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# HOW WILL WE REGULATE GENETIC ENHANCEMENT?

*Maxwell J. Mehlman\**

*Genetic enhancement technologies present difficult and novel regulatory issues, including the problem of measuring and comparing risks and benefits and dealing with the impact of these technologies on social values. This Article describes and evaluates the potential approaches that may be taken to regulate these technologies. The author concludes that a variety of approaches will be necessary, involving self-regulation, government restrictions on access and use, licensing, and a national lottery.*

## INTRODUCTION

On September 11, 1997, the National Institutes of Health ("NIH") convened the first of its "Gene Therapy Policy Conferences." The subject was the regulation of genetic enhancement. This meeting marked a new attitude toward the subject; previously, genetic enhancement was regarded largely as science fiction, and serious discussion of its attendant ethical, legal, and social issues was conspicuously absent from serious genetics journals.<sup>1</sup> The meeting was prompted by a request to NIH to approve a protocol for conducting a

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1. No doubt the legitimization of the topic of genetic enhancement was aided by the successful cloning of "Dolly" in Scotland, an accomplishment previously dismissed as science fiction. See Gina Kolata, *Little-Known Panel Challenged to Make Quick Cloning Study*, N.Y. TIMES, Mar. 18, 1997, at C1 ("Dr. Wilmut's feat shocked the world, for even most scientists had assumed that the cloning of adults was biologically impossible and was merely the stuff of science fiction.")

gene therapy experiment on healthy volunteers, rather than on patients.<sup>2</sup> Although the experiment was part of an effort to develop treatments for cystic fibrosis, the proposed use of healthy subjects raised, for the first time, the question of whether and in what circumstances it was appropriate to use gene insertion technology in "normal" individuals.<sup>3</sup> Officials at NIH realized that it was a short step from preliminary testing in healthy subjects of a genetic treatment for disease to experiments intended to genetically enhance a normal person's physical or mental characteristics.<sup>4</sup>

In a sense, genetic enhancement has been with us for some time if we include within that category genetically engineered drug products used to alter physical traits. Human growth hormone ("HGH"), which had been obtainable prior to 1985 only in limited quantities from cadaveric pituitary glands,<sup>5</sup> now can be produced in a virtually inexhaustible supply using recombinant DNA technology.<sup>6</sup> When its supply was more limited, HGH was prescribed for children with short stature caused by classical growth hormone deficiency.<sup>7</sup> With the advent of recombinant DNA manufacturing, however, some physicians have begun recommending use of HGH for non-hormone-deficient children who are below "normal" height.<sup>8</sup> A survey of pediatric endocrinologists, for example, found that as many as thirty-three percent of the respondents would recommend HGH for children who were not hormone-deficient, but who were in the lowest three percent of their age group in terms of height.<sup>9</sup> Endocrinologists also report being asked by parents of "normal" children to prescribe HGH in order to give their children an advantage in competi-

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2. See Rick Weiss, *Gene Enhancements' Thorny Ethical Traits*, WASH. POST, Oct. 12, 1997, at A1 (describing a meeting between the NIH and the Food and Drug Administration ("FDA") that considered regulation of cosmetic gene therapy).

3. See *id.*

4. See *id.*

5. See Mark McDonald, *A Growth Industry: Some Athletes Are Turning to Hormone for Competitive Edge, but Safety Debated*, DALLAS MORNING NEWS, May 21, 1995, at 1A.

6. See American Academy of Pediatrics, *Considerations Related to the Use of Recombinant Human Growth Hormone in Children*, 99 PEDIATRICS 122 (1997).

7. See *id.*

8. See *id.*; see also Leona Cuttler et al., *Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns*, 276 JAMA 531, 531 (1996) (indicating many pediatric endocrinologists consider growth hormone treatment appropriate for non-growth hormone deficient children).

9. See Cuttler et al., *supra* note 8, at 533 fig.1. Children in the survey were two standard deviations from the mean height for their age. See *id.* Approximately 90,000 of the three million children born each year will fall into this category. See Barry Werth, *How Short Is Too Short?*, N.Y. TIMES, June 16, 1991, § 6, at 14.

tive sports.<sup>10</sup> Adult athletes are believed to use HGH to spur bone and muscle growth.<sup>11</sup>

Although the use of recombinant drugs such as HGH raises important regulatory issues, as we shall see, the NIH conference was inspired by the prospect of genetic enhancement achieved by more radical technologies—in particular, gene insertion. This involves the introduction of actual genetic material into a person's cells. When the goal is therapeutic, the genetic material may consist of a "normal" gene that compensates for a missing or defective gene.<sup>12</sup> When the goal is enhancement, the gene may supplement the functioning of normal genes or supersede them with "supergenes" that have been engineered to produce a desired enhancement effect.<sup>13</sup> Gene insertion may be intended to affect a single individual, or it may target a person's reproductive cells, in which case the resulting effect, if complemented by the cells of the person's reproductive partner, will be produced in their children and passed on to succeeding generations.<sup>14</sup>

Genetic enhancement raises a host of ethical, legal, and social questions. When should parents give drugs such as HGH to children of "normal" stature? For that matter, what is meant by "normal"—i.e., when is a genetic intervention "enhancing" or "therapeutic"? (This distinction is critical, for example, in determining whether the intervention will be covered by health insurance.) How should the benefit from a genetic enhancement be calculated in comparing its risks and benefits? Would people who have been genetically enhanced enjoy an unfair advantage in competing for scarce resources, from sports awards to the allocation of academic and professional opportunities? If so, how should these competitions be conducted to avoid or reduce the unfairness? Concerns like these

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10. See McDonald, *supra* note 5, at 1A.

11. See *Chinese Takeaway: HGH*, IRISH TIMES, Jan. 10, 1998, at 57 (noting that while HGH burns fat and promotes bone, connective tissue, and muscle growth, the muscle is weak in relation to its size); *On the Track of the Drug Cheats: The Battle Between the Sports Authorities and Athletes Who Break the Rules Is Being Fought at Ever Higher Levels, Says Clive Cookson*, FIN. TIMES (London), July 20, 1996, Comment and Analysis, at 9 (noting that Atlanta Olympics officials worried about use of HGH by competing athletes).

12. See Theodore Friedman, *Overcoming the Obstacles to Gene Therapy*, SCI. AM., June 1997, at 96, 97-98.

13. For an overview of gene insertion techniques, see generally *Special Report: Making Gene Therapy Work*, SCI. AM., June 1997, at 95, 95-123 (offering five articles that outline current developments in genetic technology). The insertion of normal genes or "supergenes" to supplement the working of normal genes also can be intended to achieve therapeutic objectives, such as providing added immunity to disease. See Eric Juengst, *What Does "Enhancement" Mean?*, in ENHANCING HUMAN TRAITS: ETHICAL AND SOCIAL IMPLICATIONS (Erick Parens ed., 1998). This complicates both the definition of "genetic enhancement" and the regulatory response.

14. See Steve Mirsky & John Rennie, *What Cloning Means for Gene Therapy*, SCI. AM., June 1997, at 122, 123.

arguably would be exacerbated by germ cell genetic enhancement, in which these risks and benefits, advantages and harms, would be transferred to successive generations.

As genetic enhancement technology emerges, responses to these and similar concerns necessarily will be forthcoming. The nature of these responses, and how successfully they resolve the problems that they target, will depend in the first instance on identifying the responding individuals or institutions, and the principles and decision-making algorithms that they will employ.

### I. DEFINING GENETIC ENHANCEMENT

Identifying what we mean by genetic enhancement presents two major difficulties. First, when is an enhancement "genetic?" Second, when is a genetic manipulation "enhancement?" People constantly try to improve themselves and their children by means of diet, exercise, education, marriage, job changes, cosmetic surgery, and the like. Some of these efforts are successful, at least in part, by virtue of the person's genetic endowment. For example, someone who has inherited good looks is likely to find it easier to marry someone attractive, which may enhance their social standing and lead, in turn, to the production of handsome children.<sup>15</sup> Getting into a prestigious college is influenced by the applicant's aptitude—to some degree a matter of genetic endowment. In addition, one's genetic make-up helps determine how much improvement is required to achieve a desired effect. Someone who inherits a fine facial bone structure, for example, may require less radical plastic surgery to continue to appear young than someone with coarser features.

For purposes of this Article, an enhancement will be deemed genetic when it is produced by biotechnological processes, such as by a pharmacological product made using recombinant DNA technology or by gene insertion. These processes raise significant, new challenges to our regulatory capabilities. There is little precedent for germ cell enhancement engineering modifications at the genetic level that biologically affect succeeding generations. Techniques such as education and exercise are apt to be far more gradual and less pronounced than genetic enhancement. Even the relatively rapid changes produced by cosmetic surgery and the use of performance enhancement drugs in sports lack the potential depth and breadth of genetic alteration.

Obviously, not all genetic interventions will be enhancements. Some, indeed almost all at the outset, will aim to treat or to prevent disease or disorders. A genetic *enhancement*, then, refers to an in-

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15. While discussing herself and other top models, Linda Evangelista stated, "We were blessed with genetic good fortune, and we have long bodies and a lot of us have hardly any body fat. . . . I hate using this term, but we are genetic freaks." *Model Says Super Looks Just a Freak of Nature*, PLAIN DEALER, May 16, 1996, at 2A.

tervention that is not undertaken for purposes of treating or preventing diseases or disorders.<sup>16</sup> Instead, an enhancement is aimed at improving a characteristic that, but for the enhancement, would be within what is generally regarded as a "normal" range,<sup>17</sup> or at installing a characteristic that would not normally be present.<sup>18</sup>

## II. REGULATORY CONCERNS

### A. Efficacy

As genetic enhancement technologies are developed, serious questions will arise concerning the appropriateness of their use. Answers to these questions will depend, in the first instance, on the effectiveness of these technologies in achieving their intended effects. Consider a genetically engineered drug or gene insertion technique that purports to improve mental acuity. Does it work? If so, how well does it work? The answers to these questions are necessary to enable individuals or regulators to compare the positive and negative consequences of the technology in order to decide

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16. There is burgeoning, insightful literature dealing with the distinction between enhancement and therapy. See, e.g., LEROY WALTERS & JULIE G. PALMER, *THE ETHICS OF HUMAN GENE THERAPY* (1997); Norman Daniels, *Growth Hormone Therapy for Short Stature: Can We Support the Treatment/Enhancement Distinction?*, 8 *GROWTH GENETICS & HORMONES* 46, 46-48 (Supp. I 1992); Eric T. Juengst, *Can Enhancement Be Distinguished from Prevention in Genetic Medicine?*, 22 *J. MED. & PHIL.* 125, 125-42 (1997); Eric Parens, *The Goodness of Fragility: On the Prospect of Genetic Technologies Aimed at the Enhancement of Human Capabilities*, 5 *KENNEDY INST. ETHICS J.* 141, 141-51 (1995). As Eric Juengst observes, it is not satisfactory to classify an intervention as an enhancement merely because the intervention is aimed at improving the functioning of healthy systems and normal traits; like enhancements, preventive medicine, especially immunizations, "fixes" bodily functions that aren't broken." Juengst, *supra* note 13, at 33.

17. The concept of "normalcy" is so value-laden, arbitrary, and subjective that the term must be placed in quotation marks. Typically, it refers to a certain distribution of the population around an average measure for a particular trait. Clinicians generally consider a person to be clinically "short" or "tall" if their height is more than two standard deviations from the mean of the population. See Werth, *supra* note 9, § 6, at 14. Since two standard deviations comprise, by definition, approximately 95% of the population, 5% of the population automatically becomes defined as above or below "normal" height. See GARY L. TEITJEN, *A TOPICAL DICTIONARY OF STATISTICS 4-5* (1986). A more sophisticated attempt defines "normalcy" as a level of functionality that allows an individual to enjoy the opportunity range typical of their species, an approach championed by Norman Daniels. See Daniels, *supra* note 16, at 47. This approach falters when it attempts to delineate the boundary between therapy and enhancement. As Eric Juengst observes, Daniels' thesis assumes that we can define "species-typical function" and that an individual's "skills and talents" are fixed according to the "natural lottery" of human genetics, neither of which obtains once genetic enhancements become available. See Juengst, *supra* note 13, at 36.

18. These might be cosmetic alterations of appearance, such as creating human hair or eye colors that were not found in nature.

whether or not the benefits are worth the risks. Suppliers of the product need efficacy information in order to gauge how much they should charge for it. Potential purchasers, whether patient-consumers or third-party payers, need the information to know whether or not the charge is worth it.

Establishing the efficacy of genetic enhancements will present many of the same difficulties as establishing the efficacy of medical and biological interventions. The effect of the intervention will have to be detected and measured. For enhancements that achieve their effect in the next generation, this will necessitate waiting until the enhanced person has matured enough to display the effect, if any.

Measuring the effect will require appropriate instruments and standardized scales. In some cases, the degree of the effect that is achieved will be measurable in objective terms. The effect of an enhancement that improved visual acuity could be ascertained by conventional, standardized techniques such as reading an eye chart. Similar tests exist for height, strength, and even memory and intelligence.<sup>19</sup> But some traits that might be the subject of genetic enhancement, such as beauty or charisma, do not lend themselves to traditional measurement approaches.<sup>20</sup> Perhaps instruments and scales for these traits will be developed in the future in response to the emergence of enhancement technologies.

Once the effect of a genetic enhancement technology is measured, the effect must be valued. For a health effect, the first step usually is assessing the effect in terms of its clinical benefit and then expressing that benefit in standardized units. Drugs used to treat heart attacks, called "clot-busters," are a good example. They dissolve blood clots that interfere with circulation to the heart muscle, causing the infarct or heart attack. Determining their efficacy, however, requires more than simply ascertaining if they dissolve blood clots, for that is only a means to achieve their clinical benefits: reducing the severity of the heart attack, preventing a recurrence, easing discomfort, increasing recovery time, restoring functionality, and, ultimately, prolonging life. These effects must be measured over many years if the question is how well the drugs prolong life.<sup>21</sup>

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19. See, e.g., CLINICAL NEUROPSYCHOLOGICAL ASSESSMENT: A COGNITIVE APPROACH (Robert L. Mapou & Jack Spector eds., 1995) (discussing neuropsychological testing); ALAN S. KAUFMAN, ASSESSING ADOLESCENT AND ADULT INTELLIGENCE (1990) (discussing intelligence tests); MUSCLE STRENGTH TESTING: INSTRUMENTED AND NON-INSTRUMENTED SYSTEMS (Louis R. Amundson ed., 1990) (testing muscle strength in physical therapy settings). Even these tests are subjective in that they depend upon the cooperation of and the accurate performance by the subject.

20. Cf. John T. Molloy, *Acquiring Charisma Demands a Change in Attitude*, HOUS. CHRON., Nov. 16, 1995, at 7 (declaring that the only way to measure charisma is in terms of its effect); Simon Perry, *That's Beauty Baby: Why Good Looks Dazzle Even Those Only Three Months Old*, EVENING STANDARD (London), May 28, 1996, at 3 (testing for the effects that beauty has on infants).

21. See BARUCH A. BRODY, ETHICAL ISSUES IN DRUG TESTING, APPROVAL, AND

Finally, in order to compare the effectiveness of different interventions, clinical benefit must be expressed in standardized ways, such as in terms of providing additional years of life.

Up to this point, we have been largely objective. We measure effects such as functionality, recovery time and prolongation of life by observation, and we protect against observer bias by various techniques such as blinding the observers to whether the patients they are evaluating have or have not received the experimental modality. But we also employ subjective measures, such as relief from pain. Most importantly, the ultimate value that we place on the observed benefits is subjective: an additional year of life, for example, may be worth more to one person than to another.<sup>22</sup>

The same tasks would be necessary in assessing the efficacy of genetic enhancements. We would need to evaluate their effect not only in terms of the magnitude of their direct impact—extra inches of height or IQ points, for example—but in terms of the ultimate benefits that these effects produced: the increased probability of becoming a professional basketball player or of getting into Harvard. In addition, we would need to place a value on being a professional basketball player or a Harvard graduate. This value is likely to

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PRICING 23 (1995) (discussing concept of clinical efficacy).

22. Researchers have struggled to develop ways to standardize these values. One approach attempts to convert benefits into a scale based on the person's willingness to pay for them. For example, if a person would be willing to pay \$10,000 for an additional year of life and only \$5000 for a year of restored function, then we can conclude that they value life above functionality. However, this system breaks down when we extend it to more than one individual, as we might if we were a regulatory agency determining whether the benefit from a genetic technology exceeded the risk. In this case, the willingness to pay approach falsely assumes that everyone has the same wealth and needs, so that a sum of money—say \$10,000—is worth the same to all. See generally Elizabeth Hoffman & Matthew L. Spitzer, *Willingness to Pay vs. Willingness to Accept: Legal and Economic Implications*, 71 WASH. U. L.Q. 59, 61-97 (1993) (analyzing divergence between willingness to accept and willingness to pay models); Ted R. Miller, *Willingness to Pay Comes of Age: Will the System Survive?*, 83 NW. U. L. REV. 876, 886-91 (1989) (explaining willingness to pay approach and its use in regulatory analysis); Dennis C. Taylor, *Your Money or Your Life?: Thinking About the Use of Willingness-to-Pay Studies to Calculate Hedonic Damages*, 51 WASH. & LEE L. REV. 1519, 1552-55 (1994) (criticizing willingness to pay approach for majority of torts contexts). The subjectivity of valuing benefit confounds another standardization technique, called quality-adjusted life years ("QALYs"), which attempts to adjust the additional years of life produced by a medical intervention in order to take into account the patient's quality of life. Valuing different qualities of life is highly subjective; the state of being deaf may be much worse for a musician, for example, than for a computer programmer. In fact, advocates for persons with disabilities contend that disabilities are often valued as more serious detriments than they are perceived by those who have them. See Alexander M. Capron, *Oregon's Disability: Principles or Politics?*, HASTINGS CTR. RPT., Nov. 1992, at 18; Paul T. Menzel, *Oregon's Denial: Disabilities and Quality of Life*, HASTINGS CTR. RPT., Nov. 1992, at 21.



vary substantially from person to person.

An analogy might be cosmetic surgery. How would we establish that the surgery was efficacious? One way would be to construct a visual image of the desired outcome and compare it to the surgical result. But one could argue that we have still failed to measure the ultimate effect, such as whether the patient gains a better self-image or is more successful at business or at attracting a mate. These effects are highly subjective, as was recognized by a panel of outside experts advising the FDA on the efficacy of liposuction devices.<sup>23</sup> The panel decided that it could only characterize the benefits from these devices in terms of patient satisfaction.<sup>24</sup>

In one respect, moreover, evaluating the efficacy of genetic enhancements is likely to prove particularly difficult: valid and reliable efficacy data for genetic enhancement technologies are likely to be extremely scarce. This will be the case for two reasons. First, depending on how genetic enhancement is achieved, providers and suppliers may not be required to submit safety and efficacy data to the government and obtain government approval before marketing enhancement technologies. To the extent that genetic enhancement is deemed a surgical or medical procedure, as opposed to the administration of a drug, biological, or medical device,<sup>25</sup> it will not require prior approval by the FDA, which would be based on adequate and well-controlled clinical investigations.<sup>26</sup> Without being required to submit this data, it is unlikely that anyone would go to the enormous expense of creating it.<sup>27</sup> More importantly, even if regulators regard genetic enhancements as drugs, biologicals, or medical devices, these technologies are likely to emerge first as unapproved or "off-label" uses of therapeutic technologies—that is, uses for which the manufacturers are not labeling or promoting the technologies—and manufacturers are not required to conduct clinical investigations to support such uses.<sup>28</sup> The experience with HGH,

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23. See Notice of Panel Recommendation, 61 Fed. Reg. 58,195-96 (1996) (giving notice that the FDA General Surgery and Plastic Surgery Devices Panel voted to reclassify liposuction devices from Class III to Class II).

24. See *id.* at 58,197.

25. For a description of these different modalities and a discussion of the differences in their regulation by the FDA, see *infra* Section III.E.

26. See 21 U.S.C.S. § 321(g)(1), (h) (Law. Co-op. 1997) (defining requirements for drugs and medical devices); 42 U.S.C.S. § 262 (Law. Co-op. 1994 & Supp. 1999) (outlining current regulation of biological products).

27. It is estimated that it costs an average of \$359 million to research a new drug and send it through the FDA approval process. See Theresa Beeby Lewis, Comment, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L LAW. 835, 842 (1996).

28. However, manufacturers and providers are required by the FDA to submit reports of adverse events that occur in connection with the use of their products, whether through approved or unapproved uses. See 21 U.S.C.S. § 360i (Law. Co-op. 1997). Prior to mandatory reporting, some amount of safety data would be available, although it is not clear how complete this information

mentioned earlier, is a good example. The drug was approved by the FDA for use in individuals who were deficient in growth hormone. Nevertheless, pediatric endocrinologists began prescribing it for other individuals with short stature. There are reports that parents are seeking the drug—and no doubt obtaining it—for use in children who are of normal height and even for use in some who are tall, in the hopes that the drug will enable them to grow tall enough to become successful basketball players.<sup>29</sup> Efficacy data exists for the approved use of HGH, but there are likely to be only unconfirmed reports from uncontrolled case studies for the off-label uses.<sup>30</sup>

### B. *Adverse Effects*

The same difficulties in determining the efficacy of genetic enhancements will interfere with assessing their risks. The likelihood that genetic enhancement will not trigger regulatory requirements applicable to drugs, biologics, or medical devices or that enhancement technologies will emerge as unapproved uses of approved drugs and devices will limit the availability of safety and efficacy information. Safety information may be especially deficient since the hazards of genetic enhancement may only manifest themselves in succeeding generations, and therefore may not be apparent for many years. Even if safety data were available, standardized measurement tools are lacking for effects such as pain. Furthermore, the valuation of harms, like that of benefits, is subjective; the shortening of life by a year, for example, may be viewed much more seriously by one person than another.

These limitations confound the central regulatory function of comparing risks and benefits. No intervention is completely safe; even the most innocuous treatment carries with it some element of risk however improbable or trivial. The question is whether the expected benefit is worth the potential risk. Given the problems in assessing the safety and efficacy of genetic enhancements, the most that may be possible may be to compare the risks involved in employing different means to achieve similar enhancement effects. For example, suppose that eye color can be changed using either genetic manipulation or colored contact lenses. Holding the desired benefit constant—producing a certain eye color—may allow us to compare the hazards without as much uncertainty and subjectivity as if we

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would be since reporting of adverse events is not rigorously enforced. See, e.g., Kathleen Kerr, *FDA Didn't Link Heart-valve Damage to Diet Drugs*, SEATTLE TIMES, Dec. 22, 1997, at A2 (criticizing FDA for limited follow-up of serious adverse event reports).

29. See Rita Rubin, *Giving Growth a Synthetic Hand: Use of Hormone Sparks Debate*, DALLAS MORNING NEWS, July 7, 1986, at 1A.

30. The FDA Modernization Act of 1997 changed the law to permit manufacturers to distribute literature on unapproved uses of drugs so long as the manufacturers are conducting studies intended to lead to eventual approval for the uses. 21 U.S.C.S. § 360aaa (Law. Co-op. 1997).

were comparing, say, changing eye color versus increasing height. Yet even this limited comparison of risks assumes that safety data are known.

Still, these problems also beset the regulation of technologies other than genetic enhancement. For example, the FDA is constantly struggling with the problem of regulating off-label uses of drugs and devices.<sup>31</sup> The gaps in the regulation of medical and surgical interventions, as opposed to new drugs and devices, is well-known and much-lamented.<sup>32</sup> The subjectivity of risk is a fundamental complication in all types of regulatory decision-making.<sup>33</sup> These problems may be exacerbated in the case of genetic enhance-

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31. Off-label use within the medical community is accepted as part of a physician's discretion and considered essential to medical care. The FDA acknowledges the need for this discretion as do courts and Congress, which enacted legislation to prohibit FDA intrusion into medical practice by restricting off-label use. See 21 U.S.C.S. § 396 (Law. Co-op. 1997); James M. Beck & Elizabeth D. Azari, *FDA, Off-label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 78 (1998). The FDA encounters problems regulating off-label use because it can be hard to draw the line between the legitimate flow of information (which is part of a doctor's practice and therefore not subject to FDA regulation) and a manufacturer's promotion of off-label use strictly for profit. See William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 248-51 (1993). A federal district court ruled in July 1998 that the FDA's present rules regulating the dissemination of information regarding off-label use constituted a restriction of commercial free speech. See *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998), *amended by*, 36 F. Supp. 2d 16 (D.D.C. 1999), *and amended by*, 36 F. Supp. 2d 418 (D.D.C. 1999). The court approved an injunction blocking enforcement of the existing rules. See *id.* at 74-75. This decision allows manufacturers to inform physician of uses of products even if those uses have not been approved by the FDA, subject to certain conditions. See *Federal Court Holds FDA May Not Restrict Information Involving Off-Label Use of Drugs*, 7 HEALTH LAW REP. (BNA) 1243 (Aug. 6, 1998).

32. New surgical procedures are typically subject only to approval from an institutional review board. See Jodi K. Fredrickson, *He's All Heart . . . And a Little Pig Too: A Look at the FDA Draft Xenotransplant Guideline*, 52 FOOD & DRUG L.J. 429, 438-43 (1997). However, the vast development of biotechnology products is pushing the limits of the FDA's definitions and approaches to regulation and challenging the traditional notion that the FDA doesn't regulate medical procedures. The dividing line as to the FDA's jurisdiction has become blurred by new cellular and related therapies that are often developed by processing cells and tissues. See Edward L. Korwek, *Human Biological Drug Regulation: Past, Present, and Beyond the Year 2000*, 50 FOOD & DRUG L.J. 123, 145-47 (1995); see also Jack M. Kress, *Xenotransplantation: Ethics and Economics*, 53 FOOD & DRUG L.J. 353, 381-84 (1998) (explaining that some transplant physicians argue xenotransplantation doesn't fall within FDA's jurisdiction because it is a surgical procedure and not a regulatory product).

33. Conclusive, direct evidence that a particular drug or device will threaten human health is rare. For example, science can establish the effects of high doses of formaldehyde in mice, "but quantification of the effects of low doses on humans currently lies beyond the reach of science." Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1619 (1995).

ment because of its novelty and the dearth of relevant data. But, by themselves, they do not indicate that the regulation of genetic enhancement would be fundamentally different than the regulation of other technologies, nor that regulating genetic enhancement would require the development of new regulatory approaches or entities.

Yet genetic enhancement does raise a host of truly unprecedented risks that are noteworthy not only for their novelty but for their subtlety. For, unlike the risks from traditional therapeutic interventions, which predominantly involve health hazards to the individual receiving the therapy, the principal risks from genetic enhancement are risks to third parties. They fall into three main categories: threats to social equality, "cheating," and the loss of personal autonomy. Let us turn to this last category first.

### 1. *Personal Autonomy*

Genetic enhancement threatens personal autonomy when it is imposed on persons without their consent. This could occur if enhancement were mandated by the government, say as part of a eugenics program, but a more likely scenario would be when a parent genetically enhanced a fetus or child, or when a person opted for germ cell enhancement for themselves or their offspring. These cases raise concerns because the effects of the enhancements, both positive and negative, are not chosen by those whom they will affect, and might not be chosen by them if they were given the choice.

We have had considerable experience with this problem in contexts other than genetic enhancement. Similar issues arise when medical treatment decisions are contemplated for persons who cannot make those decisions for themselves, such as when persons are unconscious;<sup>34</sup> when parents make treatment or lifestyle decisions for their children;<sup>35</sup> when researchers propose to experiment on em-

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34. With respect to persons who are unconscious, the Supreme Court of New Jersey held that the only practical way to prevent destruction of an unconscious patient's right to privacy is to permit the guardian and family to make their best judgment as to how the patient would exercise her judgment. *See In re Quinlan*, 355 A.2d 647, 664 (N.J. 1976) (involving a father who sought to remove extraordinary treatment from daughter who was in persistent vegetative state). Furthermore, if the decision is to forgo treatment, then it should be a decision acceptable to a society in which the overwhelming majority would make the same choice in similar circumstances. *See id.*

35. Parental autonomy is constitutionally protected. The United States Supreme Court has extended the concept of a right to privacy to child rearing. *See United States v. Orito*, 413 U.S. 139, 142 (1973); *Wisconsin v. Yoder*, 406 U.S. 205, 213-14 (1972). "Parental autonomy, however, is not absolute." *In re Philip B.*, 92 Cal. App. 3d 796, 802 (1979) (holding that the parents had a right to refuse surgery for their child with Down's syndrome even though it would significantly expand his life span and improve his physical functioning). Because the state has an interest in preserving life, if parents fail to provide their children with adequate care, the state is justified to intervene. However, since parental rights are sacred, they should only be invaded for the most compelling

bryos, fetuses, children, or persons who are mentally incompetent;<sup>36</sup> in connection with abortion;<sup>37</sup> and in treatment decisions by or for pregnant women that may affect their fetuses.<sup>38</sup> We respond to these situations in general by first trying to ascertain the wishes of the affected person or persons whenever possible and however imperfectly, such as by seeking statements by them of what they would prefer in related situations (the inaptly-named "substituted judgment" approach),<sup>39</sup> or by estimating what they would choose for themselves if they could do so, given what we know about them. If it is impossible to tell what the affected individual would have wanted, such as when the individual is *in utero*, the decision is made based on what "we" (society, family members, caregivers, legislators, judges, juries, ethics committee members—whoever is making or reviewing the decision) would want done if we were in the same cir-

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reason. *See id.* In order to intervene, the state has the "burden of proving by clear and convincing evidence that intervening in the parent-child relationship is necessary to ensure the safety or health of the child, or to protect the public at large." *Newmark v. Williams*, 588 A.2d 1108, 1110 (Del. 1990) (allowing Christian Scientist parents to refuse chemotherapy to treat their child's cancer). Parents also have a right to decide their child's lifestyle to a degree. *See Yoder*, 406 U.S. at 211, 234-35 (holding that Amish parents have a right to teach their children the "specific skills needed to perform the adult role of an Amish farmer or housewife").

36. A mental illness does not necessarily mean that a person is incompetent. A mentally ill patient can still retain the ability to communicate and understand information. A patient diagnosed with schizophrenia still has the right to refuse treatment if her decision is made while she is competent. *See United States v. Charters*, 829 F.2d 479, 499 (4th Cir. 1987). Furthermore, life-sustaining treatment can be removed from an incompetent patient if it is clear that the patient would have wanted it removed. *See In re Conroy*, 486 A.2d 1209, 1229 (N.J. 1985). The decision "should be that which would be made by the incompetent person, if that person were competent, but taking into account the present and future incompetence of the individual as one of the factors which would necessarily enter into the decision-making process of the competent person." *Superintendent of Belchertown State Sch. v. Saikewicz*, 370 N.E.2d 417, 431 (Mass. 1977).

37. *See Mary Mahowald & Virginia Abernethy, When a Mentally Ill Woman Refuses Abortion*, HASTINGS CTR. REP., April 1985, at 22 (discussing a chronic paranoid schizophrenic woman's choice to continue her pregnancy against the advice of her mother who has legal custody).

38. *See VAW v. Johnson Controls, Inc.*, 499 U.S. 187, 211 (1991) (holding that it was not appropriate for courts or employers to decide whether women should have children despite the fact that women, through their jobs, were exposed to lead which threatened the health of their fetuses); THOMAS H. MURRAY, THE WORTH OF A CHILD 96-115 (1996) (arguing that each individual should do her own balancing, considering all relevant factors as opposed to society treating pregnancy as a "moral trump card").

39. The substituted judgment approach, also known as the limited-objective test, states that "life-sustaining treatment may be withheld or withdrawn . . . when there is some trustworthy evidence that the patient would have refused the treatment, and the decision-maker is satisfied that it is clear that the burdens of the patient's continued life with the treatment outweigh the benefits . . ." *Conroy*, 486 A.2d at 1232.

cumstances (the "best interests" approach).<sup>40</sup> Only in rare and controversial instances do we permit the interests of the affected individual to be overridden, such as in the case of abortion (where we sometimes content ourselves with the fiction that the affected entity has no real legal interests).<sup>41</sup>

Most importantly, we require decision-makers to act cautiously in these situations. Seldom can they act hastily or alone. Parents or family members seeking to make a treatment decision for a non-autonomous individual usually must consult at least a physician, and a physician usually must consult parents or next-of-kin. Review by a hospital ethics committee may be required. Researchers must obtain permission from an institutional review board and possibly from the FDA or NIH. In some jurisdictions, certain steps can only be taken pursuant to a court order.<sup>42</sup>

Similarly, we might expect that the regulation of genetic enhancement would include procedural protections for those who were proposed to be enhanced, but who could not choose for themselves. For example, parents might be required to get someone's permis-

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40. The best interests approach, also known as the objective standard, incorporates what society considers to be reasonable medical choices. This standard is used when there is no evidence of an incompetent patient's former treatment preferences. See Rebecca Dresser, *Bioethics and the Law* (unpublished manuscript, on file with author). To justify removal of life-saving medical treatment, the burdens on the patient's life with the treatment must clearly outweigh the benefits that the patient would derive from the treatment. In addition to this, there must be "recurring, unavoidable and severe pain . . . such that the effect of administering life-sustaining treatment would be inhumane." *Conroy*, 486 A.2d at 1232.

41. See John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 444-46 (1996) (explaining how those who view the fetus as having no legal interests may not oppose abortion of fetuses with disabilities or abortion for gender selection).

42. The Supreme Court of Massachusetts outlined the required procedures for deciding whether to give or withhold life-prolonging treatment for an incompetent patient. See *Saikewicz*, 370 N.E.2d at 432-34. The court held that the first step was to petition for the appointment of a guardian or temporary guardian in Probate Court. Although the Probate Court was the proper court to determine the best interests of the incompetent patient, the appointed guardian ad litem was responsible for investigating the situation and representing the interests of the patient. If the judge, after listening to the guardian's report, was satisfied that the incompetent person would not have chosen treatment, then the judge would order treatment to be withheld. He would refuse to issue such an order if he was not satisfied that the patient would have so chosen or if he felt that the interests of the State required treatment. In developing this procedure, the Massachusetts Supreme Court expressly rejected the approach adopted by the New Jersey Supreme Court in *In re Quinlan*, which had held the decision should be entrusted to the patients, guardians, family, doctors, and hospital ethics committees. See *Saikewicz*, 370 N.E.2d at 434; see also John D. Hodson, Annotation, *Judicial Power to Order Discontinuance of Life-Sustaining Treatment*, 48 A.L.R.4TH 67 (1998) (analyzing federal and state cases in which courts have discussed under what conditions judicial authority exists to order discontinuance of life-sustaining treatment for incompetent patients).

sion, such as an ethics committee's or a court's, before they could enhance their children (whether before or after conception or birth). Such a regimen would require three components: (1) a set of decision-making rules; (2) a procedural mechanism, such as a court or a public or private administrative body; and (3) an enforcement method, including monitoring and sanctions.

Whatever "rules" or principles parents might justifiably use in deciding whether to pursue enhancements will depend in part on the particulars of the enhancement technologies in question. Some "enhancements" primarily will be for the child's benefit, while others may be directed more towards the parents' advantage or preference. Some enhancement technologies may carry very little risk to the children on whom they are used, while others may be quite risky. The guiding principles will rely on our conceptions of good parent-child relationships, on the values at the core of those relationships, and on the impact particular forms of enhancement technologies have on those values.

Procedural decision-making and enforcement mechanisms will be discussed below, but first, we need to address the two other major "safety" concerns: threats to social equality and "cheating." Both of these remaining social concerns stem from the fact that genetic enhancement will not readily be available to everyone. The primary roadblock will be cost.<sup>43</sup> Prenatal and germ cell enhancements most likely will involve expensive techniques such as *in vitro* fertilization ("IVF"), in addition to the cost of the enhancements themselves. IVF alone now costs an average of \$38,000 per delivery.<sup>44</sup> Even somatic cell enhancement, which might be accomplished with drugs or drug-like techniques, is likely to be too expensive for most people to afford out-of-pocket. For a twenty kilogram child, growth hormone therapy costs approximately \$14,000 per year.<sup>45</sup> Most people will need to rely on insurance to cover the costs of enhancement. If public and private health insurance coverage of analogous technologies today is

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43. Other impediments will be infertility or post-reproduction age, in which cases germ cell enhancement will not be possible. Yet the age at which a woman can bear a child is advancing, and techniques such as cloning may enable reproduction to take place in cases where it is now impossible. The birth rate among women aged 30-34 rose from 61.9 per 1000 women in 1980 to 79.5 in 1991. See STEPHANIE J. VENTURA ET AL., U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Trends in Pregnancies and Pregnancy Rates: Estimates for the United States, 1980-92*, in MONTHLY VITAL STATISTICS REP. at 1, 7 (May 25, 1995). For an in-depth discussion of the reproductive possibilities of cloning technology, see LEE M. SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD (1997); Melinda Faier, *Cloning Breeds Contempt and Adulation: Now All Women May Have a Chance to Bring up Baby*, CHI. TRIB., Mar. 7, 1997, Commentary, at 23.

44. New York Taskforce Report 60.

45. Beth S. Finkelstein et al., *Insurance Coverage, Physician Recommendations, and Access to Emerging Treatments: Growth Hormone Therapy for Childhood Short Stature*, 279 JAMA 663, 663 (1998).

any indication, however, genetic enhancement will not be covered by most insurance policies.<sup>46</sup>

In case there is any doubt on this point, consider currently available products or services that might be thought of as "enhancements": cosmetics, cosmetic medicine and surgery, private education, fitness centers and trainers, and so on.<sup>47</sup> All of these must be purchased with personal funds rather than with funds furnished by third parties such as insurers or the government.<sup>48</sup>

Cosmetic surgery offers perhaps the best illustration. Medicare, for example, does not cover "items or services . . . which are not reasonable and necessary for the treatment of illness or injury, or to improve the functioning of a malformed body member," and there is an express statutory exclusion for "cosmetic surgery."<sup>49</sup> The same exclusions appear in private health insurance policies. An interesting consequence is that patients and their care-givers attempt to portray cosmetic interventions as necessary for the patient's mental and physical well-being in order to compel third-party payment. An illustration comes from an Idaho case, *Viveros v. Idaho Dept. of Health and Welfare*,<sup>50</sup> in which the state Medicaid program denied coverage of otoplastic surgery for an eight-year-old boy with unusually large ears.<sup>51</sup> The child's physicians attempted to portray the surgery as necessary for the child's self-esteem and not just to improve his appearance, but the state's rejection of their argument was upheld by the court.<sup>52</sup>

Although analogous services are not covered by current third-party payment systems, genetic enhancement is liable to be viewed as extremely desirable, especially if it is perceived to be relatively safe for the enhanced individual. Theoretically, genetic enhancement could improve any inherited trait, such as strength, stamina, height, weight, body type, beauty, intelligence, and even those that are multifactorial (that is, the product of the interaction of more than one gene) and those that are substantially affected by the individual's environment.<sup>53</sup> The demand for genetic enhancement, ac-

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46. For a more extensive discussion of insurance limitations for genetic technologies, see MAXWELL J. MEHLMAN & JEFFREY R. BOTKIN, *ACCESS TO THE GENOME: THE CHALLENGE TO EQUALITY* 62-87 (1998).

47. The list focuses on products or services to exclude self-enhancement through, say, diet, exercise, or reading. Genetic enhancements will be provided, not self-generated.

48. The only exceptions might be training and fitness services provided by employers to boost productivity or by educational institutions or national sports associations to increase institutional or national prestige, and some degree of enhancement through social interactions such as "marrying up." Yet these enhancements also are available only to a few.

49. See 42 U.S.C.S. § 1395y(a)(1)(A), (a)(10) (Law. Co-op. 1993).

50. 889 P.2d 1104 (Idaho 1995).

51. *Id.* at 1105.

52. See *id.* at 1107.

53. There is a vigorous debate among scientists and social scientists over



cordingly, will be enormous. But this does not mean that third-party payers will add it to their list of covered services. The cost is likely to be enormous as well. Moreover, the very desirability of the services tends to disqualify them as candidates for true insurance coverage. There is no point in insuring a population for an expense that it is certain to incur, since the premium would be the same as the cost.<sup>54</sup> Public programs like Medicare and Medicaid might consider using government funds to cover genetic enhancement for those who could not otherwise afford them. The foregoing objection to regarding coverage of genetic enhancement as insurance could be eliminated if this coverage was viewed more as a redistribution of wealth via progressive taxation than as an insurance plan funded by enrollee premiums. Still, it is highly unlikely that the government would be able to afford the provision of genetic enhancement to everybody who might wish to obtain it. Even if it cost only \$10,000,<sup>55</sup>

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the degree to which genes or the environment control individual destiny—the so-called “nature versus nurture” controversy. Francis Galton, Charles Darwin’s cousin, coined the phrase nature-nurture. His view was that “nature prevail[ed] enormously over nurture . . .” ROBERT PLOMIN, *GENETICS AND EXPERIENCE: THE INTERPLAY BETWEEN NATURE AND NURTURE* 2-3 (1994) (quoting FRANCIS GALTON, *INQUIRIES INTO HUMAN FACULTY AND ITS DEVELOPMENT* 241 (1883)). Galton thought environment played a minor role in behavioral development. People in this school of thought became known as “hereditarians.” The “environmentalists” argued that there was “no such thing as an inheritance of capacity, talent, temperament, mental constitution and characteristics” and that the environment determined our behavior. *Id.* at 3 (quoting J.B. WATSON, *BEHAVIORISM* 74 (1925)). Today, there is probably not a single scientist that would assert that behavior is ruled completely by the environment or completely by genetics. Research in the field of behavioral genetics has shown that “genetic influence is significant and substantial for most areas of behavioral development, even though it is not true that ‘nature prevails enormously over nurture.’” *Id.* Some argue that this conclusion leads to problems in and of itself. See Susan M. Wolf, *Beyond “Genetic Discrimination”: Toward the Broader Harm of Geneticism*, 23 *J.L. MED. & ETHICS* 345, 350 (1995) (pointing out that those who assert the importance of genetic factors are criticized by others for their “genetic discrimination” or “geneticism”). Nevertheless, it seems clear that even if genes are not the whole story, in that environmental conditions may moderate or modify genetic interventions, genetic manipulation will have a substantial impact on individual ability. See Natalie Angier, *Separated by Birth?*, *N.Y. TIMES*, Feb. 8, 1998, § 7, at 9 (mentioning the work of Thomas J. Bouchard, who conducted twin research at the University of Minnesota to study the effect of genes versus the environment, as well as his recent conclusion that the consensus figure for various studies is a heritability of 66% for IQ scores where heritability refers to the degree to which the difference between two people with regard to a trait is ascribed to genetic, rather than environmental factors).

54. Even life insurance, which arguably insures people against a certain event, depends for its profitability on betting on when the insured’s death will occur.

55. The consensus seems to be that IVF costs at least \$10,000 for each try. The national average for IVF programs is 20%, that is, there is a 20% chance that one egg in several will lead to a pregnancy, but not necessarily a baby. See generally Kristina Brenneman, *20 Years of In Vitro Test Tube Births Still Rais-*

and if only fifty million Americans sought coverage, the bill would be more than \$500 billion. Furthermore, this would not be a one-time cost, since people might seek enhancement for each one of their children.<sup>56</sup>

The result, then, is that genetic enhancement will not be available to all, but only to the few who can afford to purchase it out of their personal finances. This, in turn, leads to the two major threats presented by genetic enhancement: the undermining of the principle of social equality that forms the foundation of Western democratic societies, and the related problem of "cheating"—the unfair advantage enjoyed by enhanced individuals in competitions for scarce societal resources.

## 2. *Social Inequality*

In the worst case scenario, unequal access to genetic enhancement will divide society into the enhanced and the un-enhanced. Germ cell enhancement will perpetuate enhancements from generation to generation, creating a hereditary aristocracy or "genobility." Added to their wealth, a prerequisite to being able to afford genetic enhancement, will be the advantages conferred by the enhancements themselves. The result will be a group of privileged individuals and families whose position in society will be virtually unassailable.<sup>57</sup>

This will pose grave threats to our political and social structure. The belief in social equality, reflected in the words of the Declaration of Independence that "all men are created equal," is the glue that holds our society together.<sup>58</sup> In the face of the evident disparities between us, we rely on the notion of equality of opportunity.

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*ing Questions*, PATRIOT LEDGER (Quincy, Mass.), July 27, 1998, at 1 (explaining improvements in IVF technology).

56. One can imagine various efforts by the government to reduce this cost, such as limiting the number of children a person could have or the number of children who could be enhanced, but these all require government controls on private life that are unprecedented and extremely difficult to enforce.

57. The number of non-enhanced persons who become able to move upward into this social stratum is likely to be extremely limited, comprising only those who somehow accumulate enough wealth to purchase enhancements for themselves or their children, or who are able to marry into the genobility. See MEHLMAN & BOTKIN, *supra* note 46, at 99.

58. See, e.g., FRANK PARKIN, *CLASS INEQUALITY AND POLITICAL ORDER: SOCIAL STRATIFICATION IN CAPITALIST AND COMMUNIST SOCIETIES* 48 (1971). Parkin writes:

Inequality in the distribution of rewards is always a potential source of political and social instability. Because upper, relatively advantaged strata are generally fewer in number than disadvantaged lower strata, the former are faced with crucial problems of social control over the latter. One way of approaching this issue is to ask not why the unprivileged often rebel against the privileged but why they do not rebel more often than they do.

What matters is not that we are the same, or even that we are equal, so long as we believe that we have just as good an opportunity to succeed as the next person.<sup>59</sup>

Genetic enhancement of the few threatens the belief in equality of opportunity in three crucial ways. First, it increases actual inequalities between the enhanced and the "undisadvantaged." Second, it gives the enhanced opportunities that others do not have, and that, in the case of germ cell enhancement, may be passed on to succeeding generations. Third, it freezes up the crucial safety valve of upward social mobility. The enhanced would tend to monopolize desirable occupations and fill high status social roles. The undisadvantaged no longer would be able to count on traditional methods of social advancement, such as education and intermarriage, to improve their social standing.

The destruction of the belief in equality of opportunity threatens the foundations of our democratic order. Societies characterized by inherited, largely fixed social status are no stranger to the human condition, as evinced by feudalism, caste systems, and slavery. None of these states are compatible with Western democratic institutions.

### 3. "Cheating"

The preceding section dealt with the concern that the fact that only some people will be able to afford enhancement will create a societal division along genetic lines that threatens the fabric of democratic society. On a more specific level, it presents fairness problems in competitions for scarce societal benefits. These benefits include jobs, education, "good" marriages, and social status, as well as the routine, arms-length business and social transactions of daily life. Imagine evaluating the results of a law school admissions test administered to a group of applicants some of whom had genetically-enhanced cognitive functioning. Imagine a business or legal negotiation in which one party was represented by such an enhanced individual and the other was not.

We have some experience with this problem in the context of the use of performance-enhancing drugs in sports. Tom Murray, who serves on the United States Olympic Committee's advisory group, has written extensively on the difficulties of enforcing a no-drug policy in Olympic competition.<sup>60</sup> In part, the problem of perform-

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59. See, e.g., David B. Grusky & Azumi A. Takata, *Social Stratification*, in 4 *ENCYCLOPEDIA OF SOCIOLOGY* 1955, 1965 (Edgar F. Borgatta & Marie L. Borgatta eds., 1992) ("Whereas most Americans are willing to tolerate sizeable inequalities in the distribution of resources, they typically insist that individuals from all backgrounds should have an equal opportunity to secure these resources.").

60. See, e.g., Thomas H. Murray, *Drugs, Sports and Ethics*, in *FEELING GOOD AND DOING BETTER: ETHICS AND NON-THERAPEUTIC DRUG USE* 107 (Thomas H. Murray et al. eds., 1984).

ance-enhancing drugs in sports is a problem of definition. The Olympics, for example, might be said to define its competition as being between non-drug-takers, with the gold medal going to the best drug-free athlete. A different competition that did not prohibit drug use might define its winner simply as, say, the fastest or strongest person. In fact, a division along these lines already has occurred in professional weight lifting, where there are drug-free and "open" events.<sup>61</sup>

Similarly, we could attempt to redefine competition for scarce societal benefits to accommodate the possibility that some contestants would be genetically enhanced and others would not. We could establish an admissions quota for enhanced college applicants, for example. Or, we could decide that being genetically enhanced was irrelevant in that it was not substantially different than other advantages that we ignore, such as being born into a wealthy family. What is the difference, for example, between being able to afford the best trainer in the world, which is allowed in the Olympics, and taking anabolic steroids, which is prohibited? In either case, some athletes possess a significant advantage over others.

In seeking to regulate genetic enhancement, in any event, society must attend not only to the traditional regulatory concerns of safety and efficacy, but to the problems of social inequality and cheating posed by the lack of universal access to enhancement technologies. Indeed, the problems of social inequality and cheating may well pose the greater threats.

### III. POTENTIAL REGULATORY MECHANISMS

When we think of regulating an activity associated with medical interventions, we probably think first of traditional options such as the FDA or state medical licensing boards. These entities no doubt will play an important role. But we must not overlook other types of regulatory activity. As we will see, traditional regulatory actors may be ill-suited to respond to the special concerns raised by genetic enhancement.

#### A. *Self-Regulation*

Persons considering genetic enhancement for themselves or

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61. See generally Ira Berkow, *This Lifter Is Fueled by Natural Power; Operating in a Drug-Free Environment, Ted Sobel Is Soaring Above the Field*, N.Y. TIMES, Feb. 6, 1994, § 8, at 2 (describing how drug-free or natural competitions such as the World Natural Power Lifting Championships are a relatively recent phenomenon); Olga Connolly, *Steroid Debate: 'Enhanced' vs. Natural Athletes*, WASH. POST, Sept. 13, 1988, at Z15 (explaining that two separate categories of champions have been established in power lifting, "open" and "natural"); Roger Mills, *562-pound Lift Makes Ferrantelli a Champ*, ST. PETERSBURG TIMES, Jan. 5, 1997, at 4. (describing how Mike Ferrantelli placed first in both the open and drug-free portions of a power lifting competition).

their offspring (and being able to afford it) may decline to go forward for a host of reasons. For example, a parent may feel that the enhancement choice ought to be left up to the child rather than be made by the parent. Although this would preclude germ cell and other pre-natal enhancements, parents might choose this option if effective somatic cell enhancement—the kind that can be done for adults—were available. This in turn suggests that, if we are worried about the hazards of germ cell enhancement, including the societal worries described in the preceding section, we should make sure that somatic enhancements are safe and effective, such as by devoting public research funds to their development. Parents also might resist germ cell enhancements for ethical or religious reasons, or because they feel an obligation to help prevent the social dislocations that might result from the creation of a “genobility” with inherited enhancement advantages. The same concerns might motivate individuals contemplating somatic enhancements for themselves. In all these cases, individual decision-making acts as a decisive regulatory mechanism.

Self-regulation becomes critical when we recall the earlier discussion concerning the uncertainties and subjective valuation of the risks and benefits of genetic enhancement. These factors call for leaving the choice of whether or not to proceed up to the affected individual. In medical decision making, this is known as the principle of informed consent. The patient is deemed to be the best gauge of her own values, preferences, and aversion to risk; armed with accurate, comprehensible information provided by health professionals, the patient should be allowed to decide, at least in broad terms, what will or will not be done for her.<sup>62</sup>

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62. In *Natanson v. Kline*, 350 P.2d 1093, 1104 (Kan. 1960), the Kansas Supreme Court stated:

Anglo-American law starts with the premise of thorough-going self-termination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment. A doctor might well believe that an operation or form of treatment is desirable or necessary but the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception.

The court continued by adopting the standard applied in *Salgo v. Leland Stanford Jr. University Board of Trustees*:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in

Traditionally, we have abridged the individual's freedom of choice only in three situations: (1) when the individual is incompetent to choose, (2) when the choice will have a significant impact on the welfare of others, and (3) when leaving the choice up to the individual would be so inefficient that we delegate the decision to a better decision-maker. All three of these factors may affect our willingness to allow individuals to decide whether or not to obtain genetic enhancement. For example, in the same way that many question the appropriateness of permitting minors to obtain an abortion without parental consent, we may question minors' right to choose to enhance themselves. As suggested earlier, we might want to circumscribe the right of parents to enhance their children, on the ground that the children ought to be allowed to make this decision for themselves. This is particularly likely if enhancement carries with it significant risks to the enhanced individual. Moreover, society may try to deny persons the right to enhance themselves or their children because of fears of inequality or cheating described in the previous section. Finally, we have limited an individual's ability to purchase certain medical products and services when we have felt that the individual could not adequately inform herself of the risks and benefits, at least not without an unrealistic amount of effort. Thus, we have delegated to the FDA the responsibility for reviewing the safety and efficacy of drugs and medical devices and denied individuals the right to purchase unapproved products because the FDA, rather than the consumer, is deemed to possess the expertise, the access to data, and insulation from manufacturers' inducements and pressures needed to make this evaluation correctly.<sup>63</sup>

The FDA example, however, suggests a slightly different way of thinking about the role of self-regulation in deciding whether or not to obtain genetic enhancement. What FDA regulation accomplishes, it might be said, is to carve out a realm—that of approved products and services—within which individuals are free to make their own choices. This realm is one in which competent individuals are deemed capable of being given sufficient information to enable them to make meaningful choices, and in which the effects of their choices

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alarming a patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risks by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent . . . . "The instruction given should be modified to inform the jury that the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent."

*Natanson*, 350 P.2d at 407 (quoting *Salgo*, 317 P.2d at 181).

63. See BRODY, *supra* note 21, at 192-97.

on the welfare of third parties is deemed sufficiently small or acceptable. Within this realm, regulatory mechanisms, such as the FDA and health professionals, see their function primarily as one of providing data and advice to assist individuals in making their decisions.<sup>64</sup> Particularly in view of the difficulty of objectively assessing the risks and benefits of genetic enhancement, we should strive to preserve as much individual decision-making as is compatible with our concerns about competence, efficiency, and effects on others. This suggests, among other things, that we should attend to the need to make readily available to the public comprehensible information about the risks and benefits of enhancement technologies.

One other point needs to be made regarding self-regulation. Individual choice can be influenced by social concerns. People act or refrain from acting on the basis of principle, and have been known to do so even at significant personal cost. Conceivably, individuals might eschew genetic enhancement for themselves or their offspring because of their belief in the principle of equality or because of the ethical problem raised by cheating. They might be encouraged to do so by political and religious leaders. If society felt that the threats from genetic enhancement outweighed the benefits, it would be likely to employ social pressures to affect individual decision-making, a sort of "Just Say No" approach to genetic enhancement. Society might use this approach if other regulatory options were costly or not fully effective. As with the "War on Drugs," self-regulation may end up being one of the most important regulatory techniques.

### *B. Professional Self-Regulation*

Genetic enhancement is unlikely to be available on a do-it-yourself basis. Instead, it is likely to require the services of one or more health professionals. These include primary care physicians who are approached by their patients for information about, or referrals or prescriptions for, genetic enhancement; genetic counselors who explain options, risks, and benefits; infertility treatment specialists who provide the IVF services associated with germ cell enhancement; obstetricians and gynecologists who manage pregnancies involving enhanced fetuses; and a new medical specialty likely to emerge with the advent of genetic enhancement: the genetic enhancement specialist.<sup>65</sup> The involvement of these professionals opens up another regulatory avenue: relying on them to regulate themselves in providing access to enhancement services.

Professional self-regulation may be based on individual ethical, religious, social, or scientific beliefs, or it may be based on the views of professional organizations such as the American Medical Associa-

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64. See 21 U.S.C.S. § 393(b) (Law. Co-op. 1997) (describing FDA mission).

65. Other health professionals may be involved as well, such as psychiatrists, psychologists, social workers, and nurses.

tion ("AMA") and the American College of Physicians; specialty groups like the American College of Obstetrics and Gynecology and the boards that govern specialty certification; prestigious organizations like the Institute of Medicine of the National Academy of Sciences; and views expressed in influential journals such as the *New England Journal of Medicine* or *Science*. In some cases, failure to adhere to the guidelines of professional associations can subject the health care professional to sanctions such as censure or loss of membership in the association.<sup>66</sup> In other cases, the professional merely suffers the pangs of conscience.

Professional self-regulation has played an important role in the regulation of genetic technologies. In 1974, scientists adopted a voluntary moratorium on research involving recombinant DNA technology until the potential risks were more clearly understood.<sup>67</sup>

It is especially noteworthy that one professional association, the AMA, has already issued a policy statement to provide ethical guidance to its members in dealing with genetic enhancement. This statement, put forward in 1994 by the AMA's Council on Ethical and Judicial Affairs, observes that efforts to enhance "desirable" characteristics through the insertion of a modified or additional gene, or efforts to "improve" complex human traits—the eugenic development of offspring—are contrary not only to the ethical tradition of medicine but also to the egalitarian values of our society.<sup>68</sup> The statement goes on to assert that "genetic interventions to enhance traits should be considered permissible only in severely restricted

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66. See CODE OF MEDICAL ETHICS Rules XII-XIII (AMA Council on Ethical and Judicial Affairs 1996-1997 ed.) (providing that the Council may expel a person from membership in the association on grounds of ethical misconduct). Professional sanctions differ from adverse actions taken by state medical boards for failure to adhere to state licensing laws and regulations, in that professional sanctions are imposed for breaches of rules adopted by the professionals themselves rather than by the government. For a discussion of government regulation of genetic enhancement, see *infra* Section III.E-F. Note that the distinction between professional self-regulation and government regulation is not always clear, since government agencies in some cases delegate some of their regulatory oversight responsibilities to professional or industry self-regulatory bodies. A prime example is the Health Care Financing Administration's reliance on the Joint Commission for the Accreditation of Healthcare Organizations to certify hospitals to be eligible to receive Medicare reimbursement. See 42 U.S.C.S. §§ 1395x(e)(9), 1395bb (Law. Co-op. 1999) (noting accredited hospitals deemed to meet Medicare certification requirements).

67. See Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, SCIENCE, July 26, 1974, at 303 (1974). Apparently, the moratorium was universally adhered to until it was replaced by a regulatory review process within NIH in 1975. See generally Judith P. Swazey et al., *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019 (1978) (outlining significant developments in the recombinant DNA debate from 1971-1977).

68. *Report on Ethical Issues Related to Prenatal Genetic Screening*, 3 ARCH FAM. MED. 633, 637-39 (1994).



situations."<sup>69</sup>

Without additional explanation, the Council lists three preconditions: (1) "clear and meaningful benefit to the fetus or child,"<sup>70</sup> (2) "no trade-off with other characteristics or traits,"<sup>71</sup> and (3) "equal access . . . irrespective of income or other socioeconomic characteristics."<sup>72</sup> A physician who failed to comply with these conditions would be violating the code of ethics of her profession.

The second of the Council's conditions is perplexing. What is meant by a "trade-off with other characteristics or traits"? Why should an individual not be permitted to accept, say, a slight reduction in dexterity for a significant increase in strength? Moreover, if health itself is regarded as a "characteristic," then the Council's statement, unwittingly perhaps, may call for a complete ban on genetic enhancement, since as mentioned earlier, no physical intervention in the human organism occurs without some chance of an adverse effect on health or well-being, however slight the probability or trivial the effect.

The Council's third condition responds to fairness concerns. It too is problematic. How is a physician or geneticist supposed to assure equal access to genetic enhancements regardless of a patient's income (which bears on the patient's ability to pay)? Only if the government provided universal coverage of genetic enhancements for all who desired them would the Council's statement seem to permit physicians and other health care professionals to provide enhancement to anyone.

Yet the fact that the AMA Council addresses the fairness question at all is highly significant. The services of health care professionals are likely to be indispensable to an individual seeking genetic enhancement, because enhancement will entail manipulating DNA *in vitro* or *in utero*, or prescribing a drug or biologic. A concerted refusal by professionals to supply genetic enhancement unless certain social conditions were met could block or at least substantially reduce access to genetic enhancement. The technology would be available only from non-cooperating professionals on the black market, or in foreign countries whose professionals did not recognize similar self-limitations.

It remains to be seen how successful professional self-regulation would be in solving the fairness and cheating problems. Genetic enhancement is certain to be lucrative. In an era of dwindling professional incomes, caused in part by the shift to managed care, physicians and other health care providers may be unable to resist the economic incentives to provide genetic enhancements to those will-

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69. *Id.* at 640.

70. *Id.* The Council's statement focused on genetic interventions in children and fetuses, and did not address self-enhancement by adults.

71. *Id.*

72. *Id.* at 641.

ing to pay for them.<sup>73</sup> Not all professionals may agree with the egalitarian philosophy represented by the Council's statement. While the AMA, for example, has long endorsed the principle that physicians have a duty to provide health care services to the indigent,<sup>74</sup> the organization also supports the view that physicians should be permitted to charge Medicare patients any amount that the physician wishes, so long as the patient agrees not to seek Medicare reimbursement for any part of the fee,<sup>75</sup> which would lift existing restrictions on physician charges and, in the view of some, would undermine the egalitarian features of the Medicare program.<sup>76</sup> Regardless of the position taken by medical organizations, individual doctors and other health care professionals may follow their own consciences.

### C. Restrictions on Research Funding

The federal government currently finances a substantial portion of the research associated with the Human Genome Project, and is likely to continue to do so for the foreseeable future.<sup>77</sup> A refusal by the government to fund research on genetic enhancement, or a refusal to do so unless certain conditions were met, could significantly affect the development of these technologies.

Historical precedent for this type of regulation is found in the activities of the NIH's Recombinant DNA Advisory Committee ("RAC").<sup>78</sup> The RAC was formed in 1975 to review applications for

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73. See *Internal Medicine's Identity Crisis*, MED. ECON., May 12, 1997, at 110 (reporting the results of a survey by the American College of Physicians of 417 members' views on managed care, with half reporting a decrease in income).

74. See CODE OF MEDICAL ETHICS § 9.065 (AMA Council on Ethical and Judicial Affairs 1996-97 ed.).

75. See Sean Martin, *Private Contracting Heats Up: Right to Opt Out of Medicare at Issue in Lausuit*, AM. MED. NEWS, Jan. 19, 1998, at 23.

76. See *Physician Contracting: Debate over KYL Amendment Grows*, HEALTH LINE, Nov. 26, 1997, available in LEXIS, Genmed Library, RXMEGA File (explaining the position of the American College of Physicians).

77. See Daniel S. Greenberg, *Bad Blood in U.S. Genome Research*, 351 LANCET 1939, 1939-40 (1998).

78. Other examples are the ban on funding of research using fetal tissue or embryos and the proposed ban on human cloning. See *infra* notes 126-128 and accompanying text for a discussion of the proposed ban on funding human cloning. The first ban related to research using fetuses accompanied the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. See National Research Service Award Act of 1974, Pub. L. No. 93-348, § 213, 88 Stat. 342, 392 (prohibiting research "on a living human fetus" that is not done "for the purpose of assuring the survival of such fetus"). The recommendations of the National Commission were codified in 45 C.F.R. § 46 (1998). 45 C.F.R. § 46.208 governs activities directed toward fetuses *in utero*, while 45 C.F.R. § 46.209 governs activities directed toward fetuses *ex utero*. Both are geared towards allowing only research posing a minimal risk to the fetus. Additionally, 45 C.F.R. § 46.204 provides for the establishment of Ethical Advisory Boards responsible for evaluating the merit of

NIH funding for experiments involving recombinant DNA technology. Following the creation of the RAC, scientists lifted their voluntary moratorium on recombinant DNA experiments mentioned earlier.<sup>79</sup> The RAC historically concerned itself chiefly with issues of safety and the protection of human research subjects, restricting the release of recombinant DNA-altered plants into the environment,<sup>80</sup> and limiting the conditions in which gene insertion could be attempted on patients.<sup>81</sup> The RAC also has addressed the conditions, if any, in which genetic enhancement experiments could be undertaken, and the committee has been mindful of the fairness and

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individual research proposals that fall outside of 45 C.F.R. § 46. The creation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research drained resources from the Ethical Advisory Board, however, thus creating a de facto "moratorium on fetal research posing more than minimal risk, unless expected to enhance the health of the particular fetus." Robert Mullan Cook-Deegan, *Cloning Human Beings: Do Research Moratoria Work?*, in 2 CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION, at H8 (1997). In 1985, Congress amended the Public Health Service Act, banning funding for "any research or experimentation . . . on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained" unless the research was geared towards increasing the survival prospects of the particular fetus or the research would not subject the fetus to increased risk of harm. Health Research Extension Act of 1985, Pub. L. 99-158, 99 Stat. 820, 877 (1985). The 1988 NIH authorization continued this moratorium. See Cook-Deegan, *supra*, at H9. Funding for experiments using fetal tissue became a concern soon thereafter. Assistant Secretary of Health Robert Windom responded to an NIH request for authorization to support research into using fetal tissue to treat Parkinson's disease by imposing a funding moratorium pending consideration by an *ad hoc* panel of his questions. See Letter from Robert Windom to Dr. Wyngaarden, *reprinted in* REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL (1988). In 1993, the National Institutes of Health Revitalization Act of 1993 removed the legislative moratorium on fetal research that had been in place since 1985. Pub. L. No. 103-43, 107 Stat. 122, 129 (1993). This moratorium was restored in the NIH appropriations bills for fiscal years 1996 through 1998. See Departments of Labor, Health and Human Services, and Education Appropriations Act, Pub. L. No. 105-78, 111 Stat. 1467, 1517 (1998); Cook-Deegan, *supra*, at H10. For a discussion of these moratoria, see generally Cook-Deegan, *supra*.

79. See *supra* notes 66-75 and accompanying text.

80. The RAC provides guidelines specifying physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant DNA-containing plants and plant-associated microorganisms. See generally *Guidelines for Research Involving Recombinant DNA*, app. P (1999) (visited June 6, 1999) <<http://www.nih.gov/od/orda/apndxp.htm>>.

81. NIH regulations required all proposals for federally funded research involving gene insertion into humans to be reviewed by the RAC. Germ line alterations were prohibited. Somatic cell alterations were to be considered if their aim was to protect the health and well being of human subjects being treated at the same time that generalized knowledge was being gathered. See *Guidelines for Research Involving Recombinant DNA*, *supra* note 80, at § III-c-1, app. M.

cheating concerns discussed above.<sup>82</sup> The RAC therefore might be an important regulatory mechanism. However, its mission recently has been redefined and its authority to rule on whether or not the NIH should fund specific research applications largely has been transferred to the FDA.<sup>83</sup> In order for the NIH to come to grips with the social policy issues raised by genetic enhancement, it either would have to restore the regulatory authority of the RAC or create a new entity with authority comparable to that which the RAC previously exercised.

NIH funding restrictions only affect government-sponsored research. Private companies are likely to sponsor genetic enhancement experiments that would avoid NIH controls, especially if the government restricted its own research funding. However, the government does impose a set of requirements on research conducted at hospitals and other institutions that receive reimbursement under government entitlement programs such as Medicare.<sup>84</sup> These institutions are required to establish "institutional review boards" ("IRBs") to review research proposals to ensure the protection of human subjects and compliance with the requirements of informed consent.<sup>85</sup> These controls apply not only to government-funded experiments, but to research funded by private manufacturers.<sup>86</sup> Moreover, the FDA imposes a similar set of requirements on privately-funded research which is submitted to FDA in support of an application to approve the marketing of a product within the agency's regulatory jurisdiction.<sup>87</sup>

Despite this web of regulation, loopholes exist that could allow a significant degree of non-complying research to be conducted. Historically, government research requirements have tended to avoid fairness issues, except those that would affect the willingness of individuals to participate as human subjects.<sup>88</sup> Even if the govern-

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82. *See id.*

83. *See* FDC, *The Pink Sheet*, Dec. 16, 1997, TRADE & GOV'T, at 17. For a discussion of FDA regulation of genetic enhancement, see *infra* Section III.E.

84. *See* 45 C.F.R. §§ 46.102, 46.103 (1998); *see also* Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63, 99 (1993) (explaining that federal regulations for research have been made applicable to all institutions doing research, including hospitals, universities, and medical schools, regardless of the source of funding).

85. *See* 45 C.F.R. § 103(h).

86. *See id.* at § 46.103(b).

87. *See* 21 C.F.R. § 56.103(a) (1998); *see also* Goldner, *supra* note 84, at 99 (explaining that FDA requirements "mandate IRB review of all investigational studies designed to support applications to the FDA for the marketing of drugs and medical devices").

88. For example, rules issued by the Department of Health and Human Services limit the incentives that researchers can offer members of certain populations, such as prisoners, to participate in biomedical experiments. *See* 45 C.F.R. § 46.305(a)(2) (1998).

ment sought to regulate research for fairness reasons, its efforts would be limited under current law to research funded by the government, and to privately-funded research only to the extent that it accompanied an application for FDA marketing approval. As the discussion in Section E below explains, genetic enhancement is likely to emerge as an unapproved use of an approved drug or biologic product, for which no marketing approval would be sought.<sup>89</sup> The government's current regulatory control over private research relating to such uses therefore is limited. Without substantial change in the law and the government's regulatory practices, restrictions on research in the name of social concerns such as fairness and cheating are likely to be incomplete and ineffective.

#### D. *Third-Party Payers*

As previously noted, access to specific medical technologies is controlled in substantial part by coverage policies established by government and private health insurers.<sup>90</sup> Few Americans can afford to purchase expensive health care services with personal funds. The fact that genetic enhancement would not be covered under third-party payment policies currently in effect is the major cause of the unfairness and cheating problems discussed earlier.

The coverage practice of private third-party payers in regard to genetic enhancements is unlikely to change in the future in response to these social problems. Private insurers view their businesses as competitive enterprises motivated by the need to make a profit.<sup>91</sup> They are unlikely to provide third-party payment for genetic enhancement if their competitors do not. Plans that covered genetic enhancement would have to charge higher premiums, a problem exacerbated by the likelihood of "adverse selection," the phenomenon in which individuals who know in advance that they will demand particular covered services will migrate to those plans that cover them, driving up premiums.<sup>92</sup> Similarly, third-party payers are not likely to be willing voluntarily to expend significant resources to police the behavior of providers and enrollees that does not affect the payers' costs; expecting payers on their own initiative to enforce genetic enhancement prohibitions or restrictions for purposes of achieving social goals is unrealistic unless the payers are forced to do so by law. Even if state or federal legislation attempted to impose such obligations on private third-party payers,<sup>93</sup> its reach would

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89. See *infra* note 109 and accompanying text.

90. See *supra* note 46 and accompanying text.

91. Even not-for-profit insurers such as some Blue Cross/Blue Shield plans must operate in the black and, therefore, must compete effectively against for-profit plans.

92. See Steven P. Croley & Jon D. Hanson, *What Liability Crisis? An Alternative Explanation for Recent Events in Products Liability*, 8 YALE J. ON REG. 1, 28-29 (1991).

93. Under current law, state regulation of private health insurers is limited

not extend to persons who purchased genetic enhancement with their own funds.

In contrast to private insurers, government third-party payer programs such as Medicare and Medicaid might be expected to be more sensitive to social concerns. An example is the End Stage Renal Disease Program under Medicare, which covers kidney dialysis for all persons even though they are under age sixty-five or otherwise ineligible for Medicare.<sup>94</sup> Congress established this program in 1972 in response to concerns that poor people and others were dying because they could not afford kidney dialysis.

As noted earlier, however, the cost of providing universal access to genetic enhancement would be prohibitive.<sup>95</sup> Expecting a program like Medicare or Medicaid to cover enhancement is therefore unrealistic. Yet these programs might be employed as regulatory handles to control the behavior of health care providers. For example, the federal government imposes a number of requirements and restrictions on hospitals and health care professionals on pain of being disqualified from receiving Medicare reimbursement. Some of these regulations, such as the requirement that a hospital emergency room stabilize patients in emergency conditions or in active labor before transferring them, apply to all patients, not just to Medicare beneficiaries.<sup>96</sup> Similarly, the federal government might impose restrictions on access to genetic enhancement by threatening to disqualify non-compliant providers from participating in the Medicare program. This use of federal authority resembles the outright criminalization of genetic enhancement, which will be discussed later.

### E. FDA Regulation

One of the more obvious sources of government regulation of genetic enhancement is regulation by the Food and Drug Administration. The FDA licenses the marketing of drugs, biological products and medical devices, all of which may be involved in the delivery of enhancement services. Moreover, the FDA regulates research on these products when the research is submitted in support of a licensing application or an approved product. As noted in Section C,

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by the provisions of ERISA, which exempt employer self-insured health plans from state insurance regulation. See 29 U.S.C.A. § 1144(b)(2)(B) (Law. Co-op. 1999) (establishing the so-called "deemer clause"). Unless the ERISA preemption provisions were repealed, legislative control of payer policies toward genetic enhancement would have to be enacted by Congress. For a discussion of potential legislative controls on access to genetic enhancement, see *infra* text accompanying notes 126-28.

94. See Richard A. Rettig, *The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease*, LAW & CONTEMP. PROBS., Autumn 1976, at 196, 198-201.

95. See *supra* note 43 and accompanying text.

96. See 42 U.S.C. § 1395dd (1997).

the FDA now asserts authority previously held by the RAC to regulate research on genetic technologies.<sup>97</sup>

To the extent that these genetic technologies are aimed at improving the appearance of the body, they might seem to be cosmetics, which the Federal Food, Drug, and Cosmetic Act defines as "articles intended to be . . . introduced into, or otherwise applied to the human body or any part thereof for . . . cleansing, beautifying, promoting attractiveness, or altering the appearance . . ."<sup>98</sup> But the FDA exerts little regulatory effort on cosmetics. Unlike drugs or medical devices, they do not have to be approved prior to being marketed, and generally are subjected to FDA scrutiny only if they present a safety risk.<sup>99</sup> In order for the FDA to be able to control the introduction and use of genetic enhancement technologies, these techniques would have to be considered to be drugs, biologics, or medical devices.

The FDA possesses ample authority to regulate genetic enhancements within these categories, however. In regard to drugs used for enhancement purposes, the definition of a drug in the Federal Food, Drug, and Cosmetic Act includes not only "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" but "articles (other than food) intended to affect the structure or function of the body of man."<sup>100</sup> The FDA has relied on this definition to assert drug regulatory authority over products such as wrinkle creams and tanning agents that are intended to enhance the appearance of the body but that achieve their results by affecting the body's structural or functional components.<sup>101</sup> The Act similarly defines a medical device to include "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which is . . . intended to affect the structure or any function of the body of man."<sup>102</sup>

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97. See *supra* note 83 and accompanying text.

98. 21 U.S.C.S. § 321(i) (Law. Co-op. 1997).

99. See 21 U.S.C.S. § 361 (Law. Co-op. 1993).

100. 21 U.S.C.S. § 321(g)(1) (Law. Co-op. 1998).

101. See *United States v. Line Away*, 284 F. Supp. 107, 111 (D. Del. 1968) (holding that wrinkle creams are drugs); 43 Fed. Reg. 38,206 (1978) (codifying tanning agents as drugs).

102. 21 U.S.C.S. §321(h). The definition distinguishes a medical device from a drug in that a device "does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent on being metabolized for the achievement of its primary intended purposes." *Id.* Interestingly, the FDA presently regulates gene therapy products through its Center for Biologics Evaluation and Research ("CBER"), regarding them as "biologics." See FDA Notice, 58 Fed. Reg. 53,248, 53,249 (1993). The FDA has jurisdiction over biologics under the Virus, Serum, and Toxin Act of 1944, 42 U.S.C.S. § 262 (Law. Co-op. 1999). However, the definition of a "biologic" is a "virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man." 21 C.F.R. § 600.3(h) (1998) (emphasis added). Therefore, the FDA would not have jurisdiction over an enhancement under this definition. Nevertheless, the FDA has

Nevertheless, FDA regulation of genetic enhancement is likely to be inadequate to address the efficacy and safety concerns described earlier. In the first place, the scope of FDA review is statutorily limited to safety and efficacy.<sup>103</sup> It currently does not have any statutory authority to consider the threat to personal autonomy posed by parental decisions to genetically enhance children, much less the social problems of fairness or cheating. To understand how limited the FDA's authority is, consider that the agency does not even have the authority to take into account the relative need for or cost of the products it regulates. For example, the agency could not decline to approve a product because there was another product already on the market that was equally safe and effective, even if the product already being marketed was less expensive.<sup>104</sup>

Even if the FDA were to assert the authority to consider the social implications of genetic enhancement, or to be given that authority by congressional amendment of its enabling legislation, the agency currently has no experience or expertise in this realm. It would be necessary to hire additional staff or to rely on panels of outside experts. There is precedent for the latter in the form of the agency's advisory committees,<sup>105</sup> but these committees provide expert advice to the agency on safety and efficacy matters within the agency's general expertise. The agency has no track record for employing outside experts to advise the agency on matters such as social fairness.

Moreover, even the FDA's ability to regulate genetic enhancements in the traditional areas of safety and efficacy would be compromised by the data deficiencies and subjectivity of judgments about risk and benefit described above. The example of liposuction devices for weight reduction mentioned earlier, where the benefit is purely cosmetic, illustrates the agency's difficulties: how can the government conclude that a risk of complications so clearly outweighs the subjective value to patients of an improvement in appearance that a liposuction device, assuming that it actually does remove fatty deposits, should not be approved because it is unsafe or ineffective?

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taken the position that CBER can regulate drugs and devices as well as biologics in appropriate circumstances. See 21 C.F.R. § 5.33(a) (1998). Since an enhancement fits the definition of a drug or device even though it is not intended for therapeutic purposes, the allocation of regulatory authority to CBER is permissible.

103. See John Geweke & Burton A. Weisbrod, *Clinical Evaluation vs. Economic Evaluation: The Case of a New Drug*, 20 MED. CARE 821, 821 (1982).

104. See K. WARNER & B. LUCE, COST BENEFIT AND COST EFFECTIVENESS ANALYSIS IN HEALTH CARE PRINCIPLES AND POTENTIAL 198 (1982); Geweke & Weisbrod, *supra* note 103, at 821.

105. These are governed by the Federal Advisory Committee Act, 5 U.S.C.S. app. 2, § 1 (Law. Co-op. 1998), and by FDA regulations. See 21 C.F.R. §§ 14.1-14.174 (1998).



The FDA's problems with regulating enhancement-type technologies are also illustrated by its position in regard to cosmetic contact lenses and breast implants. In the latter case, the agency appears to have taken the view that the benefits from cosmetic use are outweighed by the risks, but not the benefits from therapeutic use. Thus, when the safety controversy over silicone gel-filled breast implants erupted in 1992, the agency limited their use to research for reconstructive purposes: i.e., in women who have had breast cancer surgery, severe injury to the breast, a birth defect affecting the breast, or a medical condition causing a severe breast abnormality.<sup>106</sup> The implants could not be used, much less studied, for cosmetic breast augmentation. At the same time, however, the FDA makes no distinction between cosmetic and reconstructive uses for saline breast implants: both are permitted.<sup>107</sup> This signifies either that the agency feels that the risks posed by saline implants are so small that they are outweighed by cosmetic as well as by therapeutic benefits, or that the agency simply has not come to grips with the enhancement/therapy distinction.

The possibility that the FDA lacks a clear appreciation of the enhancement/therapeutic distinction is reinforced by the agency's position on contact lenses. As with saline breast implants, the agency makes no regulatory distinction between contact lenses for corrective versus cosmetic use.<sup>108</sup> A manufacturer can market non-prescription lenses that change eye color under the same conditions as corrective lenses, despite the argument that, given the risks from contact lens use, the ratio of risks to benefits ought to be more favorable to justify the use of lenses for purely cosmetic purposes.

Finally, even if the FDA did establish a clear policy in regard to evaluating the relative safety of genetic enhancement, the agency would find itself virtually unable to enforce it. This stems primarily from the expectation that, as noted earlier, genetic enhancements may emerge as unapproved or off-label uses of approved products, uses over which the FDA lacks effective regulatory control. The agency might attempt to regulate off-label uses of genetic technologies by asserting jurisdiction over physician prescribing practices,<sup>109</sup> but the medical profession would be likely to view this as an unwarranted intrusion into their exercise of professional discretion. The other option would be for the FDA to prohibit or restrict the mar-

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106. See FDC, *The Gray Sheet*, June 22, 1992, at 11.

107. See FDC, *The Gray Sheet*, May 9, 1994, at 17-19.

108. See Letter from Muriel Gelles to Maxwell Mehlman (July 13, 1998) (on file with author).

109. The agency would most likely need additional authority from Congress to do so. FDA regulations require prescriptions for controlled substances to be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (1998). For the FDA to apply this regulatory requirement to genetic enhancements, however, they would first have to be classified as controlled substances.

keting of genetic technologies for therapeutic purposes because of fears about their enhancement uses. But it is completely unrealistic to expect society to forego therapeutic benefits in order to reduce enhancement risks. Imagine the reaction if the FDA sought to enjoin the marketing of a drug that alleviated the cognitive effects of mental retardation merely because it might be used by "normals" to "unfairly" boost their intelligence.

An additional set of constraints on the effectiveness of FDA regulation of genetic enhancements lies in the territorial limitations on the agency's jurisdiction. In the first place, under the Commerce Clause of the United States Constitution, the agency lacks jurisdiction over purely intra-state marketing.<sup>110</sup> But given the broad interpretation that the courts have given to interstate commerce, coupled with the likelihood that some elements of a genetic enhancement technology will cross state lines,<sup>111</sup> this is not likely to be a serious impediment. More significant by far will be the FDA's lack of jurisdiction over foreign providers.<sup>112</sup> A person seeking a genetic enhancement that the FDA restricted in the United States could simply travel to another country where the technology was freely available. The FDA might attempt to interdict the importation of an enhancement back into the United States,<sup>113</sup> but would be hard pressed to do so from a practical standpoint if the enhancement already had been introduced into the recipient's body, either as a drug, a drug factory, or an inserted gene.<sup>114</sup>

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110. See, e.g., 21 U.S.C.S. § 355 (Law. Co-op. 1997) (establishing FDA regulation of new drugs in interstate commerce). For an activity to be considered purely intrastate, it could not, either alone or in combination with other activities, have a substantial economic effect on interstate commerce or on movement in interstate commerce. See *United States v. Lopez*, 514 U.S. 549, 561 (1995) (possessing firearms in a school zone is not an economic activity that might have a substantial effect on interstate commerce). But see, e.g., *Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942) (holding that farmer's production of wheat for home consumption could be federally regulated because the cumulative effect of multiple instances of people doing so could be felt in interstate commerce).

111. These could be the consumers or providers as well as components of drugs, biologics, or devices used in the delivery of enhancement services.

112. See generally Julie C. Relihan, Note, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229 (1995) (comparing the FDA drug regulation system to other nations' approaches).

113. The Bureau of Customs enforces FDA restrictions by intercepting unapproved drugs and devices at the borders. This policy has proved controversial in the case of drugs to treat AIDS, which have been brought into the US from abroad and sometimes re-sold through so-called "AIDS clubs." See Jon S. Batterman, Note, *Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards Be Modified in Response to the Needs of Persons with AIDS?*, 19 HOFSTRA L. REV. 191, 193-94 (1990).

114. An argument might be made that the Fifth Amendment's protection against search and seizure prohibits such intrusiveness, although the courts have supported intrusive searches given a reasonable suspicion of an unlawful act. See, e.g., *United States v. Himmelwright*, 551 F.2d 991 (5th Cir. 1977) (holding strip searches authorized).

### F. Drug Enforcement Administration

At first, the notion of regulating genetic enhancements using the authority of the Drug Enforcement Administration ("DEA") under the Controlled Substances Act may sound peculiar, but it might be appropriate on a number of grounds. The Controlled Substances Act is the primary mechanism for regulating drugs that pose a threat to society by their use.<sup>115</sup> The Act creates a system of "schedules" that categorize these products on the basis of comparing their therapeutic value with their potential for abuse.<sup>116</sup> A similar approach might distinguish enhancement and therapeutic uses of genetic technologies. The DEA also has extensive experience with a wide range of practical techniques for restricting access to such products.

Relying on a police regime under a scheme like the Controlled Substances Act to regulate genetic enhancement, however, raises the chilling specter of a government-led "war on genes." Given the intimate contexts in which individuals would obtain genetic enhancements—the realms of reproductive behavior and the patient-physician relationship—the intrusiveness of such a program would be suspect and possibly unconstitutional.<sup>117</sup> The success to date in the War on Drugs is not an encouraging omen for a war on genes.<sup>118</sup> All of the difficulties that have marked that endeavor would be present here: the invasions of privacy, the creation of black markets,<sup>119</sup>

115. See 21 U.S.C.S. § 801(6) (Law. Co-op. 1997).

116. See *id.* § 811. Substances are scheduled as follows: Schedule I: high potential for abuse, no currently accepted medical use, lack of accepted safety for use under medical supervision; Schedule II: high potential for abuse, has a currently accepted medical use, abuse may lead to severe psychological or physical dependence; Schedule III: less potential for abuse than Schedule I and II substances, has a currently accepted medical use, abuse may lead to moderate or low physical or high psychological dependence; Schedule IV: low potential for abuse compared to Schedule III substances, has a currently accepted medical use, abuse may lead to limited physical or psychological dependence compared to Schedule III; Schedule V: low potential for abuse compared to Schedule IV, has a currently accepted medical use, may lead to limited physical or psychological dependence compared to Schedule IV. See *id.* § 812.

117. The constitutionality of a "war on genes" would be judged by the nature of the public and private interests at stake and the degree of intrusiveness of the government's actions. If the government could offer a compelling justification for why its actions were necessary to protect the public health and welfare, the courts would be likely to uphold severe regulatory restraints. Similar challenges have failed, for example, in the case of government restrictions on the use of illegal drugs and on sexual behavior that presents a threat to public health. See, e.g., *Department of Human Resources v. Smith*, 494 U.S. 872, 890 (1990) (rejecting first amendment religious challenge to drug law); *Bowers v. Hardwick*, 478 U.S. 186, 196 (1986) (upholding Georgia's sodomy statute).

118. See generally Doug Bandow, *War on Drugs or War on America?*, 1991 STAN L. & POL'Y REV. 242 (examining the costs and benefits of the drug war, concluding that legalization is the best alternative).

119. A historical analogy would be the availability of illegal abortions prior to *Roe v. Wade*, 410 U.S. 113 (1973). See, e.g., *Zad Leavy & Jerome Kummer*,

and the inability to seal the borders against the importation of contraband or its purchase abroad.<sup>120</sup> Yet thinking about a drug-enforcement approach to genetic enhancement is an important reminder of the consequences of a highly restrictive attitude toward access to these technologies. If, as some have suggested, we become determined to "ban" genetic enhancement, and to enforce such a prohibition vigorously, it is the model of the War on Drugs that we will be embracing.

### G. *Controlling Health Care Professionals Under State or Federal Law*

In contrast to professional self-regulation, in which health care professionals regulate their behavior through internalized or professionally established norms, regulation of genetic enhancement could be handled under state laws that control professional behavior. Chief among these are state licensure laws, the common and statutory laws that govern medical malpractice actions, and general criminal provisions. For example, a state could revoke a physician's license to practice medicine for providing genetic enhancements or a cause of action could be recognized for improper use of enhancement technology. A malpractice action would lie, for example, if a patient suffered adverse physical or emotional effects from an enhancement and could show that the enhancement had been provided in an improper manner (for example, the physician erred unreasonably in the dosage of an enhancement product or in the genetic manipulation of the patient's DNA) or that the physician had failed to obtain the patient's informed consent to the procedure.<sup>121</sup> Finally, the state or federal government could criminalize genetic enhancement. Criminal penalties could be imposed on those who received enhancement, but a more likely approach would be to sanction the providers.

Given the uncertainty and experimental nature of genetic enhancement, malpractice actions are not likely to be a useful regula-

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*Criminal Abortion: Human Hardship and Unyielding Laws*, 35 S. CAL. L. REV. 123 (1962) (suggesting that one out of two pregnancies terminate in illegal abortion).

120. For a complete discussion of these difficulties, see MEHLMAN & BOTKIN, *supra* note 46, at 112-21.

121. See generally Jeffrey R. Botkin & Maxwell J. Mehlman, *Wrongful Birth: Medical, Legal, and Philosophical Issues*, 22 J. LAW MED. & ETHICS 21 (1994). An action also might be brought by or on behalf of a child who complained that a physician enhanced her without her consent, but, given the presumed benefits from enhancement, such a suit would be likely to fail on the ground that the child was better off as the result of the physician's actions. An analogy would be "wrongful life" actions—suits brought by children claiming that but for the malpractice, the child would not have been born—which the courts generally dismiss. See, e.g., *Walker v. Mart*, 790 P.2d 735, 741 (Ariz. 1990) (holding that a child born with severe birth defect could not maintain a tort action against physician).

tory tool. There is likely to be little in the way of a standard of care for providing genetic enhancement, at least not when the technology is first being introduced. So long as the health care professional followed the steps required when providing a patient with an experimental treatment, including carefully informing the patient of the inherent uncertainties, the professional is likely to be protected.<sup>122</sup> Moreover, malpractice actions are expensive and, some have argued, highly inefficient techniques for regulating physician behavior.<sup>123</sup> Most importantly, the professional standard of care may have trouble incorporating social concerns such as fairness and cheating. Although, in theory, the standard of care in medical malpractice cases, as in all of tort law, is based on an assessment and comparison of risks and benefits,<sup>124</sup> judges and juries may find it difficult to sanction a physician for acting in her patient's best interest even when doing so creates a threat of social unfairness. Indeed, it may be deemed to be inappropriate for a physician to compromise the care of a patient in order to achieve a societal distributive goal. For example, a physician might be liable for denying a patient a benefit in order to conserve resources for others. For this reason, the Oregon state legislature immunizes physicians from civil liability when they deny Medicaid benefits to patients in reliance on the state's Medicaid rationing program; otherwise, physicians might be liable for malpractice for acting in a way that fell below the standard of care in a particular patient's case.<sup>125</sup>

In order to embed concerns about social justice within the professional standard of care so that physicians might be sanctioned either under licensure laws or tort actions, it would be necessary for a

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122. The Department of Health, Education & Welfare, through the NIH, developed three guidelines for human experimentation: (1) protection of rights and welfare of subjects, (2) informed consent requirement, and (3) assessment of risks and potential benefits by a review panel. See Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 174 (1998).

123. See COMMITTEE TO STUDY MED. PROF'L LIAB. & THE DELIVERY OF OBSTETRICAL CARE, INSTITUTE OF MEDICINE, 1 MEDICAL PROFESSIONAL LIABILITY AND THE DELIVERY OF OBSTETRICAL CARE 54-72 (1989); UNITED STATES DEPT. OF HEALTH AND HUMAN SERVICES, REPORT OF THE TASK FORCE ON MEDICAL LIABILITY AND MALPRACTICE 44 (1987); Harvard Medical Practice Study, Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation and Patient Compensation in New York 8-75 (1990); Paul Weiler et al., *Proposal for Medical Liability Reform*, 267 JAMA 2355, 2355 (1992). But see Maxwell J. Mehlman, *Bad "Bad Baby" Bills*, 20 AM. J.L. & MED. 129, 136 (1994) (arguing that current system protects most severely injured malpractice victims).

124. See *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

125. See Maxwell Mehlman, *The Oregon Medicaid Program: Is It Just?*, 1 HEALTH MATRIX 175, 175-76 (1991). An exception would be where the patient needed an organ transplant. There, because of the shortage of transplant organs, the physician might be justified in denying a transplant to one patient in order to maximize the benefit from the organ by giving it to another.

legislature to enact a specific prohibition into law. A legislative initiative also would be needed to criminalize research on or the provision of enhancement services, since there are no existing criminal laws that would achieve this result.

A similar approach is being considered in the case of prohibiting human cloning.<sup>126</sup> Apart from the wisdom of such a goal, questions are being raised about the appropriateness of a legislature in effect trying to "stop science."<sup>127</sup> Critics of a cloning ban argue, for example, that it would have unwanted effects.<sup>128</sup> Due to the difficulty of defining objectionable cloning practices, legislation would be overbroad, inhibiting therapeutic advances that depended on cloning techniques. Similar problems in distinguishing between therapeutic and enhancement uses of genetic technologies, described earlier, would beset legislative efforts to ban genetic enhancement.<sup>129</sup>

### 1. *Leveling the Playing Field*

The final approach to coping with the societal threats posed by genetic enhancement realistically assumes that it will be impossible to prevent some individuals from enhancing themselves or their children. Even draconian regulatory efforts like a legislative ban or a drug-war-like interdiction program would have only limited success. The question then is: are there means by which society can re-

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126. For legislation to outlaw the use of somatic cells in the production of human clones, see, e.g., H.R. 923, 105th Cong. (1997); S. 1599, 105th Cong. (1997); S. 1601, 105th Cong. (1997). For legislation to prohibit the cloning of humans, see, e.g., S. 1574, 105th Cong. (1998); S.B. 8, 1998 Reg. Sess. (Ala. 1998); S.B. 68, 1998 Reg. Sess. (Ala. 1998); S.B. 1344, 1997-98 Reg. Sess. (Cal. 1997); S.B. 1243, 90th Leg., 1997-98 Reg. Sess. (Ill. 1997); A.B. 9116, 221st Leg., 1997 Reg. Sess. (N.Y. 1998); S.B. 5993, 221st Leg., 1997 Reg. Sess. (N.Y. 1998); H.B. 675, 122d Leg., 1997-98 Reg. Sess. (Ohio 1997); S.B. 218, 122d Leg., 1997-98 Reg. Sess. (Ohio 1997). For legislation to prohibit attempts to clone through somatic cell nuclear transfer and the use of Federal funds for such purpose, see, e.g., S. 1602, 105th Cong. (1998); H.B. 2235, 90th Leg., 1997-98 Reg. Sess. (Ill. 1997); A.B. 9183, 221st Leg., 1997 Reg. Sess. (N.Y. 1998). For legislation to prohibit research using cloned cells or tissues, see A.B. 1251, 1997-98 Reg. Sess. (Cal. 1997); H.B. 1237, 1997 Reg. Sess. (Fla. 1997).

127. See Charles Krauthammer, *A Special Report on Cloning*, TIME, Mar. 10, 1997, at 60 (stating that "[n]o amount of regulation by the FDA or the NIH or even the FBI will stop . . . [human cloning]").

128. California's attempt to ban human cloning is "so sloppily worded that it prohibits a host of infertility treatments." *Confronting Cloning*, L.A. TIMES, Jan. 31, 1998, Metro Section, at 7. See also John A. Robertson, *Human Cloning: Should the United States Legislate Against It?*, A.B.A. J., May 1997, at 81 (discussing briefly the merits of human cloning); John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371, 1376-82 (1998) (discussing the potential benefits of cloning); John A. Robertson, *The Question of Human Cloning*, HASTINGS CTR. REP., Mar.-Apr. 1994, at 6 ("If we ban the immediate steps in order to prevent potentially harmful future applications, infertile couples lose the benefits of the procedure without a clear showing that future harms would necessarily have occurred.").

129. See *supra* text accompanying notes 48-49.

duce the harmful social effects that were described earlier?

A full-scale discussion of this topic is beyond the scope of this Article. However, it is interesting to consider how society has dealt with similar issues in the past. How has society responded to the fact that some people have superior attributes compared with others, attributes that they have developed, inherited, or come upon by chance, and that give them significant advantages?

Curiously, very little has been written about this subject. The literature has focused on society's response to those who are disadvantaged relative to the norm—persons with disabilities, or those who are poor or poorly educated—rather than on those whose attributes are "superior." Yet if one identifies these advantageous traits (such as beauty, size, strength, endurance, intelligence, memory, creativity, knowledge, charm, confidence, energy, experience, reputation, pedigree, socioeconomic status, wealth, and social or political power) and examines society's response to their potential impact in interactions with the unadvantaged, some interesting insights emerge.

In some cases, we ignore the advantages that some people possess. For example, we do not weight performance on college admissions tests according to the IQ of the test taker. Nor do we have basketball leagues restricted to players of "normal" height. In other instances, however, we prohibit people from taking advantage of their superiority. For example, securities trading by people who have "inside information" is illegal.<sup>130</sup> The use of performance-enhancing drugs in many sporting competitions, such as the Olympics, is against the rules.<sup>131</sup> Boxing, but not wrestling, creates com-

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130. Although Congress has addressed the issue of insider trading through the Insider Trading and Securities Fraud Enforcement Act of 1988, Pub. L. No. 100-704, 102 Stat. 4677 (1988), and the Insider Trading Sanctions Act of 1984, Pub. L. No. 98-376, 98 Stat. 1264 (1984), there is no statutory definition of insider trading. The courts and the Securities and Exchange Commission ("SEC") have primarily based the prohibition on insider trading on SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 (1998), which prohibits employment of manipulative and deceptive devices. See *In re Cady*, 40 S.E.C. 907, 912 (1961) (stating that "[i]ntimacy demands restraint lest the uninformed be exploited"). The scope of the prohibition was circumscribed in *Chiarella v. United States*, 445 U.S. 222, 233 (1980) (holding that an individual possessing information not available to the public, but who is not a corporate insider, does not violate the prohibition on insider trading in the absence of a relationship between the individual and the seller that gives rise to a special duty). In *United States v. O'Hagan*, 521 U.S. 642, 643 (1997), however, the Court reaffirmed that a person violates the insider trading prohibition "when he misappropriates confidential information for securities trading purposes, in breach of a fiduciary duty owed to the source of the information . . ." Additionally, SEC Rule 14e-3, 17 C.F.R. § 240.14e-3 (1998), prohibits insider trading in the context of tender offers. For a discussion of an alternative source of a definition of insider trading, see Steve Thel, *Statutory Findings and Insider Trading Regulation*, 50 VAND. L. REV. 1091, 1097-1100 (1997).

131. See United States Olympic Committee, *Drug Control Education* (visited

petitive categories based on body weight; featherweights are not made to box against heavyweights.

In still other cases, we permit persons with superior positions to engage in transactions involving the interests of the unadantaged, but reserve to the unadantaged the right to undo the transaction if the results seem too unfair. Contract law embodies this principle in the doctrine of unconscionability.<sup>132</sup> Fiduciary law gives this power to beneficiaries when trustees transact business with trust assets.<sup>133</sup>

Yet another approach is to adjust the position of the parties to a transaction to mitigate the effect of superiority. One example is making a person with superior information disclose the information to the other party, such as when sellers of real estate are required to

June 6, 1999) <[http://www.test.olympic-usa.org/inside/in\\_1\\_3\\_7\\_1.html](http://www.test.olympic-usa.org/inside/in_1_3_7_1.html)> (describing various drugs that are prohibited by the United States Olympic Committee including those that enhance performance such as stimulants and anabolic agents).

132. See, e.g., *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445, 449 (D.C. Cir. 1965) (stating that a contract may be unconscionable if there is "an absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party."); *Jones v. Star Credit Corp.*, 298 N.Y.S.2d 264, 265-68 (N.Y. Sup. Ct. 1969) (mem.) (holding unconscionable a defendant's sale of a \$300.00 freezer for \$1234.80, including credit charges, to the plaintiffs, who were welfare recipients); *Brooklyn Union Gas Co. v. Jimenez*, 371 N.Y.S.2d 289, 292 (N.Y. Civ. Ct. 1975) (holding as unconscionable a contract written in English only and entered into by the defendant, who spoke and read only Spanish, without the plaintiff's representative explaining the terms to him). Having found a contract to be unconscionable, the court may protect the disadvantaged individual by refusing to enforce the contract, enforcing the contract without the unconscionable clause, or limiting the application of the unconscionable clause so the result is not unconscionable. See U.C.C. § 2-302(1) (1998).

133. See AUSTIN W. SCOTT & WILLIAM FRATCHER, 1 THE LAW OF TRUSTS § 2.5, at 43 (4th ed. 1987) ("If the fiduciary enters into a transaction with the beneficiary and fails to make a full disclosure of all circumstances known to him affecting the transaction, or if the transaction is unfair to the beneficiary, it can be set aside by him.") (emphasis added). Elsewhere, Scott stated: "Where he deals directly with the beneficiaries, the transaction may stand, but only if the trustee makes full disclosure and takes no advantage of his position and the transaction is in all respects fair and reasonable." AUSTIN W. SCOTT, 2 THE LAW OF TRUSTS § 170.25, at 1387 (3d ed. 1967). Scott also stated: "In the case of a purchase by a trustee of the trust property with the consent of the beneficiaries, however, it would seem that if the price is not fair the transaction can be set aside even though the trustee made full disclosure." *Id.* § 496, at 3536; see also Alison G. Anderson, *Conflicts of Interest: Efficiency, Fairness and Corporate Structure*, 25 UCLA L. REV. 738, 760 (1978). Anderson noted:

Where bargaining power is roughly equal, specific fiduciary duties can be waived by the parties on the basis of full disclosure to and consent by the client. Because informational disparities so often mean that bargaining power is unequal, however, all fiduciaries have an unwavable obligation of fairness toward the other party.

*Id.* For a discussion of these principles, see Maxwell J. Mehlman, *Fiduciary Contracting Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365 (1991).



disclose known defects in the property that the buyer would be hard pressed to discover without unreasonable effort or expense.<sup>134</sup> Another type of adjustment is to handicap the person with superior attributes. Weights are placed in the saddles of lighter jockeys.<sup>135</sup> Strokes are added to the scores of better golfers.<sup>136</sup> Finally, the arms-length nature of a transaction can be eliminated, so that the superior party is forced to "look out for" the interests of the weaker party. Fiduciary rules do this in the case of relationships between parties with disparate power, such as patients and physicians, attorneys and clients, parents and children.<sup>137</sup> Another example is suitability rules in securities offerings, in which the seller must make sure that the buyer possesses sufficient assets that he can afford to lose his investment.<sup>138</sup>

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134. See *Ollerman v. O'Rourke Co.*, 288 N.W.2d 95, 107-08 (Wis. 1979) (stating that vendor had duty to disclose existence of underground well on residential lot); RESTATEMENT (SECOND) OF CONTRACTS § 161(b) (1979).

135. See *DIAGRAM GROUP, RULES OF THE GAME* 258 (1974) (noting that "weights are adjusted to try to give horses an equal chance of winning").

136. See *Blakney Boggs, Your Game Handicaps Help Promote Equal Competition*, ORANGE COUNTY REG. (Cal.), Aug. 13, 1998, at D13 (explaining that a handicap "is a way to level out the playing field between golfers of different abilities"); see also *Greg Wilcox, See Blue, Tee from the White; Forward Tees Mean More Iron*, L.A. DAILY NEWS, Aug. 6, 1998, at S8 (describing how players are grouped according to their handicaps so that they can compete against golfers of similar skill).

137. See generally *Dyntel Corp. v. Ebner*, 120 F.3d 488, 492 (4th Cir. 1997) (holding that an attorney owes a client a fiduciary duty which comprises meeting the standard of care); *Omnitech Int'l, Inc. v. Clorox Co.*, 11 F.3d 1316, 1331 (5th Cir. 1994) (recognizing the fiduciary relationship between an attorney and a client); *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 216, 223 (2d Cir. 1987) (recognizing the fiduciary duty of an attorney to class plaintiffs in class action suit); *Pharmacare v. Caremark*, 965 F. Supp. 1411, 1419 (D. Haw. 1996) (recognizing fraud violates the fiduciary duty a doctor owes a patient); *In re Marriage of Honkomp*, 381 N.E.2d 881, 882 (Ind. Ct. App. 1978) (holding child support for minor children received by custodial parent in a fiduciary capacity cannot be used to set off individual debts); *Ohio Cas. Ins. Corp. v. Mallison*, 354 P.2d 800, 802 (Or. 1960) (holding parents owe children a fiduciary duty when entering into a settlement on their behalf); *Alexander v. Knight*, 177 A.2d 142, 146 (Pa. Super Ct. 1962) (explaining the medical profession stands in a confidential and fiduciary capacity to their patient such that they owe a duty of total care); *Gates v. Jensen*, 595 P.2d 919, 923 (Wash. 1979) (recognizing that a physician has a fiduciary duty to inform a patient about material facts concerning the patient's body so the patient can make an informed decision).

138. National Association of Securities Dealers Conduct Rule 2310, in relevant part, provides:

- (a) In recommending to a customer the purchase, sale or exchange of any security, a member shall have reasonable grounds for believing that the recommendation is suitable for such customer upon the basis of the facts, if any, disclosed by such customer as to his other security holdings and his financial situation and needs. (b) Prior to the execution of a transaction recommended to a non-institutional customer . . . a member shall make reasonable efforts to obtain information concerning: (1) the customer's financial status; (2) the customer's tax

The question is whether these techniques would be effective to level the playing field in the case of genetic enhancements. Could genetically enhanced people be prohibited from taking advantage of their superior abilities to the disadvantage of "normals"? Could they be handicapped? Should they be made into fiduciaries for the less fortunate, a sort of genetic noblesse oblige?

The answers to these questions depend on several considerations. A key factor is how easy it will be to identify the fact that someone is enhanced. The importance of this factor is demonstrated by the difficulties that detection problems create for efforts to prohibit the use of performance-enhancing drugs in sports.<sup>139</sup> Another crucial consideration is the ratio of societal to personal benefit from allowing an individual to benefit from the enhancements. In sports competitions, for example, it is hard to discern any societal benefit from permitting athletes to use performance-enhancing drugs. But it may be sufficiently advantageous to society for enhanced individuals to be involved in scientific research that they will be permitted to compete on an equal basis with unenhanced persons for scarce research positions or grants.

An example of this is found in the law of torts. In general, people are held to the standard of a "reasonable person" under like circumstances.<sup>140</sup> A failure to behave like a reasonable person, which causes injury to another, subjects the actor to tort liability. This standard is modified, however, in the case of an actor who is physically (but not mentally) disabled.<sup>141</sup> We hold a blind person to the standard of a reasonable *blind* person. If we wanted to impose a

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status; (3) the customer's investment objectives; and (4) such other information used or considered to be reasonable by such member . . . in making recommendations to the customer.

National Ass'n of Securities Dealers, *NASD Manual & Notices to Members* (visited June 15, 1999) <<http://www.nasdr.com/wbs/NETbos.dll?RefShow?ref=NASD4;&xinfo=../webbos/goodbye.htm>>; see also Gerald F. Rath & David C. Boch, *Securities Litigation: Planning and Strategies*, SC73 ALI-ABA 191 (1998) (summarizing developments in broker and consumer litigation). The dealer must fulfill the obligation he assumes when he undertakes to counsel a customer; this rule is not limited to situations where comprehensive financial information about the customer is known to the dealer. See, e.g., *Erdos v. SEC*, 742 F.2d 507, 508 (9th Cir. 1984) (ruling that a dealer has "a duty to act with caution and to make recommendations based on the concrete information that he did have rather than on his speculation . . ." about a customer's situation); *In re Gerald M. Greenberg Nat'l Ass'n of Sec. Dealers*, 40 S.E.C. 133, 137-38 (1960) (expelling member of National Association of Securities Dealers); *In re Phillips & Co.*, 37 S.E.C. 66, 70 (1956) (suspending over-speculative broker).

139. See, e.g., Mark Zeigler, *Illegal Doping is Everywhere Now, and the Culprits are Rarely Caught*, S.D. UNION TRIB., Aug. 17, 1997, at C1 (stating that performance enhancing drugs are "seeping through the sports world like an injectable steroid is absorbed into the blood stream," and the only people who are caught are either "poor or stupid").

140. See RESTATEMENT (SECOND) OF TORTS § 283 (1965).

141. See *id.* § 283C.

duty on enhanced individuals to employ their superior traits to avoid accidents, we would not hold them to the standard of a reasonable person, but to the standard of a reasonable *enhanced* person. Thus, a driver whose vision had been enhanced to better than 20/20 would not be held to the standard of a reasonable, unadvantaged individual, but to the standard of a reasonable person with superior vision. If they should have spotted the child running across the road in time to stop the car, even though a person with normal vision would not have seen the child, then, under an enhanced person's standard, they could be liable for failing to stop in time. The enhanced person would be treated much the same way that professionals are treated, that is, held to a higher standard of care than non-professionals.

The Restatement (Second) of Torts appears to take this approach. In section 289, it states "[t]he actor is required to recognize that his conduct involves a risk of causing an invasion of another's interest if a reasonable man would do so while exercising . . . such superior attention, perception, memory, knowledge, intelligence, and judgment as the actor himself has."<sup>142</sup>

There are a few cases in which the courts have held people with superior abilities to a higher standard, but most of these involve professionals.<sup>143</sup> One of the few exceptions is *Fredericks v. Castora*,<sup>144</sup> in which the court held a professional truck driver to the standard of an ordinary driver when he caused an accident driving the family sedan.<sup>145</sup>

What is interesting about tort law in this respect is that a good argument can be made that we should not alter the standard of care

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142. *Id.* § 289.

143. In an interesting remark in *Dillenbeck v. Los Angeles*, 446 P.2d 129, 136 n.10 (Cal. 1968), however, the California Supreme Court reasoned that a professional such as an attorney or physician is held to a higher standard of care than a lay person because of the professional's greater expertise, rather than because the professional holds herself out as such: "Essentially, the 'expert' cases flow from the proposition that each person in society is expected to exercise that degree of care which can reasonably be anticipated from him in light of his peculiar attributes, including knowledge, perception, and memory."

144. 360 A.2d 696 (Pa. Super. Ct. 1976).

145. *Id.* at 698. In *Johnston v. United States*, 568 F. Supp. 351, 354 (D. Kan. 1983), a federal court noted that a government contractor cannot hide behind the so-called "contract specification defense"—which protects a contractor from products liability if the contractor follows design specifications—"where the manufacturer has special knowledge or expertise." In *Cervelli v. Graves*, 661 P.2d 1032, 1037 (Wyo. 1983), the court rejected the reasonable person standard in a case involving an accident caused by a professional truck driver, opting instead for an instruction that would permit the jury to consider evidence that the driver "was more skillful than others as a result of his experience as a driver." In *Dillenbeck v. City of Los Angeles*, 446 P.2d 129, 136 (Ca. 1968), a police officer who killed a motorist in the course of a high-speed chase was held to the standard of one who possessed superior knowledge and skill by virtue of his "extensive training and experience."

for an enhanced individual when it comes to avoiding accidents. Instead, we should hold them merely to the standard of a reasonable, unadvantaged person. The reason is that, by doing so, we encourage people to improve their vision, which in itself will avoid accidents, whereas, if we made people with better vision liable under a higher standard, thereby discouraging them from enhancing their vision, we would lose the benefit in terms of accident avoidance. Whether we imposed a higher or normal standard would depend on whether we thought that the benefits from reduced accidents on account of having drivers with better vision outweighed the costs of accidents caused by these drivers when they did not act like someone with improved vision.<sup>146</sup>

### CONCLUSION

Although this Article is merely a first stab at the question of how we may regulate genetic enhancements, several points already become clear. The first is that no single method of regulation can accomplish the objectives of assuring safety, efficacy, personal autonomy and minimizing adverse social consequences. Instead, a variety of regulatory mechanisms, public and private, must be brought to bear. In particular, it is important to recognize the limitations of specific regulatory mechanisms. Given the motivation of self-interest, for example, we should not expect personal or professional self-regulation to solve the problems of unfairness or cheating.

Another relatively obvious point is that banning genetic enhancement is unlikely to be completely successful. The allure of enhancement will motivate the creation of a black market, or will lead people to obtain enhancements in other countries that are beyond the reach of our domestic prohibitions. The question then is whether the reduction in enhancement that might be achieved by strict enforcement of a ban is worth the cost in terms of police activity and intrusion into private medical and reproductive behavior.

It follows from the previous point that, in all likelihood, some people will become genetically enhanced. The question, then, is how society should respond. If the number of enhanced individuals is sufficiently small, we may be able to ignore them on the basis that their impact in terms of unfairness and cheating will be minimal.

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146. A similar analysis might be made of rules that permit a party to a contract to benefit from superior information so long as the result is not too unfair. In this case, the argument would be that, by permitting the party with superior information to capitalize on that information, we give an incentive to create and obtain that information. The societal gain in information, it is reasoned, outweighs the unfairness to the inferior party to the transaction. See Anthony Kronman, *Mistake, Disclosure, Information, and the Law of Contracts*, 7 J. LEGAL STUD. 1, 19 n.49 (1978) (noting beneficiary "in effect purchases other party's information").

On the other hand, if a substantial minority of individuals is able to afford enhancements for themselves or their offspring, the risks to society may become too great to disregard. In that case, we will need to reduce the costs to society by leveling the playing fields on which enhanced individuals interact with the unadvantaged.