ENHANCEMENT PROHIBITION:
LIMITATIONS AND UNINTENDED CONSEQUENCES

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INTRODUCTION

Critics of using biomedical interventions to enhance human traits have expressed grave concerns over the potential for these technologies to transform society and human nature in troubling ways.[1] However, the United States' system of drug regulation provides no mechanism through which to address these concerns. The existing regulatory system was developed at a time when drugs generally were used to treat acute problems in acute timeframes, and when the success or failure of many drugs was fairly easy to determine – the acute problems abated or they did not. "Lifestyle" drugs had not been conceived of, and the regulatory system was not designed to deal with them. As a result, the Food and Drug Administration is not equipped to respond to the ethical challenges presented by biomedical enhancements.

Responding to this deficiency, some observers have proposed expanding the authority of the FDA,[2] or creating a new regulatory entity to consider drug policy questions beyond the FDA's current purview.[3] These proposals have two essential elements: (1) drawing sharp distinctions between

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[1] *See, e.g.*, M.J. Sandel, *The Case against Perfection: Ethics in the Age of Genetic Engineering* (Cambridge: Harvard University Press, 2007); L. Kass, *Life, Liberty, and Defense of Dignity: The Challenge for Bioethics* (San Francisco: Encounter Books, 2002); President's Council on Bioethics, Beyond Therapy: Biotechnology and the Pursuit of Happiness (October 2003).

[2] D. Fox, "Safety, Efficacy and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking," *Michigan State Law Review* 2005, no. 4 (2005): 1135-1197.

[3] F. Fukuyama and F. Furger, Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies (November 2006).

treatment and enhancement, and (2) addressing ethical concerns by restricting access to certain enhancements. The basic logic of this proscriptive approach is that the ethical problems raised by enhancements can be prevented or mitigated by enacting policies that limit access to these interventions.

In this thesis I argue that even if one accepts the validity and importance of the ethical concerns raised by enhancements, there are reasons to be wary of this proposed regulatory approach. Just as biomedical technologies can have unintended consequences, so too can regulatory policies. If, for example, we are not clear about the ethical concerns that motivate calls for regulation, and thoughtful about how key stakeholders will respond to particular policies, our approach may exacerbate the problems that regulation seeks to avoid. This is particularly true of proscriptive policies that restrict access to technologies without addressing or accounting for the elements of culture that spur demand for these interventions.

In addition, once we have identified the concerns that motivate calls to restrict access to enhancements, it is important to ask whether these are permissible bases for regulation. Some non-therapeutic uses of medical technology implicate fundamental liberties related to individuals' control over their own bodies and minds -- liberties that are protected by the U.S. Constitution. Although the Constitutional implications of restricting access to enhancements may not be obvious in the context of today's largely cosmetic interventions, the prospect of future technologies that profoundly alter cognition, perception and

identity -- such as hypothesized brain-computer interfaces -- highlight the need for thoughtful consideration of the boundaries of government's authority to regulate enhancements on the basis of moral concerns.

This thesis is presented in three parts. Part 1 briefly describes some of the key ethical concerns raised by enhancement practices and analyzes the inability of the existing regulatory system to address these concerns. Part 1 also describes proposals to expand the scope of regulatory authority to restrict access to enhancements on moral grounds.

Part 2 examines potential unintended consequences of proscriptive approaches to regulating enhancements. First, I highlight the importance of being clear about the true nature of the ethical concerns that motivate this regulatory approach, using the example of proposals to punish healthy college students for using stimulants as study aids. Proponents of this policy frame their concern as an issue of fairness, analogizing the use of "study drugs" to the use of steroids by athletes. However, on closer inspection it is not clear that the problem with this practice is that it is unfair. Rather, the core ethical concern implicated by the use of study drugs relates to students' agency -- in particular the extent to which this practice reflects a shift among students away from deep engagement with the practice of education and toward a view of education as a competition for credentials in which drugs can confer advantages. Far from ameliorating this problem, a policy of prohibition reinforces the debased culture of education that spurs demand for study drugs.

Next, I analyze Norman Daniels' argument that fairness requires fortifying the conceptual barrier between "normal" human functioning and biomedically-enhanced functioning. While Daniels argues that failing to privilege treatments over enhancements would undermine support for the cooperative schemes that promote public health, his argument overlooks the incentives this policy creates for pharmaceutical companies, patients and doctors to erode that distinction. Relying on the treatment/enhancement distinction to determine access to medical interventions gives pharmaceutical companies an enormous stake in ensuring that their products are thought of as treatments, which in turn requires that the "indications" for these drugs be considered illnesses. To the extent patients believe a drug may help alleviate unwanted conditions, they too will have an interest in having those conditions characterized as diseases in need of treatment -- an interest that sympathetic doctors may share. A policy that relies so heavily on the treatment/enhancement distinction is likely to accelerate this process of "medicalizing" normal, unwanted conditions, which in turn may threaten support for cooperative health schemes.

Part 3 turns from questions regarding the wisdom of the proscriptive approach to analyze its legal permissibility. The United States Supreme Court has invalidated previous government efforts to restrict access to non-therapeutic medical interventions, such as birth control and non-therapeutic abortions, in order to enforce certain conceptions of traditional morality. These precedents call into question whether the Constitution would permit regulators to

restrict access to enhancements -- another form of non-therapeutic medical intervention -- on the basis of moral concerns. Using the example of brain-computer interfaces, Part 3 analyzes the extent to which the Fourteenth Amendment to the U.S. Constitution may constrain proscriptive approaches to enhancement technologies.

PART 1
Enhancement practices, ethical concerns and regulatory proposals

I. Enhancement practices and ethical concerns

Human beings have long used medical technologies for purposes other than treating illness or injury. Cosmetic procedures have a long history, and are exceedingly popular in contemporary American society. The use of stimulants -- like Ritalin, Adderall and especially caffeine -- to boost energy and enhance concentration likewise has become ubiquitous in the U.S.[4] Seemingly no athletic endeavor has been untouched by the proliferation of drugs that improve athletic performance, most notably steroids. Some parents inject their healthy children with human growth hormone to try to make them grow taller -- and indeed, in many cases these "treatments" are even covered by health insurance.[5] And the introduction of a new wave of antidepressants in the 1980s produced considerable handwringing about the use of such drugs to alter personality rather than treat mental illness -- a practice sometimes referred to as "cosmetic psychopharmacology."[6]

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[4] A.D. DeSantis, Elizabeth M. Webb, & Seth M. Noar, "Illicit Use of Prescription ADHD Medications on a College Campus: A Multimethodological Approach," *Journal of American College Health*, Vol. 57, No. 3, 315-323.

[5] B.S. Finkelstein et al, "Insurance Coverage, Physician Recommendations, and Access to Emerging Treatments," *JAMA* 279, no. 9 (1998): 663-668, at 666 (estimating that in 1998 10-13% of children with so-called "Idiopathic Short Stature" would have insurance that covers growth hormone treatment).

[6] P.D. Kramer, *Listening to Prozac: The Landmark Book About Antidepressants and the Remaking of the Self, Revised Edition* (New York: Penguin Group, 1997), at 1-21. Psychiatrist Peter Kramer described his experiences prescribing Prozac to ease the suffering of his patients, not all of whom were

Despite the prevalence of biomedical enhancement technologies today, "[t]hese are nothing compared with what might be on the way."[7] There is good reason to expect continued advances in biomedical enhancement technologies. The spectacular success of Rogaine, Botox, Adderall, HGH, Viagra and the like reflect robust consumer demand for these technologies, incentivizing pharmaceutical companies to pursue further research into drugs that make people stronger, smarter and more attractive. Advances in medical technology promise to increase the scope, precision and power of enhancement technologies -- particularly in modifying the functioning of the human brain. Brain imaging technologies using functional Magnetic Resonance Imaging (fMRI) are offering new insights into how the human brain works, and with them increased power to modify those processes.[8] Emerging nanotechnologies may enable profound integration of computing technologies with the human brain, potentially augmenting human intelligence and adding new sensory capabilities.[9]

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clinically depressed.

[7] S. Fuller, "Knowledge politics and new converging technologies: a social epistemological perspective," *Innovation -- The European Journal of Social Science Research* Vol. 22, No. 1, March 2009, 7-34.

[8] *See, e.g.*, R.A. Poldrack, "The role of fMRI in Cognitive Neuroscience: where do we stand?" *Current Opinion in Neurobiology* 2008, 18:223–227.

[9] *See, e.g.,* M.C. Roco and W.S. Bainbridge, "Converging technologies for improving human performance: Integrating from the nanoscale," *Journal of Nanoparticle Research* 4:281–295, 2002 (proposing that nanotechnologies may enable "brain to brain interactions," "brain–machine interfaces," and "improving sensorial capacities and expanding functions," among other cognitive enhancements).

Many observers have expressed serious concerns about the prospect of a coming wave of ever more powerful enhancement technologies. Some decry these practices as improperly altering "human nature,"[10] while others express concern about the potential for these technologies to produce social ills and undermine important values.

Some worry that enhancements could exacerbate social inequalities.[11] Under the current U.S. healthcare system, most people rely on private insurance or public programs like Medicare to pay for most medical interventions. Insurance pays for many treatments for illnesses, but generally does not cover enhancements. For example, insurers often pay for breast reconstruction after mastectomy, but they will not cover breast enlargement just because a woman would prefer to have bigger breasts.[12] Instead, women pay for breast augmentation out of their own pockets. Because these procedures are expensive, wealthier women can get them but poorer women cannot.

In a hypercompetitive society that places enormous importance on physical appearance, being considered “attractive” can confer significant economic advantages.[13] This is why, when the U.S. Senate proposed levying a

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[10] *See, e.g.*, M.J. Sandel, "The Case against Perfection," *Atlantic Monthly* 293.3 (2004): 51–62; Kass, *supra* n. 1 at 48.

[11] *See, e.g*, N. Daniels, *Just Health* (Cambridge: Cambridge University Press, 2008), 1147.

[12] *Id*. at 150.

[13] *See, e.g.*, M. Lamkin, "Racist Appearance Standards and the Enhancements that Love Them: Norman Daniels and Skin-Lightening Cosmetics," *Bioethics*,

tax on cosmetic surgery, the president of the National Organization for Women complained that the proposal would impose economic hardship on older women competing for jobs. These women need Botox, she explained, to impress potential employers.[14]

Other enhancements can promote inequality more directly. Drugs that enhance various aspects of cognition may confer critical competitive advantages to (non-disabled) students and employees, further stratifying society's cognitive “haves” and “have nots.” For example, while insurers may pay for a student with ADHD to take a stimulant like Adderall, they will not cover the use of this drug to boost cognitive performance in healthy students. Nevertheless, students who can afford to purchase Adderall with their own money have easy access to the drug,[15] while their less advantaged peers do not. Thus, to the extent these drugs can improve academic performance in healthy people, their limited availability may reinforce economic disparities in educational achievement.

A related concern about enhancements is the worry that, as the use of enhancements proliferates, it may become increasingly difficult for people who might prefer not to enhance to resist doing so. If, for example, taking cognition-

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(2011) 25(4):185-201, 185.

[14] J. McKinley, "A Tax on Nips and Tucks Angers Patients, Surgeons," *The New York Times*, November 30, 2009, A14.

[15] DeSantis et al. *supra* n. 4 (finding that 34% of undergraduates at the University of Kentucky had used ADHD stimulants illegally).

enhancing drugs could add 100 points to a high school student's SAT scores, not taking those drugs when many other students are doing so could profoundly undermine a student's college admissions prospects. Similarly, if a brain-computer interface had the effect of "raising our productivity, efficiency, [and] response time,"[16] people who have undergone this "upgrade" may have significant competitive advantages -- e.g., in schools and workplaces -- over those who have not. The "unenhanced" may then face enormous pressure to use these technologies simply to be able to secure employment.

Another common objection to enhancements is that these technologies may change how we think about our bodies and minds, undermining important values and elements of individual character. Bert Gordijn has suggested that "[w]idespread use of NBIC[17] enabled enhancement technologies will result in an increasingly close association of the body with technology," which he argues "will contribute to a more technologically inspired image of the body as something very similar to a machine. . . increasingly de-hallowed and de-mystified."[18] The increasing use of technology to modify human

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[16] F. Allhoff et al., "Ethics of Human Enhancement: 25 Questions & Answers," US National Science Foundation, August 31, 2009 (http://digitalcommons.calpoly.edu/cgi/viewcontent.cgi?article=1000&context=phil_fac).

[17] "NBIC" is an acronym for Nano/Bio/Info/Cogno, referring to the convergence of these technologies.

[18] B. Gordijn, "Converging NBIC Technologies for Improving Human Performance: A Critical Assessment of the Novelty and the Prospects of the Project," *Journal of Law, Medicine & Ethics*, Winter 2006, 729.

bodies and minds might also change the way people think about human agency, promoting a “shift *away* from achievements humans *undertake* through self-initiated striving, and *toward* those they experience by biochemical interventions, which *act on us* as passive subjects.”[19] Some describe this as a concern about undermining human agency, while others worry that enhancements may deprive people of the “internal goods” inherent in certain practices, or undermine forms of human engagement in meaningful activities.[20] If enhancement technologies allow people to acquire new knowledge or skills -- for example, through a technologically-enabled "information gulp"[21] -- we may miss out on the "internal goods" or excellences inherent in the forms of effort these undertakings traditionally have required.

Others worry that using drugs to modify our brains and bodies can change “who we are” and how we relate to the world in ways that are inconsistent with our “authentic” selves, leaving us “estrange[d] . . . emotionally from life as it really is.”[22] Enhancements may encourage us to ignore ugly realities and insulate ourselves from unpleasant, but appropriate, emotional responses. When Asian women get eye surgery to look more Western, or

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[19] Fox, *supra* n. 2 at 1150.

[20] M. Schermer, "Enhancements, Easy Shortcuts, and the Richness of Human Activities," *Bioethics* 22, no. 7 (2008): 355-363, at 360-362.

[21] Gordijn, *supra* n. 18 at 729.

[22] President's Council on Bioethics, *supra* n. 1, at 292.

Sammy Sosa uses a cream to lighten his skin,[23] they seem to be seeking acceptance and validation not on the basis of who they truly are – e.g., by overcoming prejudices – but rather by acceding to those prejudices. Similarly, life often presents circumstances that seem to call for emotions that we often try to avoid – sadness, anger, alienation, and so on.[24] If we use drugs like Prozac to alter our emotional responses to the world, we may be preventing ourselves from "responding to events and experiences, whether good or bad, in a fitting way."[25]

II. Expanding the scope of enhancement regulation

A. Deficiencies in the current approach

Some observers have proposed that government should address these concerns by restricting access to enhancement technologies.[26] However, the United Sates' existing regulatory scheme governing drugs and medical devices does not provide a mechanism for regulating on the basis of ethical considerations. Rather, the Food and Drug Administration is charged only with ensuring the safety and efficacy of these interventions.[27]

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[23] C. Saint Louis, "Creams Offering Lighter Skin May Bring Risks," *The New York Times*, January 15, 2010, A1.

[24] *See, e.g.*, C. Elliott, "Pursued by Happiness and Beaten Senseless," *Hastings Center Report* 30, no. 2 (2000): 7-12, at 11.

[25] President's Council on Bioethics, *supra* n. 1, at 292.

[26] *See, e.g.*, Fox, *supra* n. 2 at 1194-96; Fukuyama, *supra* n. 3 at 17.

[27] United States Food & Drug Administration, "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm.

The limited scope of the FDA's mandate is a function of the broad consensus around the importance of treating illnesses.[28] When presented with a new drug that is effective at treating certain illnesses, we typically do not feel the need to pause and reflect on whether this is a good thing that ought to be allowed. Rather, we ask the FDA to ensure that the drug is safe and effective, and the Agency has enlisted staff and created modes of evaluation that are tailored to that "science-based" mission.[29]

By contrast, there is considerable divergence of opinion regarding whether and under what circumstances enhancement is appropriate. Enhancements raise numerous ethical questions that the FDA lacks the legal authority and institutional expertise to consider. Should heathy students be allowed to take Ritalin to enhance their ability to study or take exams? Should people who are not depressed be allowed to take Prozac because they like themselves better on the drug? As Marchant et al. explain:

> Unlike safety and efficacy, where people can fairly easily reach consensus on what is a good or bad result (e.g., causing tumors is bad), there is more room for disagreement on what is a good or bad moral or social effect . . . . [S]ocial and ethical risks

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[28] Daniels, *supra* n. 11, at 155.

[29] *See, e.g.*, United States Food & Drug Administration, "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," *supra* n. 27 (explaining that the FDA's role in evaluating new drug applications is to determine the drugs' safety and efficacy); G.E. Marchant, D.J. Sylvester & K.W. Abbott, "What Does the History of Technology Regulation Teach Us about Nano Oversight?" *Journal of Law, Medicine & Ethics*, Winter 2009, 724-31, 728 (noting that "[t]he professional staff of regulatory agencies currently consists primarily of scientists, economists, and attorneys.").

> are more intangible, harder to define and quantify, and thus do not lend themselves to the same type of quantitative analyses common for safety or efficacy determinations.[30]

Although there is some debate about whether the FDA has the legal authority to consider these broader ethical concerns in its approval process,[31] the Agency itself has categorically denied that "moral, religious, or ethical issues" fall within its purview.[32] Moreover, "the agency's organizational culture and its professional expertise, both of which have developed around safety and efficacy, make the FDA ill-suited to address broader ethical dilemmas."[33]

Nor does the FDA exercise authority over how doctors prescribe

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[30] Marchant, *supra* n. 29 at 728.

[31] *Compare* Marchant, *id*. ("The FDA's refusal to consider such concerns is undoubtedly correct in a legal sense, since the agency has only been charged by Congress with ensuring that products are 'safe' and 'efficacious,' criteria which do not seem to incorporate broader ethical or social concerns."); Z. Meghani & I. de Melo-Martín, "The U.S. Food and Drug Administration's Evaluation of the Safety of Animal Clones: A Failure to Recognize the Normativity of Risk Assessment Projects," *Bulletin of Science Technology & Society* 2009 29: 9-17, 9 (questioning "the FDA's stance that its mission to protect and advance the public health . . . can be met without taking into consideration ethical issues or without making ethical judgments.").

[32] 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 (Docket No. 2003N-0573) (available at http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055491.htm). *See also* Fukuyama, *supra* n. 3 at 57 ("even if it could be demonstrated that the FDA would have [the] statutory authority to inject ethical considerations into its decision-making process, the agency is very unlikely to do so. The FDA does not consider regulatory demands other than those pertaining to safety and efficacy as part of its core mission.").

[33] Fukuyama, *supra* n. 3 at 57.

drugs to patients. The FDA approves drugs as safe and effective to treat particular medical conditions, and regulates how drug companies can market these drugs to doctors and consumers. But the FDA does not regulate the practice of medicine.[34] Doctors can prescribe drugs more or less as they see fit, and they do not hesitate to do so: by one estimate, off-label uses account for about a fifth of all prescriptions.[35] For some psychiatric drugs, that proportion exceeds 50%.[36] Thus, while the FDA may approve a drug as a treatment for memory loss in Alzheimer's patients, there is no regulatory mechanism to prevent doctors from prescribing it to students studying for exams.

The FDA's approval of synthetic human growth hormone ("HGH") to make short children taller illustrates the narrow focus of the Agency's analysis, and the limited scope of its enforcement authority. In 2003, Eli Lilly & Company sought the FDA's approval to promote HGH as a treatment for Idiopathic Short Stature ("ISS") -- extreme shortness that is not caused by inadequate growth hormone production or unusually short parents.[37] This application raised ethical concerns because of the potential for HGH to be used as an enhancement: although HGH can be used to treat disorders that stunt children's growth, it can

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[34] *Id*. at 39.

[35] D.C. Radley, S.N. Finkelstein and R.S. Stafford, "Off-label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine* 166, no. 9 (2006): 1021-1026, at 1023.

[36] *Id*., at 1025.

[37] Fox, *supra* n. 2 at 1135.

also make healthy children grow taller. Indeed, as described below,[38] there is considerable debate regarding whether ISS should be considered a disorder at all, or whether the use of HGH in short, healthy children is itself a form of enhancement. However, in evaluating Eli Lilly's application the FDA expressly rejected the contention that it should consider the propriety of potential "cosmetic" uses of the drug. During a meeting of the Division of Metabolic and Endocrine Drug Products at the FDA's Center for Drug Evaluation and Research, the Division's director explained:

> […] I just want to raise one other issue that has not actually been raised here explicitly, but may be in the back of some people's minds, and in the minds of those perhaps listening from the audience. And that is . . . whether the use of growth hormone in non-growth hormone deficient short stature represents "cosmetic" use of growth hormone, and . . . might be construed somehow as setting a broad precedent for cosmetic use of drugs.
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> The first point I'd like to say is that any 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 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***

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[38] *See infra* Part 2(II)(B).

weigh the potential benefits of the therapy against the potential risks.[39]

Once the FDA approved the use of HGH for children with ISS -- or children in the shortest 1.2% of the population[40] -- there was nothing to stop pediatricians from prescribing the drug more widely. According to one survey, even before the FDA approved the use of HGH for children who were not suffering from growth hormone deficiencies, 94% of endocrinologists reported having recommended HGH for such children within the previous five years.[41]

B. Proposals for regulatory reform

In light of the FDA's circumscribed analysis of interventions that can be used as enhancements, and its inability to control when and how doctors prescribe such interventions, some critics of enhancement practices have proposed expanding regulatory authority to limit access to enhancements on the basis of moral concerns. For example, in their 2006 report *Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies*, Francis Fukuyama and Franco Furger called for the creation of a new regulatory entity to

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[39] Food and Drug Administration Center for Drug Evaluation and Research, "Endocrinologic and Metabolic Drugs Advisory Committee Meeting," ed. Food and Drug Administration Department of Health and Human Services (October 7, 2003), p. 248-49 (emphasis added).

[40] P. Conrad & V. Leiter, "Medicalization, Markets and Consumers," *Simmons College Journal of Health and Social Behavior* 2004, Vol 45 (Extra Issue): 158–176, 166.

[41] Cuttler, Leona, J. B. Silvers, Jagdip Singh, Ursula Marrero, Beth Finkelstein, Grace Tannin, and Duncan Neuhauser. 1996. “Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns.” Journal of American Medical Association 276:531–37.

oversee emerging medical technologies -- in particular, medical practices related to human reproduction.[42] Arguing that "it is perfectly legitimate for the government to raise higher regulatory hurdles . . . [for] practices aimed at enhancement rather than therapy,"[43] the authors distinguish between "standard" or "uncontroversial" reproductive procedures[44] and "innovative" procedures whose common feature is that "they are very likely to raise significant ethical concerns."[45] In determining whether a medical technology should be permitted, the proposed new regulatory entity would be empowered to "adjudicate among competing ethical claims."[46] The agency's decisions would be informed by public opinion on the propriety of the medical practices at issue, as determined by a process of broad public consultation.[47] When the new regulator determined that a particular medical practice or technology is unethical, the entity would have the power to completely prohibit that practice. For example, Fukuyama and Furger argue that any reproductive technology that produces babies carrying DNA from

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[42] Although Fukuyama and Furger focus on reproduction technologies, they also suggest that other enhancement practices might benefit from a similar regulatory approach, noting that "[p]sychopharmacology is an area of pharmaceutical development that is exploding, one that is regulated already and may deserve a fresh look in light of new drugs coming on the market in the near future." Fukuyama, *supra* n. 3 at 41.

[43] *Id*. at 67.

[44] *Id*. at 77.

[45] *Id*. at 80.

[46] *Id*. at 16.

[47] *Id*. at 19.

more than two parents should be banned in their entirety -- even when these technologies are used to prevent parents from passing on genetic defects to their offspring.[48]

While Fukuyama and Furger focus on human reproduction technologies, Dov Fox advocates expanding the FDA's mandate to encompass ethical concerns and empowering the agency to restrict access to any drug that might be used for enhancement purposes. Central to Fox's proposal is the idea that "the FDA should distinguish medical products with enhancement capacities as a separate category called 'potential enhancement products,'" which would be "earmarked for special analysis and consideration" in a new administrative process.[49] With respect to potential enhancement products, the FDA would be tasked with considering social values implicated by the products and their potential social consequences, including: "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."[50] Fox further proposes closing the "off-label" loophole by giving the FDA new authority to prohibit doctors from prescribing certain medical

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[48] *Id*. at 6; 81-83.

[49] Fox, *supra* n. 2 at 1194-95.

[50] *Id*. at 1195.

technologies for enhancement purposes.[51]

Reducing or eliminating some enhancement practices could offer some important potential benefits. Reproduction technologies appear particularly fraught: novel techniques could inflict psychological harms on the children produced through these technologies, while germline genetic modifications could threaten future generations.[52] But changing human behavior is not like flipping a switch. Enacting regulations that purport to restrict access to certain enhancement practices does not guarantee that those practices -- or the ethical concerns they raise -- will cease. Part 2 sounds notes of caution for proposals to use regulation to address the ethical concerns raised by enhancements.

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[51] *Id*. at 1196.

[52] Fukuyama, *supra* n. 3 at 67-69.

PART 2
Unintended Consequences

The diversity of current and anticipated enhancement technologies, and the profoundly different ethical issues they raise, argue for a variety of regulatory approaches that are tailored to different contexts. Proscriptive approaches may be effective in addressing the concerns raised by germline genetic modifications or steroids in sports. In other cases, however, proscriptive policies may actually exacerbate the ethical concerns that increased regulation is intended to mitigate. The discussion that follows highlights two examples of how this approach can go awry. Section I considers college students' use of cognition-enhancing drugs to illustrate how misdiagnosing the ethical concerns raised by enhancements can give rise to proscriptive policies that reinforce the cultural factors that spur demand for these drugs. Section II examines how key stakeholders may evade proscriptive policies by recasting enhancements as "treatments" for newly-fashioned "diseases," and in the process erode support for cooperative schemes that protect public health.

I. Study Drugs: How misdiagnosing the illness can yield damaging cures.

On college campuses, drugs that were developed as treatments for attention-deficit and sleep disorders are proving popular with healthy students who believe these drugs help them study more effectively and perform better in school. While there is a dearth of research regarding the effectiveness of these drugs as “cognitive enhancements,” many college students seem convinced. Surveys suggest that as many as 16% of students have used psychostimulants

for enhancement purposes.[53] The trend appears even more pronounced at some elite institutions, where students may be particularly driven and competition particularly intense. One Harvard student described Ritalin and Adderall as "more popular than pot" on her campus,[54] while a student at Columbia complained, "I don't think I could keep a 3.9 average without this stuff."[55]

The most common reaction to this trend is to label the use of cognitive enhancement drugs as a form of cheating.[56] Analogizing to the use of steroids in sports, some critics sounding the alarm over "brain boosters" have even called for testing students' urine before exams to determine whether they have been "doping." In 2008, the Academy of Medical Sciences urged the UK's government "to be alert to the misuse of 'cognitive-enhancers' and to prepare the ground for regulations and even urine tests to control their use in schools, universities and workplaces."[57]

Before we ask students to pee in cups for the privilege of taking tests, we need to be clear about whether the use of cognitive enhancements in the university setting is wrong – wrong enough to do something about – and if so,

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[53] M. Schermer, "The Future of Psychopharmacological Enhancements: Expectations and Policies," *Neuroethics* (2009) 2:75–87, 79.

[54] V. Chau, "Popping Pills to Study: Neuroethics in Education," *Stanford Journal of Neuroscience*, Vol. 1, Issue 1, Fall 2007.

[55] A. Jacobs, "The Adderall Advantage," *New York Times*, July 31, 2005.

[56] *See, e.g.*, Chau, *supra* n. 54, p. 18 ("Cognitive stimulants for studying are what steroids are for sports – a form of cheating, and as such, should be banned.").

[57] I. Sample, "Exam cheating alert over brain drugs," *The Guardian*, May 22, 2008.

why. If we misdiagnose the illness, we are likely to choose the wrong cure. While the term “cheating” captures an intuitive sense that there is something troubling about healthy people using drugs to improve academic performance, on closer inspection it is not clear that what is unsettling about this practice is that it is “unfair.” Framing the problem this way tells us nothing about why the proper response is to ban these drugs rather than putting them in the drinking water.

The deeper source of concern regarding the use of cognitive enhancement drugs has less to do with fairness than with the potential for this trend to undermine deep student engagement in the practice of education. The instinct to talk about enhancements in terms of unfair competitive advantages is itself a manifestation of the erosion of this value. Thus the proscriptive approach actually exacerbates the core ethical problem raised by study drugs by reinforcing a commodified view of education as a competition for credentials.

A. Cognitive enhancement is not inherently unfair

As an initial matter, the use of cognitive enhancement drugs is not “cheating,” because it is not “against the rules.” If cheating is “the intentional violation of a rule, in order to gain an unfair advantage over others,”[58] then using enhancements before a test is not cheating unless a school's rules forbid it. Most formal sports organizations expressly prohibit competitors from taking steroids. Within that regulatory environment, it is clearly unfair for some competitors to gain an advantage over their peers by disregarding these rules. But because

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[58] S.P. Green, "Cheating," *Law and Philosophy* (2004) 23:136-85.

most universities have not implemented similar rules against cognitive enhancement drugs, students who take these drugs are not gaining advantage by shirking a rule that all participants are obligated to obey.[59]

To be fair, critics of enhancement probably do not mean the practice *is* cheating, but that it ought to be considered as such – i.e., that universities should enact rules against the practice to prevent some students from gaining an unfair advantage over others. If these drugs improve academic performance, clearly it would be unfair to permit some students to use them while denying that opportunity to others. If, for example, these drugs were so expensive that only wealthy students could afford them, this would give wealthy students an advantage that seems unfair, and might justify a policy banning the use of these drugs.

Proponents of cognitive enhancement often counter this line of argument by noting that privileged students already enjoy many advantages over their less wealthy peers, and we do not implement rules to prevent them from doing so.[60] Wealthier students can engage private tutors. They may not have to work to put themselves through school, leaving them more time to study. These advantages are likely to be much more significant than the benefits of cognitive enhancement drugs. If we are not inclined to remedy these disparities,

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[59] M. Schermer, "On the argument that enhancement is 'cheating,'" *J. Med Ethics* (2008) 34:85-88.

[60] *See, e.g.*, M. Quigley, "Enhancing Me Enhancing You: Academic Enhancement as a Moral Duty," Expositions 2.2 (2008), 157-162.

proponents ask, why should we treat enhancements differently?

At one level, this objection is easily dismissed as a form of what Frank Pasquale has called “complacent continuumism” – i.e., “put[ting] all manner of social change on a continuum and say[ing] 'See, we've been doing X for years, this new technology just lets us do it more quickly.'”[61] The fact that we permit certain injustices (if they are that) does not justify accepting others. Indeed, it may be that one of the reasons we tolerate these social disparities is that there is not much we can do about them. It would be considerably more difficult, if not impossible, to mitigate the disparity in the amount of time students have to study than it would be to implement rules banning particular drugs.

At another level, however, this objection raises a legitimate issue. To the extent we could reasonably “do something” about these social disparities, our objective would almost certainly be to help poor students enjoy these advantages – not take them away from wealthy students. While we would certainly support (resources permitting) providing poor students access to private tutors or scholarships that give them more time to study, few would suggest barring wealthy students from employing tutors, or setting limits on the amount of time they can spend studying. Clearly in the context of higher education there are some things we value more than a level playing field. We would rather tolerate considerable unfair advantages than mitigate these disparities by putting limits on how fully students can engage in their education.

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[61] F. Pasquale, "Technology, Competition and Values," 8 Minn. J.L. Sci. & Tech. 607, 617-18.

Moreover, if the key problem with cognitive enhancements is disparate access to these drugs, this problem can be remedied by providing these drugs to all students.[62] Unlike scholarships and private tutors, which require enormous resources, schools could provide cognitive enhancement drugs fairly cheaply. Generic Adderall substitutes are available for a little over a dollar per pill,[63] and universities buying in bulk could presumably negotiate even lower prices. In addition, there is some evidence that drugs like Adderall offer greater advantages to those who are "naturally" the lowest performers, and may actually impair cognitive performance among higher performers.[64] Thus, making cognitive enhancements available to all students could do more to promote fairness than banning them.

Advocates of the fairness argument might raise two objections to this analysis. The first is a practical argument: Sure we *could* promote access to cognitive enhancement among poor students, but we have a poor track record of helping disadvantaged people. If we do not ban these enhancements, the most likely scenario is that wealthy students will get them and poorer students will not. While this objection is well-taken, if the primary reason we tend to fail to help poor people is that we do not want to spend money that way, it is important to note that the costs of enforcing a ban on enhancements may be greater than the

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[62] Schermer, *supra* n. 59, p. 86.

[63] At www.drugstore.com, 100 tablets of a generic Adderall substitute cost $135.

[64] *See, e.g.*, M.J. Farah et al, "Neurocognitive enhancement: what can we do and what should we do?," *Nature*, Vol. 5, May 2004, 421-425.

cost of subsidizing cognitive enhancement drugs.

Others might object that even if all students had access to enhancements, allowing students to take them would be unfair to students who do not wish to do so. This view is more difficult to defend. If all students had access to a private tutor, it would not be unfair for some students to use this resource simply because some of their peers chose not to.[65] This argument takes on some additional force if the drug in question has substantial health risks. Students should not feel compelled to assume serious health risks simply to stay afloat in school. But this seems less like an argument about fairness than one about safety. While safety is a valid ethical concern, it is one that can be overcome by better drug design. If a drug is safe as can be, it becomes far more difficult to explain why it would be fair for some students to use a tutor when others declined, but unfair to use a drug.

In sum, concerns about fairness do not tell us much about whether enhancement ought to be allowed in the academic context. While it is clearly unfair to allow some students to enhance but not others, these concerns could be remedied with policies that promote, rather than restrict, access to these drugs. If we are still troubled by a safe and universally available cognitive enhancement, we have to look for other sources of our discomfort.

B. Cheating ourselves

There is another sense in which we use the word “cheating” that

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[65] Quigley, *supra* n. 60 at 157-162.

has nothing to do with unfair competition. When someone has achieved some end without engaging in the proper means, we might say that person has "cheated himself" out of whatever rewards we think are inherent in those means. Maartje Schermer expresses this type of concern in her discussion of enhancements as "easy shortcuts."[66] Schermer borrows Alisdair MacIntyre's vocabulary of "internal goods" and "practices" to frame her concern that taking shortcuts can cause us to "lose sight of the complexities of our means and ends," thereby "reducing the richness of human activities." Practices, according to MacIntyre, are:

> specific forms of human activity . . . . [that] have internal goods – goods that are specific to that practice and can only be gained by participating and trying to live up to the internal standards of excellence specific to that practice. The point of practices lies not in the external goods that can be gained – like money or status, which can also be gained through other practices or activities – but in the internal goods, the specific human forms of excellence they make possible.[67]

Schermer uses the example of climbing a mountain to illustrate the distinction between engaging in a practice and simply obtaining external goods, noting that a person who is delivered to the summit by helicopter achieves none of the internal goods or excellences inherent in the practice of mountain climbing.[68]

Schermer also employs Albert Borgman's "theory of the device

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[66] Schermer, *supra* n. 20 at 355-363.

[67] *Id.* at 360.

[68] *Id*.

paradigm" to articulate this concern. Borgman argues that in our contemporary culture, we tend to substitute "things" – objects that are "inseparable from their context and . . . require forms of human engagement" – with "devices" – "technologies that produce commodities in a way that does not involve any engagement."[69] Borgman illustrates by contrasting a hearth to centralized heating. While the hearth involves regular human engagement, manifested in an accompanying set of practices, a central heater heats the home without any human involvement. In Borgman's view, the problem with substituting things for devices is that "devices diminish our engagement with the world and substitute this with consumption."[70]

Thus, according to Schermer, the potential problem with enhancement technologies is that they can corrode or replace practices, and therefore deprive individuals of the internal goods inherent in those practices. Schermer also acknowledges, however, that not every technology that makes it easier for us to achieve some end necessarily robs us of a practice's internal goods. Indeed, technology can even promote opportunities to experience those internal goods. In the case of mountain climbing, for example, the ability of climbers to carry extra oxygen enables some people to experience the internal goods of climbing who otherwise would never be able to engage in that practice.

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[69] *Id*. at 361.

[70] *Id*.

[71] *Id*. at 362.

On the other hand, it is entirely possible that for a more capable climber, using extra oxygen to scale a mountain that she could have climbed without it might deprive her of some benefits she might have obtained without this "enhancement."

Is taking Ritalin while studying for an exam more like being dropped off at the summit, or like taking along extra oxygen? Does this type of enhancement promote or diminish engagement in the practice of higher education? Applying Schermer's nuanced account, it seems the real problem is not enhancement as such, but the way particular enhancements work and the way individual students use them. Schermer's account suggests we may want to draw a moral distinction between the student who uses Ritalin to maintain a 3.9 GPA at Columbia and the student who (though not suffering from a "disorder") could not stay in college without it. In the latter case, enhancement enables the student to enjoy the practice of higher education and the internal goods conferred thereby – goods she might be denied without this type of assistance. When an enhancement allows students to engage more fully in the practice of education, it is not a "shortcut" any more than engaging a private tutor would be. Working with a tutor does not corrode the practice of education but enriches it by helping students to engage in that practice more deeply. If, on the other hand, students use enhancements to mitigate the consequences of procrastination, this may prevent them from developing mental discipline, time management skills and other internal goods that can be conferred by the practice of education.

Of course, enhancements will probably be used in both these ways, and many others, even by the same student in varying circumstances. The concern about enhancements undermining the practice of education suggests, then, that a proscriptive approach to study drugs is unlikely to yield the results we want. Instead, we need to find ways of encouraging students to engage in the practice of education rather than seeking shortcuts.

C. The culture of commodification

Students take cues about what to value – the types of achievements and undertakings that are worthwhile, the elements of character that are important, the modes of behavior that are honorable – from the cultures at their schools and in the wider society. There is good reason to believe that simply having the opportunity to enhance cognition will exacerbate existing cultural trends away from engagement in the meaningful practices of education, and toward viewing education – and even our own brains – as mere means to certain ends. The more prevalent this view becomes, the more we can expect increasing pressure on students to "upgrade" their brains in order to compete more effectively for the credentials and employment opportunities (the external goods) they are using their education to obtain. Indeed, within this context, a decision not to take an effective enhancement could have serious economic consequences.

While some commentators have framed this as a concern about "coercion," this label overstates the problem in a way that obscures what is truly

troubling about it. Coercion refers to external pressure so great that its victim has effectively no choice of action.[72] And there are situations in which coercion, or something approaching coercion, could be a real issue with respect to cognitive enhancement. For example, employers may begin to require their employees to enhance cognition as a condition of employment. This situation would present employees with a very narrow range of choices – enhance or lose their income – that does seem coercive. But this kind of coercion is relatively easy to address. We can, for example, pass laws that prohibit employers from requiring employees to take enhancement drugs.

More disconcerting than true coercion is the pressure we feel to compete. We live in a society that exalts competition and its monetary rewards. High school students compete for college admissions. College students compete with their classmates for grades, then for jobs. Employees compete for promotions, and their employers compete for market share. Within that context, "just saying no" to drugs that might confer a competitive edge can start to look like a kind of moral failing. While this kind of pressure can come from many external sources – parents, employers, coaches, peers, "the media" – the most potent source is within. We can prohibit employers from requiring enhancements, but our internalization of competitive values cannot simply be regulated away.

Note that this concern about the commodification of education is

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[72] *See, e.g.*, R. Faden & T. Beauchamp, A History and Theory of Informed Consent, Oxford University Press (1986), 339.

not merely different from the argument that enhancement is unfair, but is in some ways its opposite. As noted above, enhancement could actually promote fairness by boosting the competitiveness of cognitively disadvantaged students. But it is precisely this emphasis on competition that fuels the pressure to value educational outcomes over practices. Viewed in this light, the rush to label enhancement as "cheating," and to propose punitive measures to enforce a ban, looks less like a cure than a symptom of the disease.

D. Punishing cheaters, or encouraging engagement

Framing concerns about cognitive enhancement on campus as cheating tends to inspire punitive policy proposals of the sort applied to other types of cheating. Analogizing students' use of Ritalin to athletes' use of steroids suggests we ought to respond to the former as we have to the latter – specifically, by requiring students to submit to urine tests to determine if they have been "doping." This approach is seriously misguided in both its assumptions and conclusions.

As an initial matter, prohibition of other drugs in the United States has been an unmitigated failure. Even if we wanted to ban cognitive enhancement drugs, there is no reason to believe prohibition would be more effective in this context than it has been with other drugs. Indeed, the pressure to use enhancements to compete for better credentials and more lucrative jobs would likely far outstrip whatever pressures exist to use so-called "recreational" drugs.

More fundamentally, the punitive approach is based on the flawed assumption that what is wrong with enhancements in higher ed is that their use is inherently unfair. If the key concern about enhancements is, instead, that they exacerbate cultural trends toward commodification of education, the proscriptive approach does nothing to mitigate that problem – and in fact may reinforce it.

If we understand the key problems with cognitive enhancement not as "cheating" others but as cheating one's self, then the punitive approach sends precisely the wrong message. Banning study drugs reinforces the idea that education is a high-stakes competition for credentials, and that using cognitive enhancement drugs confers advantages in this pursuit. It affirms the value of these drugs in the context of education, since it is precisely these advantages that motivate the ban. If this is what students believe, and it is affirmed by the school administration, we are likely to get more of what we currently have – on-campus black markets driven by consumer demand.[73]

If our goal is to promote students' enjoyment of the internal goods of education, what we really want to argue is that these drugs are not helpful after all. The most effective way to send that message is by making it true. That

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[73] Ironically, this approach seems more likely to undermine fairness than to promote it, since prohibition drives up prices and favors students with the social capital necessary to pry prescriptions from their doctors. *See, e.g.*, N. Bostrom & R. Roache, Smart Policy: Cognitive Enhancement and the Public Interest, in J. Savulescu et al, Enhancing Human Capacities, Oxford: Wiley-Blackwell, 2009, p. 8 ("The medicine-as-treatment-for-disease framework creates problems . . . for users ('patients') whose access 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.").

requires restructuring educational incentives to align them with the appreciation of education's internal goods, so that students are not rewarded for taking shortcuts. In drug policy terms, this is a “demand reduction” strategy that works by draining enhancements of their value, rather than catching perpetrators.

This is not an undertaking that can be accomplished in one fell swoop, like a urine testing regime. Rather, it requires a series of smaller steps that gradually reshape the character of higher education over time. For example, colleges could de-emphasize applicants' SAT scores in admissions decisions – perhaps setting a floor above which students are presumed to have the requisite aptitude, but not otherwise preferring higher scores to lower – in favor of criteria that reflect deeper forms of student engagement in the practice of education. Adderall may boost SAT scores, but it is unlikely to help students develop interesting resumes.

Similarly, at the University of Chicago Law School, students receive grades, but the school does not disclose grade point averages or assign class rank.[74] Accordingly, employers interested in hiring graduates of this prestigious school must rely on other criteria in making hiring decisions. Students can still show achievement in other ways – such as writing for one of the law journals, or participating in public interest legal clinics – and there is still an element of competition in some of these undertakings. But the stakes attached to grades would seem to be substantially reduced, and with them the incentive to use a

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[74] *See* <http://www.law.uchicago.edu/employers/policies>.

“brain booster” in connection with a particular test.

Even if prohibition prevails, it would be far more sensible to implement this policy through mechanisms such as honor codes, rather than urine testing. Thomas Jefferson's experience instilling discipline among the students at the University of Virginia illustrates the difference between these approaches. When Jefferson founded UVA, he is said to have ruled the students “with an iron-clad straitjacket system of discipline,” to the great chagrin of the institution's students.[75] Above all, the students despised the methods their professors used to guard against cheating on tests, whereby “[t]he students were allowed to bring only a pencil to the classroom, they were forbidden to speak, and the professors, operating in shifts, watched them with 'lynx-like' eyes during the course of the examinations.”[76] However, Jefferson also expressed doubts about this method of promoting proper conduct, writing that:

> It may well be questioned whether fear, after a certain age, is a motive to which we should have ordinary recourse. The human character is susceptible to other incitements to correct conduct more worthy of employ and of better effect. Pride of character, laudable ambition and moral disposition are innate correctives of that lively age and when strengthened by habitual appeal and exercise, have a happier effect on future character than the motive of fear. Hardening them to disgrace, to corporal

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[75] C.A. Smith, "'I Certify On My Honor,' The Real Story of How the Famed 'Honor System' at University of Virginia Functions and What Matriculating Students Should Know About It," *Richmond Times Dispatch*, November 29, 1936.

[76] *Id*.

> punishment, and servile regulations cannot be the best process for producing erect character.[77]

Thus, Jefferson called on the University's trustees "to perfect and prepare a system of government which, if founded in reason and comity, will be more likely to nourish in the minds of our youths the combined spirit of ardor and self-respect so congenial without political institutions, and so important to be woven into the American character."[78] Eventually, the University threw out its antagonistic policy in favor of a requirement that when students submitted their exams, each would attach a statement attesting that "I hereby certify on my honor that I have neither given nor received any assistance during this examination."[79]

Unlike the policing approach, which effectively challenges students to see what they can get away with, honor codes ask students to internalize values we believe are important to education, and to character in general. Although students who violate honor codes face sanctions, the primary aim is not to deter improper conduct with threats, but to persuade students that to breach the code is to betray themselves. If we believe that enhancing cognition with drugs deprives students of the true value of their education, we would be best served by encouraging students to adopt that value as their own.

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[77] *Id*.

[78] *Id*.

[79] *Id*.

II. Medicalization: How emphasizing the treatment/enhancement distinction can erode support for cooperative health schemes.

A. Treatment, enhancement and the engines of medicalization

Concerns about fairness also underlie Norman Daniels' argument that justice requires distinguishing between treatments and enhancements in determining access to medical interventions. In Daniels' view, justice requires protecting citizens' health in order to promote fair equality of opportunity.[80] However, Daniels rejects the suggestion that justice requires enhancing normal human traits, even when providing enhancements might do more to mitigate economic disparities than treating certain illnesses.[81] Central to Daniels' argument is the idea that placing enhancements on equal footing with treating diseases would undermine support for cooperative schemes that promote public health.[82] Daniels argues that protecting normal human functioning represents "a focal point for convergence in our public conception of what we owe each other by way of medical assistance or health protection," irrespective of people's comprehensive moral doctrines.[83] By contrast, enhancing normal human traits is

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[80] Daniels, *supra* n. 11 at 21.

[81] *Id*. at 149-155.

[82] *Id*. at 149.

[83] *Id*. at 155 ("People generally agree that this 'natural baseline' forms a reasonable and relevant basis for public action despite many other disagreements they may have about other issues of value. Despite many other sorts of comprehensive moral views, people generally agree that maintaining normal functioning contributes in a reasonable and central way to protecting opportunity.").

exceedingly controversial. Public support for cooperative health schemes would diminish, Daniels argues, if those schemes moved from healing the sick to enhancing the well.[84]

Daniels' argument has considerable force. It is reasonable to suppose that public support for Medicare would be diminished if it were revealed that public funds were being used to provide facelifts and liposuction. However, Daniels' argument does not take into account how the market has responded to the way our cooperative health schemes have prioritized treatment of disease and largely excluded enhancements. This emphasis on the treatment/enhancement distinction creates powerful incentives for key stakeholders to redefine normal human traits as “diseases” or “disorders” that medical technology can “cure” – a process often referred to as “medicalization.”[85]

Peter Conrad and Valerie Leiter write that "[t]he engines of medicalization are found in the marketplace nexus of the biotechnology industry and rising consumerism."[86] On the supply side, pharmaceutical companies have enormous incentives to refashion enhancements as treatments for disorders. While there is a finite pool of people who suffer from heart disease or high blood pressure, the number of people suffering from shyness, anxiety or feelings of

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[84] *Id*.

[85] *See, e.g.*, Schermer, *supra* n. 53 at 81.

[86] Conrad, *supra* n. 40 at 172.

inadequacy is virtually limitless.[87] The more drug companies can convince potential consumers that their problems are disorders that can be treated with drugs, the more drugs they can sell. Equally important, insurance generally covers treatments but not enhancements, so that people who want enhancements generally must pay out of their own pockets. As a result, pharmaceutical companies have far fewer “customers” who can afford enhancements than those who, with the help of insurance, can afford treatments.[88]

The existing regulatory scheme also provides incentives toward medicalization. As Maartje Schermer has noted, “[g]iven the current regulations, purposeful development of drugs aimed at the enhancement of normal functioning is not opportune for pharmaceutical companies.”[89] Although the FDA has approved some cosmetic interventions, these are still pitched as "treatments" -- just as Botox is approved to treat "glabellular lines" (i.e., frown lines).[90] At the

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[87] Conrad, *supra* n. 40 at 170 ("While prevention of disease is a major market for drugs and interventions, the relatively common problems of life, on the margins of medicine, hold the greatest potential for market expansion and medicalization.").

[88] *Id*. ("the only way to get human services paid for is to turn life difficulties into medical problems.").

[89] Schermer, *supra* n. 53 at 78; *see also* Bostrom, *supra* n. 73 at 7 (“This system was created to deal with medicine that aims to prevent, detect, cure or mitigate diseases. In this framework, there is no room for enhancing medicine. Drug companies seeking regulatory approval for a pharmaceutical useful solely for improving functioning in the healthy population would face an uphill struggle without major changes to the current licensing framework.”).

[90] U.S. Food and Drug Administration. June 23, 2003 FDA Warning Letter to

very least, the Agency is more likely to find an intervention efficacious, and to find that its benefits outweigh its risks, if the applicant seeks to promote the drug as a treatment for attention deficits, rather than claiming the drug makes healthy people smarter.[91]

The public and medical practitioners are often witting or unwitting co-conspirators in the process of medicalization. People increasingly look to medicine to help them with problems that we have not traditionally regarded as medical. As Conrad and Leiter observe, "there has been growth in consumer demand for medical solutions. . . . [T]he public's tolerance for mild symptoms and benign problems has decreased, spurring a progressive medicalization of physical distress in which uncomfortable body states and isolated symptoms are reclassified as diseases."[92] For their part, doctors have an understandable desire to help patients who are suffering, often regardless of whether their conditions meet diagnostic criteria precisely.[93] Through the use of off-label prescriptions,

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Allergan, Inc.(available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147551.htm).

[91] *See, e.g.,* Fukuyama, *supra* n. 3 at 67 ("It is a well-established principle that greater risks are permissible when treating a clearly pathological condition than in cases of elective treatment.").

[92] Conrad, *supra* n. 40 at 159 (internal quotation omitted).

[93] For example, in *Listening to Prozac*, psychiatrist Peter Kramer famously described his experiences prescribing Prozac to ease the suffering of his patients, not all of whom were clinically depressed. Kramer, *supra* n. 6 at 1-21. *See also* Conrad, *supra* n. 40 at 170 ("Doctors commonly prescribe drugs for unapproved uses if, in their judgment, the drugs would be an effective treatment for a patient's problem."); Cuttler, *supra* n. 41 at 531–37. (According

doctors play a key facilitating role in the process of medicalization.

There is no shortage of examples that illustrate how pharmaceutical companies, doctors and consumers can together transform life difficulties into medical diagnoses. Take, for example, the condition of being short. Tragically, recent studies suggest that nearly half of all people are of below average height. While physicians have long used human growth hormone to treat children whose growth was stunted by malfunctions of the pituitary gland, it was this malfunction (human growth hormone deficiency) that was considered the disorder, not shortness itself.[94] That began to change in the 1980s, when pharmaceutical companies Genentech and Eli Lilly developed the ability to produce an effectively limitless supply of synthetic human growth hormone. Although the FDA initially approved HGH "only for treating hypopituitary dwarfism and chronic renal failure . . . . [a]s time went on, physicians, patients and drug companies all sought other medical uses for human growth hormone."[95] Genentech and Eli Lilly enlisted patients in this effort by working with groups like the Human Growth Foundation, a nonprofit group that advocated for short children.[96] Genentech also established its own Foundation for Growth and Development, which funded

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to Cuttler's 1996 survey of endocrinologists, 94% reported having recommended HGH off-label to increase the height of children who were not suffering from growth hormone deficiencies).

[94] Fox, *supra* n. 2 at 1179.

[95] Conrad, *supra* n. 40 at 165.

[96] *Id*.

"growth-tracking projects in which non-GHD [growth hormone deficient] children and their families were counseled about the wisdom of growth hormone to treat short stature."[97] Patient advocate groups characterized human growth hormone as a medical necessity, "since medical treatment could mitigate the suffering, stigma, and discrimination due to the biological limitation of extreme shortness."[98] By 1998, many insurers offered coverage for HGH treatments for children who did not suffer from growth hormone deficiency.[99]

In 2003, Eli Lilly brought this blurring of the line between treatment and enhancement uses of HGH to its logical conclusion, when it sought and obtained the FDA's permission to promote the product for the "treatment" of "Idiopathic Short Stature" -- i.e., to prescribe HGH to children who were simply very short.[100] In effect, Lilly and the FDA transformed the normal human condition of being very short into a medical condition that Lilly profits from "treating." As John Lantos has observed, "Until growth hormone came along, no one called normal shortness a disease. . . . It's become a disease only because a manipulation [synthetically engineered hGH] has become available and because doctors and insurance companies, in order to rationalize their action,

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[97] Fox, *supra* n. 2 at 1188.

[98] Conrad, *supra* n. 40 at 169.

[99] Finkelstein, supra n. 5 at 666 (estimating that in 1998 10-13% of children with ISS had insurance that covered growth hormone treatment).

[100] Conrad, *supra* n. 40 at 166.

have had to perceive it as one."[101]

Thus, by publicly placing so much weight on preserving normal functioning, and largely refusing to endorse and pay for enhancements, we create enormous incentives – for industry, practitioners and patients – to manipulate the meaning of "normal." While there is considerable public handwringing about the societal effects of medicalization and enhancement, when it comes to people's own problems that may be helped by taking drugs, people do not seem particularly reticent – or so it would appear from the enormous popularity of Prozac, Rogaine, Adderall, HGH, Viagra, Botox and the like. In other words, there is a profound disconnect between the voluble public expressions of concern about the societal effects of enhancement and the seemingly insatiable private demand for these interventions. We publicly disclaim enhancements while affirming the importance of treating diseases, but then quietly conform our disease categories to whatever unwanted conditions a drug may help mitigate. This allows us to accomplish through the back door ("treating" unwanted, normal conditions) what we are unwilling to allow through the front (by legitimizing various enhancement projects).

However, some people are not willing to go along with this unwritten agreement, viewing it as a kind of fraud that ought to be resisted. Consider the case of the impotence drug Viagra. The drug was initially covered by Medicare's prescription drug benefit, prompting howls that taxpayers were

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[101] Fox, *supra* n. 2 at 1189.

paying "to subsidize Grandpa's recreational sex."[102] This report from MSNBC.com captures the angst:

> The next time you see one of those ubiquitous television advertisements for erectile dysfunction drugs such as Cialis or Viagra, just remember your tax dollars will be helping pay for older Americans who want to use them.
>
> With Medicare spending soaring in the next several years, why, an Iowa congressman wants to know, is the taxpayer helping subsidize Viagra for older men?
>
> The drugs are taxpayer-subsidized, thanks to the Medicare prescription drug program Congress created in 2003.
>
> Rep. Steve King, R- Iowa, says the focus should be on providing life-saving drugs for truly needy seniors, not on subsidizing older men who want to enjoy the erectile function they had when they were younger.[103]

Although Congress ultimately eliminated Medicare reimbursements for impotence drugs[104] (over Pfizer's objections that treating "erectile dysfunction" was a medical necessity), this episode fanned concerns about the cost of the Medicare prescription drug plan as a whole. Rep. King, for example, used the Viagra reimbursements as an opportunity to express his "sticker shock" regarding the rising costs of the prescription drug plan: "I'm looking at this now and

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[102] T. Curry, "House members protest Medicare Viagra bill," MSNBC.com, February 10, 2005 (available at: http://www.msnbc.msn.com/cleanprint/CleanPrintProxy.aspx?unique=1305144520574).

[103] *Id*.

[104] P. Anstett, "Medicare Limits Sex Drug Coverage," Detroit Free Press, January 27, 2007.

wondering: $400 billion up to $720 billion. If I had known that then [when voting for the plan], I would voted 'no' on the bill. . . . How much of this new number is going for non-essential drugs?"[105]

As diagnostic categories expand to encompass an increasing range of normal human conditions, support for public health schemes may further erode. Thus, by placing such enormous weight on the treatment/enhancement distinction, and thereby fueling the trend toward medicalization, we may be hastening the result that Daniels seeks to avoid by prioritizing normal functioning. We can expect this problem to grow if, as many expect, pharmaceutical companies begin producing a flood of enhancement technologies in the coming decades.

B. An alternative approach: bringing enhancement into the fold

In light of these distorting effects, it may be that we can better preserve public support for cooperative health schemes by reducing the importance we attach to the treatment/enhancement distinction – reducing the stakes, for industry and individuals, that attach to whether a drug falls into one category or the other. Rather than attempting to draw sharp distinctions between treatments and enhancements and imposing heightened regulatory hurdles on the latter, as Fukuyama and Fox propose, we may be better served by asking regulators to analyze the costs and benefits of various medical interventions without a bias against enhancement practices.

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[105] Curry, *supra* n. 102.

This kind of review might resemble the "technology appraisals" that are routinely conducted by the United Kingdom's National Institute for Health and Clinical Excellence (NICE).[106] These appraisals evaluate the costs and benefits of various medical interventions and determine whether and when they should be provided by the country's National Health Service.[107] In addition to analyzing the efficacy and cost-effectiveness of medical technologies, NICE makes a broad range of judgments about the social value of these interventions. These social value judgments consider, for example, "how the effects of a health technology may deliver differential benefits across the population,"[108] and the importance of "distribut[ing] health resources in the fairest way within society as a whole."[109]

With the proper scope of authority and the right guiding considerations, this process could address the social concerns raised by enhancements while reducing the incentives for medicalization. This expanded form of technology oversight would enable regulators to do more than evaluate the safety of new drugs and their efficacy in treating particular conditions, in addition considering the various uses to which a drug (including existing drugs)

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[106] National Institute for Health and Clinical Excellence, *About technology appraisals*, at <http://www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp>.

[107] *Id*.

[108] National Institute for Health and Clinical Excellence, Guide to Methods of Technology Appraisal, June 2008, at 17.

[109] National Institute for Health and Clinical Excellence, Social Value Judgements: Principles for the development of NICE guidance (2d ed.), July 2008, at 18.

may be put and the social effects of those uses. As Fox proposes,[110] regulators using these broadened criteria could be authorized to determine: (1) which drugs should be permitted, and for what purposes, (2) which drugs should require prescriptions, (3) whether off-label uses should be permitted, (4) whether or when public or private insurers must pay for a particular drug, and (5) whether individuals should be permitted to purchase a particular drug with out-of-pocket funds when insurance does not cover it. However, to reduce the incentives for medicalization of normal traits, within that process the fact that a drug could be used for enhancement purposes would not by itself reflect unfavorably on the drug. Rather, decisions regarding which drugs and which drug uses are permitted and subsidized would be made according to an unbiased cost/benefit analysis, with "costs" and "benefits" construed broadly to encompass social considerations.

For example, in analyzing a drug like Adderall that can be used for both therapeutic and cognitive enhancement purposes, the agency could take into account the possibility that this drug could exacerbate socioeconomic disparities, or result in unacceptable pressures to enhance in schools or in the workplace. The agency also could consider the potential benefits of cognitive enhancement, including in particular the prospect of improving school performance among disadvantaged children. Depending on the outcome of those deliberations, the agency might determine that the drug should not be

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[110] Fox, *supra* n. 2 at 1196.

approved for enhancement purposes, that the drug should be freely provided to all who want it, or that insurers must cover the drug only for people who are lower cognitive performers, even if they do not meet diagnostic criteria for a disorder.

By permitting, and even subsidizing, certain enhancement uses, this approach could substantially reduce the incentives toward medicalization of normal traits. From the perspective of the pharmaceutical industry, this approach offers the potential for profit from enhancements as enhancements, and – if the regulator is effective – less potential for profit from recasting normal conditions as diseases. From the perspectives of medical practitioners and the public, legitimizing certain enhancements would eliminate the need to characterize normal conditions as diseases as a precondition to getting help. Perhaps most important, this process would move what have been behind-the-scenes, ad hoc decisions about enhancement toward open and honest public debate.[111]

C. Key limitations

While an unbiased approach to regulating enhancements might produce some benefits, at best this alternative approach could only mitigate, not eliminate, concerns about enhancement. There would be several limitations on the ability of a regulator to address these concerns.

First, even under this alternative regime there would still be strong incentives toward medicalization. Even if enhancement purposes were not

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[111] *See, e.g.*, Schermer, *supra* n. 53 at 82 ("It would indeed be more honest, and probably do less harm, if medication to enhance certain traits would be clearly named as such, and not sold under the guise of 'treatment.'").

presumptively invalid, it seems likely that regulators and the public would be more receptive to claims that health insurance should cover treatments for diseases rather than providing subsidies for enhancements. Accordingly, the pharmaceutical industry would continue to have an incentive to transform normal traits into diseases. It is also reasonable to assume that these companies would exert substantial influence over the regulatory process – both directly (through lobbying) and indirectly (through influencing public opinion).

On the other hand, concerns about excessive corporate influence are common to virtually any regulatory activity.[112] While manipulation of the regulatory process is common, the creation of an agency charged with evaluating the costs and benefits of enhancements would bring some level of oversight where currently there is none. Moreover, that oversight would far exceed the regulatory scrutiny we apply to virtually any other technology or consumer product. For example, a computer program that produced the same brain boosting effects as Adderall would go straight to market without any regulatory mechanism between manufacturer and consumer.[113] But this heightened regulatory authority points to a deeper challenge presented by this approach: how much authority should we give to a federal agency to determine how people

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[112] *See, e.g.*, Fukuyama, *supra* n. 3 at 15 (noting that "[a]ll good regulatory institutions, if they are to do their jobs, must avoid being 'captured' by the sector or interests they are meant to regulate.").

[113] Indeed, Lumosity.com purports to offer "scientifically designed" games that are "[s]hown to improve memory and attention." Lumosity, *Brain Games and Brain Training*, at <http://www.lumosity.com/>.

may modify their own bodies and shape their own identities? Marchant et al. note that:

> [t]he FDA's reluctance to approve over-the-counter sales of the "Plan B" post-coital contraceptive on what appeared to be moral rather than scientific grounds caused widespread unease and objections. Would we accept a government agency making such moral and social decisions explicitly, especially when the outcome could shift dramatically with a change in administration?[114]

Certain concerns about enhancements – such as considerations of unequal access or coercion – are relatively easy to address. The health system could address equality concerns by subsidizing the provision of certain enhancements. Legislators could counter (though not eliminate) many forms of coercion by, for example, barring employers from requiring employees to use enhancements. But the most worrisome concerns about enhancement are those related to altering human nature, such as the concerns about authenticity and agency. As discussed in Part 3 below, it is far from clear that these more fundamental concerns are proper targets of regulation.

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[114] Marchant, *supra* n. 29 at 728.

PART 3
Constitutional Limitations

Any effort to expand the scope of regulation of medical interventions in the United States would be constrained by the limits on government authority imposed by the U.S. Constitution. While there is no question that the federal government can regulate medical interventions to ensure their safety,[115] it is equally clear that restricting access to these interventions on the basis of moral or ethical concerns can impermissibly intrude on a sphere of personal autonomy guaranteed by the Constitution. The U.S. Supreme Court has repeatedly determined that government efforts to enforce particular conceptions of morality by restricting access to certain non-therapeutic medical interventions -- birth control and non-therapeutic abortions -- violate the substantive due process rights protected by the Fourteenth Amendment. As described below, these legal precedents suggest that empowering a federal agency to restrict access to certain enhancements on the basis of moral concerns would face heightened judicial scrutiny, and may be invalidated.

Section I outlines U.S. Supreme Court substantive due process jurisprudence and describes how the Court has extended Fourteenth Amendment protection to fundamental decisions regarding individuals' own bodies and identities, as well as to the values that inform these decisions.

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[115] *See, e.g., Robinson v. California*, 370 U.S. 660, 664 (1962) ("There 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.").

Section II examines how the Court has invoked this protection to strike down government actions limiting access to non-therapeutic medical interventions. Section III examines how these precedents may be extended to efforts to restrict access to enhancements on moral grounds. This section uses hypothesized brain-computer interfaces ("BCI") to illustrate how non-therapeutic medical technologies could profoundly implicate bodily integrity, self-determination and identity formation, and therefore warrant Constitutional protection.

I. The Fourteenth Amendment and Substantive Due Process

The Fourteenth Amendment provides that no State may "deprive any person of life, liberty, or property, without due process of law."[116] The Supreme Court has held that this Amendment contains a substantive component that embodies the promise that "there is a realm of personal liberty which the government may not enter."[117] That realm of personal liberty is not boundless. Virtually every government action impinges on individual liberty in some way. If that fact alone were sufficient to invalidate a government action, government simply could not function. Thus, rather than barring any infringement on individual liberty, due process "has represented the balance which our Nation, built on postulates of respect for the liberty of the individual, has struck between that liberty and the demands of organized society."[118] Accordingly, the Court has

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[116] U.S. Const., Amd. XIV.

[117] *Casey,* 505 U.S. 833, 851 (1992).

[118] *Id*. at 850 (quoting *Poe v. Ullman*, 367 U.S. at 542 (Harlan, J. dissenting)).

held that the Fourteenth Amendment protects only "fundamental" liberties, which the court has defined as rights that are "implicit in the concept of ordered liberty."[119]

When the Court determines that a government action infringes on a fundamental liberty, it analyzes that action with "strict scrutiny," or a strong skepticism that the action is Constitutional.[120] For the action to survive this heightened scrutiny, the government must show that the action: (1) substantially furthers a compelling governmental interest, (2) is narrowly tailored to achieve that interest, and (3) uses the least restrictive means necessary to achieve that goal.[121] Strict scrutiny sets a high bar for government to justify its actions; historically the Court has invalidated most government actions evaluated with this heightened level of scrutiny.[122]

The Court has identified the types of personal decisions that are subject to substantive due process protection through a series of decisions in which the Court has held that government actions impermissibly violated fundamental individual liberties. These decisions have afforded constitutional protection to "personal decisions relating to marriage, procreation, contraception,

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[119] *Id*. at 951 (Scalia, J. dissenting) (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

[120] *Griswold v. Connecticut*, 381 U.S. 479, 485 (Stevens, J. concurring).

[121] *Id.*

[122] A. Winkler, "Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts," *Vanderbilt Law Review*, Vol. 59, p. 793, 2006.

family relationships, child rearing, and education."[123] The Court has recognized these kinds of decisions as "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, [which] are central to the liberty protected by the Fourteenth Amendment."[124]

The protection afforded by substantive due process also extends to rights to bodily integrity and self-determination. As Justice O'Connor noted in *Cruzan v. Missouri Department of Health*, "our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination."[125] Consistent with that principle, the Court has recognized a fundamental liberty interest in refusing unwanted medical treatments.[126] For example, in *Washington* v. *Harper*, the Court recognized that even prisoners -- whose liberty obviously is severely limited -- possess "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the

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[123] *Casey,* 505 U.S. at 852, quoting *Carey v. Population Services International*, 431 U.S. at 685 (striking down a law that placed an undue burden on a woman's right to terminate a pregnancy). *See also Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (affirming parents' right to send their children to private schools); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (affirming the right of parochial schools to teach a foreign language); *Loving v. Virginia*, 388 U.S. 1 (1967) (striking down a law barring people of different races from marrying); *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942) (recognizing a right to procreate); *Griswold*, 381 U.S. 479 and *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (recognizing a right to use contraceptives).

[124] *Casey,* 505 U.S. at 878.

[125] *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 287 (1990) (O'Connor, concurring).

[126] *Id.*

Fourteenth Amendment."[127]

Importantly, the autonomy rights protected by substantive due process extend not only to decisions affecting one's own body, but to the values that inform those decisions. As Justice Kennedy stated in *Planned Parenthood v. Casey*, "At 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."[128] In essence, the Court has determined that fundamental choices regarding what a person does with her own body must be an expression of her own values.[129] Government may not interfere with these choices out of a desire to enforce traditional values or those prevailing in the dominant culture. As Justice Kennedy explained in striking down the criminal prosecution of two men for engaging in homosexual conduct:

> [F]or centuries there have been powerful voices to condemn homosexual conduct as immoral. The condemnation has been shaped by religious beliefs, conceptions of right and acceptable behavior, and respect for the traditional family. For many persons these are not trivial concerns but profound and deep convictions accepted as ethical and moral principles to which they aspire and which thus determine the course of their lives. These considerations do not

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[127] *Washington* v. *Harper*, 494 U.S. 210, 221-222 (1990). *See also Vitek* v. *Jones*, 445 U.S. 480 (1980) (transfer to mental hospital coupled with mandatory behavior modification treatment implicates liberty interests).

[128] *Casey,* 505 U.S. at 851.

[129] *Id*. at 852 ("The destiny of the woman must be shaped to a large extent on her own conception of her spiritual imperatives and her place in society.").

> answer the question before us, however. The issue is whether the majority may use the power of the State to enforce these views on the whole society through operation of the criminal law. Our obligation is to define the liberty of all, not to mandate our own moral code.[130]

The Court concluded that "the fact that the governing majority in a State has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice."[131]

This jurisprudence suggests that to the extent certain uses of medical technology implicate fundamental choices related to bodily integrity and self-determination, efforts to restrict access to these technologies on moral grounds will be subject to heightened scrutiny and may be invalidated. As described in the following section, this issue has arisen repeatedly in connection with State laws designed to restrict access to non-therapeutic medical interventions. Where the Court has determined that the purpose of these efforts was to enforce certain conceptions of morality, the Court has invalidated these laws. These decisions cast doubt on the legal permissibility of empowering a regulatory agency to restrict access to enhancements on the basis of moral concerns.

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[130] *Lawrence v. Texas, 539 U.S. 558,* 577-578 (2003).

[131] *Id*.

II. Access to non-therapeutic medical interventions

As noted above,[132] there is broad consensus about the importance of treating illnesses. With very few exceptions -- such as Christian Scientists who reject all medical treatment -- the propriety of treating cancer or heart disease is not in dispute. This consensus stands in marked contrast to the heated debate over enhancements, the use of which is often condemned as morally wrong. This disparity is a product of the fact that while treating diseases is a manifestation of the universal desire to be well, the desire to use medical technology for non-therapeutic purposes is an expression of individual values. While everyone values health, not everyone values having bigger breasts, or being stronger, smarter or more outgoing. Others who do desire these things may subscribe to a system of values in which those desires are subordinate to moral objections to using medical technology to achieve these ends.

This clash of values is precisely why proponents of restricting access to enhancements have proposed expanding regulatory authority over medical interventions to include moral concerns: to empower government to overrule individual values regarding enhancements.[133] However, to the extent

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[132] *See* Part 2(II)(A) *infra*.

[133] Fukuyama and Furger liken the need for expanded regulatory control over emerging enhancement technologies to Ulysses' strategy of resisting the Sirens' songs by ordering his crew to tie him to the mast of his ship: "Like modern argonauts, we may soon be exposed to the chants of medical and scientific Sirens we may be too weak to resist." Fukuyama, *supra* n. 3 at 59. Critically, however, Ulysses chose to be tied to the mast. By contrast, Fukuyama and Furger propose that society should restrain individuals who

decisions to use enhancements implicate bodily integrity and self-determination in fundamental ways, these decisions can fall within the zone of autonomy protected by substantive due process.

Consider birth control. Contraception does not treat any disease. Far from promoting normal functioning of the human body, the purpose of contraception is to interfere with that functioning. For this reason some people object to birth control as immoral,[134] and in the past have enacted laws restricting access to contraception. When the Supreme Court has determined that these actions were motivated by a desire to enforce a particular conception of morality, it has invalidated these laws.

In *Griswold v. Connecticut*, the Court concluded that a Connecticut law that imposed criminal penalties on "[a]ny person who uses any drug, medical article or instrument for the purpose of preventing conception" violated the Fourteenth Amendment rights of married couples.[135] In so ruling, the Court observed that "[t]his law . . . operates directly on an intimate relation of husband and wife and their physician's role in one aspect of that relation,"[136] and found

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may not believe that enhancements are Sirens at all.

[134] *See, e.g.*, Catholic Answers, "Birth Control." (available at 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.' The natural law purpose of sex is procreation. . . . God's gift of the sex act, along with its pleasure and intimacy, must not be abused by deliberately frustrating its natural end—procreation.").

[135] *Griswold*, 381 U.S. at 480.

[136] *Id.* at 482.

that this interference infringed on "a relationship lying within the zone of privacy created by several fundamental constitutional guarantees," including the Fourteenth Amendment.[137] In *Eisenstadt* v. *Baird*, the Court made clear that this zone of privacy does not inhere only in the relationship between married people; rather it is a right held by every individual: "If the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[138] The Court rejected the contention that the purpose of restricting access to contraception was to protect public health, finding instead that the law's "plain purpose" was to enforce a particular conception of moral conduct: "to protect purity, to preserve chastity, to encourage continence and self-restraint, to defend the sanctity of the home, and thus to engender in the State and the nation a virile and virtuous race of men and women."[139] The Court held that states could not substitute their own moral judgments on these matters for those of the individuals who sought to use contraceptives; the states' interest was insufficient to outweigh individuals' liberty interest in making their own choices regarding sex and procreation.

The Court went even further in *Planned Parenthood v. Casey*, ruling

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[137] *Id.* at 485.

[138] *Eisenstadt*, 405 U.S. at 453.

[139] *Id*. at 448.

that even "the interest of the State in the protection of potential life"[140] does not outweigh "the urgent claims of the woman to retain the ultimate control over her destiny and her body, claims implicit in the meaning of liberty."[141] As in *Griswold* and *Eisenstadt*, the Court affirmed the power of the State to pass laws to ensure public health and safety in the provision of medical services, but rejected the State's authority to pass regulations with "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."[142]

By rejecting government authority to restrict access to contraceptives, the Court affirmed the right of individuals to set the terms that define their intimate relationships and sexual expression, by deciding whether those relationships and activities may result in offspring. Likewise in protecting the right of a woman to terminate her pregnancy the Court declared that this decision must be an expression of the woman's "own conception of her spiritual imperatives and her place in society."[143] The Court has determined that substantive due process does not permit majorities -- through legislative or regulatory action -- to substitute their own moral judgments regarding the propriety of these medical technologies for the decisions of individuals. As

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[140] *Casey,* 505 U.S. at 871

[141] *Id*. at 869.

[142] *Id*. at 877.

[143] *Id*. at 852.

described below, enhancement technologies may similarly implicate choices within the scope of that Constitutional protection.

III. A Constitutional right to enhance?

Whether regulators may restrict access to enhancement technologies based on ethical concerns hinges most importantly on whether these interventions likewise implicate liberty interests that are "fundamental." That question will depend on the nature of the biomedical intervention at issue -- specifically, the extent to which the use of a particular enhancement implicates "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy."[144] Accordingly a court examining a government restriction on access to a medical intervention on moral grounds would first need to understand how the technology can be used and how much those uses reflect expressions of the kinds of fundamental choices that are central to personal dignity.

In the context of currently available medical technologies, the idea that limiting access to enhancements might have Constitutional implications sounds implausible -- presumably using Botox to eliminate wrinkles would not rank as a fundamental liberty. But the primary impetus for proposals to expand regulatory oversight of enhancement technologies is not to address today's technologies, but tomorrow's.[145] These proposals are largely motivated by

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[144] *Id*. at 878.

[145] *See, e.g.*, Fukuyama, *supra* n. 3 at 37 (arguing that the existing regulatory

concerns that impending technological advances will make possible profound alterations of human bodies and minds. Since these hypothesized future technologies are the target of proposals to expand regulation, it is important to consider whether restricting access to these kinds of interventions would pass Constitutional muster. Moreover, examining how some of the more radical hypothesized interventions could implicate the right to define "one's own concept of existence" and "the attributes of personhood"[146] can help illuminate the outer limits of government authority to regulate enhancements.

Among these more radical interventions are brain-computer interfaces, or "BCI." Although "brain-machine interfaces that allow direct two-way interaction between neural tissue and electronic transducers remain in the 'proof of concept' stage . . . they show substantial promise."[147] As George Khushf has written:

> Some of this research is already in the human testing stage, enabling paraplegics to control “smart rooms” or blind people to detect objects through video glasses that completely bypass the natural eyes with electrodes that feed directly into the brain. And while the initial stages of human subjects’ research will largely focus on medical treatments, many of the most prominent researchers have broader interests, seeking . . . a major paradigm shift in the way normal healthy subjects can interact with their environment

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scheme "contains certain gaps or omissions that will render it increasingly inadequate to meet the challenges posed by new biotechnologies and medical procedures in the coming years.").

[146] *Casey,* 505 U.S. at 851.

[147] Farah, *supra* n. 64 at 421.

> with unprecedented ability to augment perception and performance in almost all human activities.[148]

Proponents suggest that BCI could provide humans with "always-on access to information as well as unprecedented information-processing powers."[149] Using brain-computer interfaces could, for example, enable "an information-gulping sixth sense," that would allow us "to instantaneously gulp down the information of an entire book, making it a structural part of our wetware ready for inferencing, reference, etc., with some residual sense of the whole, as part of the gulp experience."[150]

If realized, these kinds of modifications would appear to strike at the very heart of human identity and self-determination. As Walter Glannon has argued:

> techniques that target the brain can reveal and directly affect the source of the mind and the deepest aspects of our selves: free will; personhood; personal identity through time; the relation between the mind and the body; the soul. These interrelated philosophical concepts all encompass cognitive, affective, and conative mental capacities, which include beliefs, emotions, desires, and volitions that are generated and sustained by the brain. One's identity as a person, one's experience of agency, and one's general sense of self consist in the unity and integrity of one's mental states. It is because the

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[148] G. Khushf, "The use of emergent technologies for enhancing human performance: Are we prepared to address the ethical and policy issues?" *Public Policy and Practice* 4 (2) (2005), (available at: <www.ipspr.sc.edu/ejournal/thisIssue511.asp>).

[149] Allhoff, *supra* n. 16.

[150] Gordijn, *supra* n. 18 at 728-729 (internal quotation omitted).

> brain generates and sustains these states that intervening in the brain can affect the nature and content of our minds and thus who we essentially are.[151]

If Glannon is right, it would be difficult to conclude that these kinds of interventions do not implicate fundamental liberties that merit Constitutional protection from government interference.

Nevertheless, supporters of women's procreative rights might bristle at the suggestion that enhancing normal human traits, which strikes many as a frivolous undertaking, bears the same importance as the right to prevent conception or terminate a pregnancy. One might reasonably argue that being denied the opportunity to add new capabilities to a healthy, functional brain does not violate the dignity of that individual to the same extent as forcing a woman to carry a pregnancy to term. Indeed, the Court itself has observed that in the context of abortion, "the liberty of the woman is at stake in a sense unique to the human condition and so unique to the law."[152]

That said, while certain enhancements may seem less momentous, in terms of personal dignity and autonomy, than abortion, it is worth noting that the State interests supporting restrictions on enhancement technologies are far more nebulous than the "important and legitimate interest in protecting the potentiality of human life." *Id*., at 871. If the interest in protecting nascent human

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[151] F. Jotterand, "Beyond Therapy and Enhancement: The Alteration of Human Nature," *NanoEthics* (2008) 2:15–23.

[152] *Casey,* 505 U.S. at 852.

life is insufficient to outweigh the liberty to control one's own body, it is difficult to conclude that abstract notions of protecting traditional conceptions of "human agency" should override individuals' autonomy interests. Moreover, the Court has determined that substantive due process rights extend beyond abortion to encompass a range of personal decisions related to bodily integrity and self-determination -- including rights to engage in sex without producing offspring, to engage in homosexual sexual activity, and to refuse unwanted medical interventions.

In *Casey*, the Court offered an instructive thought experiment one might employ to determine whether an asserted liberty interest is fundamental. The Court observed that "[i]f indeed the woman's interest in deciding whether to bear and beget a child had not been recognized as in *Roe* [*v. Wade*[153]], the State might as readily restrict a woman's right to choose to carry a pregnancy to term as to terminate it, to further asserted state interests in population control, or eugenics."[154] The Court noted that lower courts had rightly relied on *Roe* to reject state efforts to coerce women to terminate pregnancies or undergo unwanted sterilization.[155] Applying similar logic to a brain-computer interventions, it appears

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[153] 410 U.S. 113 (1973).

[154] *Casey,* 505 U.S. at 859.

[155] *Id*. (citing *Arnold v. Board of Education of Escambia County, Ala.*, 880 F.2d 305, 311 (11th Cir. 1989) (forcing a minor to have an abortion violates the Constitution); *Avery v. County of Burke*, 660 F.2d 111, 115 (4th Cir. 1981) (county agency acted unconstitutionally in inducing teenage girl to undergo unwanted sterilization)).

plain that a government action forcing an individual to undergo such a procedure would violate her fundamental liberty interest in controlling her own body.[156] By the Court's reasoning in *Casey*, this fact strongly suggests that restricting access to such technologies would likewise infringe on fundamental liberties.

If the Court were to determine that the decision of whether to modify one's own brain through a computer interface lies within the zone of privacy protected by the Fourteenth Amendment, it would employ strict scrutiny in evaluating government actions restricting access to these technologies. This would require the government to defend its actions as necessary to achieve a compelling government interest, and as narrowly tailored to meet that objective, using the least restrictive means.[157]

In assessing the strength of the government's interest in restricting access to an enhancement, the Court would consider whether the purpose of the restriction is to protect public health and safety, or to enforce a traditional or prevailing morality.[158] In this regard, it seems clear that the purpose of expanding regulatory authority over enhancement technologies is not to protect public health or safety -- the FDA has long possessed and exercised that authority.

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[156] *See, e.g., Harper*, 494 U.S. at 221-222 (1990) (finding that prisoners possess "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment."); *Vitek*, 445 U.S. 480 (transfer to mental hospital coupled with mandatory behavior modification treatment implicates liberty interests).

[157] *Griswold*, 381 U.S. at 485 (Stevens, J. concurring).

[158] See the discussion of *Griswold* and *Eisenstadt infra* Part 3(II).

Rather, the express purpose of the proposals to expand regulatory authority over enhancement technologies is to empower regulators to place restrictions on medical interventions on the basis of prevailing moral values. Indeed, Fukuyama proposes to incorporate public opinion about the ethics of particular enhancement practices into regulatory decision-making.[159] Similarly, a key purpose of Fox's proposal is to enable regulators to consider how enhancement technologies might undermine "values of character or virtue" or "threaten[] the moral status of nature."[160] The precedents of *Casey*, *Lawrence*, *Eisenstadt* and *Griswold*, among others, strongly suggest that in the context of fundamental decisions affecting bodily integrity and self-determination, the Constitution does not permit government to substitute its moral judgments about such issues for those of individuals.[161]

While BCI technologies that fundamentally alter human perception, cognition and identity may never come to fruition, the possibility of such technologies illustrates how enhancement technology can implicate protected liberties. This example also points to a conundrum regarding enhancement regulation: the more profoundly a medical technology alters human nature, the greater the moral concern, but also the stronger the claim to a protected liberty

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[159] *See, e.g.*, Fukuyama, *supra* n. 3 at 16-23.

[160] Fox, *supra* n. 2 at 1191-92.

[161] *See, e.g.*, *Lawrence*, 539 U.S. at 577-578 ("the fact that the governing majority in a State has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice.").

interest -- considerations that pull in opposite directions in the substantive due process analysis. Efforts to regulate enhancement technologies on moral grounds will have to contend with that tension with respect to a range of interventions -- from mood and personality modifications to memory and cognition enhancements -- whose implications for bodily integrity and identity formation lie on a broad spectrum between Botox and BCI.

CONCLUSION

Because enhancements raise serious ethical concerns that treatments do not, it is not surprising that a regulatory process designed for the latter would be ill-suited to the former. The desire to apply a different regulatory process to enhancements -- one that incorporates ethical concerns into the traditional, "science-based" inquiry into safety and efficacy -- is understandable.

But just as enhancements can produce unintended negative consequences, regulatory policies can backfire as well. As proscriptive policies toward study drugs on college campuses highlight, the culture that produces the ethical problems related to enhancements is the same culture that crafts the regulations -- and that process is therefore subject to the same infirmities and blind spots. Similarly, efforts by pharmaceutical companies, doctors and patients to medicalize a broad range of life problems reveal that restricting access to enhancements does nothing to address the underlying elements of culture that spur demand for problematic uses of these technologies -- and can actually reinforce the cultural conditions that are the true source of ethical concern.

Finally, allowing government to substitute prevailing morality for individual decisions regarding one's own body is a tricky business. Although there are compelling concerns about the cumulative societal effects of individual decisions regarding enhancements, those concerns must be balanced against fundamental individual liberties that are "implicit in the concept of ordered

liberty."[162] Striking that balance will be a perpetual challenge as new technologies make possible unanticipated modifications to human bodies and minds.

[162] *Casey,* 505 U.S. at 951 (Scalia, J. dissenting) (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

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