices conformed to widely accepted standards.<sup>80</sup>

### B. Defining “Medical” Motives

In addition to the difficulty physicians face in gleaning patients’ motives for seeking a prescription, defining “legitimate medical purpose” in terms of patients’ motives for drug-taking poses a deeper

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<sup>76</sup> DEA 2004 FAQ, *supra* note 48, at 77 (emphasis added).

<sup>77</sup> See Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67,170.

<sup>78</sup> Hoffmann, *supra* note 23, at 305.

<sup>79</sup> *Id.* (internal quotations omitted). See also *United States v. Ignasiak*, 667 F.3d 1217, 1236 (11th Cir. 2012) (The court endorsed a theory of prosecution that seemed to sound in mere negligence — i.e., that Dr. Ignasiak was “on notice” that his prescribing practices were harming patients, and “that at the very least should have served as notice to Dr. Ignasiak that perhaps there was something wrong with the way that he was prescribing controlled substances.”).

<sup>80</sup> See Hoffmann, *supra* note 23, at 283-90. For example, in the prosecution of Dr. William Hurwitz, “the prosecution argued that it was beyond the ‘bounds of medicine’ for Dr. Hurwitz to prescribe more than 195 milligrams of morphine per day,” despite the fact that “dosages more than 60 times that level are considered acceptable in a medical textbook.” John Tierney, *Trafficker or Healer? And Who’s the Victim?*, N.Y. TIMES (Mar. 27, 2007), <https://www.nytimes.com/2007/03/27/science/27tier.html>. In *United States v. Ignasiak*, 667 F.3d 1217, 1227 (11th Cir. 2012), the Eleventh Circuit found the evidence in the record sufficient to support a conviction against a physician for prescribing excessive amounts of controlled substances, despite the fact that the government’s own expert testified — and the government did not dispute — that the defendant’s prescriptions “never exceeded the diagnosis-specific dosages and quantities listed in the Physician’s Desk Reference (‘PDR’), a compilation of all medications, monographs, and FDA approval limitations.”

challenge: determining which motives count as legitimate. As with many common terms, it is easy to imagine one has a solid grasp of which kinds of practices qualify as “medical.” But on closer inspection this is far from clear, as the U.S. Supreme Court discovered in *Gonzales v. Oregon*.<sup>81</sup>

*Gonzales* concerned a challenge to Attorney General John Ashcroft’s declaration that helping a terminally ill patient commit suicide was not a legitimate medical purpose for prescribing controlled substances.<sup>82</sup> The Attorney General’s action came in response to the enactment of the Oregon Death With Dignity Act, which allowed physicians to prescribe lethal doses of drugs to certain terminally ill patients at their request.<sup>83</sup> The Attorney General issued an Interpretive Rule that threatened to revoke the DEA registrations of physicians who prescribed drugs to assist suicide.<sup>84</sup> The State of Oregon sued, challenging the Attorney General’s authority under the CSA to designate as “illegitimate” a medical practice expressly permitted by state law.<sup>85</sup>

The crux of the federal government’s defense was that assisting suicide could not be considered a legitimate medical purpose because the practice did not aim to promote patients’ health:

The ordinary meaning of the term “medical” is “[p]ertaining or related to the *healing art* or . . . to ‘medicine,’” and the term “medicine” refers to “[t]hat department of knowledge and practice which is concerned with the *cure, alleviation, and prevention of disease* in human beings, and with the *restoration and preservation of health* . . . .” Assisting an individual’s suicide does not fit within the ordinary meaning of the phrases “legitimate medical purpose” or “usual course of professional treatment,” because it does not aim to preserve the patient’s health or to cure, alleviate, prevent, or “treat” the disease or its symptoms in the patient.<sup>86</sup>

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<sup>81</sup> 546 U.S. 243 (2006).

<sup>82</sup> *See id.* at 249.

<sup>83</sup> *Id.*; OR. REV. STAT. § 127.800 (2003).

<sup>84</sup> As described above, doctors must register with the Attorney General in order to prescribe controlled substances. *See* 21 U.S.C. § 823 (2019). “Because these substances are necessary for treatment of many patients, virtually all practicing physicians register with the DEA.” Hoffmann, *supra* note 23, at 265.

<sup>85</sup> *See* Brief for Respondents at 8-9, *Gonzales v. Oregon*, 546 U.S. 243 (2006), (No. 04-623), 2005 WL 1687168, at \*9.

<sup>86</sup> Brief for Petitioners at 18-19, *Gonzales v. Oregon*, 546 U.S. 243 (2006), (No. 04-623) 2005 WL 1126079, at \*18-19 (emphasis added). Several members of Congress had previously taken a similar position, writing that “assisting in a suicide by prescribing or

The State of Oregon responded that where Congress has not clearly barred a practice — as it has done in expressly banning the prescription of Schedule I substances — the CSA leaves States free to define the scope of legitimate medicine.<sup>87</sup> Although a majority of the Court ultimately sided with Oregon, at oral argument several justices were confounded by the implications of the State’s argument. The federal government’s position — that a prescription is legitimate only when written for “the cure, alleviation, and prevention of disease” — had the benefit of clarity. Without that anchor, however, the justices strained to identify a principle that would clearly distinguish legitimate medical practices from abuse. In particular, the justices repeatedly struggled with when it is legitimate to prescribe drugs to help people “feel better.”<sup>88</sup>

Justice Scalia asserted that when Congress enacted the CSA, “it would have been unthinkable for a State to allow . . . drugs to be [prescribed] by a doctor to make the patient feel better.”<sup>89</sup> He then quickly corrected himself, indicating he was referring to “prescribing cocaine just for recreational use.”<sup>90</sup> Later, when Oregon’s counsel noted that the practice of medicine had “evolved” to include nontherapeutic interventions like Botox, Justice Scalia suggested these were legitimate practices because “[t]hese are all different manners of . . . assisting people to feel better.”<sup>91</sup>

Several justices seized on a hypothetical scenario in which a State authorized doctors to prescribe morphine more liberally than the justices were comfortable with — although they struggled to state their reservations with particularity. Justice Ginsburg seemed concerned that accepting Oregon’s argument would mean States could allow doctors to prescribe morphine whenever, in their medical judgment, it would “make[] people happy.”<sup>92</sup> Chief Justice Roberts expressed skepticism that a State could decide “that it’s legitimate medical practice to make

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filling a prescription for a controlled substance cannot be a ‘legitimate medical purpose’ under DEA regulations, especially when *the practice is not reasonable and necessary to the diagnosis and treatment of disease and injury, legitimate health care, or compatible with the physician’s role as healer.*” Letter from Henry J. Hyde, Chairman, Comm. on the Judiciary, U.S. House of Representatives, & Orrin G. Hatch, Chairman, Comm. on the Judiciary, U.S. Senate, to Thomas A. Constantine, Adm’r, Drug Enf’t Admin. (July 25, 1997) (emphasis added), *reprinted in* S. REP. NO. 105-372, at 7 n.6 (1998).

<sup>87</sup> See Transcript of Oral Argument at 32, *Gonzales v. Oregon*, 546 U.S. 243 (2006).

<sup>88</sup> *Id.* at 34, 36 (statement of Roberts, J.), 32, 54 (statement of Scalia, J.).

<sup>89</sup> *Id.* at 32.

<sup>90</sup> *Id.* at 32.

<sup>91</sup> *Id.* at 54.

<sup>92</sup> *Id.* at 33.

patients feel better, and morphine does that; and so, the State can allow them to prescribe morphine to make people feel better.”<sup>93</sup>

Ultimately, a majority of the Court rejected the Attorney General’s action as beyond the authority granted to him by the CSA.<sup>94</sup> But in doing so, it largely sidestepped the problems that vexed it in oral argument. The Court concluded that drug-assisted suicide did not qualify as a form of “drug abuse” that Congress intended the CSA to prohibit.<sup>95</sup> Rather, the Court observed that “[t]he statutory criteria for deciding what substances are controlled, determinations which are central to the Act, consistently connect the undefined term ‘drug abuse’ with addiction or abnormal effects on the nervous system.”<sup>96</sup> Since prescribing drugs to help patients end their lives does not pose these dangers, the Court concluded this was not the kind of drug use that Congress intended the CSA to prohibit.<sup>97</sup>

While this reasoning was sufficient to determine that assisted suicide did not qualify as “abuse,” outside that limited context this analysis raises more questions than it answers.<sup>98</sup> In particular, which “effects on the nervous system” are “abnormal,” so that prescribing drugs for these purposes falls outside the bounds of legitimate medicine? The Court’s insistence that “abuse” relates to the use of drugs for “stimulant, depressant, or hallucinogenic effect”<sup>99</sup> does little to clarify the issue. Many drugs are prescribed precisely for their stimulant or depressant effects, and the FDA has encouraged research into the therapeutic value of at least one hallucinogenic drug.<sup>100</sup>

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<sup>93</sup> *Id.* at 34.

<sup>94</sup> *Gonzales*, 546 U.S. 243, 274-75.

<sup>95</sup> *Id.* at 274.

<sup>96</sup> *Id.* at 273.

<sup>97</sup> *Id.* at 270 (“Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood.”).

<sup>98</sup> *See id.* at 275 (Scalia, J., dissenting) (arguing that the Court reached its conclusion through a “question-begging” determination that “the Attorney General lacked authority to declare assisted suicide illicit under the Controlled Substances Act (CSA), because the CSA is concerned only with ‘illicit drug dealing and trafficking.’”).

<sup>99</sup> Statement of Attorney Gen. Janet Reno on Oregon’s Death With Dignity Act, U.S. Dep’t of Justice (June 5, 1998), <https://www.justice.gov/archive/opa/pr/1998/June/259ag.htm.html> [<https://perma.cc/F694-EGJ7>] [hereinafter Statement of Attorney Gen. Janet Reno] (“[The CSA] sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriving from the drug’s ‘stimulant, depressant, or hallucinogenic effect on the central nervous system.’”).

<sup>100</sup> Jackman, *supra* note 16 (noting the FDA has granted “breakthrough therapy” status to studies of psilocybin as a treatment for depression).

The reason it has proved so difficult to pin down which purposes qualify as “medical” is that medicine’s scope cannot be defined by reference to narrowly-defined purposes. What determines whether a practice is “medical” is not primarily the purpose for which an intervention is used, but the nature of the means employed.

### III. MEDICINE AS CONSUMER PRODUCT

The Attorney General’s position in *Gonzales v. Oregon* seized on an intuitive sense that “medicine” is defined by interventions that are intended to promote “health.” As Justice Scalia argued in his dissent, the ordinary meaning of “medicine” is “[a]ny substance or preparation used in *treating disease*.”<sup>101</sup> But this intuitive definition is both too broad and too narrow.

It is too broad because there are many interventions people use for the purpose of promoting health that are not considered “medical.” Exercise has an astonishingly broad range of therapeutic and preventative effects, leading the United Kingdom’s Academy of Medical Royal Colleges to declare it a “miracle cure.”<sup>102</sup> Nevertheless, yoga and spin classes are not regulated as medicine, nor are their instructors likely to be licensed medical professionals — or, lacking that license, to be prosecuted for “unauthorized practice of medicine.”

Conversely — and more importantly for present purposes — medicine and medical practice have always extended beyond the narrow aim of treating disease. Moreover, the scope of medicine has broadened considerably over the past fifty years. As medicine has increasingly become a consumer product, it has come to encompass endlessly proliferating methods of using biomedical technology to help patients

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<sup>101</sup> *Gonzales*, 546 U.S. at 278 (Scalia, J., dissenting) (citing WEBSTER’S NEW INTERNATIONAL DICTIONARY 1954 (2d ed. 1950)). See also *United States v. Rosen*, 582 F.2d 1032, 1035 (5th Cir. 1978) (“A physician is restricted to dispensing or prescribing drugs in the bona fide treatment of a patient’s disease.”).

<sup>102</sup> ACAD. OF MED. ROYAL COLL., EXERCISE: THE MIRACLE CURE AND THE ROLE OF THE DOCTOR IN PROMOTING IT (2015), [https://www.aomrc.org.uk/wp-content/uploads/2016/05/Exercise\\_the\\_Miracle\\_Cure\\_0215.pdf](https://www.aomrc.org.uk/wp-content/uploads/2016/05/Exercise_the_Miracle_Cure_0215.pdf) (case study on the role of exercise); Huseyin Naci & John P.A. Ioannidis, *Comparative Effectiveness of Exercise and Drug Interventions on Mortality Outcomes: Metaepidemiological Study*, 347 *BMJ* f5577 (2013) (“Population level cohort studies have shown that people who exercise enjoy a higher quality of life and improved health status compared with those with sedentary behaviours, with subsequent reductions in their risk of adverse outcomes such as admissions to hospital. Randomised controlled trials have shown similarly favourable findings in arthritis, cancer, diabetes, heart disease, and respiratory illnesses, among other chronic conditions. Large scale observational studies have also established a clear association between exercise and all cause mortality.”).

satisfy personal goals beyond physical health, narrowly construed. As medicine has embraced a broad array of practices aimed at helping basically healthy people feel happier and function better in society, many ostensibly therapeutic interventions increasingly resemble “recreational” practices. When drugs are routinely prescribed to enhance quality of life — in particular, to produce mental states that individuals find desirable in the absence of any illness — it becomes difficult to distinguish medical practices from illegitimate drug use by reference to the purposes for which drugs are used. The more this line blurs, the more pressing it becomes to rethink existing legal standards governing drug control and the practice of medicine.

A. *Contraception and Abortion: Cures Without Illness*

“As a matter of history, whenever one supposes the Western medical tradition began, physicians from the start have done things other than to fight disease and promote health.”<sup>103</sup> Perhaps the oldest examples of nontherapeutic medical practices involve preventing and terminating pregnancies. Although pregnancy can pose serious health risks to mothers, neither fertility nor pregnancy is itself an illness. In fact, tubal ligation, vasectomies, and oral contraception disrupt the normal (healthy) functioning of reproductive organs and induce infertility — in effect, giving a healthy person a pathological condition.<sup>104</sup> Likewise a normal pregnancy is not a disease, regardless of whether it is desired.

Yet while the purpose of contraception is not typically to prevent illness,<sup>105</sup> the practice can “be regarded as a universal phenomenon, to be found at different times and in the most diverse of societies.”<sup>106</sup> Birth

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<sup>103</sup> Boorse, *supra* note 22, at 146. The history of physicians’ role in providing contraception and abortion interventions provided here is drawn primarily from Boorse’s description and the sources cited therein.

<sup>104</sup> *Id.* at 150. The fact that a person wants to become infertile cannot turn fertility into pathology or infertility into health, unless we are willing to define “health” as whatever physical state the patient desires. In that case, the only medical practices that would not be “legitimate” would be those inflicted on a non-consenting person.

<sup>105</sup> In the United States, 93% of women who take birth control indicate they do so for the purpose of preventing pregnancy. See *Fact Sheet, Contraceptive Use in the United States*, GUTTMACHER INST. (July 2018), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> [<https://perma.cc/B83K-QJ85>]. Certainly, some contraceptive interventions can be used to promote health in a variety of ways. For example, for women for whom pregnancy presents a health risk, interventions that help avoid or terminate pregnancies promote their health. But in these cases, the intervention is not “treating” fertility as an illness, but rather impairing the healthy functioning of the reproductive system in order to prevent some other harm.

<sup>106</sup> ROBERT JÜTTE, *CONTRACEPTION: A HISTORY* 4 (Vicky Russell trans., 2008).

control recipes — many apparently effective — appear “in ancient and medieval Western medical tracts, as well as in Vedic and Chinese works.”<sup>107</sup> Ancient Egyptian papyri from as early as 1550 BCE contain recipes for contraceptives.<sup>108</sup> In a play by Aristophanes from the fifth century B.C.E., the god Hermes advises a newlywed husband to use pennyroyal — a common contraceptive in ancient Greece — to prevent his wife from becoming pregnant.<sup>109</sup> These practices were so widespread in ancient Rome that, according to the writings of first century stoic Musonius Rufus, lawmakers concerned about low birth rates at one point prohibited women from using contraceptives.<sup>110</sup>

Abortion, too, has been part of human cultures for millennia.<sup>111</sup> Socrates observed that “the midwives, by means of drugs (*pharmakia*) and incantations (*epadousai*), are able to . . . cause miscarriages if they think them desirable.”<sup>112</sup> Aristotle bluntly urged that “when couples have children in excess, let abortion be procured before sense and life have begun.”<sup>113</sup> By the first century A.D., “[t]he literature . . . abounds with references to the reluctance of women to have children and to the fashionable acceptance of abortion.”<sup>114</sup>

These reproductive practices were not merely folk remedies practiced by common people; these interventions were studied and dispensed by ancient physicians.<sup>115</sup> If, as is often claimed, the Western medical tradition starts with Hippocrates,<sup>116</sup> it is important to note that

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<sup>107</sup> JOHN M. RIDDLE, *EVE'S HERBS: A HISTORY OF CONTRACEPTION AND ABORTION IN THE WEST* 13 (1999). See also JÜTTE, *supra* note 106, at 31 (“A study of the history of medicine has identified a total of 413 remedies handed down to us as part of a body of specialist literature dating from ancient times, all of which have considerable abortive as well as contraceptive effects.”).

<sup>108</sup> JÜTTE, *supra* note 106, at 29.

<sup>109</sup> See *id.* at 39.

<sup>110</sup> *Id.* at 14.

<sup>111</sup> See *Roe v. Wade*, 410 U.S. 113, 130 (1973).

<sup>112</sup> RIDDLE, *supra* note 107, at 64.

<sup>113</sup> ARISTOTLE, *POLITICS*, BOOK VII, PART XVI (Benjamin Jowett trans. 1999); see also RIDDLE, *supra* note 107, at 65 (quoting PLATO, *THE LAWS*, 5.740) (“[I]f too many [babies] were being born, Plato said, ‘There are many devices available.’”).

<sup>114</sup> Keith Hopkins, *A Textual Emendation in a Fragment of Musonius Rufus: A Note on Contraception*, 15 *CLASSICAL Q.* 72, 72-74 (1965).

<sup>115</sup> See JÜTTE, *supra* note 106, at 31 (“[W]e are not dealing here with medical self-help advice, but with specialist literature for medical practitioners.”).

<sup>116</sup> See, e.g., Philip J van der Eijk, *Hippocrates: The Protean Father of Medicine*, 359 *LANCET* 2285 (2002) (“Hippocrates and his medical school in the fifth century BC did, after all, inaugurate an approach to health and sickness that, for all its limitations, can be seen as a first step to the development of medical science. Moreover, Hippocrates, by

Hippocratic doctors prescribed remedies for the purpose of preventing or terminating undesired pregnancies.<sup>117</sup> One passage in the Hippocratic Corpus advises, “[i]f a woman does not want to become pregnant, give to her in a drink of water moistened [or diluted] copper ore [misy] in the amount of a *vicia* bean, and she will not become pregnant for a year.”<sup>118</sup> Historian Robert Jütte counts well over one hundred such remedies in scripts attributed to Hippocrates, with dozens more by ancient physicians Dioscorides, Soranus, Oribasius, and Aetius.<sup>119</sup> “The frequent reference to methods of abortion and contraception in Hippocratic documents,” Jütte observes, “points to the fact that such knowledge was greatly sought after in the ancient world, and probably even played a role in the education of medical practitioners.”<sup>120</sup>

Nor were these interventions prescribed solely to protect women’s health. Plato and Aristotle advocated the use of contraception and abortion for purposes of population control.<sup>121</sup> One Hippocratic text tells the story of a female musician “who kept frequent company with men,” but who “did not dare to become pregnant . . . since she did not want to forfeit her good reputation.”<sup>122</sup> She consults with a physician, who successfully induces an abortion.<sup>123</sup> There is no suggestion that this woman desired to terminate her pregnancy for therapeutic reasons. Rather, “[s]he asks for, and is prescribed, an abortion for the sake of her work, not of her health.”<sup>124</sup> “In sum . . . contraception by doctors for no

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his famous Oath, was the first to lay down a moral code for medical behaviour, the effect of which on later and contemporary notions of medical ethics is unparalleled.”).

<sup>117</sup> Although abortion foes often point to the Hippocratic Oath in support of the claim that Hippocratic medicine bars abortion, “most modern scholars conclude that this oath was not written by Hippocrates and does not reflect the norms of Hippocratic medicine.” Boorse, *supra* note 22, at 165-66. See also *Roe v. Wade*, 410 U.S. 113, 131-32 (1973).

<sup>118</sup> Boorse, *supra* note 22, at 165.

<sup>119</sup> JÜTTE, *supra* note 106, at 32.

<sup>120</sup> *Id.*

<sup>121</sup> Boorse, *supra* note 22, at 164; PLATO, *THE LAWS*, 5.740 (“There are many devices available: if too many children are being born, there are measures to check propagation . . . .”); ARISTOTLE, *supra* note 113 (“on the ground of an excess in the number of children, if the established customs of the state forbid this (for in our state population has a limit), no child is to be exposed. But when couples have children in excess, let abortion be procured before sense and life have begun”).

<sup>122</sup> JÜTTE, *supra* note 106, at 33.

<sup>123</sup> See Boorse, *supra* note 22, at 165.

<sup>124</sup> *Id.*



health-related purpose was routine at what is usually seen as the dawn of Western medicine.”<sup>125</sup>

Today, contraception and abortion are unquestionably within the scope of legitimate medicine — notwithstanding hotly contested debates about the morality of these practices, which interventions should be allowed, and who should have to pay for them.<sup>126</sup> Millions of Americans lawfully avail themselves of these interventions, most often for nontherapeutic purposes.<sup>127</sup> Abortion procedures, surgical sterilization, and oral contraceptives are regulated as medicine and generally can only be provided by licensed medical professionals.<sup>128</sup>

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<sup>125</sup> *Id.* at 166.

<sup>126</sup> See, e.g., *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292 (2016) (striking down two Texas statutes deemed to unduly burden women’s access to abortion); *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014) (allowing closely held for-profit corporations to be exempt from a regulation requiring employers to cover certain contraceptives); *Gonzales v. Carhart*, 550 U.S. 124 (2007) (upholding a federal ban on a late-term abortion procedure); Ariana Eunjung Cha, Juliet Eilperin & Josh Dawsey, *Trump Administration Will Pull Funds from Groups That Perform Abortions or Provide Referrals*, WASH. POST (May 18, 2018, 4:25 PM), <https://www.washingtonpost.com/news/to-your-health/wp/2018/05/18/planned-parenthood-likely-to-lose-millions-under-trump-administrations-new-title-x-family-planning-rules/>.

<sup>127</sup> In 2011, more than 900,000 abortions were performed in the United States. Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2011*, 46 PERSP. ON SEXUAL & REPROD. HEALTH 3, 3 (2014). “While a small proportion of women who have abortions do so because of health concerns or fetal anomalies, the large majority choose termination in response to an unintended pregnancy.” Lawrence B. Finer et al., *Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives*, 37 PERSP. ON SEXUAL & REPROD. HEALTH 110, 110 (2005). The most common reasons women cite for obtaining an abortion are that “having a child would interfere with a woman’s education, work or ability to care for dependents (74%); [and] that she could not afford a baby now (73%).” *Id.* Nearly 90% of women of reproductive age who had ever had sexual intercourse have used “birth control pills, an injectable method, a contraceptive patch, or an intrauterine device.” Kimberly Daniels, William D. Mosher & Jo Jones, *Contraceptive Methods Women Have Ever Used: United States, 1982–2010*, NAT’L HEALTH STAT. REP., Feb. 2013, at 1, <http://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf>.

<sup>128</sup> Forty-one states have laws requiring that only licensed physicians can perform abortion procedures. *An Overview of Abortion Laws*, GUTTMACHER INST. (July 1, 2018), <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws>. A minority of states allow other licensed medical professionals, such as registered nurses or physician assistants, to perform abortion procedures. See Holly Yan, *Nurses, Other Non-Physicians Can Perform Abortions in California*, CNN (Oct. 10, 2013, 3:21 AM), <https://www.cnn.com/2013/10/10/politics/california-nurse-practitioners-abortion/index.html>. “In the U.S., daily oral contraceptive pills have traditionally only been available with a prescription,” but several states have passed legislation that allows pharmacists — also medical professionals — to provide oral contraceptives. *Oral Contraceptive Pills*, KAISER FAMILY FOUND. (May 23, 2019), <https://www.kff.org/womens-health-policy/fact-sheet/oral-contraceptive-pills/>. One notable exception is a

Moreover, the Supreme Court has repeatedly turned back state legislation aimed at placing contraception and nontherapeutic abortion outside the bounds of medicine.<sup>129</sup> In recent years, even state laws aimed at curbing abortions have emphasized, rather than denied, that these procedures are medical in nature — by, for example, requiring abortion facilities to meet standards for ambulatory surgical centers.<sup>130</sup>

As the examples of contraception and abortion reflect, the practice of medicine has always extended beyond treating and preventing illnesses. As described below, in recent years medicine's scope has only expanded.

### B. Social Challenges as Sickness

#### 1. Cosmetic Surgery: From Quackery, to "Treatment," to Service on Demand

Although physicians have provided nontherapeutic interventions to control reproduction since the dawn of Western medicine, doctors have sometimes been reluctant to use medical means for other nontherapeutic purposes. That resistance has gradually eroded as the pervasive consumerism in American culture has increasingly infiltrated medicine. As a result, interventions that were previously viewed as outside the scope of legitimate medicine have been brought squarely within its ambit.

The history of cosmetic surgery offers an early example. As Elizabeth Haiken has recounted, when surgeons began developing techniques to address facial wounds of soldiers returning from World War I, they quickly realized the potential to use these new techniques to enhance appearance as well.<sup>131</sup> However, many plastic surgeons were reluctant to use their skills for cosmetic purposes because they "continued to believe that medicine was meant to heal rather than beautify."<sup>132</sup>

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form of emergency contraception often called "Plan B" or the "morning after pill," which the FDA has approved for sale without a prescription. Lauran Neergaard, *FDA Allows OTC Morning-After Pill, Lifts Age Limit*, NBC NEWS: WOMEN'S HEALTH (June 20, 2013, 6:31 PM), <https://www.nbcnews.com/healthmain/fda-allows-otc-morning-after-pill-lifts-age-limit-6C10399714>.

<sup>129</sup> See, e.g., *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

<sup>130</sup> See *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2296 (2016) (striking down TEX. HEALTH & SAFETY CODE ANN. § 171.0031(a) and TEX. HEALTH & SAFETY CODE ANN. § 245.010(a)).

<sup>131</sup> ELIZABETH HAIKEN, *VENUS ENVY: A HISTORY OF COSMETIC SURGERY* 29 (1997).

<sup>132</sup> *Id.* at 93. In an influential 1926 article, one surgeon asked rhetorically, "What is the ethical difference between doing an abdominal operation and removing wrinkles

Although the medical profession initially resisted cosmetic surgery as a legitimate use of physicians' skills, an increasingly consumer-oriented culture gradually eroded their resolve.<sup>133</sup> At the same time that plastic surgeons were developing their techniques, a confluence of technological and social trends rendered physical appearance increasingly important to social functioning and economic mobility.<sup>134</sup> "[T]he interrelated processes of industrialization, urbanization, and immigration and migration transformed the United States from a predominantly rural culture, in which identity was firmly grounded in family and locale, to a predominantly urban culture, in which identity derives from 'personality' or self-presentation."<sup>135</sup> Advertisers exploited this shift by warning that "in an increasingly mobile and individualistic society, personal presentation counted for more than ever before."<sup>136</sup> The ubiquity of advertising and the movie boom that began in the 1920s flooded the marketplace with images of attractive people, rendering American eyes more attuned to physical beauty.<sup>137</sup>

Accordingly, even when undesired physical features did not directly threaten people's health, they were recognized as having real consequences — in the job market, marriage market, and individual satisfaction.<sup>138</sup> As consumers clamored for surgical solutions to address features they found undesirable, plastic surgeons were forced to search for a principle they could apply to justify using surgery to modify physical features that were functionally sound, but not aesthetically ideal.<sup>139</sup>

They found such a principle in the form of the "inferiority complex."<sup>140</sup> Surgeons latched onto the idea that unattractive physical features could instill in individuals a pathological sense of inferiority and that plastic surgery could, in the words of one pioneer, "alleviate or remedy illnesses which in many cases are far more serious than bodily pain; namely mental anguish due to the patient's constant realization of

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from a sagging face? . . . The abdominal operation is necessary to the health of the patient, the operation for removal of wrinkles is unessential and is simply decorative surgery . . . . True plastic surgery . . . without question . . . is absolutely distinct and separate from what is known as cosmetic or decorative surgery." *Id.*

<sup>133</sup> CARL ELLIOTT, *BETTER THAN WELL: AMERICAN MEDICINE MEETS THE AMERICAN DREAM* 120-21 (2003); HAIKEN, *supra* note 131, at 102-03.

<sup>134</sup> HAIKEN, *supra* note 131, at 7, 92.

<sup>135</sup> *Id.* at 7.

<sup>136</sup> *Id.* at 101.

<sup>137</sup> *Id.* at 91-92.

<sup>138</sup> *See id.* at 39.

<sup>139</sup> *See id.* at 10, 38, 103-04.

<sup>140</sup> ELLIOTT, *supra* note 133, at 121-22.

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the defect . . . .”<sup>141</sup> In 1935, one of the fathers of plastic surgery, Dr. Jacques Maliniak, argued that “[j]ust as Americans recognized a social debt to citizens’ physical welfare, [s]hould it not offer relief when psychic health is threatened by a congenital or acquired deformity that stands between the individual and normal living?”<sup>142</sup>

This move provided a diagnosis that transformed interventions formerly condemned as cosmetic into forms of treatment. At the same, cosmetic surgeons expanded the range of attributes that qualified as “deformities” justifying medical intervention. Over time, the term came to encompass virtually any physical feature that threatened an individual’s self-esteem — whether “baggy eyelids,” “pendulous breast,” or countless variations in the shape of the nose.<sup>143</sup> Conceiving of social discomfort as the hallmark of deformity “released the surgeon from the impossible responsibility of deciding where to draw the line” between therapeutic and cosmetic surgery.<sup>144</sup> Instead, the responsibility for diagnosis shifted from physicians to patients, whose subjective distress was sufficient to legitimize surgical intervention.<sup>145</sup>

Over time, cosmetic surgeons gradually dispensed with the pretense of treatment and came to embrace the idea that medical professionals could legitimately provide surgery to enhance physical appearance without the need for a medical diagnosis. Today there can be no doubt that legitimate medicine includes cosmetic procedures that have little plausible connection to physical illness or “deformity.” The American Society of Plastic Surgeons claims more than 7,000 current members, all of whom are board-certified physicians and operate in accredited surgical facilities.<sup>146</sup> The vast majority of the procedures these physicians perform are patently cosmetic, not reconstructive. In 2016, physicians offered fewer than 6 million reconstructive procedures, such as tumor removals, laceration repairs, and scar revisions.<sup>147</sup> During that same period, Americans received more than 17 million cosmetic procedures (at a cost of \$16 billion), the most common of which were

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<sup>141</sup> HAIKEN, *supra* note 131, at 115.

<sup>142</sup> *Id.* at 115-16 (internal quotation omitted).

<sup>143</sup> *Id.* at 122-23.

<sup>144</sup> *Id.* at 130.

<sup>145</sup> *Id.* at 122 (“Not the surgeon’s objective judgment but the patient’s subjective evaluation became the factor that determined whether a deformity existed and whether surgery would take place.”).

<sup>146</sup> AM. SOC’Y OF PLASTIC SURGEONS, *supra* note 12, at 3.

<sup>147</sup> *Id.* at 5.

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breast augmentations, liposuctions, nose reshaping, eyelid surgeries, and face lifts.<sup>148</sup>

In sum, although the purpose for which most patients seek plastic surgery — beautification — was once dismissed as outside the scope of legitimate medicine, increased consumerism gradually brought this aim within its ambit. The fact that medicine’s domain can expand in response to consumer demand belies the notion that medical practice is limited to a narrow set of objectively prescribed goals.

## 2. Consumer Culture and the Medicalization of Everyday Life

As the example of the inferiority complex illustrates, attempting to define medicine’s scope by reference to a narrow set of purposes — such as the treatment of illnesses — is complicated by the extraordinary flexibility of the concepts of health and disease. Although limiting medicine to treatment appears to offer a bright line distinction between legitimate and illegitimate prescriptions, this conception of medicine’s scope is not only descriptively inaccurate, it is conceptually impotent given how easily (and frequently) all manner of complaints can be redefined as illnesses that warrant treatment. The concept of illness is not confined to conditions that shorten lifespan, cause physical pain, or damage the functioning of the human body. Virtually any complaint that can be ameliorated through biomedical interventions can be conceived of as a type of illness. As medicine has increasingly applied diagnostic labels to common patient complaints, the distinction between therapeutic and nontherapeutic purposes seems increasingly illusory and an extremely tenuous basis for defining the legitimate scope of medicine.

The process of reconceptualizing social and emotional problems as medical conditions — a trend often referred to as “medicalization” — has been characterized as “one of the most potent social transformations of the last half of the twentieth century in the West.”<sup>149</sup> During that span, medicine’s domain has expanded dramatically, with a wide range of conditions that were formerly considered outside medicine’s ambit being reconceived as treatable illnesses. Conditions once viewed as character flaws or sins, such as “gluttony” and “drunkenness,” are now

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<sup>148</sup> *Id.* at 5-6. Notably, breast augmentation surgery not only provides no medical benefit to patients, it can impair the healthy functioning of mammary glands and negatively impact lactation. *Breastfeeding: Breast Surgery*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/maternal-or-infant-illnesses/breast-surgery.html> (last updated Jan. 24, 2018).

<sup>149</sup> Adele E. Clarke et al., *Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine*, 68 *AM. SOC. REV.* 161, 161 (2003).

often viewed as medical disorders.<sup>150</sup> Myriad “symptoms” of typical old age have likewise become common targets for medical intervention. In a single decade, the number of eyelid lifts charged to Medicare more than tripled — all ostensibly for therapeutic purposes.<sup>151</sup> Declining muscle mass, libido, and sexual performance in aging men are now labeled as testosterone deficiencies and erectile dysfunction — medical ailments that can be effectively treated with prescriptions.<sup>152</sup>

As the evolution of cosmetic surgery reflects, this shift has dovetailed with growing consumerism in both medicine and the broader society.<sup>153</sup> The FDA accelerated this trend in the late 1990s, when the agency loosened its regulations to permit “direct-to-consumer” advertising of prescription drugs.<sup>154</sup> As a result, rather than merely communicating with physicians about medications, today pharmaceutical companies promote their drugs directly to consumers (né “patients”) much like other commercial products.

The ability to market directly to consumers allows pharmaceutical companies to grow the market for their products by encouraging individuals to think of their problems in medical terms.<sup>155</sup> This shift has helped drug companies market a growing menu of so-called “lifestyle drugs” — interventions designed to treat a range of problems that do not threaten health, narrowly construed, but erode quality of life.<sup>156</sup>

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<sup>150</sup> See AM. PSYCHIATRIC ASS'N, FEEDING AND EATING DISORDERS 1 (2013); *Alcohol Use Disorder*, NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM, <http://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-use-disorders> (last visited July 26, 2018); see also *Estimate of Bariatric Surgery Numbers, 2011–2017*, AM. SOC'Y FOR METABOLIC & BARIATRIC SURGERY, <https://asmbs.org/resources/estimate-of-bariatric-surgery-numbers> (last visited July 26, 2018) (explaining that in 2017, U.S. doctors performed some 228,000 bariatric surgeries — an increase of 44% since 2011).

<sup>151</sup> Joe Eaton & David Donald, *Eyelid Lifts Skyrocket Among Medicare Patients, Costing Taxpayers Millions*, CTR. FOR PUB. INTEGRITY, <http://www.publicintegrity.org/2013/05/28/12713/eyelid-lifts-skyrocket-among-medicare-patients-costing-taxpayers-millions> (last updated May 19, 2014, 12:19 PM).

<sup>152</sup> See John-Manuel Andriote, *Should the Modern Man Be Taking Testosterone?*, ATLANTIC, (Apr. 5, 2013), <https://www.theatlantic.com/health/archive/2013/04/should-the-modern-man-be-taking-testosterone/274663/>; Conrad & Leiter, *supra* note 7, at 162.

<sup>153</sup> See Clarke et al., *supra* note 149, at 171 (“In commodity cultures, health becomes another commodity, and the biomedically (re)engineered body becomes a prized possession.”).

<sup>154</sup> See Conrad & Leiter, *supra* note 7, at 161.

<sup>155</sup> *Id.* at 161-62 (“The direct-to-consumer advertising may well shape the way the public conceptualizes problems and it may increase consumer demand for medical solutions.”).

<sup>156</sup> Mamo & Fishman, *supra* note 8, at 16 (“While the severity of these conditions varies, what all lifestyle drugs seem to have in common is the promise not just to alleviate what are perceived to be ‘life-limiting’ conditions, but in doing so to make life

Drug companies use “consumer education campaigns” to persuade consumers to think of various complaints as symptoms of illnesses that can be treated with these drugs.<sup>157</sup>

As plastic surgeons’ eager embrace of the inferiority complex suggests, this process of transforming everyday complaints into illnesses is particularly straightforward in the context of psychiatric complaints. Unlike tumors, blood sugar levels, or plaque in the arteries — all of which physicians can measure and diagnose objectively — diagnoses of mental illnesses often hinge on patients’ subjective experiences of distress. Whether a patient’s complaints warrant a psychiatric diagnosis often depends critically on the extent to which the patient herself believes the condition interferes with her quality of life. For example, an individual who is easily distracted does not qualify for a diagnosis of ADHD unless that individual (or his parent) believes this lack of focus “negatively impacts . . . social and academic/occupational activities.”<sup>158</sup> Likewise, if two women have the same amount of sexual desire, one may suffer from “hypoactive sexual desire disorder” while the other does not, depending solely on whether each woman’s level of sexual desire “is troubling to them.”<sup>159</sup> In other words, much of the authority for mental illness diagnosis shifts from doctors to patients.<sup>160</sup> Granting individuals broader authority to determine when their complaints warrant treatment facilitates the consumerization of medical care, allowing patients to seek out the interventions they believe will best enhance their quality of life.

The medical industry has legitimized this shift by expanding the range of human experiences that qualify for medical diagnoses. As Henry Greely observes, “[b]ehaviors do not come naturally labeled as ‘disease’ and ‘nondisease’; humans make those distinctions, and, as various versions of the Diagnostic and Statistical Manual of Mental Disorders reveal, we regularly change them.”<sup>161</sup> The flexibility of the

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in general more comfortable, more enjoyable and just plain better.”) (emphasis omitted).

<sup>157</sup> See Conrad & Leiter, *supra* note 7, at 161-62, 171; Alan Schwarz, *The Selling of Attention Deficit Disorder*, N.Y. TIMES (Dec. 14, 2013) [hereafter *Selling Attention Deficit Disorder*], <https://www.nytimes.com/2013/12/15/health/the-selling-of-attention-deficit-disorder.html?pagewanted=all>.

<sup>158</sup> Barbara T. Felt et al., *Diagnosis and Management of ADHD in Children*, 90 AM. FAM. PHYSICIAN 456, 459 (2014).

<sup>159</sup> U.S. FOOD & DRUG ADMIN., MEDICATION GUIDE: ADDYI™ (ADD-EE) (FLIBANSERIN) TABLETS 1 (2015), <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM459254.pdf>.

<sup>160</sup> HAIKEN, *supra* note 131, at 6-7, 122.

<sup>161</sup> Henry T. Greely, *Direct Brain Interventions to “Treat” Disfavored Human Behaviors: Ethical and Social Issues*, 91 CLINICAL PHARMACOLOGY & THERAPEUTICS 163, 163 (2012).

concept of mental illness makes it relatively easy to expand the scope of medicine by broadening the definitions of illnesses and narrowing conceptions of health.<sup>162</sup>

Sometimes this process involves recognizing new disorders, thereby creating new targets for drug therapies. The latest iteration of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders ("DSM-5") recognized no fewer than fifteen new diagnostic categories.<sup>163</sup> According to the DSM-5, women who, shortly before menses, experience mood swings, tearfulness, and irritability, as well as physical symptoms like lacking of energy and bloating, may be diagnosed with "premenstrual dysphoric disorder" ("PMDD").<sup>164</sup> The American College of Obstetricians and Gynecologists recommends that patients suffering from PMDD be prescribed antidepressants.<sup>165</sup> DSM-5 also instructs that children who display frequent, severe temper outbursts and "irritable or angry mood most of the day, nearly every day" over an extended period of time suffer from "disruptive mood dysregulation disorder" ("DMDD").<sup>166</sup> According to the National Institute of Mental Health, DMDD is treated with stimulants, antidepressants, and/or antipsychotic medications.<sup>167</sup>

More commonly, behaviors can be brought under medicine's ambit by simply expanding the definitions of previously recognized disorders. For example, the American Psychiatric Association has gradually expanded the diagnostic criteria for attention deficit disorder ("ADD") to include common childhood behavior like "makes careless mistakes" or "often has difficulty waiting his or her turn."<sup>168</sup> Psychiatrist Lawrence Diller argues the criteria have become so expansive that "the behavior and symptoms of an inconsistently-motivated teenager are identical to the criteria of ADD."<sup>169</sup>

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<sup>162</sup> See Conrad & Leiter, *supra* note 7, at 171.

<sup>163</sup> Mark Rubinstein, *New Psychiatric Disorders and Their Social Side Effects*, HUFFINGTON POST (Aug. 7, 2013), [https://www.huffingtonpost.com/mark-rubinstein/dsm-5\\_b\\_3328188.html](https://www.huffingtonpost.com/mark-rubinstein/dsm-5_b_3328188.html).

<sup>164</sup> Liisa Hantsoo & C. Neill Epperson, *Premenstrual Dysphoric Disorder: Epidemiology and Treatment*, 17 CURRENT PSYCHIATRY REP. 87, 87 (2016).

<sup>165</sup> *Id.* at 87.

<sup>166</sup> *Disruptive Mood Dysregulation Disorder*, NAT'L INST. OF MENTAL HEALTH, <https://www.nimh.nih.gov/health/topics/disruptive-mood-dysregulation-disorder-dmdd/disruptive-mood-dysregulation-disorder.shtml> [<https://perma.cc/6DAE-6BYW>] (last visited Aug. 2, 2018).

<sup>167</sup> *Id.*

<sup>168</sup> Schwarz, *Selling Attention Deficit Disorder*, *supra* note 157.

<sup>169</sup> Lawrence Diller, *The Homework Pill*, HUFFINGTON POST (Aug. 5, 2012), [http://www.huffingtonpost.com/larry-diller/adderallhomework\\_b\\_1549595.html](http://www.huffingtonpost.com/larry-diller/adderallhomework_b_1549595.html).



Each expansion of diagnostic criteria transforms an ever-larger group of previously-healthy people into patients who warrant medical treatment.<sup>170</sup> Together with aggressive marketing from the makers of stimulant drugs, these changes helped drive a 40% increase in the number of American children diagnosed with ADHD in a single decade.<sup>171</sup> As of 2013, more than 10% of all school-age children — and one out of every five high school-age boys — were diagnosed with this condition.<sup>172</sup> In 2012, doctors wrote nearly 16 million prescriptions for stimulants for people ages 20 to 39 — nearly triple the number written just five years earlier.<sup>173</sup> In total, the production of methylphenidate, the drug marketed under the brand name Ritalin, increased by nearly 900% between 1990 and 2000 — then grew by another 40% in the following two years.<sup>174</sup> From 1993 to 2001, the production of amphetamines like Adderall increased by 5,767%.<sup>175</sup>

Other common conditions reflect similar trajectories. From 1998 to 2011, antidepressant prescriptions in the United States rose by nearly 400%.<sup>176</sup> Today more than 10% of Americans over age 12 — and more than one in five women between age 40 and 59 — take antidepressant medications.<sup>177</sup> In 1980, “social anxiety disorder” was thought to affect roughly 2.75% of the population.<sup>178</sup> By the 1990s, studies estimated that the illness afflicted one out of every eight Americans — a four-fold increase.<sup>179</sup> In 1994, only 25 out of every 100,000 children were diagnosed with bipolar disorder.<sup>180</sup> A mere decade later, that number had risen to more than 1,000.<sup>181</sup>

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<sup>170</sup> See Alan Schwarz & Sarah Cohen, *A.D.H.D. Seen in 11% of U.S. Children as Diagnoses Rise*, N.Y. TIMES (Mar. 31, 2013), <https://www.nytimes.com/2013/04/01/health/more-diagnoses-of-hyperactivity-causing-concern.html>.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> Schwarz, *Selling Attention Deficit Disorder*, *supra* note 157.

<sup>174</sup> Kristina M. Hall et al., *Illicit Use of Prescribed Stimulant Medication Among College Students*, 53 J. AM. C. HEALTH 167, 167 (2005).

<sup>175</sup> *Id.*

<sup>176</sup> LAURA A. PRATT ET AL., ANTIDEPRESSANT USE IN PERSONS AGED 12 AND OVER: UNITED STATES, 2005–2008 1 (2011), <http://www.cdc.gov/nchs/data/databriefs/db76.pdf>.

<sup>177</sup> *Id.*

<sup>178</sup> Allan V. Horwitz, *Creating Mental Illness in Non-disordered Community Populations*, in ESTABLISHING MEDICAL REALITY: ESSAYS IN THE METAPHYSICS AND EPISTEMOLOGY OF BIOMEDICAL SCIENCE 123, 130 (Harold Kincaid & Jennifer McKittrick eds., 2007).

<sup>179</sup> *Id.*; Conrad & Leiter, *supra* note 7, at 163-64.

<sup>180</sup> See Hal Arkowitz & Scott O. Lilienfeld, *Do Kids Get Bipolar Disorder?*, SCI. AM. (July 1, 2012), <https://www.scientificamerican.com/article/do-kids-get-bipolar-disorder/>.

<sup>181</sup> *Id.*

Some portion of these exploding diagnoses could be driven by deteriorating social conditions generating increasing rates of mental distress and/or an increased willingness of afflicted individuals to seek medical care. But it is also clear that conceptions of mental illness have expanded so that a range of behaviors and emotional responses that were once considered normal are now labeled “disordered” — and are therefore legitimate targets for psychotropic drugs. Today roughly one third of all American adults, and more than 40% of adolescents, meet diagnostic criteria for a mental disorder in any given year.<sup>182</sup> Under current DSM-5 definitions, half of all Americans will qualify as mentally ill at some point during their lives.<sup>183</sup> Although these estimates may seem extraordinarily high, epidemiologist Ronald Kessler argues these numbers are not surprising because “[t]he criteria for some of the disorders are not that difficult to meet.”<sup>184</sup>

Thus, using treatment as the litmus test for medical legitimacy accomplishes very little in a medical marketplace in which diagnosis responds to and legitimizes consumer demand. When a biomedical intervention can enhance quality of life in some way (such as enhanced mood, increased sociability, or greater energy and focus), the absence of these benefits can easily be characterized as types of health deficits, thereby rendering the intervention a form of therapy.

### 3. The New Normal: Better Living Through Chemistry

Further complicating any effort to limit the scope of medicine to treating illnesses, in recent decades doctors have shown increasing comfort with prescribing drugs without any pretense that their patients suffer from any recognized illness — just as plastic surgeons gradually dispensed with the need for a diagnosis as a condition for surgery. As medical practice has expanded beyond the seriously ill to include more common forms of dysfunction and distress, it has become commonplace for physicians to prescribe drugs to patients whose complaints do not match the DSM-5 criteria for any disorder, but who simply value the

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<sup>182</sup> ERIN BAGALMAN & ADA S. CORNELL, PREVALENCE OF MENTAL ILLNESS IN THE UNITED STATES: DATA SOURCES AND ESTIMATES 4-6 (2018), <https://fas.org/sgp/crs/misc/R43047.pdf>.

<sup>183</sup> Ronald C. Kessler et al., *Lifetime Prevalence and Age-of-Onset Distributions of Mental Disorders in the World Health Organization's World Mental Health Survey Initiative*, 6 *WORLD PSYCH.* 168, 170 (2007).

<sup>184</sup> *This Month's Expert: Psychiatric Epidemiology by Ron Kessler, PhD*, PSYCHCENTRAL, <https://pro.psychcentral.com/this-months-expert-psychiatric-epidemiology-by-ron-kessler-phd/004803.html> [<https://perma.cc/6C3Z-GP33>] (last visited Aug. 2, 2018).

mental states they achieve when taking psychoactive drugs — a practice that psychiatrist Peter Kramer labeled “cosmetic psychopharmacology.”<sup>185</sup>

For example, many doctors are willing to ignore the diagnostic criteria for ADHD when prescribing stimulants in response to patient requests. Although “a proper evaluation for the disorder typically requires an extensive inquiry into a patient’s history of impulsivity and inattention,”<sup>186</sup> a 2010 study found that “at least 20% of doctors said they did not follow this protocol when making their A.D.H.D. diagnoses, with many of them following personal instinct.”<sup>187</sup> Sometimes this instinct moves doctors to prescribe stimulants even when they do not believe their patients suffer from an illness.<sup>188</sup> In 2012, the *New York Times* reported on a growing number of physicians who prescribe stimulants to struggling, low-income students “not to treat A.D.H.D., necessarily, but to boost their academic performance.”<sup>189</sup> One profiled doctor argued that “a family should be able to choose for itself whether Adderall can benefit its non-A.D.H.D. child.”<sup>190</sup>

Prescriptions of anti-anxiety drugs reflect similar practices. The population of patients who have truly disabling anxiety is relatively small.<sup>191</sup> Yet since the 1950s Americans have consumed anti-anxiety medications — particularly a class of minor tranquilizers called benzodiazepines — in massive quantities.<sup>192</sup> In the 1960s Valium quickly became “the best-selling prescription drug in America,” with doctors writing nearly 60 million prescriptions a year.<sup>193</sup> Today, Xanax (along with its generic equivalent) is the most-prescribed psychiatric

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<sup>185</sup> See PETER D. KRAMER, *LISTENING TO PROZAC: THE LANDMARK BOOK ABOUT ANTIDEPRESSANTS AND THE REMAKING OF THE SELF* 15 (rev. ed. 1997).

<sup>186</sup> Alan Schwarz, *Workers Seeking Productivity in a Pill Are Abusing A.D.H.D. Drugs*, N.Y. TIMES (Apr. 18, 2015), <https://www.nytimes.com/2015/04/19/us/workers-seeking-productivity-in-a-pill-are-abusing-adhd-drugs.html>.

<sup>187</sup> Alan Schwarz, *Attention Disorder or Not, Pills to Help in School*, N.Y. TIMES (Oct. 9, 2012) [hereinafter *Pills to Help in School*], <https://www.nytimes.com/2012/10/09/health/attention-disorder-or-not-children-prescribed-pills-to-help-in-school.html>.

<sup>188</sup> See Diller, *supra* note 169 (“Doctors routinely ‘upgrade’ diagnoses to fit either a treatment or garner a reimbursement.”).

<sup>189</sup> Schwarz, *Pills to Help in School*, *supra* note 187.

<sup>190</sup> *Id.*

<sup>191</sup> ANXIETY DISORDERS, NAT’L INST. OF MENTAL HEALTH, [https://www.nimh.nih.gov/health/statistics/prevalence/file\\_148008.pdf](https://www.nimh.nih.gov/health/statistics/prevalence/file_148008.pdf) (last visited Aug. 2, 2019) (estimating the 12-month prevalence of “severe” anxiety disorders as 4.1% of American adults).

<sup>192</sup> See ELLIOTT, *supra* note 133, at 130.

<sup>193</sup> Robin Marantz Henig, Opinion, *Valium’s Contribution to Our New Normal*, N.Y. TIMES (Sept. 29, 2012), <http://www.nytimes.com/2012/09/30/sunday-review/valium-and-the-new-normal.html>.

drug in the United States.<sup>194</sup> Doctors wrote nearly 94 million prescriptions for benzodiazepines in 2011.<sup>195</sup> In terms of sales, “[o]nly drugs for chronic conditions like high blood pressure and high cholesterol do better.”<sup>196</sup>

From the outset, these drugs have frequently been used not to treat serious mental illnesses, but to reduce the anxiety that healthy people naturally feel in response to stressful circumstances. One early tranquilizer, a drug called Serenitril, carried the slogan “[f]or the anxiety that comes with not fitting in.”<sup>197</sup> In the early 1960s, ads for a drug called Librium promoted it as a way to help college-bound young women cope with the stress of their new environments, helpfully noting that “[h]er newly stimulated intellectual curiosity may make her more sensitive to and apprehensive about unstable national and world conditions.”<sup>198</sup> The maker of Valium overtly “encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever,” advising doctors “[f]or this kind of patient — with no demonstrable pathology — consider the usefulness of Valium.”<sup>199</sup>

Today benzodiazepines are commonly prescribed for people whose anxiety falls far short of a diagnosable mental disorder.<sup>200</sup> Only 16% of prescriptions for benzodiazepines are written by psychiatrists — i.e., the specialists who are trained to diagnose mental illnesses.<sup>201</sup> More

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<sup>194</sup> John M. Grohol, *Top 25 Psychiatric Medication Prescriptions for 2013*, PSYCH. CENTRAL, <https://psychcentral.com/lib/top-25-psychiatric-medication-prescriptions-for-2013/> (last updated Oct. 8, 2018); Matthew Herper, *America’s Most Popular Mind Medicines*, FORBES (Sept. 17, 2010, 6:00 AM), <https://www.forbes.com/2010/09/16/prozac-xanax-valium-business-healthcare-psychiatric-drugs.html>.

<sup>195</sup> Lisa Miller, *Listening To Xanax*, N.Y. MAG. (Mar. 16, 2012), <http://nymag.com/news/features/xanax-2012-3/>.

<sup>196</sup> *Id.*

<sup>197</sup> ELLIOTT, *supra* note 133, at xv.

<sup>198</sup> Henig, *supra* note 193.

<sup>199</sup> Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

<sup>200</sup> Although Xanax was originally approved for “panic disorder,” which had only recently been recognized as a mental disorder, “a growing number of Americans found that it worked on quotidian panic as well, the kind that comes with a child’s disappointing, future-ruining report card or an intimate dinner party at the home of the person who signs your paychecks.” See Jules Angst, *Panic Disorder: History and Epidemiology*, 13 EUR. PSYCHIATRY 51s, 51s (1998); Miller, *supra* note 195.

<sup>201</sup> Elisa Cascade & Amir H. Kalali, *Use of Benzodiazepines in the Treatment of Anxiety*, 5 PSYCHIATRY 21, 21 (2008).

than half are written by primary care practitioners.<sup>202</sup> The uses of tranquilizers like Xanax are as multifarious as potential sources of stress, including flying on a plane,<sup>203</sup> receiving dental care,<sup>204</sup> sending a child off to kindergarten, enduring holidays with the in-laws, and facing — or unwinding after — a challenging day at work.<sup>205</sup> Dr. Ronald Kessler argues that even when a person's distress does not qualify for a diagnosis, "a pharmacological solution" can be a smart response to this kind of "situational anxiety."<sup>206</sup> Unless all of these doctors are acting as outlaw drug traffickers, it is clear that the scope of legitimate medicine is not limited to the treatment and prevention of disease.

### C. *The Blurring Line Between Medical and Recreational Use*

As doctors increasingly prescribe psychotropic drugs to healthy people to relieve stress, enhance performance, and otherwise obtain desired mental states, it becomes harder to distinguish these uses from "recreational" drug-taking. Although the CSA prohibits prescribing drugs without a legitimate medical purpose, in many cases drug "abusers" consume drugs for precisely the same purposes as legitimate users.

For example, the use of prescription tranquilizers to cope with the relatively minor stresses of everyday life looks very similar to how many people use alcohol — so much so that drugs like Xanax have earned a reputation as "alcohol in a pill."<sup>207</sup> Many people consume cannabis for the same purposes. The Institute of Medicine has noted that marijuana's

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<sup>202</sup> *Id.*; see also Mark Olfson, et al., *Benzodiazepine Use in the United States*, 72 JAMA PSYCHIATRY 136, 137 (2015) ("At all ages and across both sexes, a great majority of benzodiazepines were prescribed by nonpsychiatrist prescribers.").

<sup>203</sup> See Frank H. Wilhelm & Walton T. Roth, *Acute and Delayed Effects of Alprazolam on Flight Phobics During Exposure*, 35 BEHAV. RES. THER. 831, 831 (1997) (noting that some clinicians "recommend the acute administration of benzodiazepines for flying phobia").

<sup>204</sup> See Mark Donaldson, et al., *Oral Sedation: A Primer on Anxiolysis for the Adult Patient*, 54 ANESTHESIA PROGRESS 118, 118 (2007) (endorsing the use of minor tranquilizers for people with "a moderate to high level of fear and anxiety" regarding receiving dental care).

<sup>205</sup> See Miller, *supra* note 195.

<sup>206</sup> *Id.*

<sup>207</sup> See *id.* These drugs are like alcohol not only in their uses, but pharmacologically as well. Anne Rogers et al., *Prescribing Benzodiazepines in General Practice: A New View of an Old Problem*, 11 HEALTH 181, 183 (2007) ("Like other tranquillizing drugs (for example the barbiturates and alcohol) the benzodiazepines reinforce the action of a naturally occurring neurotransmitter (gamma-aminobutyric acid or GABA). GABA has a general calming effect on neural activity.").

therapeutic benefits include inducing sedation and reducing anxiety.<sup>208</sup> In California, where state law has long allowed patients to obtain cannabis pursuant to a doctor's recommendation, nearly 40% of medical marijuana patients reported using the drug to relieve anxiety and 55% reported using it to improve relaxation.<sup>209</sup>

Illicit users of stimulants like Adderall (amphetamines) and Ritalin (methylphenidate) overwhelmingly use these drugs for precisely the same purposes as patients who are prescribed these drugs to treat ADHD. Physicians prescribe stimulants to help ADHD patients focus on their work, reduce distraction and impulsivity, and enhance their organization, often with the aim of improving their performance at school or work.<sup>210</sup> As for illicit users, the most common reasons students cite for taking these drugs without a prescription are “[t]o concentrate better while studying,” “to improve study skills,” “to stay awake to study longer,” and “to improve concentration.”<sup>211</sup> Indeed, the strongest predictor of whether an individual will “abuse” a stimulant drug is whether that person has undiagnosed symptoms of ADHD.<sup>212</sup> According to one study, “71.1% of stimulant medication misusers screened positive for adult ADHD symptoms.”<sup>213</sup>

In light of the fact that both licit and illicit drug users often consume drugs for the same purposes, drug enforcement actors often define “drug abuse” not in terms of the purposes for which drugs are used, but simply by whether the user has a prescription for the drug and is using it as prescribed.<sup>214</sup> For example, the National Institute on Drug Abuse equates “misuse” of prescription drugs with “nonmedical use,” which includes “taking someone else’s prescription, even if for a legitimate

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<sup>208</sup> See ALISON MACK & JANET JOY, *MARIJUANA AS MEDICINE?: THE SCIENCE BEYOND THE CONTROVERSY* 58 (2000).

<sup>209</sup> Craig Reinerman et al., *Who Are Medical Marijuana Patients? Population Characteristics from Nine California Assessment Clinics*, 43 J. PSYCHOACTIVE DRUGS 128, 131 (2011).

<sup>210</sup> See Kate Flory et al., *Misuse of Prescription Stimulant Medication Among College Students: Summary of the Research Literature and Clinical Recommendations*, 21 J. CLINICAL OUTCOMES MGMT. 559, 559 (2014) (“Prescription stimulant medications (e.g., methylphenidate, amphetamines) are typically used for the treatment of attention-deficit/hyperactivity disorder (ADHD) to increase attentiveness, decrease distractibility, and improve daily functioning.”).

<sup>211</sup> *Id.* at 561. “Nonacademic reasons, such as to get high, to prolong effects of alcohol and other drugs, and to lose weight, were less commonly endorsed.” *Id.*

<sup>212</sup> *See id.*

<sup>213</sup> *Id.*

<sup>214</sup> *See id.* at 559 (“Throughout this review, ‘misuse of stimulant medication’ refers to using prescription stimulant medications without a prescription or using more stimulant medication than prescribed (i.e., a higher or more frequent dosage).”).

medical complaint.”<sup>215</sup> The Substance Abuse and Mental Health Services Administration likewise characterizes any “use of prescription drugs without a prescription of the individual’s own” as a “nonmedical use,” regardless of the purposes for which the individual consumes the drug.<sup>216</sup>

One can see the same logic reflected in a booklet that Shire, the maker of Adderall, distributed to physicians to market the drug.<sup>217</sup> Although Adderall’s chemical composition and its effects on users are virtually identical to the street drug, methamphetamine,<sup>218</sup> the booklet reassured doctors that a prescription acts as a talisman that transforms amphetamines from drugs of abuse into helpful tools. It quoted a patient as saying, “If you give me a drink or a drug, I’ll abuse it, but not this medication. I don’t consider it a drug. Drugs get abused. Medication helps people have satisfying lives.”<sup>219</sup>

Defining drug abuse in this way embraces a type of formalism — the presence or absence of a prescription — that abandons any pretense of defining medical legitimacy by reference to users’ purposes. Instead, under this approach drug “abusers” can be transformed into legitimate users simply by obtaining prescriptions, without any change in the purposes for which they consume drugs.

This approach to defining drug abuse offers doctors no guidance regarding how to avoid prescribing drugs without a legitimate medical purpose. For example, if cannabis were moved to Schedule II — as a bipartisan bill in the U.S. Senate proposes — for which purposes could doctors legitimately prescribe it? Could a physician prescribe cannabis to help a stressed-out patient relax — just as doctors currently prescribe Xanax to help healthy patients cope with sub-diagnostic levels of

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<sup>215</sup> NAT’L INST. ON DRUG ABUSE, MISUSE OF PRESCRIPTION DRUGS 3 (2018), <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/2609-misuse-of-prescription-drugs.pdf>.

<sup>216</sup> SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., BEHAVIORAL HEALTH TRENDS IN THE UNITED STATES: RESULTS FROM THE 2014 NATIONAL SURVEY ON DRUG USE AND HEALTH 1 (2015), <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>.

<sup>217</sup> See Schwarz, *Selling Attention Deficit Disorder* *supra* note 157.

<sup>218</sup> See Matthew G. Kirkpatrick et al., *Comparison of Intranasal Methamphetamine and D-Amphetamine Self-Administration by Humans*, 107 ADDICTION 783, 783 (2012); Carl L. Hart, *Neuroscientist: Meth Is Virtually Identical to Adderall — This Is How I Found Out*, INFLUENCE (Feb. 10, 2016), <http://theinfluence.org/neuroscientist-meth-is-virtually-identical-to-adderall-this-is-how-i-found-out/> (noting that “methamphetamine and d-amphetamine are both FDA-approved medications to treat ADHD” and that “methamphetamine produces nearly identical effects to those produced by the popular ADHD medication d-amphetamine (dextroamphetamine)” — i.e., Adderall).

<sup>219</sup> Schwarz, *Selling Attention Deficit Disorder*, *supra* note 157.

anxiety? Or would this constitute an abuse of the physician's prescribing power that would render her a criminal? Would it be permissible to prescribe cannabis to enhance a patient's level of sexual desire?<sup>220</sup> If not, why can physicians lawfully prescribe another drug, Addyi, which the FDA approved specifically for this purpose?<sup>221</sup> If an alcoholic patient finds that he drinks considerably less when he has cannabis available as an alternative — and thereby greatly enhances both his health and his quality of life — could a physician lawfully prescribe cannabis for that purpose? How can we distinguish therapeutic practices from recreational drug use when the recreational uses have therapeutic value and the therapeutic uses have recreational value?

This is not a purely academic question. After the FDA approved Marinol, a cannabis-derived pharmaceutical, the DEA initially assigned the drug to Schedule II and issued a "Statement of Policy" warning that any physician who prescribed the drug "for medical indications outside the approved use associated with cancer treatment" could face criminal sanctions and de-registration of her prescribing authority.<sup>222</sup> Although it is doubtful that the Controlled Substances Act grants the DEA authority to unilaterally ban all off-label uses of an FDA-approved drug,<sup>223</sup> the Agency clearly has the authority to prosecute physicians for prescribing a drug without a legitimate medical purpose. Hence, if cannabis were moved to Schedule II, it would be imperative for doctors and patients to understand the purposes for which the drug may be

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<sup>220</sup> See generally Green, et al., *supra* note 20, at 456 (noting increased sexual arousal and decreased anxiety as endorsed effects reported by cannabis users); Ingraham, *supra* note 20 ("Regular marijuana users have about 20 percent more sex than abstainers, according to a new study from researchers at Stanford University.").

<sup>221</sup> Addyi, *supra* note 21.

<sup>222</sup> Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy, 51 Fed. Reg. 17,476 (proposed May 13, 1986) (to be codified at 21 C.F.R. pt. 1308). The DEA was concerned that there was a "significant risk that Marinol would be dispensed by physicians for improper purposes, rather than the accepted use recognized by the FDA, and that practitioners might 'attempt to justify illegal or improper distribution or dispensing by claiming unique knowledge of [the] drug's effectiveness for a broad range of medical indications.'" Brief for Petitioners at 30, *Gonzales v. Oregon*, 546 U.S. 243 (No. 04-623), 2005 WL 1126079, at \*30 (citing 51 Fed. Reg. at 17,477).

<sup>223</sup> See Edward Lowenstein & Sidney H. Wanzer, *Attorney General's Intrusion into Clinical Practice*, 346 N. ENG. J. MED. 1918, 1918-19 (2002) ("This action was controversial at the time and of dubious legality; since it was never challenged in court, the question of its legality remains open.").



lawfully prescribed. The incantation that a prescription must have a “legitimate medical purpose” provides no such guidance.

#### IV. REGULATING DRUGS IN THE ERA OF MEDICAL CONSUMERISM

The difficulty of distinguishing therapeutic practices from recreational drug use — at a time when drugs are prescribed for an ever-broadening array of reasons — demonstrates the folly of attempting to define legitimate medical practice by reference to the purposes for which patients use medical interventions. Medicine cannot be confined to a narrow set of specific aims. Rather, as philosopher of medicine Christopher Boorse has argued, the goals of medicine can only be defined very broadly as “[u]sing biomedical knowledge or technology in the best interests of the patient.”<sup>224</sup> As bioethicist Tom Beauchamp contends:

If beneficence is a general moral principle (and it is), and if physicians are positioned to supply many forms of benefit (and they are), then there is no manifest reason to tie physicians’ hands or duties to the single benefit of healing. Patients and society may, with good reason, regard cosmetic surgery, sleep therapies, assistance in reproduction, genetic counseling, hospice care, physician-assisted suicide, abortion, sterilization, and other actual or potential areas of medical practice as important benefits that only physicians can safely and efficiently provide. These activities are not forms of healing . . . .<sup>225</sup>

In other words, what distinguishes “medical” practices from other kinds of interventions is not primarily the kinds of *ends* being pursued, but whether certain *means* are being used to achieve those ends. In this view we can think of medicine as involving a broad range of knowledge and interventions — especially, but not exclusively, those rooted in biology and biochemistry<sup>226</sup> — with respect to which we have entrusted a particular set of trained professionals with responsibility for delivering and overseeing their use. Although many interventions act on human physiology (food, exercise, etc.), some types of interventions merit a

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<sup>224</sup> Boorse, *supra* note 22, at 170, 173.

<sup>225</sup> Tom L. Beauchamp, *Internal and External Standards for Medical Morality*, 26 J. MED. & PHIL. 601, 603 (2001).

<sup>226</sup> As Peter Schwartz notes in response to Boorse’s conception of the goals of medicine, some common physician practices, such as psychiatric talk therapy or even simply “comfort[ing] a suffering patient by listening to him empathetically” are not applications of biomedical knowledge or technology. Schwartz, *supra* note 59, at 202.

heightened degree of regulation because they pose greater risks to consumers or are more difficult for laypeople to understand and use safely.<sup>227</sup> This regulation includes deputizing as gatekeepers certain professionals who have extensive knowledge and training regarding these interventions and human physiology.<sup>228</sup>

This expansive definition of medicine's aims argues for giving physicians broad latitude to prescribe drugs when, in their professional judgment, doing so is likely to promote their patients' well-being — with "well-being" defined in large part by patients themselves.<sup>229</sup> Although the vast majority of medical interventions may be applied with the aim of treating and preventing illnesses, it is also legitimate to apply medical technology to produce other kinds of benefits, including enhancing appearance, cognition, and social functioning.

As described below, this broader understanding of medicine would not require abandoning efforts to police doctors' prescribing powers or to mitigate the harms of drug abuse. Instead it would provide clarity regarding the kinds of physician conduct that violate drug trafficking laws and open the door to new ways to regulate drug use.

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<sup>227</sup> This is an important justification for requiring drug-makers to demonstrate a drug's safety and efficacy and obtain FDA approval before marketing it to consumers, unlike other consumer products. See Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1, 7-8 (2007) ("The standard justification for drug regulation is a perceived market failure . . . . This market failure results from information imperfection: customers' inability to obtain full information about the benefits and risks of new drugs . . . . While such imperfections characterize many consumer products, the potentially severe and irreversible threats to human health from drug consumption justify extensive government intervention beyond the general domains of tort law or consumer protection law. Seen in this light, drug regulation is essentially paternalistic because it seeks to protect the misinformed consumer from better-informed sellers.").

<sup>228</sup> As Schwartz observes, "In cases where medical professionals have specialized skills and a monopoly on using them, as for surgery and prescription of medication currently, there may be times when only medical practitioners are available to use these skills in situations where society supports their use even though there is no disease present or threatened. For instance, a society may wish to allow plastic surgery, and may license medical professionals to step beyond their usual goals to provide it. If not the surgeons, then who? Similarly, for the prescription of enhancement medications." Schwartz, *supra* note 59, at 203.

<sup>229</sup> Although patients necessarily decide which interventions they wish to use, physicians are by no means legally or morally obligated to provide any intervention a patient requests. Rather, "[t]he physician is an independent moral agent, committed to the internal morality of medicine, not a tool at the command of the autonomous patient." Franklin G. Miller & Howard Brody, *Professional Integrity and Physician-Assisted Death*, 25 HASTINGS CTR. REP. 8, 14 (1995).

*A. Narrow Criminal Liability for Improper Prescribing*

Defining medicine broadly as using biomedical knowledge and technology to benefit patients does not require allowing doctors to prescribe controlled substances however they wish. It does, however, require clarifying the kinds of prescribing practices that run afoul of the CSA.

As an initial matter, in light of changes in the medical marketplace over the past fifty years, courts should revisit whether CSA regulations governing prescriptions are too vague to give physicians fair notice of which conduct is proscribed.<sup>230</sup> If it was ever clear what “legitimate medical purpose” meant, the term has become increasingly nebulous as the scope of medicine has expanded to encompass a broad range of nontherapeutic practices.<sup>231</sup> Certainly the argument advanced by the Fifth Circuit in dismissing a vagueness challenge — that “[a] physician is restricted to dispensing or prescribing drugs in the bona fide treatment of a patient’s disease” — is no longer remotely tenable.<sup>232</sup> If courts cannot clearly identify which physician conduct violates the CSA, it is unreasonable to expect doctors to be able to do so.

Even if the CSA’s prescription provisions are not so vague as to violate the Fifth Amendment, courts should recognize the shortcomings of the standards they have historically applied and revise them to better reflect Congress’ intentions in enacting the law. Indeed, courts have failed to update these standards in light of the Supreme Court’s conclusion in *Gonzales v. Oregon* that, in enacting the CSA, Congress did not intend to empower the DEA to become the arbiter of the bounds of legitimate medicine.<sup>233</sup>

As the Court observed in *Gonzales*, “when Congress wants to regulate medical practice in the given scheme, it does so by explicit statutory language.”<sup>234</sup> For example, in enacting the CSA Congress clearly barred doctors from prescribing Schedule I drugs for any purpose.<sup>235</sup> Congress has likewise expressly restricted the purposes for which human growth hormone may be prescribed, adding a provision to the Federal Food, Drug, and Cosmetic Act that prohibits distributing the hormone “for

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<sup>230</sup> See *Rabe v. Washington*, 405 U.S. 313, 315 (1972) (per curiam) (“To avoid the constitutional vice of vagueness, it is necessary, at a minimum, that a statute give fair notice that certain conduct is proscribed.”).

<sup>231</sup> See Hoffmann, *supra* note 23, at 291 (“[T]he standard is arguably vaguer today than it was thirty years ago.”).

<sup>232</sup> See *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973).

<sup>233</sup> *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

<sup>234</sup> *Id.* at 246.

<sup>235</sup> See 21 U.S.C. § 812(b)(1)(B) (2019).

any use in humans other than the treatment of a disease or other recognized medical condition” for which the drug has been approved by the Secretary of Health and Human Services.<sup>236</sup> Similarly, in passing the Drug Addiction Treatment Act of 2000 (“DATA”), Congress expressly granted the Secretary of Health and Human Services the authority to “determine the appropriate methods of professional practice in the medical treatment of narcotic addiction . . . .”<sup>237</sup>

In *Gonzales*, the Court determined that the lack of similar explicit language elsewhere in the CSA showed that Congress did not intend that statute to become a vehicle for regulating medicine in general.<sup>238</sup> Instead, the Act “regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood.”<sup>239</sup> Consistent with the Court’s interpretation of the Act, physicians should not be convicted under the CSA simply for prescribing in ways that violate professional standards or for negligently allowing patients to misuse or divert their medications.<sup>240</sup> Rather, as Diane Hoffmann has proposed, the key question should be whether, in writing prescriptions for controlled substances, a physician acted *as a doctor* or abandoned that role in favor of becoming a drug trafficker.<sup>241</sup>

Even in our consumer-driven medical marketplace, doctors retain legal and ethical duties toward patients — often described as fiduciary in nature<sup>242</sup> — that require them to use their knowledge and judgment

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<sup>236</sup> *Id.* at § 333(e)(1).

<sup>237</sup> 42 U.S.C. § 290bb–2a (2019).

<sup>238</sup> *Gonzales*, 546 U.S. at 270.

<sup>239</sup> *Id.*; *see also* 21 U.S.C. § 903 (“No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.”); Statement of Attorney Gen. Janet Reno, *supra* note 99 (“There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state’s determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs except for certain specific regulations dealing with the treatment of addicts.”).

<sup>240</sup> Hoffmann, *supra* note 23, at 305-06.

<sup>241</sup> *See id.* at 286.

<sup>242</sup> Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 489 (2002) (“[N]umerous courts and commentators have classified physicians as fiduciaries and imposed on them a variety of obligations and liabilities.”).

to promote patients' well-being and to avoid harming patients.<sup>243</sup> These norms are what Leib and Galoob refer to as "deliberation sensitive," meaning they "bear upon what goes on inside people's heads" by "demanding that [fiduciaries] have or form certain attitudes and that [they] think or deliberate in certain ways."<sup>244</sup> Acting as a physician requires making decisions that are the product of deliberation shaped by the patient's interest.<sup>245</sup> Rather than prosecuting doctors simply for prescribing in ways that fall below professional standards, to convict a physician under the CSA prosecutors should have to prove that the doctor abandoned her role as protector of the patient's interest and instead used her prescription-writing authority to generate illicit profits.

Courts have often acknowledged prescribing for profit as an important consideration in physician prosecutions under the CSA — sometimes implicitly and other times explicitly. When first presented with a question about the CSA's reach in *United States v. Moore*, the Supreme Court noted that "[i]mplicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician.'"<sup>246</sup> Hence, the Court concluded the CSA imposes criminal penalties on doctors "who sold drugs . . . 'primarily for the profits to be derived therefrom.'"<sup>247</sup> More recently the Ninth Circuit concluded that "[a]

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<sup>243</sup> See Ethan J. Leib & Stephen R. Galoob, *Fiduciary Political Theory: A Critique*, 125 YALE L.J. 1820, 1826 (2016) ("The fiduciary is obligated to prioritize the beneficiary's interests over her own."). As Boorse notes, the notion that medicine's legitimate purposes are very broad "leaves intact two canons of medical ethics: the duty of doctors not to harm their patients, and their duty to use their own judgment in deciding what is harm." Boorse, *supra* note 22, at 174. Boorse further notes that "[t]hese duties are not limited to medicine. In all fiduciary relationships, as opposed to 'arm's-length' transactions, the professional has a moral and legal duty to act in the client's interest, consistently with his own best judgment." *Id.* at 174 n.52.

<sup>244</sup> Leib & Galoob, *supra* note 243, at 1829 (citing GEOFFREY BRENNEN ET AL., EXPLAINING NORMS 193, 245 (2013)).

<sup>245</sup> See *id.* ("A fiduciary whose deliberation is not shaped by the beneficiary's interests does not live up to the duty of loyalty . . ."); see also BARRY R. FURROW ET AL., LAW AND HEALTH CARE QUALITY, PATIENT SAFETY, AND MEDICAL LIABILITY 159 (7th ed. 2013) (defining a health care fiduciary as "someone who commits to becoming and remaining scientifically and clinically competent, acts primarily to protect and promote the interests of the patient and keeps self-interest systematically secondary, and maintains and passes on medicine as a public trust for current and future physicians and patients").

<sup>246</sup> *United States v. Moore*, 423 U.S. 122, 141 (1975) (emphasis added).

<sup>247</sup> *Id.* at 135 (quoting H.R. REP. NO. 91-1444, at 10 (1970)); see also *United States v. Katz*, 445 F.3d 1023, 1028 (2006) (emphasis added) ("A prosecution under §841 requires 'proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was

practitioner becomes a criminal not when he is a *bad* or *negligent* physician, but when he ceases to be a physician *at all*.<sup>248</sup> Similarly, in its later-disavowed FAQ, the DEA claimed that it sought to pursue only physicians who “knowingly and intentionally prescribe opioid medications *for profit or other personal gain*.”<sup>249</sup>

Many successful prosecutions under the CSA involve precisely this kind of conduct. For example, in *United States v. Singh*, a physician pre-signed blank prescriptions and allowed non-physician employees (who were neither legally authorized to prescribe drugs nor trained to evaluate patients) to fill in the drug types, dosages, and quantities, and provide the prescriptions to patients.<sup>250</sup> This practice allowed the physician to profit from prescriptions provided to patients — including “at least 76,000 tablets of Schedule II Controlled Substances” — without even having to be present at the office.<sup>251</sup> In *United States v. Moore*, the defendant prescribed drugs without first examining patients and without regulating the dosages prescribed. Instead, he prescribed as much and as frequently as the patient requested.<sup>252</sup> Dr. Moore “used a ‘sliding-fee scale’ pegged solely to the quantity prescribed, rather than to the medical services performed.”<sup>253</sup> In both of these cases it is clear that, in making their prescribing decisions, the physicians were not reasoning as a medical fiduciary should. The problem is not merely that the defendants breached the standard of care by acting outside the “usual course of practice,” but that their motive was to use their prescribing power for personal gain.

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being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, *i.e. the personal profit of the physician.*”).

<sup>248</sup> *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006).

<sup>249</sup> DEA 2004 FAQ, *supra* note 48, at 93 (emphasis added).

<sup>250</sup> *United States v. Singh*, 390 F.3d 168, 176 (2d Cir. 2004).

<sup>251</sup> Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006) (citing *Singh*, 390 F.3d 168).

<sup>252</sup> *Moore*, 423 U.S. at 142-43. *See generally* *United States v. Rosen*, 582 F.2d 1032, 1035-36 (noting that in many cases affirming convictions of physicians under the CSA, courts have seized on the fact that the defendant did not conduct any examination of her patients before prescribing controlled substances); *Katz*, 445 F.3d at 1027-28 (in affirming the defendant’s conviction under the CSA, the court emphasized the physician’s practice of prescribing narcotics without first examining patients).

<sup>253</sup> *Moore*, 423 U.S. at 126. *See generally* Robert A. Smith, M.D., Revocation of Registration, 70 Fed. Reg. 33,207 (June 7, 2005) (defendant physician wrote prescriptions to individuals he had not examined, charged patients a \$65 fee for each office visit plus an additional \$100 for prescriptions, and asked one patient for sexual favors in exchange for prescriptions).

Although courts have acknowledged that illicit gain is an important factor in convictions under the CSA, they have also repeatedly allowed physicians to be convicted without any showing that the defendants prescribed controlled substances for illicit personal gain.<sup>254</sup> For example, in *United States v. Ignasiak*, the Eleventh Circuit endorsed the conviction of a physician for improper prescribing of narcotics.<sup>255</sup> At trial, the prosecution's theory focused on the volume of controlled substances he prescribed — both to individual patients and overall — and the adverse effects his practices had on some patients.<sup>256</sup> In rejecting Dr. Ignasiak's challenge to the sufficiency of the evidence against him, the appellate court did not point to evidence indicating the defendant had ceased to act as a doctor. On the contrary, the evidence recited by the court showed that Dr. Ignasiak examined his patients before prescribing them medications, treated them for a broad range of conditions with a variety of non-narcotic medications, and repeatedly took steps to protect against addiction and abuse.<sup>257</sup> The court noted that all of the patients referenced in the indictment in fact suffered from "illnesses or conditions that caused them pain, anxiety and/or depression, ailments that could well have justified the use of controlled substances within the range of discretion accorded physicians."<sup>258</sup> As for whether Dr. Ignasiak's prescribing practices fell within that range of discretion, the government's own expert testified — and the government did not dispute — that "Ignasiak's prescriptions never exceeded the diagnosis-specific dosages and quantities listed in the Physician's Desk Reference ('PDR'), a compilation of all medications, monographs, and FDA approval limitations."<sup>259</sup> Nevertheless, the court concluded the evidence was sufficient to support criminal liability under the CSA, endorsing a theory of prosecution that appeared to sound in mere negligence — i.e., that Dr. Ignasiak was "on notice" that his prescribing practices were harming patients and that, based on some of his patients' abuse of the narcotics he prescribed, the doctor should

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<sup>254</sup> See Hoffmann, *supra* note 23, at 306 (noting that courts have routinely allowed doctors to be convicted despite that fact that "prosecutors have generally not provided evidence of financial gain or other benefit on the part of the physician, other than office fees, nor evidence of intent to divert"). Hoffmann cites numerous cases illustrating this trend. *Id.* at 239-56.

<sup>255</sup> *United States v. Ignasiak*, 667 F.3d 1217 (11th Cir. 2012). Although the court overturned the conviction on other grounds, it rejected the defendant's argument that the evidence against him was insufficient to support his conviction. *Id.* at 1220, 1229.

<sup>256</sup> *Id.* at 1219, 1236.

<sup>257</sup> *Id.* at 1220-21, 1223, 1226.

<sup>258</sup> *Id.* at 1228.

<sup>259</sup> *Id.* at 1227.

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have known “that perhaps there was something wrong with the way that he was prescribing controlled substances.”<sup>260</sup>

Although evidence that a doctor breached professional standards — e.g., by repeatedly failing to detect or guard against misuse or diversion by patients — could help support an inference that a physician acted as a trafficker, it should not be sufficient on its own to establish criminal liability. Rather, such evidence should be relevant only to the extent it helps establish that the defendant had ceased to act as a physician in order to profit from drug trafficking.<sup>261</sup> As Hoffmann argues, poor prescribing practices should not establish criminal liability under the CSA unless accompanied by evidence that “the physician received a tangible benefit (in excess of ordinary fees) for his prescribing.”<sup>262</sup> This proposed standard:

would change the nature of the evidence and expert testimony required for successful prosecution from one where physicians are called upon to testify to the defendant’s lack of conformance with current standards of practice to one where evidence of financial gain or other benefit is put forward to establish intent or knowledge.<sup>263</sup>

Narrowing the scope of criminal liability under the CSA would not preclude holding doctors accountable for prescribing practices that harm patients. The law provides multiple robust means of policing doctors whose practices fall below professional standards. The medical profession sets standards for appropriate practice and every state empowers medical licensing boards to oversee physicians’ conduct to ensure that they are adhering to those standards.<sup>264</sup> Physicians whose

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<sup>260</sup> *Id.* at 1236.

<sup>261</sup> *Cf.* Hoffmann, *supra* note 23, at 306.

<sup>262</sup> *Id.* Curiously, however, Hoffmann would require not only prescribing for profit, but also a showing that the physician had “knowingly or intentionally prescribed a controlled substance for a non-medical purpose or a purpose not authorized by law.” *Id.* It is surprising that Hoffmann endorses this concept of “non-medical purpose” after having convincingly argued that this language is irredeemably vague. *Id.* at 291. In any event, given that Hoffmann argues doctors should not be prosecuted “in the absence of some kickback or tangible benefit . . . , or incontrovertible evidence that the doctor has simply exercised no medical judgment at all,” it is not clear what work the reference to a “non-medical purpose” performs in her proposed standard. *Id.* at 286.

<sup>263</sup> *Id.* at 306.

<sup>264</sup> As Hoffmann argues, a narrower standard for prosecutions under the CSA “should be accompanied by more aggressive action on the part of state medical boards to weed out physicians who are engaging in prescribing practices that are unsafe, inappropriate, or inconsistent with prevailing standards of care.” *Id.* at 307. Hoffmann further notes that “[s]tate medical boards are certainly better equipped to determine



prescribing practices violate professional norms can have their medical licenses suspended or revoked. In addition, patients who suffer harm as a result of physicians' improper prescribing can hold doctors civilly liable via state law negligence claims. Moreover, Congress and the states can, and often do, directly restrict the scope of permissible medical practice through statutes that expressly place certain practices out of bounds — just as federal law limits the uses for which doctors may prescribe human growth hormone and many states prohibit physicians from prescribing drugs to assist with suicide.<sup>265</sup> But the Controlled Substances Act does not empower the DEA to define the legitimate aims of medicine.<sup>266</sup> Physicians should not face the draconian penalties imposed on drug traffickers absent evidence they have used their prescription-writing authority to pursue illicit profits.

*B. Construe the Benefits of Medical Interventions Broadly*

Acknowledging that medications are routinely prescribed without therapeutic purposes also reveals that the CSA's approach to scheduling drugs is arbitrary and incoherent. If the goal of the scheduling regime is to protect public health and welfare, restrictions should be calibrated according to the balance of risks and benefits each drug presents. Instead, the current regime simply dismisses the benefits of certain drugs as “nonmedical” in nature, even when other drugs are lawfully prescribed to produce similar benefits.

The key dividing line between banned and legal drugs is not how dangerous a drug is to users, but the supposed presence or absence of an “accepted medical use.”<sup>267</sup> For example, opioids are both highly addictive and dangerous to users, as is amply demonstrated by the current public health crisis of opioid addiction.<sup>268</sup> Yet because opioids have an accepted use in treating pain, the CSA did not bar doctors from

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whether the volume and dosages of opioids prescribed for a patient are consistent with acceptable medical practice than are federal and state prosecutors. Moreover, state medical boards have taken action in numerous cases where physicians have improperly prescribed opioids.” *Id.* at 307-08.

<sup>265</sup> 21 U.S.C. § 333(e)(1) (2019); See Lawrence O. Gostin & Anna E. Roberts, *Physician Assisted Dying: A Turning Point?*, 315 JAMA 249 (2016). “Even though regulation of health and safety is ‘primarily, and historically, a matter of local concern,’ there is no question that the Federal Government can set uniform national standards in these areas.” *Gonzales v. Oregon*, 546 U.S. 243, 271 (2006) (citing *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)).

<sup>266</sup> See *Gonzales*, 546 U.S. at 270.

<sup>267</sup> See 21 U.S.C. § 812(b)(1); Kreit, *supra* note 29, at 357.

<sup>268</sup> See, e.g., Anne Schuchat, Debra Houry & Gery P. Guy, Jr., *New Data on Opioid Use and Prescribing in the United States*, 318 JAMA 425 (2017).

writing 214 million opioid prescriptions in 2016 — enough to medicate every American around the clock for three weeks.<sup>269</sup>

Conversely, drugs that pose much lower health risks and little to no potential for addiction are banned entirely because they are deemed to lack medical uses. For example, a 2004 study funded by the National Institute on Drug Abuse acknowledged that hallucinogens like psilocybin are not toxic and “do not engender drug dependence or addiction.”<sup>270</sup> A 2010 analysis that examined the harms of various psychotropic drugs across a broad range of variables — including potential for dependence, drug-related mortality, harm to physical health, harm to mental functioning, damage to relationships, and criminality — determined that psilocybin produces one-fifth as much harm to users and society as methamphetamine (a Schedule II drug) and one-twelfth as much harm as alcohol (which has no schedule at all).<sup>271</sup> Yet psilocybin cannot be lawfully prescribed because it is deemed to lack an accepted medical use.

However, the CSA does not define “currently accepted medical use,” nor does it provide useful guidance regarding how the phrase should be interpreted.<sup>272</sup> As described above, it is clear that medical uses are not limited to therapeutic practices.<sup>273</sup> Yet if what distinguishes “medical” uses from illicit abuse is not the distinction between therapeutic and nontherapeutic uses, the drug enforcement regime offers no alternative definition or principle with which to make this distinction.

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<sup>269</sup> U.S. *Opioid Prescribing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited July 16, 2019); see also *Opioid Prescribing*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vitalsigns/opioids/index.html> (last visited July 16, 2019).

<sup>270</sup> David E. Nichols, *Hallucinogens*, 101 PHARMACOLOGY & THERAPEUTICS 131, 134 (2004).

<sup>271</sup> David J. Nutt, Leslie A. King & Lawrence D. Phillips, *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 LANCET 1558, 1560-61 (2010).

<sup>272</sup> See, e.g., Kreit, *supra* note 29, at 349 (“The CSA does not define ‘currently accepted medical use in treatment in the United States’ with the exception of the term ‘United States,’ which ‘means all places and waters, continental or insular, subject to the jurisdiction of the United States.’”); *id.* at 349-50 (indicating that in 1992, DEA director Robert C. Bonner acknowledged, “[r]egrettably, . . . the Controlled Substances Act does not speak directly to what is meant by ‘currently accepted medical use’”) (citing Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,503 (Mar. 26, 1992)); *id.* at 344 (“Shortly after passage of the CSA . . . an internal Department of Health, Education, and Welfare memo . . . worried the CSA’s scheduling scheme would ‘provide little practical guidance in deciding particular cases’ in part because the law left ‘undefined the concepts of drug abuse potential, of drug dependence, and of risk to public health.’”) (quoting *United States v. Pastor*, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975)).

<sup>273</sup> See *supra* Part IV.A.

This lack of clarity is even more evident in drug enforcement agencies' tautological definition of "abuse." In order to place a drug in Schedule I, the DEA must determine not only that it lacks a "currently accepted medical use," but that it also possesses a "high potential for abuse."<sup>274</sup> Once again the CSA does not define this phrase, nor has its meaning been tested by courts.<sup>275</sup> The DEA clearly does not limit this category to addictive drugs, since Schedule I includes several drugs that have either no addictive properties or relatively low dependence potential.<sup>276</sup> Instead, drug control agencies have defined "abuse" as any "nonmedical" use of a drug, and have in turn defined "nonmedical" use as any use without a prescription.<sup>277</sup>

According to this circular logic, any use of cannabis — whether for relieving pain or treating seizure disorders — is "nonmedical" because cannabis cannot be lawfully prescribed for any purpose. If any and all use of cannabis is, by definition, nonmedical, then the fact that many people consume the drug without a prescription shows it has a "high potential for abuse" — which in turn justifies barring cannabis from being prescribed for any purpose. As the federal government has argued in defending the placement of cannabis in Schedule I, "the drug has a 'high potential for abuse,' in that millions of Americans use marijuana

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<sup>274</sup> 21 U.S.C. § 812(b)(1) (2019). According to the text of the CSA, in order to place a drug in Schedule I the DEA must also find there is "a lack of accepted safety for use . . . under medical supervision." *Id.* However, "the CSA's legislative history has been cited for the proposition that the first two criteria — the potential for abuse and the medical applications of a drug — are the major bases for classification. Indeed, for Schedule I substances, the DEA's current position appears to be that the third criteria is not, in fact, an independent required finding at all." Kreit, *supra* note 29, at 351 (internal quotation omitted).

<sup>275</sup> Kreit, *supra* note 29, at 348 ("Is data that a large number of people use a substance recreationally evidence of a 'high potential for abuse'? Or, does relative abuse potential turn on factors like problematic use and addiction? Is it based on the potential harms that use might cause? Like many aspects of the CSA, these questions remain largely untested in the courts, though overall use rates and comparisons to already-scheduled substances have been common features in the DEA's scheduling findings.").

<sup>276</sup> See MACK & JOY, *supra* note 208, at 50, 58 ("[M]arijuana's abuse potential appears relatively small and certainly within manageable limits for patients under the care of a physician . . . . To our knowledge no marijuana user has ever died of such an overdose."); Nichols, *supra* note 270, at 134 ("In contrast to many other abused drugs, hallucinogens do not engender drug dependence or addiction and are not considered to be reinforcing substances."); David J. Nutt, Leslie A. King & David E. Nichols, *Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation*, 14 NATURE REV. NEUROSCIENCE 577, 578 (2013) (noting that "there is no evidence that psychedelics have addictive properties, and in fact, LSD has been used successfully to treat other addictions . . . . MDMA similarly has low dependence potential").

<sup>277</sup> See *supra* Part III.B.

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on their own initiative rather than on the basis of medical advice.”<sup>278</sup> In other words, because people use the drug without a prescription, no prescriptions should be permitted.

With respect to drugs that are particularly addictive, the notion that high rates of use may signal danger seems reasonable. We may worry that people seek out these drugs not because they truly benefit from them — or even subjectively believe they benefit from them — but because users find it hard to stop taking these drugs even when they are threatening users’ health and ruining their lives.<sup>279</sup> But this logic does not hold when applied to drugs that are not particularly addictive. On the contrary, the same principles of self-determination that support patients’ rights to accept or decline medical treatments suggest we should afford these decisions considerable deference.<sup>280</sup>

The principle of informed consent that lies at the core of medical ethics is grounded in the idea that competent individuals have the right to determine what happens to their own bodies.<sup>281</sup> This does not mean patients have an inviolable right of access to any medical intervention they may wish to use. But it does suggest that if many people believe a particular drug provides them benefits, by default we should attribute rationality to that conclusion — rather than pointing to high demand for a drug as conclusive evidence that it is dangerous. In other words, perhaps if many people consume a non-addictive drug without prescriptions, rather than viewing this as proof that the drug poses a high potential for “abuse,” we should make the opposite inference —

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<sup>278</sup> Nat’l Org. for Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 140 (D.D.C. 1980). A House Committee report accompanying the bill that became the CSA similarly suggested that the fact that “[i]ndividuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner” should be a basis for determining that a substance has a high potential for abuse. H.R. REP. NO. 91-1444, at 4601 (1970), as reprinted in 1970 U.S.C.C.A.N. 4566, 4601-02.

<sup>279</sup> See, e.g., Johnna Medina, *Symptoms of Substance Use Disorder*, PSYCHCENTRAL, <https://psychcentral.com/disorders/addictions/substance-use-disorder-symptoms/> (last updated May 17, 2016) (noting that current DSM criteria for substance use disorder include such factors as consistently failing to control one’s consumption and continuing to consume the drug even when it results in failure to fulfill major obligations, damages relationships, and/or harms the user’s health).

<sup>280</sup> See, e.g., *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”).

<sup>281</sup> See RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 8 (1986).

i.e., that widespread use is prima facie evidence that users derive some value from these practices.<sup>282</sup>

To illustrate, imagine that the drugs known as selective serotonin reuptake inhibitors (“SSRIs”) — antidepressants like Prozac — were assigned to Schedule I, so that these drugs could not be lawfully prescribed for any purpose. If depressed people discovered that SSRIs relieved their symptoms but they could not obtain these drugs by prescription, many might be moved to purchase these drugs on the black market. Under the logic of the current drug control regime, the fact that many people used SSRIs without a prescription would be evidence that these drugs pose a high risk of abuse. But it would be far more reasonable to conclude that the demand for this non-addictive drug<sup>283</sup> strongly suggests that it offers meaningful benefits to users.

If the goal of drug regulation is to promote public welfare, it is critical to have a clear and unbiased understanding of the potential costs and benefits of various drugs. That analysis cannot be conducted competently — or even in good faith — while assigning zero value to drug effects that many people clearly do find valuable. Rather than arbitrarily dismissing the potential benefits of banned drugs as “nonmedical” in nature, we should seek to understand those benefits and the countervailing risks, using dispassionate, science-based assessments of both.<sup>284</sup>

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<sup>282</sup> Humans have used psychoactive substances for at least 10,000 years. Christian P. Müller & Gunter Schumann, *Drugs as Instruments: A New Framework for Non-Addictive Psychoactive Drug Use*, 34 BEHAV. & BRAIN SCI. 293, 296 (2011). Epidemiological data reveal that the overwhelming majority of psychoactive drug users “are not and will never be drug addicts.” *Id.* at 294. Moreover, the instrumental use of these substances is not limited to humans, but rather is common to mammals as a class. Serge H. Ahmed, Commentary, *Toward an Evolutionary Basis for Resilience to Drug Addiction*, 34 BEHAV. & BRAIN SCI. 293, 311 (2011). Given the striking persistence of these practices across millennia and even species, it would be more reasonable to suppose they offer adaptive benefits than to assume they are inherently detrimental to human flourishing. Müller & Schumann, *supra* note 282, at 310 (arguing that “non-addictive drug use may have a number of beneficial effects on behaviors relevant for survival and reproduction, which may explain the persistence of drug use in human societies”); Daniel H. Lende, Commentary, *Drug Instrumentalization and Evolution: Going Even Further*, 34 BEHAV. & BRAIN SCI. 293, 317-18 (2011) (arguing that psychoactive drug use can provide adaptive benefits for competition and reproduction).

<sup>283</sup> *Selective Serotonin Reuptake Inhibitors (SSRIs)*, MAYO CLINIC, <https://www.mayoclinic.org/diseases-conditions/depression/in-depth/ssris/art-20044825> [<https://perma.cc/5J9Q-28JQ>] (last visited Oct. 19, 2019) (“SSRIs aren’t addictive.”).

<sup>284</sup> In practice, however, “drug regulatory decision-making in the United States over the past 150 years has often borne very little relationship to science. Many drugs are regulated in ways that belie scientific or medical evidence regarding their pharmacological characteristics.” Kimani Paul-Emile, *Making Sense of Drug Regulation*:

As an initial matter, this would require drug enforcement agencies to stop impeding research into the effects of Schedule I drugs. The DEA's history of obstructing research on Schedule I drugs has been well-documented.<sup>285</sup> These restrictions cannot be justified on the grounds that Schedule I drugs are too dangerous to study, since researchers routinely study drugs that pose much greater risks to research subjects.<sup>286</sup> Pharmaceutical companies spend billions each year testing new drugs that may pose risks not only of dependency, but of causing cancer and other serious side effects.<sup>287</sup> The vast majority of these drugs never make it to market because they are deemed insufficiently safe and/or effective.<sup>288</sup> Yet although research on dangerous, untested drugs is commonplace, federal restrictions make it exceedingly difficult, time-consuming, and costly to perform similar research on drugs that are known to have therapeutic potential, low toxicity, and little potential for addiction.<sup>289</sup> A drug policy that promotes public welfare requires more research, not less.

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*A Theory of Law for Drug Control Policy*, 19 CORNELL J.L. & PUB. POL'Y 691, 692 (2010). Jeffrey Lieberman and Daniel Shalev have similarly observed, "While the restriction of compounds with abuse potential is deployed in the interest of public health, much of the policy is not scientifically informed. Many compounds have been criminalized and effectively excluded from research without an understanding of their pharmacology and toxicology. Recent studies have demonstrated that the degree of restriction for illegal drugs does not correlate with their risk of harm, and there is no formalized process for reviewing these determinations at the national or international level." Jeffrey A. Lieberman & Daniel Shalev, *Back to the Future: Research Renewed on the Clinical Utility of Psychedelic Drugs*, 30 J. PSYCHOPHARMACOLOGY 1198, 1199 (2016). In 2015, then-incoming DEA director Chuck Rosenberg expressed uncertainty about whether marijuana is as dangerous as heroin, confessing "I'm not an expert." Steven Nelson, *New DEA Leader: Pot Probably Not as Bad as Heroin*, U.S. NEWS & WORLD REP. (July 28, 2015, 3:20 PM), <https://www.usnews.com/news/articles/2015/07/28/new-dea-leader-pot-probably-not-as-bad-as-heroin>. Rosenberg's predecessor had previously refused to answer the question while testifying before a Congressional committee. *See id.*

<sup>285</sup> *See, e.g.*, DRUG POL'Y ALLIANCE & MULTIDISCIPLINARY ASS'N FOR PSYCHEDELIC STUDIES, THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE (2014), [http://www.drugpolicy.org/sites/default/files/DPA-MAPS\\_DEA\\_Science\\_Final.pdf](http://www.drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf); JOHN HUDAK & GRACE WALLACK, CTR. FOR EFFECTIVE PUBLIC MGMT. AT BROOKINGS, ENDING THE U.S. GOVERNMENT'S WAR ON MEDICAL MARIJUANA RESEARCH (2015), <https://www.brookings.edu/wp-content/uploads/2016/06/Ending-the-US-governments-war-on-medical-marijuana-research.pdf>; Nutt et al., *supra* note 276, at 579.

<sup>286</sup> *See* Kreit, *supra* note 29, at 357.

<sup>287</sup> *See id.*

<sup>288</sup> Chi Heem Wong, Kien Wei Siah, & Andrew W. Lo, *Estimation of Clinical Trial Success Rates and Related Parameters*, BIostatistics 273, 277 (2018) (finding that fewer than 14% of all drug development programs eventually lead to FDA approval).

<sup>289</sup> *See* Kreit, *supra* note 29, at 352-58; Nutt et al., *supra* note 276.

Moreover, in studying these drugs researchers should employ a broad conception of what constitutes a benefit — one that is not limited to potential as therapies for illnesses. If there is high demand for a banned drug that has low addiction potential, evaluations of these drugs should include characterizing and cataloging the benefits that motivate people to consume the drug.

For example, researchers at Johns Hopkins have found that when healthy participants with no history of hallucinogen use were given psilocybin, nearly 80% of participants reported their experiences “increased their current sense of personal well-being or life satisfaction ‘moderately’ (50%) or ‘very much’ (29%),” while none reported negative effects on these parameters.<sup>290</sup> These effects — including “positive changes in attitudes, mood, altruism, behavior and life satisfaction” — persisted for more than a year.<sup>291</sup> In a subsequent Johns Hopkins study, healthy participants who received a single dose of psilocybin reported lasting, positive increases in their level of “openness” — a core personality trait that encompasses aesthetic appreciation, imagination, and “broad-minded tolerance of others’ viewpoints and values.”<sup>292</sup> A more recent study found that experiences with psilocybin produced long-term enhancements to subjects’ appreciation of art, music, and nature.<sup>293</sup> The researchers concluded that “[g]iven the positive changes in attitudes and values reported by a relatively large proportion of subjects, it would be tempting to conclude that hallucinogenic drugs

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<sup>290</sup> Roland R. Griffiths et al., *Psilocybin Can Occasion Mystical-type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance*, 187 J. PSYCHOPHARMACOLOGY 268, 277 (2006). Two-thirds of participants reported that the experience was “either the single most meaningful experience of his or her life or among the top five most meaningful experiences” — on par with the birth of a first child or the death of a parent. *Id.* at 276-77.

<sup>291</sup> Roland R. Griffiths et al., *Mystical-Type Experiences Occasioned by Psilocybin Mediate the Attribution of Personal Meaning and Spiritual Significance 14 Months Later*, 22 J. PSYCHOPHARMACOLOGY 1, 11(2008).

<sup>292</sup> Katherine A. MacLean et al., *Mystical Experiences Occasioned by the Hallucinogen Psilocybin Lead to Increases in the Personality Domain of Openness*, 25 J. PSYCHOPHARMACOLOGY 1453, 1454 (2011). The personality changes reported by participants “were larger in magnitude than changes in personality typically observed in healthy adults over decades of life experience.” *Id.* at 1457. The increases in openness from this single session were greater than increases produced by successful treatment with antidepressants, and comparable to another study involving “hundreds of hours of solitary meditation over the course of 3 months.” *Id.* at 1458. These effects persisted for more than a year, and were corroborated by “independent ratings from participants’ romantic partners, coworkers, and friends.” *Id.* at 1453-58.

<sup>293</sup> Erich Studerus et al., *Acute, Subacute and Long-term Subjective Effects of Psilocybin in Healthy Humans: A Pooled Analysis of Experimental Studies*, 25 J. PSYCHOPHARMACOLOGY 1434, 1447 (2011).

hold a large and presently unused potential for increasing life-satisfaction and personal growth and for assisting psychotherapy.”<sup>294</sup>

Similarly, although the current drug control regime dismisses any use of MDMA as a form of drug “abuse,” a growing body of research suggests this drug can produce enormous benefits even when used by people who are not suffering from any illness. Studies have repeatedly shown that MDMA enhances emotional empathy,<sup>295</sup> increases understanding and closeness,<sup>296</sup> and “encourages an increased thoughtfulness and contemplativeness.”<sup>297</sup> These effects could prove useful in a broad range of ways — including, for example, helping couples enhance the quality of intimate relationships.<sup>298</sup> Indeed, “before it was classified in the USA as a controlled substance, MDMA was used as an adjunct to psychotherapy by therapists because it appeared to decrease defensiveness and enhance feelings of emotional closeness.”<sup>299</sup> In one study from that period on the use of MDMA in couples therapy, “the overwhelming majority of subjects reported positive individual effects, improved well-being and the resolution of relationship problems after their therapy.”<sup>300</sup>

Although considerable research suggests psilocybin and MDMA can be used safely and effectively as therapies for a range of serious afflictions, such as PTSD and end-of-life anxiety,<sup>301</sup> the “medical use” of these drugs should not be limited to the treatment of illnesses.<sup>302</sup> True,

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<sup>294</sup> *Id.* at 1447.

<sup>295</sup> See e.g. Cédric M. Hysek et al., *MDMA Enhances Emotional Empathy and Prosocial Behavior*, 9 SOC. COGNITIVE & AFFECTIVE NEUROSCI. 1645, 1648-1651 (2014) (proving an example of a study that shows that MDMA increases emotional empathy).

<sup>296</sup> See Ben Sessa & David Nutt, *Making a Medicine out of MDMA*, 206 BRIT. J. PSYCHIATRY 4, 4 (2015).

<sup>297</sup> Ben Sessa, *Is There a Case for MDMA-assisted Psychotherapy in the UK?*, 21 J. PSYCHOPHARMACOLOGY 220, 220 (2007).

<sup>298</sup> See Carolyn Gregoire, *Why MDMA May One Day Be Used in Couples Therapy*, HUFFINGTON POST (May 1, 2015), [https://www.huffingtonpost.com/2015/05/01/mdma-therapy\\_n\\_7181200.html](https://www.huffingtonpost.com/2015/05/01/mdma-therapy_n_7181200.html).

<sup>299</sup> Matthew J. Baggott et al., *Intimate Insight: MDMA Changes how People Talk about Significant Others*, 29 J. PSYCHOPHARMACOLOGY 669, 669-70 (2015).

<sup>300</sup> Sessa, *supra* note 297, at 221 (citing George R. Greer & Requa Tolbert, *Subjective Reports of the Effects of MDMA in a Clinical Setting*, 18 J. PSYCHOACTIVE DRUGS 319 (1986)).

<sup>301</sup> See, e.g., Charles S. Grob et al., *Pilot Study of Psilocybin Treatment for Anxiety in Patients with Advanced-Stage Cancer*, 68 ARCH. GEN. PSYCHIATRY 71 (2011); Stephen Ross et al., *Rapid and Sustained Symptom Reduction Following Psilocybin Treatment for Anxiety and Depression in Patients with Life-Threatening Cancer: A Randomized Controlled Trial*, 30 J. PSYCHOPHARMACOLOGY 1165 (2016).

<sup>302</sup> Notably, indigenous inhabitants of the Americas have long used psychedelic compounds found in plants, such as peyote and ayahuasca, to induce mystical



it would be simple enough to fashion new “illnesses” — say, “Openness Deficiency Disorder” and “Intimacy Impairment Disorder” — that would render the prosocial benefits of these drugs therapeutic in nature.<sup>303</sup> But it is not clear why it would be preferable to require people to label themselves as mentally ill in order to gain access to the benefits of these interventions. Rather, just as the FDA has approved Botox for the “treatment” of frown lines and human growth hormone to make healthy children grow taller,<sup>304</sup> our systems of drug control could recognize that enhanced empathy, altruism, and life satisfaction are medical benefits even in the absence of disease. The potential for psychopharmacological interventions to be used for “the betterment of well people”<sup>305</sup> should qualify as a significant medical benefit, to be weighed — judiciously and without bias — against the potential harms of these drugs.

### C. *Regulate People and Places*

Acknowledging that some banned drugs may have legitimate uses — therapeutic or otherwise — does not require allowing these drugs to flow freely throughout society. But exposing the incoherence of the existing drug control regime does support moving away from arbitrarily banning certain drugs in favor of crafting new strategies to maximize their benefits while minimizing their risks. Those risks are products not only of the pharmacological properties of drugs themselves, but of the interaction between those properties and the contexts in which drugs are used and the characteristics of the individuals who use them.<sup>306</sup> A

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experiences. *See, e.g.*, *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006). Rather than dismissing these nontherapeutic drug uses as “abuse,” the federal government has acknowledged the importance of these practices to certain religions by carving out exemptions from the CSA for these uses. “[B]oth the Executive and Congress have decreed an exception from the Controlled Substances Act for Native American religious use of peyote.” *Id.* at 420 (citing 21 C.F.R. § 1307.31; 42 U.S.C. § 1996a(b)(1)). The United States Supreme Court has concluded that the Religious Freedom Restoration Act of 1993 bars the federal government from enforcing the CSA against an indigenous group’s use of ayahuasca. *Id.*

<sup>303</sup> Lamkin, *supra* note 4, at 559-62.

<sup>304</sup> Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1140-46 (2005).

<sup>305</sup> MICHAEL POLLAN, *HOW TO CHANGE YOUR MIND: WHAT THE NEW SCIENCE OF PSYCHEDELICS TEACHES US ABOUT CONSCIOUSNESS, DYING, ADDICTION, DEPRESSION, AND TRANSCENDENCE* 401 (2018).

<sup>306</sup> Clinical researchers have repeatedly found that extra-pharmacological factors — including in particular the personality and mindset of the user and the “physical, social, and cultural environment in which the experience takes place” — are responsible for a significant portion of how users experience a wide variety of psychoactive drugs. This

more sophisticated approach to protecting public health would broaden the focus of regulation to address these other factors.

For example, rather than banning drugs that may offer real benefits, drug enforcement efforts could instead emphasize approaches along the lines of the Risk Evaluation and Mitigation Strategies (“REMS”) employed by the FDA.<sup>307</sup> Under the Federal Food, Drug, and Cosmetic Act, once the FDA approves a drug, physicians generally may prescribe it as they see fit.<sup>308</sup> In many cases, however, the FDA determines that a particular drug poses risks that are not adequately addressed through disclosures in product labeling.<sup>309</sup> In these situations, the FDA may impose additional requirements — REMS — in order to ensure that the drug is used in ways that reduce its risks.<sup>310</sup>

REMS may take many different forms, with “specific safety measures unique to the safety risks associated with a particular drug or class of drugs.”<sup>311</sup> For example, a risk management plan may require that in order to prescribe a drug, a physician must first register with the FDA and/or have specific training or special certifications.<sup>312</sup> The plan may also require that the drug “be dispensed only in certain healthcare settings,” and/or that each patient using the drug be subject to monitoring.<sup>313</sup>

To the extent currently banned drugs pose special risks to users, similar strategies could be employed to mitigate those risks while allowing people access to these drugs’ benefits. For example, one can imagine a system in which individuals could obtain the benefits of MDMA without having to claim a mental illness, but would not simply be handed the drug and sent on their merry way. Rather, the drug could

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is often true of both therapeutic use and use by healthy individuals. Ido Hartogsohn, *Constructing Drug Effects: A History of Set and Setting*, 3 *DRUG SCI., POL’Y & L.* 1, 1-2 (2017).

<sup>307</sup> Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 *N.Y.U. J. LEGIS. & PUB. POL’Y* 69, 114 (2018).

<sup>308</sup> Zettler, *supra* note 17, at 1061. As Zettler notes, there are exceptions to this general rule, including restrictions on the conditions for which human growth hormone can be prescribed. *Id.* at 1081.

<sup>309</sup> *Id.* at 1083 (noting that the FDA currently “requires REMS for about 40% of the novel drugs that it approves”).

<sup>310</sup> See 21 U.S.C. § 355-1(d)-(f) (2019); U.S. FOOD & DRUG ADMIN., STANDARDIZING AND EVALUATING RISK EVALUATION AND MITIGATION STRATEGIES (REMS) 3 (2012), <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm415751.pdf>.

<sup>311</sup> U.S. FOOD & DRUG ADMIN., A BRIEF OVERVIEW OF RISK EVALUATION & MITIGATION STRATEGIES (REMS) 4, <https://www.fda.gov/downloads/aboutfda/transparency/basics/ucm328784.pdf>.

<sup>312</sup> 21 U.S.C. § 355-1(f)(3).

<sup>313</sup> *Id.*

be lawfully prescribed subject to a requirement that it only be administered by a specially trained physician as part of a guided therapy session.<sup>314</sup> Studies have repeatedly found that MDMA can be safely administered in this kind of setting without “any significant neurophysiological impairments or evidence of dependence following its use clinically.”<sup>315</sup> Recent research involving psilocybin has produced similar findings, concluding the drug can be safely administered “with careful volunteer screening and preparation and when sessions are conducted in a comfortable, well-supervised setting.”<sup>316</sup> Rather than focusing exclusively on the risks of these drugs and relying on prohibition to avoid them, drug control policies could acknowledge the benefits of these practices for users while minimizing their potential harms by limiting their use to certain contexts.<sup>317</sup>

Another possible approach to balancing the risks and benefits of these interventions would be to expand the targets of regulation beyond the drugs themselves to their users as well — for example, by restricting specific individuals’ access to certain drugs based on users’ risk profiles. To illustrate, under current law virtually everyone over age 21 can possess and consume alcohol, regardless of whether they have demonstrated that they can manage this privilege responsibly.<sup>318</sup> Although irresponsible alcohol use causes an astounding amount of harm to individuals and society,<sup>319</sup> banning alcohol altogether proved to incur more costs than benefits.<sup>320</sup> One can imagine an alternative regime in which individuals would be required to obtain a license to drink alcohol — a license that could be denied or revoked if, for example, the individual commits a crime while under its influence or has a history of violence or reckless driving. A similar approach could

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<sup>314</sup> Cf. Marks, *supra* note 307, at 114.

<sup>315</sup> Sessa & Nutt, *supra* note 296, at 5.

<sup>316</sup> Griffiths et al., *supra* note 290, at 281.

<sup>317</sup> That said, the risks of some banned drugs may not be sufficiently significant to justify such heightened measures. This seems to be the conclusion reached by the eleven states that have legalized “recreational” use of cannabis — i.e., that the restrictions placed on the drug imposed greater costs than benefits. *State Marijuana Laws in 2019 Map*, GOVERNING (June 25, 2019), <http://www.governing.com/gov-data/state-marijuana-laws-map-medical-recreational.html> [<https://perma.cc/5BCS-26E4>].

<sup>318</sup> There are limited exceptions. For example, courts may require convicted criminals to “refrain from excessive use of alcohol” as a condition of probation. 18 U.S.C. § 3563(b)(7) (2019).

<sup>319</sup> In a 2010 assessment of the harms various drugs impose on individual users and on society in the UK, alcohol ranked as by far the most damaging to society, as well as the most harmful overall. Nutt et al., *supra* note 271, at 1561, fig.2.

<sup>320</sup> See U.S. CONST. amend. XXI (repealing the Eighteenth Amendment, which prohibited “the manufacture, sale, or transportation of intoxicating liquors”).

be employed with respect to currently banned drugs.<sup>321</sup> Such an approach would be both more permissive and more restrictive than current law. Some drugs that are currently banned entirely could be available to people who demonstrated responsible behavior, while other drugs that are currently freely available to all adults — such as alcohol and, in several states, cannabis — would be off limits to individuals who are deemed to pose unacceptable risks.

These exploratory suggestions simply highlight the potential benefits of moving away from the narrow view imposed by the CSA, in which some drugs are deemed to have medical benefits while others are merely, inevitably, drugs of abuse. Moving beyond this dichotomy reveals a more nuanced — and more accurate — picture that can open the door to more effective approaches to harnessing the benefits of biomedical interventions while mitigating their harms.

#### CONCLUSION

In 1972, psychiatrist Gerald Klerman observed that the proliferation of drugs used to modify cognition, emotions, and behavior was giving rise to a conflict over the propriety of these practices.<sup>322</sup> Noting a disjuncture between Americans' "espoused values on abstinence and our actual behavior," Klerman framed the conflict as pitting "psychotropic hedonists," who embrace the use of drugs to enhance quality of life, against "pharmacological Calvinists," who condemn these practices as immoral.<sup>323</sup> "Given the likelihood that further advances in pharmacology will increase the effectiveness of drugs in this realm," Klerman wrote, "the values conflict for society is likely to become more intensified."<sup>324</sup>

One year later, the Calvinists scored an early win with the passage of the Controlled Substances Act which, among other goals, sought to combat the counterculture's exploding use of drugs to alter consciousness. As in the fable, however, over the following decades hedonists won the race by slowly and steadily expanding the bounds of medicine to encompass the use of drugs to obtain desired mental states.

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<sup>321</sup> I credit Rick Doblin, founder and executive director of the Multidisciplinary Association for Psychedelic Studies, for the idea of licensing drug users. See stanfordlawschool, *Developing Psychedelics & Marijuana into Prescription Meds: Cutting-Edge Research & Legal Challenges*, YOUTUBE (Feb. 22, 2013), <https://www.youtube.com/watch?v=8TXK-OPCPdg> [<https://perma.cc/2TXM-MRWL>].

<sup>322</sup> Gerald L. Klerman, *Psychotropic Hedonism vs. Pharmacological Calvinism*, 2 HASTINGS CTR. REP. 1 (1972).

<sup>323</sup> *Id.* at 3.

<sup>324</sup> *Id.*

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Psychiatry continues to bring an ever-broader range of human behavior into its orbit, even as physicians show increasing comfort with prescribing drugs to enhance quality of life in the absence of any diagnosis. As medicine has succumbed to the logic of the marketplace, decisions regarding which forms of distress warrant treatment are increasingly made by consumers.

As a result, today Americans are floating, and too often drowning, in a sea of psychoactive drugs — most of them sold by multinational corporations and prescribed by physicians. Four decades into the “war on drugs,” dozens of states treat cannabis as medicine, banned drugs seem easier to find than affordable health insurance, and the country faces the most devastating epidemic of prescription drug deaths in its history. If this is victory, one shudders to imagine what would constitute defeat.

Rather than calling in reinforcements or waving the white flag, Congress and the DEA should sue for peace. Drugs’ potential to cause serious harm is beyond question. Given the complexity of human biology and the close relationship between biomedical interventions and health, some paternalism in the regulation of drugs is amply justified.<sup>325</sup> Yet our drug control efforts have failed to keep pace with the evolving medical marketplace, yielding incoherent policies that are increasingly disconnected from the realities of contemporary medical practice. As a result, doctors face criminal prosecution without clear standards, potentially valuable interventions are arbitrarily barred from the market, and millions seek the benefits of drugs without professional medical guidance to mitigate their risks. Abandoning the drug war’s outdated dichotomies can open the door to new strategies that promote public health and welfare by balancing consumer protection with respect for individual autonomy.

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<sup>325</sup> See, e.g., Katz, *supra* note 227, at 8.