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# Regulating Identity: Medical Regulation as Social Control

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## Regulating Identity: Medical Regulation as Social Control

*Matt Lamkin* \*

*New biomedical technologies offer growing opportunities not only to prevent and treat illnesses, but also to change how healthy people think, feel, behave, and appear to others. Controversies over these nontherapeutic practices are a pervasive feature of contemporary American culture, from students on “study drugs” and cops on steroids to skin-lightening by black celebrities and the over-prescription of antidepressants. Yet the diversity of these controversies often masks their common root—namely, disputes about the propriety of using medical technologies as tools for shaping one’s identity.*

*Some observers believe these so-called “enhancement” practices threaten important values, offering unfair advantages to users and undermining their ability to lead “authentic” lives. But existing systems of medical regulation, which were designed to promote the safety of therapeutic treatments and to deter drug abuse, are largely blind to concerns beyond protecting human health. As identity-modifying practices continue to proliferate, calls are growing to restrict access to these technologies on moral grounds.*

*These proposals overlook the United States’ extensive and unfortunate experiences regulating nontherapeutic medical practices to enforce contested conceptions of morality. From Prohibition and the war on drugs to laws restricting contraceptives and abortion procedures, these efforts have been costly, ineffective, and intrusive. They have also interfered with fundamental liberties involving bodily integrity and identity—a fact that is widely recognized in the context of reproduction technologies, but largely overlooked with respect to other medical interventions. Rather than expanding our reliance on contested moral*

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*concerns in policing access to medical interventions, the U.S. should purge its existing regulation of morality-based intrusions and recommit itself to protecting human health.*

#### TABLE OF CONTENTS

INTRODUCTION .....	503
I. IDENTITY-MODIFYING INTERVENTIONS AND THEIR DISCONTENTS .....	506
A. Our Identities Are Increasingly Susceptible to Modification by Biological Interventions.....	506
1. Beauty .....	507
2. Race and ethnicity.....	508
3. Sex .....	510
4. Intelligence.....	511
5. Personality.....	514
6. Spirituality .....	516
7. Memory .....	517
B. Key Concerns About Identity-Modifying Interventions ...	519
1. Fairness and coercion .....	522
2. Agency .....	524
3. Authenticity.....	526
II. REGULATING IDENTITY-MODIFYING INTERVENTIONS .....	532
A. Existing Medical Regulation Is Largely Blind to Moral Concerns Beyond Protecting Health .....	533
1. The Federal Food, Drug, and Cosmetic Act.....	534
2. The Controlled Substances Act.....	536
3. State regulation.....	538
4. A notable exception: reproduction technology .....	541
B. Proposals to broaden the scope of medical regulation .....	542
III. THE HAZARDS OF MEDICAL REGULATION AS SOCIAL CONTROL .....	545
A. Restricting Biological Interventions on Moral Grounds Is Ineffective .....	546
1. Existing drug prohibitions are based largely on moral condemnation.....	546
2. Prohibition is costly and fails to deter forbidden practices .....	550
B. The Treatment/Enhancement Distinction Is a Poor Foundation for Regulatory Policy .....	554
C. Government Should Not Interfere with Deeply Personal Medical Decisions to Enforce Contested Moral Views .....	564

1. Many decisions regarding medical interventions are protected from undue state interference .....	564
2. Enhancement technologies can likewise implicate individual liberty in fundamental ways .....	569
CONCLUSION .....	571

## INTRODUCTION

New biomedical technologies offer growing opportunities not only to prevent and treat illnesses, but also to modify identities. Cosmetic procedures can change one's physical appearance, including altering one's sex and perceptions of one's race or age. Healthy students and professionals seek to enhance their intelligence using drugs designed to treat attention deficit disorders, while others use antidepressants not to treat depression, but to alter their personalities—to become more confident and outgoing, less anxious and brooding.

Some observers believe these identity-modifying practices threaten important values. Disparities in access to drugs that improve cognition could exacerbate economic inequalities. Using cosmetic procedures to lighten one's skin or to produce more "Western-looking" eyes can reinforce beauty standards that are infused with bigotry. Responding to feelings of sadness or anger by taking antidepressants may reduce individuals' motivation to address the life challenges and social injustices that sometimes underlie these emotions.

These concerns are qualitatively different from the key aim that ostensibly animates the United States' existing systems of medical regulation: protecting human health. The Federal Food, Drug, and Cosmetic Act seeks to protect health by ensuring that the therapeutic benefits of drugs and medical devices outweigh these products' risks. The Controlled Substances Act likewise purports to restrict access to drugs based on assessments of their health risks and therapeutic benefits. State-level regulation of medical practice, including physician licensing and malpractice statutes, aims to deter doctors from acting in ways that threaten patient health.

Because these existing regulatory systems are not designed to respond to the moral concerns raised by identity-modifying interventions—often referred to as “enhancements”<sup>1</sup>—some observers have called for expanding the scope of medical regulation to address such concerns. While these proposals vary in their particulars, they share a common core: empowering regulators not merely to protect health, but to “adjudicate among competing ethical claims”<sup>2</sup> and restrict access to biomedical interventions based on “judgments about the technology’s social and ethical implications.”<sup>3</sup> As Francis Fukuyama has argued: “What should we do in response to biotechnology that in the future will mix great potential benefits with threats that are either physical and overt or spiritual and subtle? The answer is obvious: We should use the power of the state to regulate it.”<sup>4</sup>

This article argues it is far from obvious that we should use state power to address the “spiritual and subtle” threats posed by biotechnology. Indeed, the United States’ considerable experience in restricting biomedical interventions on moral grounds provides ample reason to be skeptical of such proposals. From alcohol and drug prohibition to laws restricting contraceptives and abortion procedures, when regulation has strayed from protecting health to enforcing morals these efforts have been costly, ineffective, and intrusive. The United States would be better served by reducing, rather than expanding, its reliance on contested moral considerations in limiting access to biomedical interventions.

Part I describes how aspects of human identities are increasingly susceptible to modification by biomedical interventions, and outlines the concerns these practices raise among bioethicists and other observers. Part II describes how the United States’ existing systems of medical regulation, which ostensibly focus on protecting human

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1. CARL ELLIOTT, *BETTER THAN WELL: AMERICAN MEDICINE MEETS THE AMERICAN DREAM* xvii–xviii (2003) (defining “enhancement technologies” as “drugs and procedures that are employed by doctors not just to control illness, but also to improve human capacities or characteristics.”).

2. FRANCIS FUKUYAMA & FRANCO FURGER, *BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES* 17 (2007).

3. FRANCIS FUKUYAMA, *OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION* 214 (2002).

4. *Id.* at 10.

health, are generally blind to the broader moral concerns expressed by critics of enhancements. This part also describes several proposals to empower regulators to restrict identity-modifying practices on the basis of concerns other than protecting individuals from physical harm.

Part III offers three arguments against regulating medical interventions to enforce contested moral views. First, the abject failure of the United States' efforts to prohibit the use of alcohol and other mind-altering drugs cautions against expanding this strategy to restrict identity-modifying practices. Despite the Controlled Substances Act's purported emphasis on preserving health, in its implementation the federal government has used the Act as an instrument of social control—to enforce prevailing morality and combat social deviance. Like Prohibition before it, the “war on drugs” has been both costly and ineffective, offering a poor model for reforming the regulation of biomedical interventions.

Second, these reform proposals rest on a distinction between “therapies” and “enhancements” that is too malleable to accomplish reform advocates' goals. Proponents of expanding the scope of medical regulation call for distinguishing between interventions that treat illnesses, which would continue to be regulated on the basis of safety, and enhancements, which would be subjected to broader scrutiny and tighter restrictions. But it is remarkably easy to characterize any biomedical intervention that alleviates some form of human suffering as a treatment for a legitimate illness. Policies that singled out identity-modifying interventions for special restrictions would merely increase incentives to characterize these practices as treatments for illnesses.

Finally, some medical interventions can implicate bodily integrity and identity in profound ways. Restricting these practices is tantamount to regulating who people are allowed to become—including how we think, feel, behave, and are perceived by others. As the history of restrictions on reproductive technologies illustrates, government should not interfere with deeply personal decisions regarding one's own body and mind in order to enforce contested views of morality.

In concluding, I argue that rather than expanding our reliance on moral concerns in regulating medical technologies, the United States would be better served by purging its existing medical regulation of morality-based intrusions, whether latent or overt, and

recommitting itself to regulating medicine for the purpose of protecting human health.

I. IDENTITY-MODIFYING INTERVENTIONS AND THEIR  
DISCONTENTS

*A. Our Identities Are Increasingly Susceptible to Modification by  
Biological Interventions*

The United States' systems of medical regulation have long distinguished between two types of uses of biological interventions: therapeutic practices aimed at treating or preventing disease and disability, and the "recreational" use of psychotropic drugs. But there is another set of practices that does not rest comfortably in either of these categories: the use of biomedical interventions to enhance or otherwise modify certain features of healthy bodies and brains.

Although some of these practices date back to prehistoric times, new technologies have expanded the range of potential modifications and growing medical consumerism has spurred demand for them. Today people can use biomedical interventions to shape an ever-expanding range of physiological and psychological traits, changing how we appear to others and how we feel, behave, and think. These practices have become so ubiquitous that it is easy to overlook this increasingly prominent feature of American culture: the use of medical interventions as tools for forging our identities.<sup>5</sup>

These practices take many different forms and raise concerns that differ in both degree and type. Grouping them together is not intended to deny these differences, but to highlight what these seemingly disparate practices share in common: all of them can have profound (even if not necessarily *equally* profound) implications for individuals' sense of identity. It is often precisely that potential that worries critics and motivates proposals to regulate these practices on moral grounds.

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5. ELLIOTT, *supra* note 1, at 52–53 (“Enhancement technologies have become part of ‘the governance of the soul’ . . . the management of meaning through the management of the self.”).

### 1. *Beauty*

In 2012, Americans spent some \$11 billion to receive more than fourteen million cosmetic procedures—nearly triple the number of reconstructive procedures performed in the same period.<sup>6</sup> While cosmetic interventions are often dismissed as vain trivialities, enhancing one’s attractiveness can yield tangible benefits. People who are perceived as attractive tend to get better grades in school, earn higher incomes, and receive shorter prison sentences than their less attractive peers.<sup>7</sup>

But the demand for cosmetic procedures is not merely, or even primarily, driven by the pursuit of positional advantages. The growth of cosmetic surgery also illustrates “the tightening relationship between the body and self-identity.”<sup>8</sup> As philosopher Carl Elliott writes, cosmetic interventions can play an important role in gaining social affirmation of one’s chosen identity, by altering one’s outward appearance to match his internal sense of self. Drawing on Charles Taylor’s *The Ethics of Authenticity*, Elliott argues that “identity can never be wholly inwardly generated. It must be developed in dialogue with others.”<sup>9</sup> Modifying one’s appearance can be a way of ensuring that one’s chosen identity will be affirmed when standing in front of the “social mirror.”<sup>10</sup>

For example, Kathy Davis’ *Reshaping the Female Body* describes a woman who explained her decision to have a breast reduction by pointing to a disjuncture between the way she thought of herself and the way others perceived her.<sup>11</sup> “Big breasts are *supposed* to be sexy,”

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6. AMERICAN SOCIETY OF PLASTIC SURGEONS, 2012 PLASTIC SURGERY STATISTICS REPORT 5–6 (2012).

7. Timothy Judge et al., *Does It Pay to Be Smart, Attractive, or Confident (or All Three)? Relationships Among General Mental Ability, Physical Attractiveness, Core Self-Evaluations, and Income*, 94 J. APPL. PSYCHOL. 742, 744–55 (2009); Andrea DeSantis & Wesley Kayson, *Defendants’ Characteristics of Attractiveness, Race, and Sex and Sentencing Decisions*, PSYCHOL. REP. 81, 679–83 (1997); Irene Frieze et al., *Attractiveness and Income for Men and Women in Management*, 21 J. APPLIED SOC. PSYCHOL. 1039, 1039–57 (1991); John Salvia et al., *Attractiveness and School Achievement*, 15 J. SCH. PSYCHOL. 60 (1977).

8. CHRIS SHILLING, *THE BODY AND SOCIAL THEORY* 9 (1993).

9. ELLIOTT, *supra* note 1, at 41 (citing CHARLES TAYLOR, *THE ETHICS OF AUTHENTICITY* 47–48 (1991)).

10. *Id.* at 42.

11. KATHY DAVIS, *RESHAPING THE FEMALE BODY: THE DILEMMA OF COSMETIC SURGERY* 77–78 (1995).



she explained. “So *you* get to be a sex bomb whether you want to be or not.”<sup>12</sup> Her breast reduction allowed her to conform her outward appearance to her internal sense of her identity as “the small-breasted type.”<sup>13</sup> Similarly, in his memoir *Muscle*, Sam Fussell describes becoming drawn to steroids as a means of ensuring that others would recognize his chosen identity as a bodybuilder.<sup>14</sup> As Fussell explains, “If who you are is what you do, and as a bodybuilder, what you do is what you look like, then . . . I was distinctly in trouble, because I didn’t look like a bodybuilder.”<sup>15</sup> While Fussell participated in bodybuilding competitions, by his own telling “I was concerned far less with competition than with self-identity. As long as the part I played was simply interior, I felt like a fraud.”<sup>16</sup>

## 2. *Race and ethnicity*

Although racial categories are social, not biological facts, people can and do use biological interventions to change how others perceive their race. Like other features of identity, race is constructed through dialogue between individuals and the broader society.<sup>17</sup> This dialogue creates spaces within which individuals can engage in what Snow and Anderson have called “identity work,” deploying various strategies to construct racial identities and to have them recognized by others.<sup>18</sup> These strategies can include selectively associating with people of the individual’s chosen race, highlighting or downplaying certain cultural symbols, and selectively disclosing information about one’s racial heritage.<sup>19</sup> However, because perceptions of race are tightly connected to physical appearance, “if one’s phenotype differs significantly from socially constructed notions of what members of a

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12. *Id.* at 77.

13. *Id.* at 78.

14. SAMUEL WILSON FUSSELL, *MUSCLE: CONFESSIONS OF AN UNLIKELY BODYBUILDER* (2015)).

15. *Id.* at 122.

16. *Id.* at 123.

17. Nikki Khanna & Cathryn Johnson, *Passing as Black: Racial Identity Work Among Biracial Americans*, 73 *SOC. PSYCHOL. Q.* 380, 383 (2010) (“[R]ace and identity arise out of a social process in which meanings are created and modified through social interaction with others.”).

18. David A. Snow & Leon Anderson, *Identity Work Among the Homeless: The Verbal Construction and Avowal of Personal Identities*, 92 *AM. J. SOC.* 1336 (1987).

19. Khanna & Johnson, *supra* note 17, at 381.

particular race are expected to look like, they have considerable difficulty asserting that racial identity no matter what identity strategy they employ.”<sup>20</sup> Accordingly, one of the most important ways individuals manage their racial identities is by changing how they look.

Racial and ethnic minorities have long used biological interventions to obscure their heritage and assimilate into American culture.<sup>21</sup> In the early twentieth century, scores of Jews—and other immigrants who feared being mistaken for Jews—sought out surgery to hide “the so-called Jewish nose, a term that had found its way into popular currency by the 1920s.”<sup>22</sup> After World War II, many Asian Americans began pursuing eyelid surgery to “westernize” their eyes.<sup>23</sup> And for many years some African Americans have used cosmetics and creams to lighten their skin—sometimes incurring serious health risks in the process.<sup>24</sup>

More recently, it has become increasingly common for people to use cosmetic interventions not to assimilate into white culture, but to accentuate their identities as racial minorities.<sup>25</sup> Research by Khanna and Johnson suggests many biracial individuals are “modifying their phenotypes to pass as black or to accent their black ancestry”—by, for example, using skin tanning.<sup>26</sup> Similarly, plastic surgeons are witnessing a shift among the preferences of immigrants to the United States. “Rather than striving to fit in to their new country, many immigrants reshape themselves to their home

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20. *Id.* at 389.

21. ELLIOTT, *supra* note 1, at 164.

22. *Id.* at 190. In 1936, the founder of the American Board of Plastic Surgery argued “[c]hange in the shape of the pronounced Jewish nose may be sought for either social or business reasons.” *Id.* at 191.

23. *Id.*

24. See, e.g., Catherine Saint Louis, *Creams Offering Lighter Skin May Bring Risks*, N.Y. TIMES, Jan. 15, 2010, at A1 (describing the story of Allison Ross, who used skin lightening creams “to be more accepted in society.” The cream made her “fairer,” but also made her skin “so thin that a touch would bruise her face. Her capillaries became visible, and she developed stubborn acne.”).

25. Khanna & Johnson, *supra* note 17, at 386 (“identity work is not just about concealing or covering a stigmatized identity, but highlighting a non-stigmatized or preferred identity, or what we term *accenting*.”).

26. *Id.* at 387.

culture's trends and tastes."<sup>27</sup> The president of the Long Island Plastic Surgical Group refers to plastic surgeons as "amateur sociologists," claiming that he can guess which procedures patients will request based on their ethnic background and age.<sup>28</sup>

### 3. *Sex*

"A person's sexual anatomy, and hence that person's sense of sexual self, is core to an individual's self-definition."<sup>29</sup> Although most people identify with their biological sex—or the sex "assigned" to them at birth by virtue of their physiological attributes—some people experience a profound discordance between their biological sex and their sense of their own sexual and gender identities.<sup>30</sup> In her memoir, *Conundrum*, Jan Morris reports that when she was a young boy she felt that she had been "born into the wrong body, and should really be a girl."<sup>31</sup> Morris describes feeling "deprived of an identity" as a man.<sup>32</sup> But after undergoing sex reassignment surgery, she felt able "to live as myself, to clothe myself in a more proper body, and achieve Identity at last."<sup>33</sup>

Like many others before and after her, Morris used medical interventions to conform her physical attributes to her internal sense of identity as a woman. Female-to-male transsexuals can use surgical procedures to have their breasts removed and genitals reshaped, and can take testosterone to increase their musculature, to grow facial and body hair, and to deepen their voices.<sup>34</sup> Male-to-female transsexuals may obtain breast implants, surgery to reshape their genitals, and/or estrogen to help produce a more typically female

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27. Sam Dolnick, *Ethnic Differences Emerge in Plastic Surgery*, N.Y. TIMES, Feb. 18, 2011, at A17.

28. *Id.*

29. Chai R. Feldblum, *The Right to Define One's Own Concept of Existence: What Lawrence Can Mean for Intersex and Transgender People*, 7 GEO. J. GENDER & L. 115, 124 (2006).

30. *Id.*

31. JAN MORRIS, CONUNDRUM 3 (1974).

32. *Id.* at 40.

33. *Id.* at 104.

34. *Female to Male Transsexuals: Gender Reassignment and FTM Surgery, Transitioning Guide*, FEMALETOMALE.ORG, [www.femaletomale.org/ftm-transitioning-guide/](http://www.femaletomale.org/ftm-transitioning-guide/) (last visited Nov. 5, 2015).

body shape.<sup>35</sup> Some trans-females also use surgical procedures—such as crico-thyroid approximation and laser-assisted voice adjustment—to raise the pitch of their voices by shortening or thinning their vocal cords.<sup>36</sup>

#### 4. *Intelligence*

Many people take drugs to improve their cognitive performance. The drugs most commonly used for these purposes include stimulants like Ritalin and Adderall, which are marketed as treatments for attention deficit disorders, and Provigil, which is approved as a treatment for sleep disorders.<sup>37</sup> “Several other compounds with different pharmacological actions are in early clinical trials, having shown positive effects on memory in healthy research subjects.”<sup>38</sup>

Although these drugs are marketed as treatments for illnesses, they are increasingly used to enhance cognition among healthy individuals.<sup>39</sup> According to one survey, “almost 7% of students in US universities have used prescription stimulants in this way, and . . . on some campuses, up to 25% of students had used them in the past year.”<sup>40</sup> These students are not alone. Media accounts are filled with stories of academics, military personnel, professional poker players,

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35. The Philadelphia Center for Transgender Surgery, *MALE-TO-FEMALE*, [www.thetransgendercenter.com/index.php/maletofemale1.html](http://www.thetransgendercenter.com/index.php/maletofemale1.html) (last visited Nov. 5, 2015).

36. ELLIOTT, *supra* note 1, at 22.

37. Hank Greely et al., *Towards Responsible Use of Cognitive-enhancing Drugs by the Healthy*, 456 *NATURE* 702, 702 (2008).

38. *Id.*; see also Peter J. Whitehouse et al., *Enhancing Cognition in the Intellectually Intact*, 27 *HASTINGS CTR. REP.* 14, 22 (1997) (“Our ability to treat dementia and other brain-based disorders is improving, and these developments will likely lead to pharmaceutical tools to increase cognition in humans who are not suffering from a clinical condition causing cognitive impairment.”).

39. Barbara Sahakian & Sharon Morein-Zamir, *Professor’s Little Helper*, 450 *NATURE* 1157, 1157 (2007) (“off-label and non-prescription use by the general public is becoming increasingly commonplace”); M. Elizabeth Smith & Martha J. Farah, *Are Prescription Stimulants “Smart Pills”? The Epidemiology and Cognitive Neuroscience of Prescription Stimulant Use by Normal Healthy Individuals*, 137 *PSYCHOL. BULL.* 717 (2011) (summarizing research on the prevalence of nonmedical use of prescription stimulants).

40. Greely et al., *supra* note 37, at 702.

and Wall Street bankers using drugs to boost intelligence and performance.<sup>41</sup>

But while there is ongoing research into new drugs that could enhance intelligence,<sup>42</sup> there is little evidence that this is what existing drugs actually accomplish.<sup>43</sup> Rather, research suggests that users are not taking these drugs to enhance their brains' processing power or memory, but to change aspects of their personalities in ways that are conducive to performing intellectual tasks—reducing daydreaming, enhancing self-control, and increasing one's interest in intellectual work.<sup>44</sup>

In a 2012 study, Dr. Ilina Singh conducted a series of interviews with children taking ADHD drugs to determine “the implications of stimulant drug use for key dimensions of children’s moral identity.”<sup>45</sup> While most of the children did not feel that the drugs made them different people, many parents reported sentiments like “[h]e’s like a different person on medication” or “I feel like I hardly recognize her now that she has started taking the medication.”<sup>46</sup> The children’s

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41. Brendan Maher, *Poll Results – Look Who’s Doping*, 452 NATURE 674, 674 (2008) (reporting that one in five readers of Nature—generally academic researchers—who responded to the journal’s informal poll reported using stimulants for nonmedical purposes, in particular, to enhance their focus and concentration); Sahakian & Morein-Zamir, *supra* note 39, at 1158 (“Cognitive-enhancing drugs are increasingly being used in non-medical situations such as shift work and by active military personnel.”); Karen Kaplan & Denise Gellene, *They’re Bulking up Mentally*, L.A. TIMES, Dec. 20, 2007, <http://articles.latimes.com/2007/dec/20/science/sci-braindoping20> (professional poker player Paul Phillips “credited the attention deficit drug Adderall and the narcolepsy pill Provigil with helping him earn more than \$2.3 million as a poker player.”); Robert Kolker, *The Real Limitless Drug Isn’t Just for Lifelackers Anymore*, N.Y. MAG. (Mar. 31, 2013), <http://nymag.com/news/intelligencer/modafinil-2013-4/>; Alexis Madrigal, *20 Percent of Scientists Admit Using Brain-Enhancing Drugs — Do You?*, WIRED (Apr. 9, 2008), [www.wired.com/2008/04/20-of-scientist/](http://www.wired.com/2008/04/20-of-scientist/).

42. Greely et al., *supra* note 37.

43. See, e.g., Smith & Farah, *supra* note 39 (cataloging and summarizing clinical studies on whether stimulants improve performance on tests designed to assess various aspects of cognition; the results were mixed, with evidence generally pointing to modest enhancing effects).

44. Scott Vrecko, *Just How Cognitive Is “Cognitive Enhancement”? On the Significance of Emotions in University Students’ Experiences with Study Drugs*, 4 AM. J. BIOETHICS NEUROSCIENCE 4 (2013).

45. ILINA SINGH, VOICES: VOICES ON IDENTITY, CHILDHOOD, ETHICS AND STIMULANTS 4 (2012), [www.adhdvoices.com/documents/12\\_0819\\_Voices\\_Report\\_LR-72dpi-GREY\\_V4.pdf](http://www.adhdvoices.com/documents/12_0819_Voices_Report_LR-72dpi-GREY_V4.pdf).

46. *Id.* at 24.

own descriptions of these drugs' effects emphasized their emotional and behavioral changes. Many reported that stimulants reduced the amount of time they spent daydreaming, which helped them improve their organization and increased their opportunities and desire for socializing.<sup>47</sup>

In another recent study, many healthy college students who take stimulants to improve academic performance asserted that the drugs did not make them smarter.<sup>48</sup> Rather, study participants emphasized the way these drugs changed their personalities, including their levels of motivation and interest in engaging in intellectual work.<sup>49</sup> Many students reported feeling more motivated to do work when taking stimulants, with some describing feeling "driven" to work and others reporting feeling more "stressed" about the importance of finishing projects.<sup>50</sup> Students also expressed feeling more interested in their academic work when under the influence of stimulants. Some reported that their work became "less tedious," "something that was sort of fun" or even "exciting."<sup>51</sup>

As they became more engaged in their academic work, many students became less interested in other endeavors, such as socializing or web surfing.<sup>52</sup> Another study found that stimulants increased participants' willingness to delay gratification, finding that when subjects were given amphetamines they were more willing to wait for a larger monetary reward rather than settling for a smaller amount immediately.<sup>53</sup>

In sum, the widespread use of so-called "smart pills" appears to extend well beyond merely enhancing intelligence. Rather, "these enhancements may well be changes critical to a person's identity, a

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47. *Id.* at 24, 37.

48. Vrecko, *supra* note 44, at 10.

49. *Id.*; see also Joshua Foer, *The Adderall Me: My Romance with ADHD Meds*, SLATE (May 10, 2005), [www.slate.com/articles/health\\_and\\_science/medical\\_examiner/2005/05/the\\_adderall\\_me.html](http://www.slate.com/articles/health_and_science/medical_examiner/2005/05/the_adderall_me.html) ("I didn't feel like I was becoming smarter or even like I was thinking more clearly. I just felt more directed, less distracted by rogue thoughts, less day-dreamy.").

50. Vrecko, *supra* note 44, at 7–8.

51. *Id.* at 9.

52. *Id.* at 8.

53. Maia Szalavitz, *Popping Smart Pills: The Case for Cognitive Enhancement*, TIME, (Jan. 6, 2009), <http://content.time.com/time/health/article/0,8599,1869435,00.html>.

person's sense of who he or she is."<sup>54</sup> Users report significant changes to their self-control and impulsivity, their tendency to daydream, and even their interest in activities like socializing and engaging in intellectual work.

### 5. *Personality*

Antidepressants like Prozac and Paxil are among the most prescribed drugs in the United States.<sup>55</sup> From 1988 to 2008, antidepressant prescriptions rose by nearly 400 percent.<sup>56</sup> According to the Centers for Disease Control and Prevention (CDC), 12 percent of Americans aged twelve years and over—and more than 22 percent of women aged forty to fifty-nine—take antidepressant medications.<sup>57</sup>

Most of these people are not clinically depressed. The CDC estimates that about eight percent of all Americans over age twelve took antidepressant medication, despite having “no current depressive symptoms.”<sup>58</sup> No doubt many of these people use antidepressants to treat anxiety disorders and other ailments. But in *Listening to Prozac*, psychiatrist Peter Kramer offered another reason for the enormous popularity of the drug: “its ability to alter personality.”<sup>59</sup>

Kramer describes his numerous experiences prescribing antidepressants to people who did not meet the diagnostic criteria for depression, but who simply liked themselves better—indeed, felt more “like themselves”—on these drugs. For a significant minority of Kramer's patients, “Prozac seemed to give social confidence to the habitually timid, to make the sensitive brash, to lend the introvert

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54. ELLIOTT, *supra* note 1, at 257.

55. *See, e.g.*, Brendan L. Smith, *Inappropriate Prescribing*, 43 AM. PSYCHOL. ASSOC. 36, 37 (2012) (antidepressants are the second most commonly prescribed drug in the United States, just after cholesterol-lowering drugs); CDC: *Antidepressants Most Prescribed Drugs in U.S.*, CNN.COM (July 9, 2007), [www.cnn.com/2007/HEALTH/07/09/antidepressants/](http://www.cnn.com/2007/HEALTH/07/09/antidepressants/).

56. Laura A. Pratt et al., *Antidepressant Use in Persons Aged 12 and Over: United States, 2005–2008*, NCHS Data Brief (Oct. 2011), [www.cdc.gov/nchs/data/databriefs/db76.pdf](http://www.cdc.gov/nchs/data/databriefs/db76.pdf).

57. *Id.*

58. *Id.*

59. PETER D. KRAMER, *LISTENING TO PROZAC: THE LANDMARK BOOK ABOUT ANTIDEPRESSANTS AND THE REMAKING OF THE SELF* 10 (rev. ed. 1997).

the social skills of a salesman.”<sup>60</sup> About a patient called “Tess,” Kramer reports:

Here was a patient whose usual method of functioning changed dramatically. She became socially capable, no longer a wallflower but a social butterfly. Where once she had focused on obligations to others, now she was vivacious and fun-loving. Before, she had pined after men; now she dated them, enjoyed them, weighed their faults and virtues.<sup>61</sup>

Kramer viewed this use of antidepressants as a kind of analog to cosmetic surgery, coining the phrase “cosmetic psychopharmacology” to capture the use of chemicals “to modify personality in useful, attractive ways.”<sup>62</sup>

Others have turned to different drugs to alter their personalities. By his own account, actor Cary Grant was “horrendous”—an “utter fake, a self-opinionated bore, a know-all who knew very little.”<sup>63</sup> But then Grant reported that “I have been through a psychiatric experience which has completely changed me,” a process he described as being “born again.”<sup>64</sup> Grant had not found religion, but LSD, a drug he claimed to have ingested more than sixty times. Grant reported that his experiences on the drug had transformed him, stripping him of the “defenses, hypocrisies and vanities” that previously had plagued him.<sup>65</sup>

Burgeoning clinical research into the effects of psychedelic substances corroborates anecdotal accounts like Grant’s. Researchers at Johns Hopkins recently reported the results of two double-blinded, placebo-controlled studies in which healthy participants with no history of using hallucinogenic drugs were given psilocybin, a psychedelic compound similar to LSD.<sup>66</sup> Notwithstanding a large body of evidence showing that core personality traits change very

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60. *Id.* at 18–19.

61. *Id.* at 10–11.

62. *Id.* at 15.

63. JAY STEVENS, *STORMING HEAVEN: LSD AND THE AMERICAN DREAM* 64–65 (1980).

64. *Id.* at 65.

65. *Id.*

66. 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 (2011).



little across the lifespan, the authors found that a single dose of psilocybin produced “fundamental changes in personal concerns, goals, and identity”—changes that endured more than a year after ingesting the drug.<sup>67</sup> The authors found that these changes “were larger in magnitude than changes in personality typically observed in healthy adults over decades of life experience”—larger 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.”<sup>68</sup>

#### 6. *Spirituality*

The Hopkins studies not only suggested lasting personality changes, they proposed a psychological mechanism for these changes: mystical experiences. Not only did study participants who ingested psilocybin have mystical experiences, sixty-seven percent rated their experience as “either the single most meaningful experience of his or her life or among the top five most meaningful experiences of his or her life,” comparable to “the birth of a first child or death of a parent.”<sup>69</sup> Moreover, participants’ judgments about the meaningfulness of these experiences had not diminished when they were assessed more than a year after their session.<sup>70</sup>

While research into the effects of various drugs on spirituality is blossoming, the phenomenon is ancient. Psilocybin itself “has been used as a sacrament for centuries, possibly millennia, in structured religious ceremonies.”<sup>71</sup> Indigenous inhabitants of the Americas have long used psychedelic compounds found in plants, such as peyote and ayahuasca, to induce spiritual transformations—practices that continue to this day.<sup>72</sup> Although these substances are banned under

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67. *Id.*

68. *Id.* at 1457.

69. R. R. Griffiths et al., *Psilocybin Can Occasion Mystical-Type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance*, 187 *PSYCHOPHARMACOLOGY* 268, 276–77 (2006).

70. R. 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* 621, 631 (2008).

71. *Id.* at 621.

72. See *Gonzales v. O Centro Espirita Beneficente União do Vegetal*, 546 U.S. 418 (2006).

the Controlled Substances Act, the U.S. government has carved out exceptions for their use by certain indigenous groups, in recognition of the importance of these drugs to their religious practices.<sup>73</sup>

The use of biological interventions to induce spiritual experiences or express spirituality includes surgical interventions as well. In the Judeo-Christian tradition, surgical removal of the foreskin is the foundation of God's covenant with Abraham.<sup>74</sup> In medieval times, devout penitents in Europe satisfied their desire to transcend the flesh by devising horrific tortures that left their bodies grotesquely deformed.<sup>75</sup> Several native North American tribes practiced forms of ritual "hookswinging," in which participants were suspended in the air by hooks skewered through the flesh of their backs. In the Mandan's O-Kee-Pa ceremony, this practice was undertaken as a ritual of rebirth and initiation into manhood.<sup>76</sup> Among the Blackfoot, the flesh that tore from the skin through this ritual was offered as a sacrifice to the Sun.<sup>77</sup>

### 7. *Memory*

When Shakespeare's Macbeth begs his royal physician to soothe his wife's conscience by "plucking" out her troubling memories, the physician responds, "[t]herein the patient [m]ust minister to himself."<sup>78</sup> But new research suggests future doctors may be able to do better. Neuroscientists are making surprising gains in their ability to dampen, erase, and even create specific memories.<sup>79</sup>

73. *Id.* at 420.

74. *Genesis* 17:9–14 (King James) ("Then God said to Abraham . . . 'you shall be circumcised . . . and it shall be a token of the covenant betwixt me and you.'").

75. SHILLING, *supra* note 8, at 191.

76. W. C. MacLeod, *The Nature, Origin, and Linkages of the Rite of Hookswinging: With Special Reference to North America*, ANTHROPOS INSTITUT, Jan.–Apr. 1934 at 1, 1–38.

77. *Id.* at 5.

78. WILLIAM SHAKESPEARE, *MACBETH* act 5, sc. 3.

"Canst thou not minister to a mind diseas'd,  
Pluck from the memory a rooted sorrow,  
Raze out the written troubles of the brain,  
And with some sweet oblivious antidote  
Cleanse the stuff'd bosom of that perilous stuff  
Which weighs upon the heart?" *Id.*

79. Raúl Andero et al., *Amygdala-Dependent Fear Is Regulated by Opr11 in Mice and Humans with PTSD*, 5 *SCI. TRANSL. MED.* 1 (2013); Adam Piore, *Totaling Recall*, 22 *SCI.*

Much of this research is directed at treating or preventing post-traumatic stress disorder (PTSD) by dampening traumatic memories. Some studies suggest that administering drugs like Propranolol to a victim shortly after a traumatic event can interfere with the consolidation of memories of the event, reducing the likelihood of developing PTSD.<sup>80</sup> More interesting, and potentially troubling, is research suggesting the potential to erase specific memories at any time. “Memory reconsolidation” theory hypothesizes that the act of recalling a memory temporarily places it in an unstable state, during which time it may be possible to modify or erase the memory.<sup>81</sup> At least one set of researchers tested this hypothesis on humans, using electroconvulsive therapy (ECT) to temporarily impair distressing memories.<sup>82</sup> Researchers first showed subjects two disturbing slide shows depicting traumatic stories—a physical assault and a car accident.<sup>83</sup> Later, they prompted subjects to recall one of the two stories and then administered ECT while the subjects’ memories of that story were “reactivated.” When the subjects were tested the next day, they performed no better than chance in trying to recall the details of the “reactivated” story.<sup>84</sup> Their memories of the other story were unaffected.<sup>85</sup>

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AM. MIND 40 (2012); Roger K. Pitman et al., *Pilot Study of Secondary Prevention of Posttraumatic Stress Disorder with Propranolol*, 51 SOC. BIOL. PSYCHOL. 189 (2002); Benedict Carey, *Brain Researchers Open Door to Editing Memory*, N.Y. TIMES (Apr. 5, 2009), [www.nytimes.com/2009/04/06/health/research/06brain.html](http://www.nytimes.com/2009/04/06/health/research/06brain.html); Meredith Cohn, *Method to Erase Traumatic Memories May Be on the Horizon*, BALT. SUN, Nov. 22, 2010, [http://articles.baltimoresun.com/2010-11-22/health/bs-hs-erasing-memories-20101122\\_1\\_fearful-memory-proteins-researchers](http://articles.baltimoresun.com/2010-11-22/health/bs-hs-erasing-memories-20101122_1_fearful-memory-proteins-researchers); Katie Drummond, *No Fear: Memory Adjustment Pills Get Pentagon Push*, WIRED (Dec. 16, 2011, 2:00 PM), [www.wired.com/2011/12/fear-erasing-drugs/](http://www.wired.com/2011/12/fear-erasing-drugs/); Alison Winter, *Should We Erase Painful Memories?*, SALON (Dec. 31, 2011), [www.salon.com/2011/12/31/should\\_we\\_erase\\_painful\\_memories/](http://www.salon.com/2011/12/31/should_we_erase_painful_memories/).

80. Andero et al., *supra* note 79; Pitman et al., *supra* note 79.

81. Piore, *supra* note 79.

82. Marijn C W Kroes et al., *An Electroconvulsive Therapy Procedure Impairs Reconsolidation of Episodic Memories in Humans*, 17 NATURE NEUROSCIENCE 204 (2014); Piore, *supra* note 79; Jonah Lehrer, *The Forgetting Pill Erases Painful Memories Forever*, WIRED (Feb. 17, 2012), [www.wired.com/magazine/2012/02/ff\\_forgettingpill/all/1](http://www.wired.com/magazine/2012/02/ff_forgettingpill/all/1).

83. Helen Shen, *Zapping the Brain Can Help to Spot-clean Nasty Memories*, NATURE (Dec. 22, 2013), [www.nature.com/news/zapping-the-brain-can-help-to-spot-clean-nasty-memories-1.14431](http://www.nature.com/news/zapping-the-brain-can-help-to-spot-clean-nasty-memories-1.14431).

84. *Id.*

85. *Id.*

Perhaps most intriguing, other research has demonstrated the ability to implant false memories in mice using optogenetics, a method that uses light to activate specific brain cells.<sup>86</sup> Researchers placed mice in a chamber and shocked them, conditioning the mice to associate that chamber with the shock. Later, when they placed the mice in a different chamber, the mice did not freeze in fear—until researchers used light to activate the memory cells connected to the first chamber. Then the mice did freeze, appearing to incorrectly recall that the second, harmless chamber was where they had been shocked.

The ability to erase or modify memory would have profound implications for identity. As Adam Kolber observes:

Memory and identity are closely linked. We feel a special connection to our past selves largely because we remember having our past experiences . . . While memory is not the sole constituent of personal identity, it creates much of the psychological continuity that makes us aware of our continuing existence over time.<sup>87</sup>

While memory-modifying interventions might gain regulatory approval as treatments for PTSD, once approved they could also be used to ease guilty consciences or eliminate memories of other painful or embarrassing events.<sup>88</sup>

### *B. Key Concerns About Identity-modifying Interventions*

As we develop powerful new technologies for modifying bodies and minds, discomfort with these practices is growing—in the popular press and among policymakers, doctors, and ethicists. Medical ethics and legal literature is teeming with books and articles raising ethical concerns about enhancement practices.<sup>89</sup> In its most

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86. Liu et al., *Optogenetic Stimulation of a Hippocampal Engram Activates Fear Memory Recall*, 484 NATURE 381 (2012); Ramirez et al., *Creating a False Memory in the Hippocampus*, 341 SCI. 387 (2013); Elizabeth Landau, *Scientists give mice false memories*, CNN (July 25, 2013), [www.cnn.com/2013/07/25/health/mouse-brain-memory](http://www.cnn.com/2013/07/25/health/mouse-brain-memory).

87. Adam Kolber, *Therapeutic Forgetting: The Legal and Ethical Implications of Memory Dampening*, 59 VAND. L. REV. 1561, 1601 (2006) (internal citation omitted).

88. PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS 207 (2003) [hereinafter BEYOND THERAPY].

89. See, e.g., *id.*; NICK BOSTROM & JULIAN SAVULESCU, HUMAN ENHANCEMENT 1–22 (2008); LEON KASS, LIFE, LIBERTY, AND DEFENSE OF DIGNITY: THE CHALLENGE FOR

recent Ten-Year Forecast, the Institute for the Future, a Palo Alto think tank, focused on the “enormous potential for chaos” from unbridled human enhancement and emphasized the need “to make explicit the rights and restrictions that would apply to the rapidly-growing set of cognitive enhancement technologies.”<sup>90</sup> News stories and popular books about these practices and their hazards—the exploding use of ADHD drugs by healthy students, the over-use of antidepressants, skin lightening by celebrities like Michael Jackson and Sammy Sosa, the prospect of memory erasure—have become ubiquitous.<sup>91</sup>

A 2007 report by the British Medical Association warned that

[m]any techniques that involve attempts to modify or improve aspects of ourselves or others are seen as ethically problematic . . . [P]articular concerns arise from interference with the brain precisely because it is intrinsically linked with our personality and individuality and because the long-term effects of interfering with this very complex system are unknown.<sup>92</sup>

Britain’s Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering, and the Royal Society have

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BIOETHICS (2008); MICHAEL J. SANDEL, THE CASE AGAINST PERFECTION: ETHICS IN THE AGE OF GENETIC ENGINEERING (2007); Henry T. Greely, *Remarks on Human Enhancement*, 56 U. KAN. L. REV. 1139 (2007–2008); I. Glenn Cohen, *What (If Anything) Is Wrong with Human Enhancement? What (If Anything) Is Right with It?*, 49 TULSA L. REV. 645 (2014).

90. Jamais Cascio, *Magna Cortica*, OPEN THE FUTURE (May 13, 2014, 12:33 PM), [www.openthefuture.com/2014/05/magna\\_cortica.html](http://www.openthefuture.com/2014/05/magna_cortica.html).

91. KATHERINE SHARPE, COMING OF AGE ON ZOLOFT: HOW ANTIDEPRESSANTS CHEERED US UP, LET US DOWN, AND CHANGED WHO WE ARE (2012) (describing the author’s experiences taking antidepressants and her concerns about their effects on her identity and relationships); Carey, *supra* note 79; Enrique Rojas, *Sammy Sosa: Facial Cream Caused Lightening of Skin*, ESPN (Nov. 10, 2009), <http://sports.espn.go.com/mlb/news/story?id=4642952>; Alan Schwarz, *Risky Rise of the Good Grade Pill*, N.Y. TIMES, June 9, 2012, [www.nytimes.com/2012/06/10/education/seeking-academic-edge-teenagers-abuse-stimulants.html](http://www.nytimes.com/2012/06/10/education/seeking-academic-edge-teenagers-abuse-stimulants.html); Thomas Watkins, *Michael Jackson Had Dozens Of Skin-Whitening Creams*, HUFFINGTON POST (Mar. 26, 2010), [www.huffingtonpost.com/2010/03/26/michael-jackson-had-dozen\\_n\\_515528.html](http://www.huffingtonpost.com/2010/03/26/michael-jackson-had-dozen_n_515528.html).

92. BRITISH MEDICAL ASSOCIATION, BOOSTING YOUR BRAINPOWER: ETHICAL ASPECTS OF COGNITIVE ENHANCEMENTS 3 (2007), [http://enhancingresponsibility.com/wp-content/uploads/2014/01/Boosting\\_brainpower\\_tcm41-147266.pdf](http://enhancingresponsibility.com/wp-content/uploads/2014/01/Boosting_brainpower_tcm41-147266.pdf).

expressed similar concerns.<sup>93</sup> On this side of the Atlantic, President George W. Bush's Council on Bioethics warned of this trend in a lengthy report entitled *Beyond Therapy: Biotechnology and the Pursuit of Happiness*. The Council argued that although “[a]lcohol, marijuana, cocaine, and other consciousness-affecting drugs offer temporary pleasures and escapes, and they can surely alter behavior and sense of self,” newer biotechnologies are more troubling because of “their capacity for more *precise, long-term, and sought-after* alterations in the human psyche.”<sup>94</sup> President Obama's Commission for the Study of Bioethical Issues recently studied the “pressing ethical issues concerning equitable access to enhancements and their benefits, appropriate management of risks, and obligations and freedoms to enhance or not.”<sup>95</sup>

Critics of enhancement argue these practices raise a host of concerns, most of which do not apply to therapeutic uses of medical technology. Many of these concerns relate to parents subjecting their children to medical interventions for purposes other than treating illnesses—to make them smarter or stronger or taller. Others relate to interventions forced upon unwilling adults, such as involuntary behavior modification for prisoners. These situations raise difficult issues—particularly surrounding consent—that are unique to those contexts, and that others have ably explored elsewhere.<sup>96</sup> This article instead focuses on the use of identity-modifying technologies by consenting adults. Within that context, critics have raised three primary concerns beyond the current system's focus on protecting

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93. THE ACADEMY OF MEDICAL SCIENCES ET AL., HUMAN ENHANCEMENT AND THE FUTURE OF WORK [hereinafter *HUMAN ENHANCEMENT AND THE FUTURE OF WORK*] (2012), <https://www.acmedsci.ac.uk/viewFile/publicationDownloads/135228646747.pdf>.

94. BEYOND THERAPY, *supra* note 88, at 208–09.

95. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, GRAY MATTERS: INTEGRATIVE APPROACHES FOR NEUROSCIENCE, ETHICS, AND SOCIETY 8 (May 2014), [www.bioethics.gov/sites/default/files/Gray%20Matters%20Vol%201.pdf](http://www.bioethics.gov/sites/default/files/Gray%20Matters%20Vol%201.pdf).

96. See, e.g., JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES (1994) (examining, e.g., whether limitations should be placed on genetic enhancement of offspring); Henry T. Greely, *Neuroscience and Criminal Justice: Not Responsibility but Treatment*, 56 U. KAN. L. REV. 1103 (2008) (discussing legal and ethical considerations raised by “treating” criminality with medical interventions); Jack M. Balkin, *How New Genetic Technologies Will Transform Roe v. Wade*, 56 EMORY L.J. 843, 844 (2007); Andrew B. Coan, *Is There a Constitutional Right to Select the Genes of One's Offspring?*, 63 HASTINGS L.J. 233 (2011); Radhika Rao, *Constitutional Misconceptions*, 93 MICH. L. REV. 1373 (1995).

users' health: fairness, agency, and authenticity.<sup>97</sup> While there is considerable debate over the validity of these concerns, the purpose of the remainder of this section is to describe these concerns, rather than to critically analyze them. The argument offered in this paper is that even if one accepts that enhancements raise important ethical concerns, restricting access to these interventions on contested moral grounds is bad policy.

### 1. *Fairness and coercion*

Some worry about the use of identity-modifying interventions as tools to obtain positional advantages. This concern is most obvious in the context of sports, where athletes have long used steroids, human growth hormone, EPO, beta blockers, stimulants, and a host of other drugs to improve their performance. Sports associations at every level have sought to ban athletes from using performance enhancing drugs, in large part because they are perceived to give users unfair advantages.<sup>98</sup> Even outside the realm of athletics, life is full of competitions in which biology can confer competitive advantages. Given the many benefits of being perceived as attractive, using cosmetic surgery to enhance appearance can boost one's prospects in countless endeavors.<sup>99</sup> Some argue that healthy students who use stimulants as study aids may gain unfair advantages in pursuing academic achievement—advantages that may help them get into better colleges or secure better jobs.<sup>100</sup>

These advantages will likely be unevenly distributed according to wealth.<sup>101</sup> “Enhancement technologies . . . are expensive and are

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97. Critics have raised a host of other concerns as well, including objecting to the perceived “unnaturalness” of these interventions, their potential to erode social solidarity, and their tendency to undermine our sense of “openness to the unbidden.” KASS, *supra* note 89; Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1146–58 (2005); Sandel, *supra* note 89.

98. World Anti-Doping Agency, *Code Signatories*, [www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code/Code-Acceptance/](http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code/Code-Acceptance/) (last visited Nov. 8, 2015) (listing the sport organizations that have adopted WADA's anti-doping code). WADA's motto is “play true.”

99. See sources cited *supra* note 7.

100. Schwarz, *supra* note 91.

101. Eric Racine & Judy Illes, *Neuroethical Responsibilities*, 33 CAN. J. NEUROLOGICAL SCI. 269, 271 (2006) (“enhancement could jeopardize distributive justice and cloud the meaning of medical intervention in modern societies”); see also Nick Bostrom & Anders

likely to remain so.”<sup>102</sup> The health insurance that most Americans rely on to pay for medical interventions covers treatments for many illnesses, but does not pay for interventions that are not considered medically necessary.<sup>103</sup> For example, insurers generally will pay for stimulants to treat attention deficit disorders, but they will not cover these drugs simply because a student feels she studies more effectively when taking them. If a cognitive enhancement were highly effective but unevenly distributed according to wealth, wealthy individuals could compound their advantages while the disadvantaged fell further behind.<sup>104</sup>

This concern about fairness gives rise to a related concern about coercion, or pressure to use biological interventions to compete for grades, jobs, and romantic partners. In some cases that pressure may be overt. For example, soldiers in the United States’ military can be legally required to take stimulants to promote alertness and enhance their performance.<sup>105</sup> One can imagine other circumstances in which employers—or even workplace safety regulations—might require healthy employees to use medical interventions to improve performance or promote safety. In 2008, Hank Greely and co-authors suggested that if there were very safe drugs that improved surgeons’ performance, it might be appropriate to require doctors to take these drugs when performing risky operations.<sup>106</sup>

Even in the absence of explicit requirements to enhance, employers or schools could implement performance requirements that are difficult to meet without medical interventions.<sup>107</sup> Many

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Sandberg, *Cognitive Enhancement: Methods, Ethics, Regulatory Challenges*, 15 *SCI. & ENGINEERING ETHICS* 311, 331 (2009) (“[A]ccess to enhancers is often dependent on being able to find an open-minded physician who will prescribe the drug. This creates inequities in access. People with high social capital and good information get access while others are excluded.”).

102. *HUMAN ENHANCEMENT AND THE FUTURE OF WORK*, *supra* note 93, at 44.

103. NORMAN DANIELS, *JUST HEALTH: MEETING HEALTH NEEDS FAIRLY* 150 (2007).

104. *HUMAN ENHANCEMENT AND THE FUTURE OF WORK*, *supra* note 93, at 44.

105. Greely et al., *supra* note 37, at 703.

106. *Id.*

107. *HUMAN ENHANCEMENT AND THE FUTURE OF WORK*, *supra* note 93, at 45 (“For example, expectations on lorry drivers could in future be based on the number of hours for which their awareness levels are sufficient with the use of a cognitive enhancer. Or individuals in labour-intensive jobs, perhaps baggage handlers or construction workers, could be required to do work that would be much more easily performed with enhanced strength.”).



people already feel pressure to use biological interventions just to remain competitive. Professional athletes appear reluctant to “play naked”—i.e., without performance enhancing drugs—out of fear that it will put them and/or their teams at a disadvantage against players who are doping.<sup>108</sup> When the U.S. Senate considered imposing a tax on cosmetic procedures, the National Organization for Women argued this would be unfair to middle-aged women who need Botox and “eye work” to be competitive in the job market.<sup>109</sup> And the trend of using stimulants as study aids has spread from college campuses to high schools, where students report that “some students who would rather not take the drugs would be compelled to [do so] because of the competition over class rank and colleges’ interest.”<sup>110</sup> One student who admitted to selling Adderall to his fellow high school students indicated that “insecurity was a main part of his sales pitch,” persuading students that if they did not use the drug they “would feel at a huge disadvantage.”<sup>111</sup>

## 2. Agency

Other concerns deal with how identity-modifying practices can change how we perceive ourselves and construct meaning in our lives—worries sometimes characterized as involving “agency” and “authenticity.” Agency concerns come in several flavors, but their common thread is the idea that using biological interventions to change how we feel, think, and behave will reinforce the idea that our identities are biologically determined.<sup>112</sup>

In *Listening to Prozac*, Peter Kramer tells the story of Sam, an architect who sought Kramer’s treatment for depression. Sam had “cultivated a continental, nonconformist manner” and prided himself

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108. Childs Walker, *Baseball’s Fast-lane Drug*, BALT. SUN, June 25, 2006, [http://articles.baltimoresun.com/2006-06-25/sports/0606250153\\_1\\_amphetamines-traber-illegal-substance/](http://articles.baltimoresun.com/2006-06-25/sports/0606250153_1_amphetamines-traber-illegal-substance/) (quoting former Major League Baseball player Ken Caminiti, “[Y]ou hear it all the time from teammates, ‘You’re not going to play naked, are you?’”); *Lance Armstrong Used PEDs to Win and “Ruthlessly” Required Teammates to Do Same, USADA says*, CBS NEWS (Oct. 10, 2012), [www.cbsnews.com/news/lance-armstrong-used-peds-to-win-and-ruthlessly-required-teammates-to-do-same-usada-says/](http://www.cbsnews.com/news/lance-armstrong-used-peds-to-win-and-ruthlessly-required-teammates-to-do-same-usada-says/).

109. Jesse McKinley, *A Tax on Nips and Tucks Angers Patients, Surgeons*, N.Y. TIMES, Nov. 29, 2009, at A14.

110. Schwarz, *supra* note 91.

111. *Id.*

112. KRAMER, *supra* note 59, at 18.

on his independent style.<sup>113</sup> While taking Prozac “Sam became less bristling, had fewer rough edges,” and he experienced that change as a loss. “The style he had nurtured and defended for years now seemed not a part of him but an illness. What he had touted as his independence of spirit was a biological tic. . . . [T]he medication redefined what was essential and what was contingent about his own personality.”<sup>114</sup> As Kramer repeatedly observed this effect of Prozac on some patients’ self-concept, he came to believe that new drugs would foster a cultural consensus that our identities are simply products of physiological processes: “When one pill at breakfast makes you a new person, or makes your patient, or relative, or neighbor a new person, it is difficult to resist the suggestion, the visceral certainty, that who people are is largely biologically determined.”<sup>115</sup>

Some worry this materialist consensus will undermine “our notions of responsibility, of free will, of unique and socially determinative individual development.”<sup>116</sup> President Bush’s Council on Bioethics argued that using biological interventions to shape who we are and how we behave can alter “the relationship between the doer and the deed, or between the human agent and the human activities he or she engages in.”<sup>117</sup> As a result we may cease to view ourselves as moral agents who are “responsible—worthy of praise or blame—for the things we do and for the way we are.”<sup>118</sup> For example, when athletes like Lance Armstrong and Alex Rodriguez are labeled “frauds” and “cheaters,” the condemnation seems to have less to do with their rule-breaking than with the idea that they falsely claimed for themselves credit that in fact belonged to their drugs.<sup>119</sup> As Michael Sandel argued, “[A]s the role of the enhancement increases, our admiration for the achievement fades.

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113. *Id.* at ix.

114. *Id.* at x.

115. *Id.* at 18.

116. *Id.*

117. BEYOND THERAPY, *supra* note 88, at 143.

118. SANDEL, *supra* note 89, at 25.

119. Thom Loverro, *Alex Rodriguez and Lance Armstrong Are Not Heroes – They Are Cheaters*, THE GUARDIAN (Aug. 13, 2013), [www.theguardian.com/sport/2013/aug/13/alex-rodriguez-lance-armstrong-cheaters](http://www.theguardian.com/sport/2013/aug/13/alex-rodriguez-lance-armstrong-cheaters).

Or rather, our admiration for the achievement shifts from the player to his pharmacist.”<sup>120</sup>

Modifying ourselves with biological interventions may reduce our sense of responsibility not only for our achievements, but for our shortcomings as well, replacing ideas like character with notions of biological inputs and outputs.<sup>121</sup> The President’s Council on Bioethics illustrated this point by contrasting dealing with “restless and unruly” children through moral instruction or biological intervention.<sup>122</sup> The Council argued that “[p]raise and blame from parents and teachers, patient instruction and extra attention, as well as the experience of performing poorly or well, can help strengthen the will of the child, which slowly increases the child’s ability to control his or her impulses and behavior.”<sup>123</sup> By contrast, addressing problematic behavior using behavior-modifying drugs “circumvent[s] that process, and act[s] directly on the brain to affect the child’s behavior without the intervening learning process.”<sup>124</sup> Rather than learning self-control, these children may instead come to the conclusion that they are “governed largely by chemical impulses and not by moral decisions grounded in some sense of what is right and appropriate.”<sup>125</sup>

### 3. *Authenticity*

Other critics of enhancement worry that by modifying ourselves, we are not being true to who we really are. As with the agency critique, this concern is not merely about individuals who may be living “inauthentic” lives, but about the effects of these practices on the broader society. Many people appear to use these technologies to relieve discomfort that arises from a broad range of social difficulties.

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120. SANDEL, *supra* note 89, at 25; *see also* FUKUYAMA, *supra* note 3, at 8 (arguing that nontherapeutic technologies “blur the line between what we achieve on our own and what we achieve because of the levels of various chemicals in our brains.”); BEYOND THERAPY, *supra* note 88, at 144.

121. BEYOND THERAPY, *supra* note 88, at 92 (“regarding ourselves and our activities in largely genetic or neurochemical terms may diminish our sense of ourselves as moral actors faced with genuine choices and options in life.”).

122. *Id.* at 91.

123. *Id.*

124. *Id.*

125. *Id.* at 92.

To the extent individuals respond to social challenges by modifying themselves, this can reduce the impetus to address the underlying problems.

*a. Acceding to social injustices.* Society's appearance standards are often infused with forms of prejudice, including a strong preference for lighter skin. An individual's skin tone can have serious financial implications. Lighter skin tone is associated with higher educational attainment for black men and women, and "strikingly" higher employment rates for black women.<sup>126</sup> Immigrants to the United States with the darkest skin color earn an average of seventeen percent less than immigrants with the lightest skin color, even after controlling for their occupations in their source countries, education levels, English language proficiency, and other factors.<sup>127</sup> Racist appearance standards can also take an emotional toll. Recent research by Margaret Beale Spencer found that when children were presented with white and black dolls and asked questions about them, both black and white children were more likely to attribute positive attributes to the white doll and negative attributes to the darker colored doll.<sup>128</sup>

While we can credit much of America's progress on racial issues to individuals who have resisted bigotry, others have adapted to racial prejudice by obscuring their racial heritage—including a long history of using skin-lightening cosmetics among African Americans.<sup>129</sup> In the United States, skin-lightening is highly controversial. Singer Michael Jackson's ever-lighter skin prompted endless speculation that he used skin-lightening interventions—rumors Jackson felt compelled to deny.<sup>130</sup> In 2009, baseball star Sammy Sosa caused a stir when he appeared in public with starkly

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126. Joni Hersch, *Skin-Tone Effects among African Americans: Perceptions and Reality*, 96 AM. ECON. REV. 251, 254 (2006).

127. Joni Hersch, *Profiling the New Immigrant Worker: The Effects of Skin Color and Height*, 26 J. LAB. ECON. 345, 346 (2008).

128. Jill Billante & Chuck Hadad, *Study: White and Black Children Biased Toward Lighter Skin*, CNN.COM (May 14, 2010, 4:24 PM), [www.cnn.com/2010/US/05/13/doll.study/](http://www.cnn.com/2010/US/05/13/doll.study/). Spencer's study recreated the landmark "Doll Study" conducted in the 1940s by Kenneth and Mamie Clark. *Id.*

129. ELLIOTT, *supra* note 1, at 190–93.

130. Madison Park, *In Life of Mysteries, Jackson's Changed Color Baffled Public*, CNN.COM (July 8, 2009), [www.cnn.com/2009/HEALTH/07/06/skin.color.vitiligo/](http://www.cnn.com/2009/HEALTH/07/06/skin.color.vitiligo/).

lighter skin. Sosa, too, denied he had intentionally lightened his skin, but later admitted using a cream to achieve this result.<sup>131</sup>

By contrast, in India, skin-lightening is a multimillion dollar industry, fueled by advertising that brazenly touts the social disadvantages of having dark skin.<sup>132</sup> In one ad, a man says to his “fairer-skinned” friend, “I am unlucky because of my face.” The friend replies, “Not because of your face, because of the color of your face.” After using a product called “Fair & Handsome,” the darker-skinned actor is miraculously whitened, and he rides off on a motorcycle with an attractive woman.<sup>133</sup> Other marketing directed at women touts skin lightening as a form of feminist empowerment, arguing lighter skin will help these women secure better jobs and become independent.<sup>134</sup>

Judging from the booming market for skin-lighteners, many Indians perceive lighter skin to be beneficial. But when individuals accede to their society’s preference for lighter skin rather than resisting it, they may improve their own prospects at the expense of reinforcing racist standards.<sup>135</sup> Philosopher Margaret Little refers to these practices as forms of “cultural complicity.”<sup>136</sup> The more skin-lighteners, nose surgeries, and double-eyelid procedures are performed, the more entrenched these preferences become.<sup>137</sup>

131. Rojas, *supra* note 91.

132. Shantanu Guha Ray, *India’s Unbearable Lightness of Being*, BBC NEWS (Mar. 23, 2010), <http://news.bbc.co.uk/2/hi/8546183.stm> (research agency AC Nielsen estimates that in 2010 the Indian whitening cream market was worth \$432 million and growing at a rate of 25 percent per year).

133. Cosmopolitan Films, *Fair Menz*, YOUTUBE (Mar. 23, 2008), [www.youtube.com/watch?v=dOeRVxWgW1g](http://www.youtube.com/watch?v=dOeRVxWgW1g); Sara Sidner, *Skin Whitener Advertisements Labeled Racist*, CNN.COM (Sept. 9, 2009), <http://edition.cnn.com/2009/WORLD/asiapcf/09/09/india.skin/>.

134. Fair & Lovely, *Changing Her Destiny*, [https://web.archive.org/web/20121016014701/http://fairandlovely.in/our\\_history/our\\_history\\_details.aspx?histid=historyDetails04](https://web.archive.org/web/20121016014701/http://fairandlovely.in/our_history/our_history_details.aspx?histid=historyDetails04) (“When [the Indian woman’s] dreams seem impossible to achieve or she felt dejected, Fair & Lovely stepped in and gave her the confidence to achieve her dreams.”); Fujifilm84, *Fair and Lovely Skin Cream Ad (in English)*, YOUTUBE (Apr. 9, 2007), [www.youtube.com/watch?v=KIUQ5hbRHxk](http://www.youtube.com/watch?v=KIUQ5hbRHxk) (“The obstacle to having my dream job was my skin.”).

135. ELLIOTT, *supra* note 1, 189–90.

136. *Id.* at 190.

137. *Id.*

The potential for complicity is not limited to cosmetic interventions. For example, the typical elementary school experience—including expectations to sit quietly and stay focused for extended periods of time—is ill-suited to many children, especially young boys. Giving cognition-enhancing drugs to children who struggle in conventional classrooms may reduce the drive to improve the learning environment for these students. One pediatrician who admits to prescribing stimulants to children who struggle in school, regardless of whether they suffer from ADHD, argues “I don’t have a whole lot of choice. . . . We’ve decided as a society that it’s too expensive to modify the kid’s environment. So we have to modify the kid.”<sup>138</sup> Medicating children to get them to sit in their seats for longer stretches, or to focus in an overcrowded classroom, may make even longer stretches or more crowded classrooms seem viable. Children who might have been able to function well in the previous environment may need medications to help them cope with the new one, creating a spiral of increasing pressure to medicate.

*b. Distorting emotional responses.* Concerns about responding to social problems by manipulating one’s personality and emotions are not new. In 1957, a Time Magazine story headlined Happiness By Prescription expressed alarm over the widespread use of tranquilizers to “treat” the common stresses and disappointments of everyday life.<sup>139</sup> In terms that now seem quaint, one pharmacologist wondered whether these practices might “make millions of people significantly indifferent to politics—or to their responsibilities as automobile drivers?”<sup>140</sup> By 1971, Richard Nixon was grouching that “[w]e have produced an environment in which people come naturally to expect that they can take a pill for every problem—that they can find satisfaction and health and happiness in a handful of tablets or a few grains of powder.”<sup>141</sup>

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138. Alan Schwarz, *Attention Disorder or Not, Pills to Help in School*, N.Y. TIMES, Oct. 9, 2012, at A1.

139. *Happiness by Prescription*, TIME, Mar. 11, 1957, at 61.

140. *Id.*

141. Richard Nixon, *Remarks to the American Medical Association’s House of Delegates Meeting in Atlantic City, New Jersey* (June 22, 1971), [www.presidency.ucsb.edu/ws/?pid=3051](http://www.presidency.ucsb.edu/ws/?pid=3051).

These early rumblings took on new urgency in the 1990s with the blockbuster success of a new class of antidepressants called SSRIs. Unlike the minor tranquilizers that preceded them, drugs like Prozac did not merely relieve anxiety, but in some cases profoundly altered personalities.<sup>142</sup> These drugs seemed to help many people whose discomfort often seemed less like manifestations of illness than understandable frustrations and anxieties in the face of challenging, though not necessarily unusual, circumstances.<sup>143</sup>

While some people may feel happier while taking antidepressants, some observers worry that using medications to tweak emotions may leave us “estrang[e] . . . emotionally from life as it really is,” preventing ourselves from “responding to events and experiences, whether good or bad, in a fitting way.”<sup>144</sup> Part of the concern about creating a disconnect between people’s emotions and the world around them relates to how this might affect individuals in their pursuit of the good life.<sup>145</sup> If we are trapped in unrewarding jobs or harmful relationships, the emotional distress caused by these circumstances can motivate us to change, to seek something better or more meaningful. If we instead use medication to blunt our emotional distress, we may be less likely to pursue these changes. Describing her experiences on antidepressants, author Katherine Sharpe writes:

Looking back, it seems remarkable that I had to work so hard to absorb an elementary lesson: Some things make me feel happy, other things make me feel sad. But for a long time antidepressants were giving me the opposite lesson. If I was suffering because of a glitch in my brain, it didn’t make much difference what I did. For me, antidepressants had promoted a kind of emotional illiteracy. They had prevented me from noticing the reasons that I felt bad when I did and from appreciating the effects of my own choices.<sup>146</sup>

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142. See KRAMER, *supra* note 59, at 18–19.

143. *Id.*

144. BEYOND THERAPY, *supra* note 88, at 255.

145. As Carl Elliott asks, “Who is better off: the contented slave, or the angry one? The man who sins happily, or the one who feels guilt and shame?” Carl Elliott, *Medicate Your Dissent*, SPEAKEASY MAG. (2003), reprinted at [www.tc.umn.edu/~ellio023/medicate.htm](http://www.tc.umn.edu/~ellio023/medicate.htm).

146. Katherine Sharpe, *The Medication Generation*, WALL STREET J., June 29, 2012, <http://online.wsj.com/article/SB10001424052702303649504577493112618709108.html>.

Beyond the potential to cause problems for individuals, some worry about the cumulative effect of these practices on society. For example, Kramer observed that Prozac caused his patient, Tess, to become less serious.<sup>147</sup> One of the “symptoms” Prozac seemed to relieve for Tess was her “heightened awareness of the needs of others.”<sup>148</sup> She was a happier individual as a result, but diminished concern for others becomes troubling when multiplied across the eleven percent of Americans age twelve or older who take antidepressants.<sup>149</sup>

Emerging technologies may provide new opportunities to sever emotional responses from external circumstances. For example, the potential to dampen, or even erase, memories could provide great relief to people who have experienced trauma, or even merely sad or embarrassing episodes. But painful memories also serve important purposes—to individuals as well as to society at large. In response to a *New York Times* story about memory-erasure research, one reader opined:

Six years ago, I watched both of my teenage boys die, several hours apart, after our car was struck by a speeding patrol car. . . . I don't mean to judge the way in which others should treat (or be treated for) their own personal tragedies. But for me, I needed to retain every detail of my memory, not only for the manslaughter trial that followed a year and a half later but also for my own well-being. I now share my experience, in vivid detail, with police officers and recruits, hoping to prevent this from happening to others. Although it's painful to relive that night and its aftermath, doing so helps me feel that I am doing something positive with this tragedy.<sup>150</sup>

If we medicate away shame and remorse for bad decisions or behavior, we may fail to learn important lessons and repeat mistakes or bad acts we might have avoided.<sup>151</sup> While few would begrudge

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147. KRAMER, *supra* note 59, at 9.

148. *Id.* at 10.

149. Pratt, *supra* note 56, at 5.

150. Michelle Norton Spicer, *Letter: The Quest to Forget*, N.Y. TIMES MAG., April 18, 2004, at 6.

151. BEYOND THERAPY, *supra* note 88, at 232 (“the power to numb or eliminate the psychic sting of certain memories risks eroding the responsibility we take for our own actions—



soldiers an intervention that might relieve them of some of the mental traumas of war, their memories of those horrors serve important purposes, as do the memories of Holocaust survivors and witnesses of other atrocities.<sup>152</sup> As the President's Council on Bioethics asked, "Would the community as a whole—would the human race—be served by such a mass numbing of this terrible but indispensable memory? Do those who suffer evil have a duty to remember and bear witness, lest we all forget the very horrors that haunt them?"<sup>153</sup>

## II. REGULATING IDENTITY-MODIFYING INTERVENTIONS

The United States' existing legal structures governing medical interventions are designed to regulate treatments for illnesses.<sup>154</sup> Within that context, the prime consideration is ensuring that these treatments are safe to use—i.e., that they promote human health. In philosopher Norman Daniels' terms, we can (nearly) all agree on the value of treating illnesses irrespective of our comprehensive moral doctrines.<sup>155</sup> So when presented with an intervention that treats cancer, we generally do not feel compelled to ask whether shrinking tumors should be permitted. Rather, the aim of regulation is to ensure that the treatment is safe and effective.

By contrast, using biological interventions to modify healthy brains and bodies is often highly controversial.<sup>156</sup> Although many people highly desire these interventions, others condemn them as immoral or socially detrimental and wish to restrict them. Catholics

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since we would never have to face the harsh judgment of our own conscience . . . or the memory of others.").

152. *Id.* at 230–31.

153. *Id.* at 231.

154. For example, the Controlled Substances Act "allows prescription of drugs only if they have a 'currently accepted medical use,' 21 U.S.C. § 812(b); requires a 'medical purpose' for dispensing the least controlled substances of those on the schedules, § 829(c); and, in its reporting provision, defines a 'valid prescription' as one 'issued for a legitimate medical purpose,' § 830(b)(3)(A)(ii)." *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006).

155. DANIELS, *supra* note 103, at 155. *But see* Paul Vitello, *Christian Science Church Seeks Truce With Modern Medicine*, N.Y. TIMES, Mar. 23, 2010, at A20 (noting that, historically, Christian Scientists have rejected using medical treatment to promote health).

156. DANIELS, *supra* note 103, at 154.

believe contraception interferes with God's will.<sup>157</sup> In the 1800s, Teetotalers argued drinking alcohol leads to "idleness, disorder, [and] pauperism."<sup>158</sup> While students diagnosed with ADHD are often encouraged to take Adderall to help them study, healthy students who use the drug for the same purpose risk academic and criminal sanctions.<sup>159</sup> But because our existing regulatory systems were not designed with nontherapeutic practices in mind, these systems are largely blind to these disputes. Accordingly, as we develop new medical technologies and practices that seem designed to change identities rather than treat illnesses, calls are growing to expand regulatory systems to address concerns other than protecting health.<sup>160</sup>

Section A of this part briefly outlines various forms of medical regulation in the United States and describes how most of these efforts are at least ostensibly directed at protecting the health of users of medical interventions. It also notes that legislation restricting reproduction technologies represents a key exception to this general emphasis. Section B describes calls to expand regulatory authority to regulate nontherapeutic medical interventions on the basis of broader moral concerns.

*A. Existing Medical Regulation Is Largely Blind to Moral Concerns Beyond Protecting Health*

Medical practices are regulated in the United States through a patchwork of overlapping federal and state laws and regulations, courts, and professional associations. Although these regulatory activities take a variety of forms, they generally share—at least on the surface—a common animating purpose: protecting the health of people who undergo biological interventions.

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157. See, e.g., Catholic Answers, *Birth Control*, [www.catholic.com/library/Birth\\_Control.asp](http://www.catholic.com/library/Birth_Control.asp) ("Contraception is wrong because it's a deliberate violation of the design God built into the human race, often referred to as 'natural law.'").

158. *Mugler v. Kansas*, 123 U.S. 623, 662 (1887).

159. See, e.g., Allie Grasgreen, *Are Prescription Drugs 'Cheating'?*, INSIDE HIGHER ED. (Oct. 13, 2010), [www.insidehighered.com/news/2010/10/13/wesleyan#ixzz38nPELRJ4](http://www.insidehighered.com/news/2010/10/13/wesleyan#ixzz38nPELRJ4) (indicating Wesleyan University's Code of Non-Academic Conduct deems the "misuse or abuse" of prescription drugs a violation of the school's student honor code).

160. See *infra* note 208.

*1. The Federal Food, Drug, and Cosmetic Act*

The Federal Food, Drug, and Cosmetic Act (FDCA), which regulates the sale of drugs and medical devices, is designed to ensure that drugs and medical devices are safe to use.<sup>161</sup> One of the key ways it does this is by requiring manufacturers to obtain approval from the Food and Drug Administration (FDA) before marketing their products.<sup>162</sup> When a pharmaceutical company wants to sell a new drug, it must submit a New Drug Application and provide evidence that the drug is safe and “will have the effect it purports or is represented to have.”<sup>163</sup> The manufacturer also must provide the FDA with the company’s proposed labeling for the drug, “which includes, inter alia, all proposed claims about the drug’s risks and benefits, as well as adequate directions for use.”<sup>164</sup> If the FDA determines that the drug is sufficiently safe and is effective for the purposes described in the drug’s label, the agency issues an order approving the application, allowing the manufacturer to market the drug in a manner consistent with its label.<sup>165</sup> The FDCA also protects patient health by, among other things, regulating how drugs and medical devices are manufactured, barring the sale of misbranded or adulterated drugs, and monitoring reports of adverse events experienced by users of these products.<sup>166</sup>

Because the focus of the FDCA is to protect patient health, neither the Act nor the FDA seeks to limit the use of medical interventions to therapeutic purposes. For example, the agency approved Botox for the “treatment” of “severe frown lines”—a condition that could hardly be considered a disease, and which poses no apparent threat to human health.<sup>167</sup> The FDA also does not seek

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161. Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA (June 1981) [www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm](http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm).

162. 21 U.S.C. § 355(a) (2012); *see also* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 725 (D.C. Cir. 2007).

163. 21 U.S.C. § 355(b).

164. Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51, 55 (D.D.C. 1998) (citing part of 21 U.S.C. § 352(f)).

165. 21 U.S.C. § 355(d).

166. *Abigail Alliance*, 495 F.3d at 725.

167. FDA, *FDA Approves Botox Cosmetic to Improve the Appearance of Crow’s Feet Lines* (Sept. 11, 2013), [www.fda.gov/newsevents/newsroom/pressannouncements/ucm367662.htm](http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm367662.htm).

to prevent doctors from prescribing medications for nontherapeutic uses. Once the FDA approves a drug to treat a particular indication, doctors generally may prescribe it for other purposes as they see fit.<sup>168</sup> So while the FDA approved the drug Adderall as a treatment for ADHD, the FDCA does not prevent doctors from prescribing it to healthy students who want to enhance their concentration when doing homework.<sup>169</sup> On the contrary, so-called “off-label” prescribing is very common, particularly for psychotropic medications.<sup>170</sup>

Nor does the FDA believe its mandate encompasses addressing concerns like fairness, coercion, or authenticity. The Agency has categorically denied that “moral, religious, or ethical issues” fall within its purview.<sup>171</sup> The FDA has made this abundantly clear on multiple occasions, most notably in connection with its approval of human growth hormone (HGH) as a treatment for children who are very short, but do not suffer from a known health deficit.<sup>172</sup> In approving Eli Lilly & Company’s application to promote HGH to help these short (but healthy) children grow taller, the FDA advisory committee evaluating the drug expressly rejected the idea that it should consider issues beyond its safety and efficacy:

[A]ny decision that’s made with regard to growth hormone in this instance will be based upon a judgment of a favorable balance of risk versus benefit for the proposed indication, and that would not, in our minds, be setting a broad policy with regard, generally, to the use of drugs for cosmetic purposes. I’d also propose that it is not the purpose of this meeting to debate the merits of approvals of other drugs for what some—usually those unaffected by the target

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168. U.S. v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012) (“Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs.”).

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

170. David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1023–24 (2006) (finding that 73 percent of off-label prescriptions by office-based doctors—and 94 percent of prescriptions for psychiatric therapies—had little or no scientific support).

171. U.S. Food and Drug Administration, *FDA’s Response to Public Comment on the Animal Cloning Risk Assessment, Risk Management Plan, and Guidance for Industry* (July 23, 2014), [www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055491.htm](http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055491.htm).

172. Fox, *supra* note 97, at 1139–40.

condition—might construe as cosmetic purposes. And I think it's safe to say that we should concede that once demonstrated to be safe and effective, the choice of whether to attempt therapy for, for example, baldness, or mild acne, or even overweight is up to doctors, patients and their families as they weigh the potential benefits of the therapy against the potential risks.<sup>173</sup>

## 2. *The Controlled Substances Act*

The federal government also regulates drugs through the Controlled Substances Act (CSA). As discussed below, in practice the CSA often seems to serve as a way of expressing moral condemnation of certain uses of drugs. But on its face the Act's primary objective is to combat drug abuse and addiction, which it seeks to accomplish through "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession" of numerous drugs, or "controlled substances."<sup>174</sup> Nothing in the Act purports, or appears designed, to further other interests like ensuring fairness or protecting authenticity.

Like the FDCA, the CSA is designed to regulate drugs based on their health risks and benefits. The Act assigns controlled substances to one of five schedules, ostensibly based on the drugs' "potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision."<sup>175</sup> Schedule I includes drugs that are considered to have "a high potential for abuse," that are deemed to have "no currently accepted medical use," and that allegedly cannot be used safely, even under medical supervision.<sup>176</sup> Substances in Schedule II are considered to have accepted medical uses, but also to pose safety risks and/or heightened potential for

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173. FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH, ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEETING (Food and Drug Administration Department of Health and Human Services ed., June 10, 2003).

174. *Gonzales v. Oregon*, 546 U.S. 243, 250; 21 U.S.C. § 841 (2000); 21 U.S.C. § 844 (2012).

175. *Gonzales*, 546 U.S. at 250; 21 U.S.C. § 812 (2012).

176. 21 U.S.C. § 812(b)(1).

abuse.<sup>177</sup> Drugs in Schedule I are banned; with very limited exceptions for drug research and religious practices, their possession is a crime.<sup>178</sup> Drugs in Schedules II through IV may be obtained lawfully only by prescription.<sup>179</sup>

Unlike the FDCA, the CSA gives federal officials some authority to regulate the practice of medicine.<sup>180</sup> To lawfully prescribe scheduled drugs, doctors must register with the Attorney General.<sup>181</sup> The Attorney General may revoke a physician's registration upon finding (among other things) that the practitioner "has committed such acts as would render his registration . . . inconsistent with the public interest."<sup>182</sup> Drug Enforcement Agency regulations provide that in order to be "effective"—i.e., to comport with the CSA—"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>183</sup> If a doctor writes a prescription for a controlled substance that is not for a "legitimate medical purpose," the prescription is invalid and the doctor can be subject to the CSA's criminal penalties.<sup>184</sup>

On their face, these broadly-worded provisions appear to give the Attorney General the power to rely on considerations other than safety to determine that prescribing drugs for nontherapeutic purposes is not legitimate.<sup>185</sup> However, the Supreme Court has determined that the CSA grants the Attorney General only very

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177. Douglas J. Behr, *Prescription Drug Control Under the Federal Controlled Substances Act: A Web of Administrative, Civil, and Criminal Law Controls*, 45 WASH. U. J. URB. & CONTEMP. L. 41, 51–52 (1994).

178. 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, 266 (2002).

179. *Id.*

180. 21 U.S.C. §§ 801–971 (2012).

181. *Id.* § 822(a)(2).

182. *Id.* § 824(a)(4).

183. 21 C.F.R. § 1306.04(a) (2015).

184. *Id.*

185. At least one scholar has interpreted the CSA in this way. See Katherine Drabiak-Syed, *Reining In the Pharmacological Enhancement Train: We Should Remain Vigilant about Regulatory Standards for Prescribing Controlled Substances*, 39 J. L. MED. & ETHICS 272, 275–76 (2011) (arguing that prescribing a Schedule IV drug to stimulate a patient's focus or concentration constitutes an enhancement purpose that may violate the CSA regulation's "legitimate medical purpose" requirement).

narrow authority to regulate the practice of medicine—specifically, to prevent doctors from acting as drug dealers.<sup>186</sup> In *Gonzales v. Oregon*, the Supreme Court addressed an action by the U.S. Attorney General declaring that assisting suicide, as Oregon state law permitted, was outside the scope of legitimate medical practice and therefore violated the Controlled Substances Act.<sup>187</sup> In invalidating the Attorney General’s action, the Court rejected the federal government’s contention that the words “medicine” and “medical” “ineluctably refer[] to a healing or curative art,” such that drugs prescribed for nontherapeutic purposes were necessarily outside the scope of legitimate medical practice.<sup>188</sup> The Court concluded that the purpose of the CSA’s prescription requirement was not to limit medical practice to therapeutic purposes, but to protect patients’ health by “ensur[ing] patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.”<sup>189</sup>

### 3. State regulation

States also regulate the prescribing of drugs, as well as other medical practices, through state statutes, medical licensing bodies, and tort law.<sup>190</sup> As at the federal level, however, state medical regulation is generally aimed at protecting patient safety, rather than restricting interventions on moral grounds.

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186. *Gonzales v. Oregon*, 546 U.S. 243, 269–70 (2006) (“The [CSA] and our case law amply support the conclusion that 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. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.”).

187. 66 Fed. Reg. 56, 607–56, 608 (Nov. 9, 2001).

188. *Gonzales*, 546 U.S. at 272.

189. *Id.* at 274. At oral argument, several Justices questioned whether the CSA permits states to include nontherapeutic practices—like giving steroids to bodybuilders, or prescribing drugs simply to make people happier—within the scope of legitimate medical practice. *Oral Argument in Gonzales v. Oregon*, 21 ISSUES L. & MED. 213, 226 (Roberts, J.), 226 (Ginsburg, J.), 227 (O’Connor, J.), 233 (Scalia, J.).

190. Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 446–53 (2015).

Although the FDCA preempts most state efforts to regulate the sale of FDA-approved drugs and devices,<sup>191</sup> states regulate controlled substances in ways that mirror the federal CSA.<sup>192</sup> All states impose criminal penalties for possessing or distributing Schedule I drugs or possessing, distributing, or prescribing other controlled substances without a valid prescription.<sup>193</sup> While states may impose additional restrictions on how doctors prescribe scheduled drugs, state drug laws are generally consonant with the CSA.<sup>194</sup>

Unlike the federal government, states play a significant role in regulating medical practice. States require physicians to be licensed by state medical boards before practicing medicine, and these boards can revoke physicians' licenses if their practices are deemed unethical or outside the bounds of accepted practice.<sup>195</sup> States also regulate the practice of medicine through malpractice suits, which enable patients harmed by medical interventions to obtain damages from physicians who breach the standard of care.<sup>196</sup>

However, neither licensing boards nor tort law seeks to constrain doctors from providing nontherapeutic interventions, or to regulate these interventions on moral grounds beyond protecting patient safety. Rather, these forms of regulation allow the medical profession to define for itself the scope of legitimate practice. For example, a plastic surgery patient could not recover in a malpractice action on the grounds that the procedure the doctor performed was not

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191. Tamsen Valoir & Shubha Ghosh, *FDA Preemption of Drug and Device Labeling: Who Should Decide What Goes on a Drug Label?*, 21 HEALTH MATRIX 555 (2011).

192. *Gonzales*, 546 U.S. at 251 (“[t]he CSA explicitly contemplates a role for the States in regulating controlled substances.”); 21 U.S.C. § 903 (2012).

193. *See, e.g.*, N.Y. PUB. HEALTH LAW § 3306 (“Schedules of controlled substances”); N.Y. PUB. HEALTH LAW § 3304 (“Prohibited Acts”).

194. Recent state marijuana laws that contradict federal prohibitions are a notable exception. *See, e.g.*, COLO. CONST. art. XVIII, § 16 (legalizing marijuana possession); 29 WASH. REV. CODE § 69.50.401(3) (2013) (also legalizing marijuana possession); Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421 (2009).

195. *See, e.g.*, Katherine Drabiak-Syed, *supra* note 185, at 276 (citing TENN. CODE ANN. § 63-6-214 (2015); LA. STAT. ANN. § 37: 1275, 1261 (2015); OHIO REV. CODE ANN. § 4731.22 (2015)).

196. States also play a limited role in regulating FDA-approved drugs and devices through tort litigation. While most state law tort suits based on harms caused by drugs and devices are preempted by the FDCA, a few actions remain viable. *See Valoir & Ghosh supra* note 191.



therapeutic. Instead, tort liability typically hinges on whether the doctor performed the procedure as other reasonably prudent plastic surgeons would.<sup>197</sup> Similarly, state medical boards can suspend or revoke physicians' licenses for things like gross negligence, repeated negligent acts, or incompetence—again, defined by reference to how reasonably prudent doctors conduct themselves.<sup>198</sup> But as long as the patient consented to the intervention and the doctor performed it competently, it matters very little whether the doctor provided the intervention for a therapeutic purpose.

On their face, some state laws suggest otherwise. For example, California's Health and Safety Code provides that a physician may prescribe controlled substances "only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment."<sup>199</sup> Taken literally, this provision appears to bar physicians from prescribing controlled substances for nontherapeutic purposes. Presumably that would be unwelcome news to the state's many doctors who prescribe Botox to individuals who want fewer wrinkles.<sup>200</sup> In practice, however, these state laws operate in a manner similar to the CSA's requirement that doctors only issue prescriptions for "legitimate medical purpose[s]"—i.e., to prosecute doctors who act as "dealers" of narcotics and other addictive prescription drugs. To make out a case under these laws, prosecutors must show indicia of drug dealing—such as charging patients by the volume of narcotics prescribed, or prescribing narcotics without first examining patients.<sup>201</sup> A review of state court opinions identified no cases in which doctors were prosecuted for prescribing drugs for nontherapeutic purposes where these other indicia of drug dealing were not also present.

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197. Anne Bloom, *Plastic Injuries*, 42 HOFSTRA L. REV. 759, 784 (2014) ("[I]n plastic surgery litigation, what matters is whether the plastic surgeon's practices deviated significantly from the practices of other plastic surgeons in the same field.").

198. CAL. BUS. & PROF. CODE § 2234 (2015).

199. CAL. HEALTH & SAFETY CODE § 11210 (2015); *see also* Rules of the Tennessee State Board of Medical Examiners, Ch. 0880-02-.14(6)(a)(3) (defining "[n]on-therapeutic in nature or manner" as "[a] medical use or purpose that is not legitimate.").

200. Medical Board of California, *Frequently Asked Questions - Cosmetic Treatments*, [www.mbc.ca.gov/Licensees/Cosmetic\\_Treatments\\_FAQ.aspx](http://www.mbc.ca.gov/Licensees/Cosmetic_Treatments_FAQ.aspx) (last visited Nov. 4, 2015).

201. 21 C.F.R. 1306 (2006); *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978).

*4. A notable exception: reproduction technology*

While most medical regulation emphasizes protecting human health, in the case of reproduction technologies governments have repeatedly sought to restrict nontherapeutic interventions to enforce a particular conception of morality. Sometimes these restrictions are framed as safety measures but in fact seem intended to bar the use of these technologies, irrespective of whether they threaten women's health. For example, in 2011 the FDA's Center for Drug Evaluation and Research (CDER) determined that a contraceptive intervention known as Plan B was effective and could be used safely by girls of all ages, such that it should be available "over the counter" at any age rather than requiring a prescription.<sup>202</sup> In an unprecedented action, the Secretary of Health and Human Services overruled the FDA's determination. Secretary Sebelius framed her action in terms of protecting health, claiming there was insufficient data to establish that younger girls could use the drug safely. But many people believe the Secretary's interference was not based on safety considerations, but rather was "a politically motivated effort to avoid riling religious groups and others opposed to making birth control available to girls."<sup>203</sup> Indeed, a federal district court thoroughly repudiated the Secretary's action as "politically motivated [and] scientifically unjustified."<sup>204</sup>

Other legislative actions regulating abortion procedures are expressly based on moral condemnation of these practices. The federal government and the overwhelming majority of states prohibit doctors from performing certain abortion procedures, generally after a designated period of fetal gestation.<sup>205</sup> Under the federal Partial-Birth Abortion Ban Act of 2003, any physician who knowingly performs an intact dilation and extraction—a procedure used to terminate some late-term pregnancies—faces up to two years in

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202. *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166–67 (E.D.N.Y. 2013).

203. Gardiner Harris, *White House and the FDA Often at Odds*, N.Y. TIMES, Apr. 3, 2012 at A1.

204. *Tummino*, 936 F. Supp. 2d at 192.

205. See, e.g., The Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108–105, 117 Stat. 1201, (codified as amended at 18 U.S.C. § 1531 (2003)) (prohibiting a later-term abortion procedure); GUTTMACHER INSTITUTE, STATE POLICIES ON LATER-TERM ABORTIONS (Nov. 1, 2015), [www.guttmacher.org/statecenter/spibs/spib\\_PLTA.pdf](http://www.guttmacher.org/statecenter/spibs/spib_PLTA.pdf) (summarizing state restrictions on late-term abortion procedures).

prison and/or a criminal fine.<sup>206</sup> The prohibition is expressly motivated by moral condemnation of a procedure that Congress has deemed nontherapeutic. The Act includes a Congressional finding that “[a] moral, medical, and ethical consensus exists that the practice of performing a partial-birth abortion . . . is a gruesome and inhumane procedure that is never medically necessary and should be prohibited.”<sup>207</sup>

In the present context these efforts to restrict reproduction technologies are noteworthy because they provide concrete examples of regulating nontherapeutic medical interventions on moral grounds other than protecting safety. In contrast to the FDA’s determinations regarding the safety and efficacy of medical interventions, these actions are not based on objective assessments of scientific data. Rather they are highly politicized, and subject to shifting public opinion and the differing priorities of new administrations. As discussed below, these actions also intrude upon deeply personal decisions that profoundly affect women’s ability to control their own bodies and identities.

### *B. Proposals to Broaden the Scope of Medical Regulation*

Some worry that existing regulatory systems focus too narrowly on protecting health, and have called for expanding the scope of federal regulation of medicine to address broader social and ethical concerns.<sup>208</sup> Francis Fukuyama argues that new medical technologies

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206. 18 U.S.C. § 1531 (2012).

207. The Partial-Birth Abortion Ban Act, Section 2(1), 117 Stat. at 1201.

208. See, e.g., Secretary of Health and Human Services’ Advisory Committee on Genetics, Health and Society, *Public Comments on Preliminary Final Recommendations on Oversight of Genetic Testing*, 65 Fed. Reg. 21,094, 21,095 (Apr. 19, 2000) (noting that the FDA’s review process does not consider “the ethical and social implications” of genetic tests and arguing that “[t]he Secretary should consider the development of a mechanism to ensure the identification and appropriate review of tests that raise major social and ethical concerns.”); FUKUYAMA, *supra* note 3 at 213 (advocating the creation of “a new agency to oversee the approval of new medicines, procedures, and technologies for human health” with the power “to make judgments about the technology’s social and ethical implications.”); Fox, *supra* note 97 (advocating expanding the FDA’s mandate to consider ethical concerns and to restrict access to interventions that could be used for enhancement purposes); Gary Marchant et al., *Integrating Social and Ethical Concerns Into Regulatory Decision-Making for Emerging Technologies*, 11 MINN. J.L. SCI. & TECH. 345 (2010) (advocating incorporating broader ethical concerns into the FDA’s review of drugs and devices); Ellen M. McGee, *Should There Be A Law? Brain Chips: Ethical and Policy Issues*, 24 T.M. COOLEY L. REV. 81 (2007) (arguing

threaten human dignity and a human nature that he believes is, “conjointly with religion, what defines our most basic values.”<sup>209</sup> Fukuyama argues it is imperative to go beyond merely exploring the ethical issues raised by emerging medical technologies, and to quickly create regulatory institutions that are empowered to limit the use of enhancement technologies.<sup>210</sup> He urges countries to “regulate the development and use of technology politically, setting up institutions that will discriminate between those technological advances that promote human flourishing, and those that pose a threat to human dignity and well-being.”<sup>211</sup>

Noting that the FDA has neither the legal authority nor the institutional capacity to address concerns beyond safety and efficacy, Fukuyama advocates creating “a new agency to oversee the approval of new medicines, procedures, and technologies for human

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FDA review “is inadequate to consider the social and policy questions raised by . . . enhancement devices” and urging the creation of new regulatory systems to address these issues); Ellen M. McGee and Gerald Q. Maguire, Jr., *Becoming Borg to Become Immortal: Regulating Brain Implant Technologies*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 291 (2007) (“No system exists for consideration of the extraordinary social and policy questions raised by . . . devices when used for enhancement. This level of scrutiny should be added and considered the equivalent of an environmental impact statement.”); Leon R. Kass, *The New Biology: What Price Relieving Man’s Estate?*, 174 SCI. 779, 787 (1971) (advocating attempts “to detect and diminish the social costs of biomedical advances by intelligent institutional regulation” and arguing that “[c]oncepts of ‘risk’ and ‘cost’ need to be broadened to include . . . social and ethical consequences.”); Eric Chan, Comment, *The Food and Drug Administration and the Future of the Brain-Computer Interface: Adapting FDA Device Law to the Challenges of Human-Machine Enhancement*, 25 J. MARSHALL J. COMPUTER & INFO. L. 117 (2007) (noting that the FDA does not address the ethical issues raised by enhancement, and advocating expanding the Agency’s authority to regulate enhancements on the basis of moral concerns unrelated to safety); Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 689 (1999) (“In seeking to regulate genetic enhancement, in any event, society must attend not only to the traditional regulatory concerns of safety and efficacy, but to the problems of social inequality and cheating posed by the lack of universal access to enhancement technologies.”); Whitehouse et. al., *supra* note 38, at 21 (“[T]he licensing process of the FDA focuses on clinical safety and efficacy. The agency has little experience with evaluating the types of social costs and benefits that regulating cognitive enhancers would entail. At the least, we would need to supplement the normal review process of the agency so that it considered these issues, and provide the agency with the expertise to do so. The former might well require a change in the enabling legislation of the agency.”).

209. FUKUYAMA, *supra* note 3, at 7.

210. *Id.* at 203–04.

211. *Id.* at 182.

health.”<sup>212</sup> This new agency would “adjudicate among competing ethical claims” in order to distinguish between “legitimate” and “illegitimate” uses of medical technology, and would be empowered to restrict or prohibit practices it deemed illegitimate.<sup>213</sup> The broader scope of this new entity’s mandate would require new staffing, including “not just the doctors and scientists who staff the FDA and oversee clinical trials for new drugs, but other societal voices that are prepared to make judgments about the technology’s social and ethical implications.”<sup>214</sup>

Other scholars have advocated incorporating this kind of ethical machinery within the FDA.<sup>215</sup> Gary Marchant and his co-authors have argued that although the regulatory approval stage of technology development offers “the best opportunity to expressly and formally consider the ethical and social impacts of new technologies,”<sup>216</sup> legal and practical restraints prevent federal regulatory agencies from addressing these issues:

Given that many of the public concerns about such technologies are ethical or social in nature, it seems inappropriate from both a normative and instrumental perspective for regulatory agencies to continue to disregard such concerns because they are outside of their stated regulatory missions. . . . [I]n a democracy, citizens should have the right to raise moral and social concerns about a proposed government action, and to have those concerns considered and addressed by government decision-makers.<sup>217</sup>

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212. *Id.* at 213–14 (noting that “[t]he FDA can disapprove a procedure only on the grounds of effectiveness and safety,” and the Agency “is not set up to make politically sensitive decisions” about the broader ethical implications of enhancements).

213. *See, e.g., id.* at 213. While Fukuyama is primarily concerned with regulating genetic modification of children—interventions that raise issues beyond the scope of this paper—his arguments also extend to the regulation of pharmaceutical interventions. *Id.* at 41–56.

214. *Id.* at 214.

215. *See, e.g.,* Whitehouse et al., *supra* note 38, at 21 (“[T]he licensing process of the FDA focuses on clinical safety and efficacy. The agency has little experience with evaluating the types of social costs and benefits that regulating cognitive enhancers would entail. At the least, we would need to supplement the normal review process of the agency so that it considered these issues, and provide the agency with the expertise to do so. The former might well require a change in the enabling legislation of the agency.”).

216. Marchant, et al., *supra* note 208, at 349.

217. *Id.*

Marchant suggests the FDA could create an “ethics review board” similar to its existing advisory committees that provide scientific advice. The board “would provide comparable advice on the ethical and social dimensions of the agency’s actions”—including such issues as new technologies’ “potential use for enhancing humans, the ‘unnatural’ nature of some of the interventions made possible by new technologies, and the commoditization or destruction of human or animal ‘life,’ however defined.”<sup>218</sup>

Dov Fox has similarly advocated expanding the FDA’s mandate to include addressing ethical concerns about medical products that can be used for nontherapeutic purposes. Fox proposes creating a new administrative process within the FDA in which drugs and devices deemed to have enhancement potential would be “earmarked for special analysis and consideration.”<sup>219</sup> That analysis would include such considerations as “unfairness in competitive activities, inequality of access to positional advantages, perpetuation of social prejudice, threats to individual agency, identity, and authenticity, social conformity and subtle coercion, and negative externalities when such technologies are pursued collectively.”<sup>220</sup> When the FDA determined an intervention would threaten adverse social consequences or important values, the agency would have authority to limit how—or whether—the intervention could be used.

Common to these proposals is the idea that regulators should distinguish therapeutic practices from nontherapeutic, and subject the latter to heightened restrictions. While therapies would continue to be evaluated based on safety, enhancements could be restricted on the basis of other moral objections.

### III. THE HAZARDS OF MEDICAL REGULATION AS SOCIAL CONTROL

As new medical technologies proliferate, offering ever more powerful and precise ways to shape identities, calls to regulate on moral grounds will likely grow louder.<sup>221</sup> Several observers have

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218. *Id.* at 347, 360.

219. Fox, *supra* note 97, at 1194–95.

220. *Id.* at 1195.

221. *See, e.g.*, Marchant et. al, *supra* note 208, at 348 (“As the number of available drugs addressing cognitive performance (e.g., Alzheimer’s treatments) is expected to expand over the

already raised the prospect of urine testing of students and employees to prevent cognitive “doping”—an approach endorsed by Britain’s Academy of Medical Sciences.<sup>222</sup> And although interventions to dampen or edit memories have only begun to be tested in humans,<sup>223</sup> the mere prospect of these technologies has spawned considerable concern, as well as discussion of possible legal restrictions.<sup>224</sup>

But even if one accepts critics’ arguments that enhancement technologies can have troubling moral or social implications, it would be a mistake to conclude that we should restrict them on that basis. Many morally problematic practices are legal. Sometimes we allow them because we do not believe legal restrictions would be effective in deterring these practices or addressing their potential harms. We allow other practices because, although many people find them morally objectionable, they are considered personal choices that lie within individuals’ rights to self-determination. Before vastly expanding government’s authority to interfere with individuals’ medical decisions, it would be prudent to examine whether legal restrictions would be effective in achieving their aims, and whether the aims themselves are proper. As it happens, the United States already has substantial experience in regulating nontherapeutic medical interventions on moral grounds, and these efforts have been both ineffective and unduly intrusive.

*A. Restricting Biological Interventions on Moral Grounds Is Ineffective*

*1. Existing drug prohibitions are based largely on moral condemnation*

In the nineteenth and early twentieth centuries, members of the temperance movement unabashedly touted the moral underpinnings

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next decade, the inability of FDA to consider factors other than safety and efficacy will become increasingly problematic and limiting.”).

222. *HUMAN ENHANCEMENT AND THE FUTURE OF WORK*, *supra* note 93; Ian Sample, *Exam Cheating Alert Over Brain Drugs*, *THE GUARDIAN* (May 22, 2008), [www.guardian.co.uk/science/2008/may/22/drugs.medicalresearch](http://www.guardian.co.uk/science/2008/may/22/drugs.medicalresearch); Rebecca Roache, *Enhancement and Cheating*, 2 *EXPOSITIONS* 153 (2008); Vince Cakic, *Smart Drugs for Cognitive Enhancement: Ethical and Pragmatic Considerations in the Era of Cosmetic Neurology*, 35 *J. MED. ETHICS* 611 (2009); Whitehouse et al., *supra* note 38.

223. Kroes et al., *supra* note 82.

224. *BEYOND THERAPY*, *supra* note 88 at 214–34; Kolber, *supra* note 87.

of their prohibitionist agenda. In *The License Cases*, counsel for the Commonwealth of Massachusetts defended laws restricting alcohol sales by arguing:

The train of evils which mark the progress of intemperance is too obvious to require comment. It brings with it degradation of character, impairs the moral and physical energies, wastes the health, increases the number of paupers and criminals, undermines the morals, and sinks its victims to the lowest depths of vice and profligacy.<sup>225</sup>

The Volstead Act, which implemented alcohol prohibition under the Eighteenth Amendment, did not ban alcohol entirely. Rather, it expressly allowed alcohol to be prescribed by a physician who “in good faith believes that the use of such liquor as a medicine by [a patient] is necessary and will afford relief to him from some known ailment.”<sup>226</sup> It also allowed alcohol to be used by “a rabbi, minister of the gospel, priest” and other religious officials “for sacramental purposes, or like religious rights.”<sup>227</sup> In other words, the problem the Act sought to address was not that alcohol was inherently too dangerous to be used, but that particular uses were viewed as posing threats to the moral and social order.

While the Controlled Substances Act lacks the overt moralism of the temperance movement—and while the motivations behind the “war on drugs” are admittedly numerous and complex—the criminalization of “recreational” drug use likewise appears to reflect moral condemnation of practices that are “perceived to violate fundamental moral values.”<sup>228</sup> Although the Act purports to restrict access to controlled substances to protect users’ health, the incongruous scheduling of many drugs appears designed instead as a means of combatting social deviance—“an aspirational endeavor . . . [that] seeks to forge notions of whom and what we should be

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225. *License Cases*, 46 U.S. 504, 521; *see also id.* at 577 (Taney, J.) (“[I]f any State deems the retail and internal traffic in ardent spirits injurious to its citizens, and calculated to produce idleness, vice, or debauchery, I see nothing in the Constitution of the United States to prevent it from regulating and restraining the traffic, or from prohibiting it altogether, if it thinks proper.”).

226. Volstead Act, ch. 85, tit. II, 41 Stat. 305, §7 (1919).

227. *Id.*

228. Kimani Paul-Emile, *Making Sense of Drug Regulation: A Theory of Law for Drug Control Policy*, 19 CORNELL J. L. & PUB. POL’Y 691, 710 (2009–2010).



individually and collectively.”<sup>229</sup> In particular, Schedule I ostensibly includes only drugs that are considered to have “a high potential for abuse,” that are deemed to have “no currently accepted medical use,” and that cannot be used safely, even under medical supervision.<sup>230</sup> Yet that category includes several drugs that have known therapeutic uses and that appear to pose less potential for abuse than drugs in lower schedules—or, in the case of alcohol and cigarettes, no schedule at all.<sup>231</sup>

Marijuana is the most notable example. At the time of the CSA’s passage, marijuana was placed in Schedule I pending a report to be issued by a National Commission on Marihuana and Drug Abuse.<sup>232</sup> The Commission concluded that the drug posed little danger of physical or psychological harm, and that “the actual and potential harm of use of the drug is not great enough to justify intrusion by the criminal law into private behavior.”<sup>233</sup> But rather than accepting the findings of the Commission it had created, the Nixon administration rejected these findings and left marijuana in Schedule I. In audio recordings of Nixon’s Oval Office conversations about the Commission’s work, the President drew a curious distinction between drinking to “have a good time” and smoking marijuana to “get high,” arguing that the latter was (along with homosexuality) immoral and “the enem[y] of strong societies.”<sup>234</sup>

Marijuana remains in Schedule I today, while cocaine, methamphetamine, and other narcotics and stimulants are in Schedule II. These prescription drugs pose substantial health threats to users, including a high potential for addiction and fatal overdoses. By contrast, an Institute of Medicine (IOM) report commissioned by the White House Office of National Drug Control Policy determined that “marijuana’s abuse potential appears relatively small

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229. *Id.* at 709.

230. 21 U.S.C. § 812(b)(1).

231. Paul-Emile, *supra* note 228, at 698.

232. Pub. L. No. 91-513, § 601 Part F, 84 Stat. 1236, 1280-81 (1970).

233. THE REPORT OF THE NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE, MARIHUANA: A SIGNAL OF MISUNDERSTANDING (1972), [www.druglibrary.org/schaffer/library/studies/nc/ncmenu.htm](http://www.druglibrary.org/schaffer/library/studies/nc/ncmenu.htm).

234. Audio Tape: Presidential Recordings, Tape 498, Part I, (May, 1971) (available at <http://millercenter.org/presidentialrecordings/rmn-e498a>) (transcribed at [www.csdp.org/research/nixonpot.txt](http://www.csdp.org/research/nixonpot.txt)).

and certainly within manageable limits for patients under the care of a physician.”<sup>235</sup> While more than twenty-two thousand people die in the United States each year from prescription drug overdoses,<sup>236</sup> the IOM found that “[t]o our knowledge no marijuana user has ever died of such an overdose.”<sup>237</sup>

Moreover, while Schedule I is ostensibly reserved for drugs that have no medical uses, there is considerable evidence that marijuana can offer substantial therapeutic benefits<sup>238</sup>—despite the Drug Enforcement Administration’s hard-fought campaign to obstruct research aimed at investigating the drug’s therapeutic qualities.<sup>239</sup> Belying the claim that marijuana has “no currently accepted medical use,” many reputable medical associations and patient advocacy groups have affirmed marijuana’s therapeutic value and twenty-three states permit the use of marijuana for medicinal purposes.<sup>240</sup>

Other banned drugs—including psilocybin, LSD, and MDMA—have shown significant therapeutic promise, and there is little evidence these drugs could not be used safely under appropriate medical supervision.<sup>241</sup> The assignment of these drugs to Schedule I appears to be based not on objective assessments of their safety for

235. INSTITUTE OF MEDICINE, *MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE* BASE 58 (1999).

236. Sabrina Tavernise, *Overdose Deaths Continue to Climb*, N.Y. TIMES, Feb. 19, 2013, [www.nytimes.com/2013/02/20/us/overdose-deaths-continue-to-climb.html?\\_r=0](http://www.nytimes.com/2013/02/20/us/overdose-deaths-continue-to-climb.html?_r=0).

237. INSTITUTE OF MEDICINE, *supra* note 235, at 50.

238. Paul-Emile, *supra* note 228, at 732 n.174.

239. DRUG POLICY ALLIANCE & MAPS, *THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE 2* (2014), [https://www.drugpolicy.org/sites/default/files/DPA-MAPS\\_DEA\\_Science\\_Final.pdf](https://www.drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf) (describing tactics the DEA has used “to maintain the existing, scientifically unsupported drug scheduling system and to obstruct research that might alter current drug schedules.”).

240. See, e.g., NORML, *Health Organizations Supporting Immediate Legal Access to Medical Marijuana*, [http://norml.org/component/zoo/item/detailed-reference?category\\_id=734](http://norml.org/component/zoo/item/detailed-reference?category_id=734) (last visited Nov. 4, 2015); 23 *Legal Medical Marijuana States and DC*, PROCON.ORG, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> (last visited Nov. 4, 2015) (listing states that have legalized marijuana for medicinal purposes).

241. Lauren Slater, *How Psychedelic Drugs Can Help Patients Face Death*, N.Y. TIMES MAG., Apr. 20, 2012, at 56 (describing research at Johns Hopkins, NYU, and elsewhere into using psilocybin and LSD to treat anxiety in terminally ill patients); MAPS, *Treating PTSD with MDMA-Assisted Psychotherapy: Research*, [www.mdmaptsd.org/research-category.html](http://www.mdmaptsd.org/research-category.html) (listing published studies suggesting MDMA can be an effective therapy for PTSD).

human consumption, but on condemnation of altering consciousness in particular ways.

*2. Prohibition is costly and fails to deter forbidden practices*

From Prohibition to the war on drugs, punitive efforts have been ineffective in preventing people from using drugs to modify consciousness in desired ways, despite the substantial risks these practices sometimes entail for users. In 2007, there were more than 1.8 million arrests for drug law violations—a more than threefold increase since 1980.<sup>242</sup> More than 80 percent of drug arrests in 2012 were for mere possession of a controlled substance.<sup>243</sup> Possessing or distributing banned drugs can result in lengthy prison sentences, asset forfeiture, termination of employment, and many other dire consequences.<sup>244</sup> Yet, while the United States spends billions each year on combatting the illegal drug trade, those expenditures appear to do little to reduce the availability of drugs or consumer demand for them.<sup>245</sup> “Drug users in the United States spend on the order of \$100 billion annually on cocaine, heroin, marijuana, and meth.”<sup>246</sup> According to the National Institute on Drug Abuse, “[a]bout 40

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242. BUREAU OF JUSTICE STATISTICS, DRUG AND CRIME FACTS, [www.bjs.gov/content/dcf/tables/arrtot.cfm](http://www.bjs.gov/content/dcf/tables/arrtot.cfm).

243. FEDERAL BUREAU OF INVESTIGATION, FBI UNIFORM CRIME REPORT: CRIME IN THE UNITED STATES 2012 – ARRESTS 1 (2013).

244. See, e.g., Martin Y. Iguchi, et al., *Elements of Well-Being Affected By Criminalizing The Drug User*, 117 (Supp. 1) PUBLIC HEALTH REP. 146 (2002) (“State and federal policies on drug felons may affect eight elements of personal and community well-being: children and families, access to health benefits, access to housing benefits, access to assistance for higher education, immigration status, employment, eligibility to vote, and drug use or recidivism.”); Nora V. Demleitner, *Collateral Damage: No Re-Entry for Drug Offenders*, 47 VILL. L. REV. 1027 (2002).

245. EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF NATIONAL DRUG CONTROL POLICY, NATIONAL DRUG CONTROL BUDGET: FY 2015 FUNDING HIGHLIGHTS 2 (2014), [https://www.whitehouse.gov/sites/default/files/ondcp/press-releases/ondcp\\_fy16\\_budget\\_highlights.pdf](https://www.whitehouse.gov/sites/default/files/ondcp/press-releases/ondcp_fy16_budget_highlights.pdf) (in 2014, Congress allocated \$25.2 billion “to reduce drug use and its consequences”); THE NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, SHOVELING UP II: THE IMPACT OF SUBSTANCE ABUSE ON STATE BUDGETS 58 (2009) (“While international efforts to step up drug seizures may affect availability, price, and consequences associated with a particular drug (i.e., cocaine or heroin), CASA was unable to find evidence that such strategies have an overall impact on reducing substance abuse and addiction or its costs to government.”).

246. BEAU KILMER ET AL., WHAT AMERICA’S USERS SPEND ON ILLEGAL DRUGS: 2000-2010 103 (2014).

percent of high school seniors admit to having taken some illegal drug in the last year—up from thirty percent two decades ago.”<sup>247</sup> Despite that increasing demand, the average price of a gram of pure cocaine has declined by 74 percent over the past thirty years, suggesting an enormous increase in supply of the drug.<sup>248</sup> In sum, despite the seemingly minimal benefits of many banned drugs, the incredibly harsh penalties for their sale and possession, and the enormous investments in trying to prevent their use, these drugs continue to be widely available and commonly used.

The difficulty of limiting access to desired drugs would be profoundly magnified in the context of interventions that offer more tangible benefits than the euphoria of cocaine or heroin. For many people the desire to transform one’s identity is so compelling that they will go to incredible lengths, and assume great risks, to make these changes.<sup>249</sup> People who pursue sex changes often undergo multiple surgeries and take hormones for the rest of their lives. Athletes who use steroids must not only accept the health risks of these drugs, but must undertake punishing workouts to obtain the drugs’ desired effects. For others, the pursuit of extrinsic rewards—such as competitive advantages in school or the workplace—may prove equally powerful. Already, people from all walks of life are taking prescription drugs in hopes of gaining a competitive edge by enhancing their cognition.<sup>250</sup> If millions of people are willing to risk lengthy prison sentences to experience fleeting euphoria, presumably millions more would be willing to do so in order to obtain the more significant benefits enhancements may offer.<sup>251</sup>

Moreover, unlike Schedule I drugs, most existing enhancements have—and future enhancements are likely to have—approved

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247. Eduardo Porter, *Numbers Tell of Failure in Drug War*, N.Y. TIMES, July 3, 2012, at B1 (citing THE UNIVERSITY OF MICHIGAN, MONITORING THE FUTURE 2011 NATIONAL SURVEY RESULTS, LONG-TERM TRENDS IN ANNUAL PREVALENCE OF USE OF VARIOUS DRUGS IN GRADE 12 (2011), <http://monitoringthefuture.org/data/11data/pr11t16.pdf>).

248. *Id.*

249. ELLIOTT, *supra* note 1, at 39.

250. *See supra* notes 37–54 and accompanying text.

251. Sahakian & Morein-Zamir, *supra* note 39, at 1159 (“We believe it would be difficult to stop the spread in use of cognitive enhancers given a global market in pharmaceuticals with increasingly easy online access. The drive for self-enhancement of cognition is likely to be as strong if not stronger than in the realms of ‘enhancement’ of beauty and sexual function.”).

therapeutic uses.<sup>252</sup> “Study drugs” like Ritalin and Adderall are FDA-approved as treatments for ADHD. Human growth hormone (HGH) can make normal kids taller, but it was originally approved as a treatment for pituitary problems.<sup>253</sup> Steroids can help bodybuilders grow enormous muscles, but they can also help rebuild tissues that have been weakened by injuries or illnesses.<sup>254</sup> While these drugs are legally available only with a prescription, their sale and manufacture is legal and common. Preventing people from using legal drugs in unapproved ways would be considerably more difficult than enforcing the ban on Schedule I drugs has been. Indeed, the wide availability of legal painkillers and stimulants may explain why abuse of prescription drugs is becoming more common than the use of banned substances.<sup>255</sup>

Relatedly, the challenge of restricting nontherapeutic practices would be magnified by the fact that many enhancements may be safer—or perceived as safer—than banned drugs. Unlike Schedule I drugs, the FDA deems approved drugs to be safe enough for use in humans.<sup>256</sup> In addition, the FDA regulates the production of prescription drugs, providing users with assurances of quality and non-adulteration that are absent for illegally manufactured banned drugs.<sup>257</sup>

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252. See Maartje Schermer et al., *The Future of Psychopharmacological Enhancements: Expectations and Policies*, 2 *NEUROETHICS* 75, 78 (2009).

253. Peter Conrad & Deborah Potter, *Human Growth Hormone and the Temptations of Biomedical Enhancement*, 26 *SOC. OF HEALTH & ILLNESS*, 184, 187–88 (2004).

254. *Anabolic Steroid (Oral Route, Parenteral Route)*, MAYO CLINIC, [www.mayoclinic.org/drugs-supplements/anabolic-steroid-oral-route-parenteral-route/description/drg-20069323](http://www.mayoclinic.org/drugs-supplements/anabolic-steroid-oral-route-parenteral-route/description/drg-20069323) (last visited Nov. 1, 2015).

255. Steven Reinberg, *Prescription Painkillers Trail Only Marijuana in Abuse Rates, Report Shows*, U.S. NEWS & WORLD REP., Jan. 10, 2013, <http://health.usnews.com/health-news/news/articles/2013/01/10/prescription-painkillers-trail-only-marijuana-in-abuse-rates-report-shows>.

256. Although the FDA assesses drugs’ safety in relation to their efficacy in treating specific indications, in many cases a drug may be no less safe, and no less beneficial, when used for enhancement purposes rather than therapy. For example, a person who is healthy, but very short gets no less benefit, and incurs no greater safety risk from using HGH to increase his height than an individual with a malfunctioning pituitary gland who uses the drug for the same purpose.

257. Pete Stark, *U.S. Taxpayers Are Funding Prescription Drug Abuse*, USA TODAY: MAG. AM. SCENE, July 1991, at 88 (“Given an option between a white powder of unknown origin and quality and a pill with a manufacturer’s logo, made under U.S. government quality control, the decision for the abuser is easy.”).

Initial forays into restricting off-label uses of HGH illustrate the difficulty of trying to limit medical interventions to certain approved therapeutic uses. In 1990, Congress banned the distribution of HGH for nontherapeutic uses, such as enhancing athletic performance or combatting the effects of aging.<sup>258</sup> However, law enforcement has faced substantial challenges in seeking to prevent patients from using the drug in unapproved ways. The U.S. Attorneys Civil Resource Manual notes the difficulty of obtaining evidence that a physician is prescribing HGH improperly, suggesting that prosecutors should consider making “‘controlled buys’ using undercover agents or informants” and issuing search warrants and grand jury subpoenas for physicians’ medical files.<sup>259</sup>

For all the intrusiveness of undercover agents posing as patients and rifling through doctors’ medical files, the payoff is elusive. Despite the efforts of prosecutors—not to mention endless sports scandals and media stories—off-label use of HGH continues to soar.<sup>260</sup> In 2006, the federal government began a crackdown in an attempt to reduce “misuse” of the drug.<sup>261</sup> While the effort succeeded in reducing the flow of illicit supplies from Mexico, China, and India, domestic consumption of HGH nevertheless skyrocketed, with sales increasing 69 percent from 2005 to 2011.<sup>262</sup> Although endocrinologists estimate that patients who meet the diagnostic criteria for the approved uses of HGH would use roughly 180,000 prescriptions or refills each year, in 2011 pharmacies filled nearly twice that many orders.<sup>263</sup> Doctors who are motivated to prescribe the drug for off-label purposes seem to have little difficulty

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258. 21 U.S.C. § 333(e)(1) (1994) (“[W]hoever knowingly distributes . . . human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services . . . is guilty of an offense punishable by not more than 5 years in prison . . .”).

259. U.S. DEPARTMENT OF JUSTICE, U.S. ATTORNEYS CIVIL RESOURCE MANUAL 19 (3d ed. 2012).

260. *Crackdown on Human Growth Hormone Instead Leads to Record Sales*, OREGONLIVE (Dec. 21, 2012), [www.oregonlive.com/today/index.ssf/2012/12/crackdown\\_on\\_human\\_growth\\_horm.html](http://www.oregonlive.com/today/index.ssf/2012/12/crackdown_on_human_growth_horm.html).

261. *Id.*

262. *Id.*

263. *Id.*

crafting diagnoses in ways that “exploit wiggle room in the law restricting use of HGH.”<sup>264</sup>

In sum, attempts to prevent people from using biological interventions to modify their bodies and minds have a poor track record, imposing significant costs while seeming to do little to prevent these practices. Restricting access to interventions that are reasonably safe, that have approved uses, and that offer important, tangible benefits is likely to fail even more profoundly than attempts to limit access to dangerous, banned substances that offer mere euphoria.<sup>265</sup>

*B. The Treatment/Enhancement Distinction Is a Poor Foundation for Regulatory Policy*

Further complicating the enforcement challenges of restricting uses of medical technology, the fundamental idea on which these reform proposals rest—a distinction between treatments and enhancements—is an unworkable basis for regulation. The concept of disease is too malleable, and diagnoses too subjective, to prevent people from using medical interventions in the ways that concern critics. Policies built on this foundation would simply increase the incentives to recast identity-modifying interventions as treatments for illnesses.

Proponents of reform do not advocate preventing people from treating their illnesses and disabilities. Rather, they argue that regulators should be empowered to identify nontherapeutic uses of medical technology and subject only these practices to broader scrutiny and tighter restrictions. Fukuyama proposes that in distinguishing between “legitimate” and “illegitimate” uses of medical technology, “[o]ne obvious way to draw red lines is to distinguish between therapy and enhancement, directing research

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264. *Id.*

265. Prohibition is particularly ineffective at restricting access to drugs, which are commodities that can be easily distributed and do not require medical expertise to use. This approach might be more effective in the context of other forms of enhancement, such as surgeries or genetic interventions that require trained physicians to administer them. That said, one need not look far to find stories of physicians providing prohibited interventions or falsely claiming therapeutic purposes for cosmetic procedures, athletic enhancements, and prescription drug abuse. *See id.*; *infra* notes 272 and 294.

toward the former while putting restrictions on the latter.”<sup>266</sup> Similarly, Fox argues, “[T]he FDA should distinguish medical products with enhancement capacities as a separate category called ‘potential enhancement products.’”<sup>267</sup> While purely therapeutic interventions would continue to be evaluated based on safety and efficacy, those with enhancement potential would be “earmarked for special analysis and consideration” to determine whether other moral or social concerns argue in favor of restricting enhancement uses.<sup>268</sup>

This approach would face profound problems in distinguishing legitimate “therapies” for illnesses from ostensibly nontherapeutic “enhancements.” While it is easy to imagine we have a clear understanding about basic concepts like health, illness, and disability, on closer inspection we find disagreement and confusion. Most people probably would agree that Tay Sachs—a fatal condition afflicting newborn infants—is a terrible illness, and an intervention that cured it would be a treatment. Conversely, most probably would agree that giving humans wings, as one surgeon has proposed, would be a form of enhancement.<sup>269</sup> But between the black and white of extreme examples lies a much broader grey area where there are no clear answers.

“Behaviors do not come naturally labeled as ‘disease’ and ‘nondisease;’ humans make those distinctions and . . . we regularly change them.”<sup>270</sup> Within the philosophical literature a debate has raged for decades over how to define health and illness and distinguish treatment from enhancement—or whether such distinctions can be meaningfully drawn at all.<sup>271</sup>

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266. FUKUYAMA, *supra* note 3, at 208.

267. Fox, *supra* note 97, at 1194.

268. *Id.* at 1194–95.

269. Lauren Slater, *Dr. Daedalus*, HARPER’S MAG., July 2001, at 57.

270. Henry T. Greely, *Direct Brain Interventions to “Treat” Disfavored Human Behaviors: Ethical and Social Issues*, 91 CLINICAL PHARMACOLOGY & THERAPEUTICS 163, 163 (2012); *see also* ANDREW SOLOMON, FAR FROM THE TREE: PARENTS, CHILDREN AND THE SEARCH FOR IDENTITY 29 (2012) (“Ability is a tyranny of the majority. If most people could flap their arms and fly, the inability to do so would be a disability. If most people were geniuses, those of moderate intelligence would be disastrously disadvantaged. There is no ontological truth enshrined in what we think of as good health; it is merely a convention, one that has been strikingly inflated in the past century.”).

271. Christopher Boorse, *On the Distinction between Disease and Illness*, 5 PHIL. & PUB. AFF. 49, 56–64 (1975); Thomas S. Szasz, *The Myth of Mental Illness*, 15 AM. PSYCHOL. 113,



This controversy also routinely plays out in the policy context, particularly when people seek medical interventions at the public's expense. Consider blepharoplasty—a procedure more commonly known as an “eyelid lift.” Cosmetic surgeons often market these lifts as a way to produce more youthful looking eyes, but the procedure can also help patients for whom sagging eyelids hinder their field of vision.<sup>272</sup> From 2001 to 2011, the number of these procedures charged to Medicare more than tripled, prompting concern that tax dollars are being used to pay for many purely cosmetic procedures.<sup>273</sup> However, distinguishing between cosmetic eyelid lifts and those that should be deemed medically necessary is “notoriously difficult” to do.<sup>274</sup> Even when a patient's drooping eyelids interfere with her vision, blepharoplasty will produce a more youthful appearance as a “side-effect.”<sup>275</sup> Doctors are skilled at documenting the therapeutic benefits patients receive from these procedures, making claims of improper Medicare billing difficult and expensive to prove.<sup>276</sup>

The State of New Jersey encountered similar problems in seeking to enforce a tax on cosmetic surgery. That tax applied only to “medical procedures performed in order to improve the human subject's appearance without significantly serving to prevent or treat illness or disease or to promote proper functioning of the body.”<sup>277</sup> The State repealed the tax just eight years after it was enacted, reportedly because disputes about whether procedures were cosmetic or therapeutic made collecting the taxes more expensive than the revenues generated.<sup>278</sup>

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114–15 (1960); Peter H. Schwartz, *Defending the Distinction Between Treatment and Enhancement*, 5 AM. J. BIOETHICS 17, 17–18 (2005).

272. Joe Eaton & David Donald, *Eyelid Lifts Skyrocket Among Medicare Patients, Costing Taxpayers Millions*, CTR. FOR PUB. INTEGRITY (May 28, 2013, 5:00 AM), [www.publicintegrity.org/2013/05/28/12713/eyelid-lifts-skyrocket-among-medicare-patients-costing-taxpayers-millions](http://www.publicintegrity.org/2013/05/28/12713/eyelid-lifts-skyrocket-among-medicare-patients-costing-taxpayers-millions).

273. *Id.*

274. *Id.*

275. *Id.*

276. *Id.*

277. Cosmetic Medical Procedures Gross Receipts Tax, N.J.S.A. 54:32E-1 (2012).

278. Christopher Beam, *Breast Practices: Why Taxing Cosmetic Surgery Is a Bad Idea*, SLATE (Nov. 3, 2009, 8:06 PM), [www.slate.com/articles/news\\_and\\_politics/politics/2009/11/breast\\_practices.html](http://www.slate.com/articles/news_and_politics/politics/2009/11/breast_practices.html) (“[T]he only plan to tax cosmetic surgery so far, in New Jersey, has been a failure, costing \$3 in administrative spending for every dollar of revenue. The main problem, apparently, has been

The challenge of distinguishing between therapy and enhancements is exponentially more difficult in the context of mental illnesses. This task requires deciding which variations of beliefs, emotions, and behaviors should be considered within the range of “normal” identities and which should be considered signs of illness. In the United States, we have largely delegated this task to the American Psychiatric Association, which publishes a compendium of mental illnesses called the *Diagnostic and Statistical Manual of Mental Disorders* (the “DSM”). The volume is important not only to psychiatrists, but to policymakers, insurers, courts, schools, and others for whom it is relevant whether individuals should be considered mentally ill.<sup>279</sup>

The DSM’s classifications and diagnostic criteria have been subjects of endless controversy. For example, the Association’s own research reveals that doctors faced with identical patients routinely reach opposite conclusions about the presence or absence of even the most common mental illnesses.<sup>280</sup> In other words, practicing psychiatrists often disagree about whether particular patients suffer from depression (in which case prescribing antidepressants would constitute treatment), or whether the patients are not ill (so that prescribing drugs would constitute enhancement).

There are no fMRI scans or blood tests that identify the presence of mental illness.<sup>281</sup> Even if psychiatrists could identify physiological factors that reliably correlate with certain behaviors, emotions, or tendencies, this would not answer which of these variations should

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the difficulty in defining ‘elective’ versus ‘reconstructive’ surgery. Who decides whether an operation to fix your nasal breathing, which also happens to make your nose look straighter, is functional or aesthetic?”).

279. Cia Bearden, *The Reality of the DSM in the Legal Arena: A Proposition for Curtailing Undesired Consequences of an Imperfect Tool*, 13 HOUS. J. HEALTH L. & POL’Y 79, 82–84 (2012).

280. Allen Frances, *DSM-5 Field Trials Discredit the American Psychiatric Association*, HUFFINGTON POST (Oct. 31, 2012), [www.huffingtonpost.com/allen-frances/dsm-5-field-trials-discre\\_b\\_2047621.html](http://www.huffingtonpost.com/allen-frances/dsm-5-field-trials-discre_b_2047621.html).

281. See Thomas Insel, *Director’s Blog: Transforming Diagnosis*, NAT’L INST. OF MENTAL HEALTH (Apr. 29, 2013), [www.nimh.nih.gov/about/director/2013/transforming-diagnosis.shtml](http://www.nimh.nih.gov/about/director/2013/transforming-diagnosis.shtml) (“Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure.”).

be categorized as illnesses rather than merely differences.<sup>282</sup> Rather, determining whether a difference should be considered an illness is an inherently subjective determination—one that is inextricably tied to contested conceptions of the good life and influenced by contemporary social expectations and prejudices.<sup>283</sup>

In 1851, a physician named Samuel Cartwright sounded the alarm over the spread of “drapetomania,” a dire affliction that caused slaves to flee captivity.<sup>284</sup> Cartwright contended this illness could be treated with “proper medical advice, strictly followed”—he prescribed “whipping the devil out of them.”<sup>285</sup> In *The Protest Psychosis*, Jonathan Metzl shows how psychiatry reflected the racial anxieties of the Civil Rights era by transforming schizophrenia from “an illness that afflicted nonviolent, white, petty criminals” to “a disorder of racialized aggression” disproportionately applied to black men.<sup>286</sup> Black men arrested for participating in civil rights protests or destroying property during civil unrest were committed to insane asylums, where their medical charts included comments like “[p]aranoid against his doctors and the police” and “[w]ould be a danger to society were he not in an institution.”<sup>287</sup> Perhaps most notoriously, for decades the American Psychiatric Association identified homosexuality as a pathological “sexual deviation,” alongside sadism and necrophilia. Following a sustained campaign by

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282. As Robert Spitzer, a leading architect of the DSM, wrote about debates regarding whether homosexuality should be considered a mental illness, “Often in discussions of this kind a hope is expressed that some biological ‘abnormality,’ such as an endocrine or genetic disturbance, will be discovered and will resolve the issue once and for all. It is hard to see how this would answer the question any more than would knowledge of the biological cause or antecedents of left-handedness (surely there must be one) indicate whether that condition should be regarded as a normal variant or pathology.” Robert L. Spitzer, *The Diagnostic Status of Homosexuality in DSM-III: A Reformulation of the Issues*, 138 AM. J. PSYCHIATRY 210, 213 (1981).

283. *Id.* at 214 (“The concept of ‘disorder’ always involves a value judgment.”).

284. Samuel A. Cartwright, *Diseases and Peculiarities of the Negro Race*, XI DEBOW’S REVIEW (1851).

285. *Id.*

286. Christopher Lane, *How Schizophrenia Became a Black Disease: An Interview with Jonathan Metzl*, PSYCHOL. TODAY (May 5, 2010), [www.psychologytoday.com/blog/side-effects/201005/how-schizophrenia-became-black-disease-interview-jonathan-metzl](http://www.psychologytoday.com/blog/side-effects/201005/how-schizophrenia-became-black-disease-interview-jonathan-metzl). See generally JONATHAN M. METZL, *THE PROTEST PSYCHOSIS: HOW SCHIZOPHRENIA BECAME A BLACK DISEASE* (2010).

287. Lane, *supra* note 286.

gay activists, the APA finally removed homosexuality from the DSM in 1973, and today, it is increasingly viewed not as a disorder, but as a valid identity.<sup>288</sup> Following this example, in recent years many other groups have argued that traits labeled as illnesses and disabilities—such as deafness, autism, and transsexualism—are simply different identities that should be respected and accommodated rather than treated.<sup>289</sup>

The blurriness of the distinction between identity and illness often cuts the other way as well, with traits and behaviors once viewed as elements of personality or character being reconceptualized as forms of illness—a process referred to as “medicalization.”<sup>290</sup> While “drunkenness” and “gluttony” were once viewed as character flaws, today they are often characterized as the mental illnesses “alcohol use disorder” and “binge eating disorder.”<sup>291</sup> A person who is tired as a result of working the night shift can be diagnosed with “shift work sleep disorder” and treated with stimulants.<sup>292</sup> Virtually any life challenge or shortcoming (e.g., picky eating, temper tantrums, or excessive shopping) can be characterized as an illness (like “selective eating disorder,”

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288. Kenneth J. Zucker & Robert L. Spitzer, *Was the Gender Identity Disorder of Childhood Diagnosis Introduced into DSM-III as a Backdoor Maneuver to Replace Homosexuality? A Historical Note*, 31 J. SEX & MARITAL THERAPY 31, 31 (2005); *Homosexuality Not an Illness, Chinese Say*, N.Y. TIMES, Mar. 8, 2001, [www.nytimes.com/2001/03/08/health/08PSYC.html](http://www.nytimes.com/2001/03/08/health/08PSYC.html) (stating Japan and China removed homosexuality as mental illness in 1995 and 2001, respectively).

289. SOLOMON, *supra* note 270, at 18 (“The reasonable corollary to the queer experience is that everyone has a defect, that everyone has an identity, and that they are often one and the same.”); Andrew Solomon, *The Autism Rights Movement*, N.Y. MAG. (May 25, 2008), <http://nymag.com/news/features/47225/>; Andrew Solomon, *Defiantly Deaf*, N.Y. TIMES MAG. (Aug. 28, 1994), [www.nytimes.com/1994/08/28/magazine/defiantly-deaf.html?pagewanted=all](http://www.nytimes.com/1994/08/28/magazine/defiantly-deaf.html?pagewanted=all).

290. Peter Conrad & Valerie Leiter, *Medicalization, Markets and Consumers*, 45 J. HEALTH SOC. BEHAV. 158, 158 (2004).

291. *Alcohol Use Disorders*, NAT’L INST. ON ALCOHOL ABUSE AND ALCOHOLISM, [www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-use-disorders](http://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-use-disorders) (last visited Mar. 4, 2015); *Feeding and Eating Disorders*, AM. PSYCHIATRIC ASS’N, [www.dsm5.org/Documents/Eating%20Disorders%20Fact%20Sheet.pdf](http://www.dsm5.org/Documents/Eating%20Disorders%20Fact%20Sheet.pdf) (last visited Mar. 4, 2015).

292. *Shift Work Sleep Disorder*, CLEVELAND CLINIC, [http://my.clevelandclinic.org/neurological\\_institute/sleep-disorders-center/disorders-conditions/hic-shift-work-sleep-disorder.aspx](http://my.clevelandclinic.org/neurological_institute/sleep-disorders-center/disorders-conditions/hic-shift-work-sleep-disorder.aspx) (last visited Nov. 4, 2015).

“intermittent explosive disorder,” and “compulsive buying disorder”).<sup>293</sup>

Singling out enhancement practices for special restrictions, as reformers propose, would increase the incentives—among drug companies, patients, and physicians—to characterize social problems as medical conditions needing treatment. Patients who want particular interventions—and the companies that want to sell them—would share a common interest in ensuring that those interventions were thought of as treating recognized illnesses, rather than labeled as “enhancements.” For their part, doctors have already demonstrated their willingness to stretch diagnostic criteria to justify prescribing interventions to suffering patients.<sup>294</sup> By broadening the conditions that are considered to be illnesses, these stakeholders could work an end-run around regulations that aim to restrict nontherapeutic practices.<sup>295</sup>

Changing whether a behavior or emotional response is normal or disordered can be as simple as tweaking the diagnostic criteria in the

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293. Patti Neighmond, *Road Rage: A Symptom of Much More than Bad Traffic?*, NPR (Dec. 12, 2011), [www.npr.org/blogs/health/2011/12/12/143457950/road-rage-a-symptom-of-much-more-than-bad-traffic](http://www.npr.org/blogs/health/2011/12/12/143457950/road-rage-a-symptom-of-much-more-than-bad-traffic); *Eating Disorders*, DUKE MED., [www.dukemedicine.org/treatments/psychiatry/eating-disorders](http://www.dukemedicine.org/treatments/psychiatry/eating-disorders) (last visited Nov. 8, 2015) (“Picky or selective eating services: We are at the forefront of care for this newly recognized eating problem, where children and adults severely restrict the types of food they eat, or reject foods on the basis of taste, texture or sensory quality.”); Donald W. Black, *A Review of Compulsive Buying Disorder*, 6 *WORLD PSYCHIATRY* 14, 14 (2007).

294. See, e.g., KRAMER, *supra* note 59 (describing psychiatrist Peter Kramer’s experiences prescribing Prozac to help patients whom he believed did not meet diagnostic criteria for mental illnesses); Leona Cuttler et al., *Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns*, 276 *JAMA* 531, 533 (1996) (ninety-four percent of surveyed endocrinologists reported having recommended HGH to increase the height of children who were not suffering from growth hormone deficiencies); BEYOND THERAPY, *supra* note 88, at 306 (“With the decline in the cultural authority of religious institutions, and with the shrinking of other communal systems of help and support for people in difficulty, physicians often find themselves simply ‘neighbor to the problem.’ Rightly extending a helping hand, they often conceive and treat the problems they encounter in a purely medical fashion.”).

295. Drug companies, doctors, and patients already have substantial incentives to medicalize unpleasant conditions because insurers will only pay for interventions that are deemed medically necessary. However, as the enormous cosmetic surgery market amply demonstrates, nontherapeutic interventions can be very profitable even when patients must pay out of their own pockets. Banning certain off-label interventions altogether would pose a much bigger threat to the profits of drug and device companies, heightening the importance to this industry of ensuring that these interventions are considered therapeutic.

DSM. For example, when the APA first recognized “social anxiety disorder” (SAD) in 1980, it was an obscure diagnosis with an estimated prevalence of roughly 2.75 percent.<sup>296</sup> Following a loosening of the criteria used to diagnose SAD—and an aggressive marketing campaign by the maker of Paxil, an antidepressant approved to treat the condition—by the 1990s that figure had quadrupled, with studies estimating one out of every eight Americans suffered from the illness.<sup>297</sup> Attention disorders reflect a similar trajectory. Again, following a loosening of diagnostic criteria and a multi-pronged public relations effort by drug makers,<sup>298</sup> the number of children diagnosed with ADHD rose by more than 40 percent in the past decade.<sup>299</sup> Today, 11 percent of all school-age children—and roughly 20 percent of high school-age boys—are diagnosed with this condition.<sup>300</sup> It is unlikely that substantially more people are extremely fearful of social situations today than they were in 1980, or that 40 percent more children have difficulty concentrating than they did a decade ago. Rather, levels of shyness and distractedness that we used to think of as normal, if sometimes disadvantageous, are now characterized as forms of mental illness that are legitimate targets for drug therapy.

Perhaps no shift better illustrates the slipperiness of the concept of mental illness than recent changes to the DSM’s definition of “major depressive disorder,” which includes criteria such as “depressed mood” and “loss of interest or pleasure” for a period of at least two weeks.<sup>301</sup> Until recently, the DSM included a “bereavement exclusion” under which a person who had experienced the death of a loved one was not considered depressed unless these

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

297. *Id.*; Conrad & Leiter, *supra* note 290, 163–64.

298. Alan Schwartz, *The Selling of Attention Deficit Disorder*, N.Y. TIMES, December 14, 2013, at A1.

299. Alan Schwarz & Sarah Cohen, *A.D.H.D. Seen in 11% of U.S. Children as Diagnoses Rise*, N.Y. TIMES, March 31, 2013, at A1.

300. *Id.*

301. *Major Depressive Disorder*, in DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (American Psychiatric Association, ed., 5th ed., 2013) (ebook), <http://dsm.psychiatryonline.org/content.aspx?bookid=556&sectionid=41101760#1034374> \9.

symptoms lasted more than two months—in recognition of the fact that grief is a normal, not disordered, response to a loved one’s death.<sup>302</sup> However, the latest version of the DSM excised that exclusion.<sup>303</sup> The result is that a person may be diagnosed as mentally ill if she experiences persistent feelings of sadness or emptiness for more than two weeks after the death of her spouse or child.<sup>304</sup> If prescribing drugs to relieve this kind of grief qualifies as “treatment,” it is hard to see how regulators could draw any defensible lines that would differentiate treatment of mental illnesses from elective modification of emotions.

Reform proponents might argue that an agency with broad powers to regulate the uses of medical technology could serve as a bulwark against increasing medicalization, drawing lines that separate treatment from enhancement.<sup>305</sup> But because there is no objective way to determine which types of distress should be characterized as illnesses, such an agency would be forced to draw distinctions that are inherently arbitrary and are wed to contemporary prejudices and contested notions of the good life. Such a body would be charged with determining which kinds of psychic distress are forms of illness and which are valid identities, personalities, or quirks. It would be responsible for determining what levels of anxiety, social discomfort, trouble concentrating, cognitive performance, or grief are sufficient to merit treatment, and what levels people should simply have to live with. Had this kind of authority existed in the 1970s, when homosexuality was categorized as a mental illness and gender

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302. Paula Span, *Grief Over New Depression Diagnosis*, N.Y. TIMES, Jan. 24, 2013, <http://newoldage.blogs.nytimes.com/2013/01/24/grief-over-new-depression-diagnosis/>.

303. AMERICAN PSYCHIATRIC ASSOCIATION, *MAJOR DEPRESSIVE DISORDER AND THE “BEREAVEMENT EXCLUSION”* (2013), [www.dsm5.org/Documents/Bereavement%20Exclusion%20Fact%20Sheet.pdf](http://www.dsm5.org/Documents/Bereavement%20Exclusion%20Fact%20Sheet.pdf).

304. Megan Brooks, *The Case for Retaining Bereavement Exclusion in DSM-5*, MEDSCAPE (Feb. 6, 2012), [www.medscape.com/viewarticle/758097](http://www.medscape.com/viewarticle/758097).

305. For example, Fukuyama argues that “even in the cases where the borderline between sickness and health, therapy and enhancement, is murkier, regulatory agencies are routinely able to make these distinctions in practice.” FUKUYAMA, *supra* note 3, at 209–10. However, Fukuyama bases his argument on the incorrect claim that CSA-scheduled drugs like Ritalin can only be taken therapeutically. *Id.* at 210. In fact, the CSA does not bar physicians from prescribing drugs off-label for nontherapeutic purposes. Indeed, Fukuyama himself believes Ritalin “is overprescribed in the United States and used in situations in which parents and teachers ought to employ more traditional means of engaging children and shaping their characters.” *Id.* at 210.

identity disorder was not, regulators might have endorsed “treating” the illness of homosexuality while disallowing sex reassignment surgery on the grounds that it constituted improper “enhancement.”

The intrusiveness of this kind of regulatory authority becomes apparent when one considers the myriad other ways people can change their brains and bodies.<sup>306</sup> Consider a drug that produced the same behavioral and personality changes as meditation practice. If such a drug raised concerns about undermining human agency or authenticity, those concerns would seem to apply equally to meditation. If it is appropriate for government to restrict access to the drug on these bases, it is not clear why that power should be limited to biomedical interventions. Yet presumably most people would recoil at the thought of empowering a regulator to try to prevent people from meditating—or exercising, changing their diets, or employing any of the other methods people use to change their physical and emotional states.

In the context of biological interventions, we empower government to operate paternalistically because these interventions pose potential health risks that most laypeople are not well-positioned to evaluate. Clinical trials provide regulators objective ways to assess and measure the physical risks posed by drugs. This limited basis for accepting paternalism in the context of biological interventions provides a limiting principle for government interference. But if it is appropriate to expand medical regulation beyond these parameters to “adjudicate among competing ethical claims,”<sup>307</sup> it is not clear why that power should be limited to biomedical interventions. Regulators would have no objective basis for making these determinations, nor would they be better positioned to make these assessments than the individuals who wish to use these technologies.<sup>308</sup>

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306. See, e.g., Greely et al., *supra* note 37, at 703 (“Drugs may seem distinctive among enhancements in that they bring about their effects by altering brain function, but in reality so does any intervention that enhances cognition. Recent research has identified beneficial neural changes engendered by exercise, nutrition and sleep, as well as instruction and reading. In short, cognitive-enhancing drugs seem morally equivalent to other, more familiar, enhancements.”).

307. FUKUYAMA & FURGER, *supra* note 2, at 17.

308. These distinctions may continue to be necessary in the context of paying for medical interventions. Public and private health insurance systems can define for themselves the boundaries of their coverage, and insurers and patients can battle over whether particular



In some cases, restricting medical practices that have profound implications for one's identity is tantamount to restricting who people are allowed to become—how they look, think, and behave. Proposals to empower a regulatory agency to make decisions of that sort, particularly to enforce conceptions of morality that many people do not share, should give pause.

*C. Government Should Not Interfere with Deeply Personal Medical Decisions to Enforce Contested Moral Views*

Although arbitrary and contentious distinctions are unavoidable features of many regulatory systems, these attributes are troubling in the context of interfering with deeply personal decisions involving modifying one's own body or mind. The United States Supreme Court has recognized—specifically in cases regarding access to medical interventions—that government should not intrude on these types of decisions to enforce contested views of morality. These cases affirm that while limited restrictions may be justified to protect patient health, such interference is improper when undertaken to enforce prevailing morality. While assessing the constitutionality of restricting access to identity-modifying interventions is beyond the scope of this article, the Court's reasoning in these cases argues for caution in expanding government power to regulate medical interventions on moral grounds.

*1. Many decisions regarding medical interventions are protected from undue state interference*

Fukuyama contends that the propriety of regulating medical interventions to enforce prevailing morality should be uncontroversial:

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interventions fall within their policies' contractual terms. But declining to pay for certain interventions—particularly by private insurers—is far less intrusive than barring people from obtaining interventions for themselves. *See Harris v. McRae*, 448 U.S. 297, 316 (1980) (finding that a woman's constitutional right to be free from undue state interference in obtaining nontherapeutic abortions does not also entail "a constitutional entitlement to the financial resources to avail herself of the full range of protected choices."). *But see* STEPHEN HOLMES & CASS SUNSTEIN, *THE COST OF RIGHTS: WHY LIBERTY DEPENDS ON TAXES* (1999) (arguing that the distinction between positive and negative rights is illusory).

The answer to the question of who gets to decide on the legitimate and illegitimate uses of science is actually pretty simple, and has been established by several centuries of political theory and practice: it is the democratically constituted political community, acting chiefly through their elected representatives, that is sovereign in these matters and has authority to control the pace and scope of technological development.<sup>309</sup>

Indeed, the United States Supreme Court has long recognized the legitimacy of regulating medical interventions. In 1921, the Court explained that “[t]here can be no question of the authority of the State in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs”—a power the Court characterized as “so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question.”<sup>310</sup>

Yet the State’s power to regulate medical interventions is not unlimited. Where medical interventions affect bodily integrity or identity in fundamental ways, the Court has repeatedly recognized that individuals’ decisions about these interventions can implicate a “realm of personal liberty which the government may not enter.”<sup>311</sup>

Many of these cases involve individuals’ rights to refuse medical interventions. In *Winston v. Lee*, the Court rejected state prosecutors’ request to have a bullet surgically removed from a criminal defendant’s chest, citing “the extent of intrusion upon the individual’s dignitary interests in personal privacy and bodily integrity.”<sup>312</sup> Other cases recognize that control over one’s body can intertwine with interests involving defining one’s identity. The Court has repeatedly determined that administering drugs to change prisoners’ and criminal defendants’ thinking and behavior implicates

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309. FUKUYAMA, *supra* note 3, at 186.

310. *Whipple v. Martinson*, 256 U.S. 41, 45 (1921).

311. *Planned Parenthood v. Casey*, 505 U.S. 833, 847 (1992); *see also id.* at 927 (Blackmun, J. concurring) (“These cases embody the principle that personal decisions that profoundly affect bodily integrity, identity, and destiny should be largely beyond the reach of government.”).

312. *Winston v. Lee*, 470 U.S. 753, 761 (1985); *see also Rochin v. California*, 342 U.S. 165, 172 (1952) (subjecting a criminal suspect to “stomach pumping” against his will in order to determine whether he had swallowed drugs “shock[ed] the conscience” and violated the suspect’s due process rights).

constitutionally protected liberties.<sup>313</sup> In *Washington v. Harper*, the Court affirmed that even prisoners—whose rights are severely circumscribed—“possess[] a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs,” emphasizing that the purpose of administering these drugs was “to alter the chemical balance in a patient’s brain” in order to produce “changes . . . in his or her cognitive processes.”<sup>314</sup>

While the aforementioned cases recognize a liberty interest in refusing unwanted medical interventions, the Court has also repeatedly recognized a protected interest in accessing desired interventions—including for nontherapeutic purposes—free from unwarranted government interference.<sup>315</sup> Although to date these cases have involved reproduction technologies, they are instructive here because they involve government efforts to restrict nontherapeutic medical practices on the basis of moral concerns other than safety.

In *Eisenstadt v. Baird*, the Court struck down a Massachusetts’ statute that prohibited unmarried persons from using contraceptives to prevent pregnancy.<sup>316</sup> In the present context, the *Eisenstadt* decision has three notable features. First, the challenged law distinguished between therapeutic and nontherapeutic uses of contraception and singled out the latter for restrictions. The statute permitted all individuals to use contraceptives to protect their health.

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313. See, e.g., *Riggins v. Nevada*, 504 U.S. 127 (1992) (finding that “[t]he forcible injection of medication into a nonconsenting person’s body . . . represents a substantial interference with that person’s liberty” and that “[i]n the case of antipsychotic drugs . . . that inference is particularly severe,” in part because of how the drugs affect the individual’s cognitive processes) (quoting *Washington v. Harper*, 494 U.S. 210, 229 (1990)); *Vitek v. Jones*, 445 U.S. 480, 494 (1980) (finding that subjecting prisoners to involuntary psychiatric treatment, including “mandatory behavior modification,” constitutes “the kind of deprivations of liberty that requires procedural protections”); *Sell v. United States*, 539 U.S. 166 (2003) (“[F]orced administration of antipsychotic drugs to render [a criminal defendant] competent to stand trial unconstitutionally deprive[d] him of his ‘liberty’ to reject medical treatment.”).

314. *Washington v. Harper*, 494 U.S. 210, 221–22, 229 (1990); see also *id.* at 237–38 (Stevens, J., dissenting) (“[W]hen the purpose or effect of forced drugging is to alter the will and the mind of the subject, it constitutes a deprivation of liberty in the most literal and fundamental sense.”).

315. *Planned Parenthood*, 505 U.S. at 927 n.3 (Blackmun, J., concurring) (“Just as the Due Process Clause protects the deeply personal decision of the individual to *refuse* medical treatment, it also must protect the deeply personal decision to *obtain* medical treatment . . .”).

316. *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

The sole effect of the challenged law was to bar single individuals from using contraceptives for a nontherapeutic purpose: preventing pregnancy.<sup>317</sup> Second, the Court determined that using contraceptives to prevent pregnancy implicates matters “fundamentally affecting a person,” even when such interventions are not used for therapeutic purposes.<sup>318</sup> Finally, the Court rejected the contention that the law’s purpose was to promote safety, noting that the statute “was cast only in terms of morals.”<sup>319</sup> The Court’s emphasis of this point suggests it might have been receptive to the statute had its purpose been to promote safety rather than to enforce a particular morality.

The Court’s key abortion cases reflect the same features: because the decision of whether to bear a child implicates women’s bodily integrity and identity in fundamental ways, the Constitution limits the State’s authority to restrict access to abortion on the basis of contested moral doctrines—even with respect to abortions that are not undertaken to protect a woman’s health. In *Planned Parenthood v. Casey*, the Court emphasized that abortion implicates “the urgent claims of the woman to retain the ultimate control over her destiny and her body,” which the Court identified as “central to personal dignity and autonomy” and “implicit in the meaning of liberty.”<sup>320</sup> In an often-quoted passage, the Court explained that “[a]t the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.”<sup>321</sup>

As in *Eisenstadt*, the *Casey* Court determined that respecting these personal choices requires protecting access not only to

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317. *Id.* at 442 (“The statutory scheme distinguishes among three distinct classes of distributees—*first*, married persons may obtain contraceptives to prevent pregnancy, but only from doctors or druggists on prescription; *second*, single persons may not obtain contraceptives from anyone to prevent pregnancy; and, *third*, married or single persons may obtain contraceptives from anyone to prevent, not pregnancy, but the spread of disease.”).

318. *Id.* at 453.

319. *Id.* at 450.

320. *Planned Parenthood*, 505 U.S. at 869, 923; *see also* *Roe v. Wade*, 410 U.S. 113, 153 (1973) (observing that pregnancy and motherhood not only present health risks to the woman’s body, but that “[m]aternity, or additional offspring, may force upon the woman a distressful life and future”).

321. *Planned Parenthood*, 505 U.S. at 851.

abortions undertaken for medical reasons, but to nontherapeutic procedures as well. The Court held that prior to fetal viability the State may not unduly interfere with a woman's decision to terminate a pregnancy, even when an abortion is not therapeutic—i.e., not necessary to protect the woman's health. The Court expressly rejected the contention that States could prohibit all abortions undertaken for nontherapeutic reasons and permit them only “in those rare circumstances in which the pregnancy is itself a danger to [a woman's] own life or health . . . .”<sup>322</sup>

Also as in *Eisenstadt*, the *Casey* Court distinguished between States' legitimate interests in protecting maternal health and improper attempts to regulate deeply personal decisions regarding reproduction to enforce particular conceptions of morality. The Court acknowledged the power of the State to “enact regulations to further the health or safety of a woman seeking an abortion,” and affirmed the validity of several regulations that it concluded furthered that goal.<sup>323</sup> But while the Court recognized the State's interest in protecting potential human life as a valid basis for restricting some abortions, it deemed even that compelling interest insufficient to overcome a woman's right to an abortion before fetal viability. The Court expressly rejected the contention that the State could interfere with these decisions based solely on contested moral grounds:

Men and women of good conscience can disagree, and we suppose some always shall disagree, about the profound moral and spiritual implications of terminating a pregnancy, even in its earliest stage. Some of us as individuals find abortion offensive to our most basic principles of morality, but that cannot control our decision. Our obligation is to define the liberty of all, not to mandate our own moral code. The underlying constitutional issue is whether the State can resolve these philosophic questions in such a definitive way that a woman lacks all choice in the matter.<sup>324</sup>

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322. *Id.* at 850–51.

323. *Id.* at 878.

324. *Id.* at 850.

The Court rejected that power, instead determining that “[t]he destiny of the woman must be shaped to a large extent on her own conception of her spiritual imperatives and her place in society.”<sup>325</sup>

*2. Enhancement technologies can likewise implicate individual liberty in fundamental ways*

Mindful of the seemingly broad implications of its conclusion that due process enshrines a right to “define one’s own concept of existence,” the *Casey* Court took pains to limit the applicability of its decision in other contexts, opining that with respect to pregnancy “the liberty of the woman is at stake in a sense unique to the human condition and so unique to the law.”<sup>326</sup> Yet other medical interventions could implicate bodily integrity and identity in similarly fundamental ways. Indeed, some of the most potent concerns regarding enhancements are driven precisely by the power of these interventions to profoundly shape individuals’ identities by modifying their bodies and brains.

Consider the increasingly plausible prospect of memory-editing interventions. If a pharmaceutical company developed a drug that erased specific memories, it might seek FDA approval for the drug as a therapy for PTSD, emphasizing its potential to help people erase memories of traumatic events.<sup>327</sup> While many people might find this approach to treating PTSD troubling,<sup>328</sup> that concern would pale compared to the outcry when doctors began prescribing these interventions “off label” to help people erase painful memories that fall short of disabling, such as experiences of loss, embarrassment, or shame.<sup>329</sup>

This is precisely the kind of intervention that a regulatory body charged with “discriminat[ing] between those technological

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325. *Id.* at 852.

326. *Id.* at 851.

327. BEYOND THERAPY, *supra* note 88, at 207 (“To be sure, these agents—and their better versions, yet to come—are, for now at least, being developed not as means for drug-induced happiness but rather as agents for combating major depression or preventing post-traumatic stress disorder (PTSD). Yet once available for those purposes, they could also be used to ease the soul and enhance the mood of nearly anyone.”).

328. For a discussion of concerns raised by memory modification, *see supra* Section I.B.7.

329. BEYOND THERAPY, *supra* note 88, at 207.

advances that promote human flourishing, and those that pose a threat to human dignity and well-being” might choose to restrict.<sup>330</sup> Yet the very concerns that might motivate such restrictions demonstrate how profoundly this would interfere with individuals’ abilities to forge their own identities and define their own personhood. Indeed, the President’s Council on Bioethics grounded its concerns about memory erasure on the premise that memory is “central to human flourishing” and is a fundamental element of the “pursuit of happiness.”<sup>331</sup> The Council worried that “an unchecked power to erase memories . . . could imperil our capacity to form a strong and coherent personal identity,”<sup>332</sup> arguing that our memory allows us to know who we are and “preserves for us the complex web of lived experiences that furnish our sense of self.”<sup>333</sup> Dr. Eric R. Kandel, a Nobel Prize-winning neuroscientist and leading memory researcher, has also expressed concern about memory-editing technologies, arguing that “we are who we are. We’re all part of what we’ve experienced.”<sup>334</sup>

According to these critics’ own assessments, then, erasing memories is troubling because it profoundly implicates how an individual “define[s] one’s own concept of existence.”<sup>335</sup> In other words, the very concerns that might animate restrictions on memory erasure make a compelling argument that the use of such interventions falls squarely within the “realm of personal liberty which the government may not enter.”<sup>336</sup> Indeed, if anything the state’s interests appear more compelling in the context of abortion, where a potential human life is at stake, than with respect to memory

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330. FUKUYAMA, *supra* note 3, at 182.

331. BEYOND THERAPY, *supra* note 88, at 215.

332. *Id.* at 212.

333. *Id.* at 214.

334. Claudia Dreifus, *A Quest to Understand How Memory Works*, N.Y. TIMES, March 5, 2012, at D2; *see also* Lehrer, *supra* note 82 (“Being able to control memory doesn’t simply give us admin access to our brains. It gives us the power to shape nearly every aspect of our lives. There’s something terrifying about this.”).

335. *Planned Parenthood v. Casey*, 505 U.S. 833, 851 (1992).

336. *Id.* at 847. Indeed, among the fundamental rights the Supreme Court has determined are implicit in the concept of liberty are “freedom of thought [and] belief.” *Lawrence v. Texas*, 539 U.S. 558, 558 (2003); *see also* *Stanley v. Georgia*, 394 U.S. 557, 565 (1969) (“Our whole constitutional heritage rebels at the thought of giving government the power to control men’s minds.”).

erasure, where the state's interests are more nebulous and speculative.

Of course, given the broad range of interventions that have some effect on identity, many medical practices may not implicate personal liberty in such profound ways. Placing restrictions on seemingly trivial interventions like facelifts and "tummy tucks," for example, would seem to be relatively minor intrusions. But neither do these practices seem sufficiently troubling to motivate imposing such restrictions. Thus, proponents of regulating medical interventions on moral grounds appear to face a Catch-22. The technologies that can most powerfully modify identities prompt the greatest moral concern, and thus the greatest impetus to restrict access to them. Yet, the greater the power of these interventions to shape identity, the more likely they are to implicate the kinds of decisions that should not be interfered with based on contested notions of morality.

#### CONCLUSION

There are compelling reasons to regulate medical interventions to protect health. Virtually everyone agrees that protecting human health is important. Medical interventions can pose substantial risks that laypeople are often ill-equipped to assess. Although FDA decisions regarding drug approvals can be controversial—e.g., because people disagree about the level of risk that is acceptable in relation to possible health benefits<sup>337</sup>—there is broad support for regulating drugs to protect health, and there are objective ways to measure drugs' risks and benefits.<sup>338</sup> Under these circumstances, it makes sense to have a body of experts assessing health risks and therapeutic benefits.

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337. See, e.g., *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 695 (D.C. Cir. 2007) (rejecting plaintiffs' argument that terminally ill patients are entitled to access to unapproved, experimental medications).

338. See, e.g., Consumers Union, *Poll: Consumers Want Host of Drug Safety Reforms* (Apr. 16, 2007), <http://consumersunion.org/news/poll-consumers-want-host-of-drug-safety-reforms/> (reporting poll results finding that 96 percent of respondents supported government authority to require warning labels on potentially dangerous prescription drugs, and 93 percent supported giving the FDA the power to order follow-up safety studies on drugs that are already on the market).



The same cannot be said of determining how people should be permitted to use reasonably safe medical technologies to shape themselves. Unlike scientists assessing the health risks of drugs, there are no similarly authoritative experts regarding perceived moral dangers like agency and authenticity. While government can regulate on the basis of contested morality in many contexts, its power to interfere with deeply personal decisions affecting control over one's body and mind should be limited. The power of individuals to make these decisions for themselves should be guarded jealously.

On a pragmatic level, attempts to restrict access to medical interventions on moral grounds have fared poorly. Despite massive government expenditures, intrusive enforcement efforts, and often devastating consequences for individuals caught using banned interventions, these practices continue unabated. The challenges of enforcing these kinds of restrictions would be greatly magnified in the context of FDA-approved interventions, which meet a baseline of safety and may offer significant benefits to users. Moreover, imposing special restrictions only on interventions deemed nontherapeutic would increase incentives for drug companies, doctors, and patients to recast normal, unwanted conditions as diseases needing treatment.

Rather than expanding government's authority to interfere with medical decisions on moral grounds, we would be better served by scrubbing the existing systems of medical regulation of these kinds of judgments and recommitting ourselves to regulating medical interventions to protect health. Many existing restrictions that are ostensibly based on safety assessments are in fact motivated by voters' moral condemnation of certain practices, leaving access to medical interventions prey to shifting political winds and the whims of changing administrations.

Limiting medical regulation to protecting human health does not suggest that the other concerns raised about enhancement practices are meritless or unworthy of respect, or that individuals or their elected representatives are powerless to respond to them. Banning technologies is not the only way to address the harms these practices may create, or even the most effective way. Legislators could address concerns about coercion by prohibiting employers and schools from requiring employees and students to use these

interventions.<sup>339</sup> Professional organizations, such as the American Medical Association, could promulgate guidelines to their members regarding the ethics of assisting with identity-modifying practices, including “how to strike the balance of limits for patient benefit and protection in a liberal democracy.”<sup>340</sup>

If all else fails, there is always moral suasion. Those who are convinced these technologies are detrimental to human flourishing can argue their case rather than forcing their views on others through the law.<sup>341</sup> Some people may be persuaded that the benefits they had hoped to obtain through medical interventions are outweighed by the risks—whether physical or spiritual—that these practices pose to themselves or the harms they may impose on society. Conversely, through dialogue some critics may themselves come to see certain practices in a new light. When dealing with decisions affecting control over one’s body and mind, the default position should be one of respect and tolerance, with a high burden of persuasion on those who would advocate coercive responses.

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339. Greely, *supra* note 37, at 704.

340. *Id.*

341. Randy E. Barnett, *The Harmful Side Effects of Drug Prohibition*, 2009 UTAH L. REV. 11, 13 (2009) (“[E]ven people who agree about the facts fail to grasp that it is the nature of the means—coercion—chosen to pursue the suppression of voluntary consumptive activity that makes these [negative effects of prohibition] unavoidable.”).

