MAXWELL J. MEHLMAN

Biomedical Enhancements

Entering a New Era

Products and services to boost performance, appearance, or capability are here to stay, and better, more sophisticated ones are on the way. Banning them would be misguided, but regulation will be needed.

Recently, the Food and Drug Administration (FDA) approved a drug to lengthen and darken eyelashes. Botox and other wrinkle-reducing injections have joined facelifts, tummy tucks, and vaginal reconstruction to combat the effects of aging. To gain a competitive edge, athletes use everything from steroids and blood transfusions to recombinant-DNA–manufactured hormones, Lasik surgery, and artificial atmospheres. Students supplement caffeine-containing energy drinks with Ritalin and the new alertness drug modafinil. The military spends millions of dollars every year on biological research to increase the warfighting abilities of our soldiers. Parents perform genetic tests on their children to determine whether they have a genetic predisposition to excel at explosive or endurance sports. All of these are examples of biomedical enhancements: interventions that use medical and biological technology to improve performance, appearance, or capability in addition to what is necessary to achieve, sustain, or restore health.

The use of biomedical enhancements, of course, is not new. Amphetamines were doled out to troops during World War II. Athletes at the turn of the 20th century ingested narcotics. The cognitive benefits of caffeine have been known for at least a millennium. Ancient Greek athletes swallowed herbal infusions before competitions. The Egyptians brewed a drink containing a relative of Viagra at least 1,000 years before Christ. But modern drug development and improvements in surgical technique are yielding biomedical enhancements that achieve safer, larger, and more targeted enhancement effects than their predecessors, and more extraordinary technologies are expected to emerge from ongoing discoveries in human genetics. (In addition, there are biomechanical enhancements that involve the use of computer implants and nanotechnology, which are beyond the scope of this article.)

What is also new is that biomedical enhancements have become controversial. Some commentators want to outlaw them altogether. Others are concerned about their use by athletes

MARTIN SCHOELLER, *Lenda Murray*, Photographic C-print, 89 x 72 inches, 2003.

and children. Still others fret that only the well-off will be able to afford them, thereby exacerbating social inequality.

Banning enhancements, however, is misguided. Still, it is important to try to ensure that they are as safe and effective as possible, that vulnerable populations such as children are not forced into using them, and that they are not available only to the well-off. This will require effective government and private action.

A misguided view

Despite the long history of enhancement use, there recently has emerged a view that it is wrong. The first manifestation of this hostility resulted from the use of performance enhancements in sports in the 1950s, especially steroids and amphetamines. European nations began adopting antidoping laws in the mid-1960s, and the Olympic Games began testing athletes in 1968. In 1980, Congress amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to make it a felony to distribute anabolic steroids for nonmedical purposes. Two years later, Congress made steroids a Schedule III controlled substance and substituted human growth hormone in the steroid provision of the FFDCA. Between 2003 and 2005, Congress held hearings lambasting professional sports for not imposing adequate testing regimens. Drug testing has also been instituted in high-school and collegiate sports.

The antipathy toward biomedical enhancements extends well beyond sports, however. Officially, at least, the National Institutes of Health (NIH) will not fund research to develop genetic technologies for human enhancement purposes, although it has funded studies in animals that the researchers tout as a step toward developing human enhancements. It is a federal crime to use steroids to increase strength even if the user is not an athlete. Human growth hormone is in a unique regulatory category in that it is a felony to prescribe it for any purpose other than a specific use approved by the FDA. (For example, the FDA has not approved it for antiaging purposes.) There is an ongoing controversy about whether musicians, especially string players, should be allowed to use beta blockers to steady their hands. And who hasn't heard of objections to the use of mood-altering drugs to make "normal" people happier? There's even a campaign against caffeine.

If the critics had their way, the government would ban the use of biomedical enhancements. It might seem that this would merely entail extending the War on Drugs to a larger number of drugs. But remember that enhancements include not just drugs, but cosmetic surgery and information technologies, such as genetic testing to identify nondisease traits. So a War on Enhancements would have to extend

Martin Schoeller

German-born and New York-based photographer Martin Schoeller writes that "a photographic close-up is perhaps the purest form of portraiture, creating a confrontation between the viewer and the subject that daily interaction makes impossible, or at least impolite." By using similar angles and the same equipment in photographing a number of people, he emphasizes each subject's individuality.

Commenting on the series *Female Bodybuilders*, Schoeller wrote, "In 2003, after taking my first Polaroid at a bodybuilding competition, I was struck by the multidimensional complexity of the portrait. The contradictions were so seemingly apparent, so numerous and exciting, that I felt compelled to build a catalog outside the range of judgment: not to celebrate, condemn, or expose, but merely to show. We all operate within narrowly constructed ideals of the good, the right, and the beautiful, all subject to the countless influences that swirl around us. The athletes presented here are no different; they are as vulnerable as any other person standing in front of a camera."

Schoeller's work is included in the exhibition "Portraiture Now: Feature Photography" on display at the National Portrait Gallery in Washington, DC, from November 26, 2008 through September 27, 2009. The exhibition focuses on six acclaimed fine-art photographers (Katy Grannan, Jocelyn Lee, Ryan McGinley, Steve Pyke, and Alec Soth as well as Schoeller) whose work has appeared in popular magazines such as the *New Yorker, Esquire,* and the *New York Times Magazine*. Their work builds on a longstanding tradition of photographic portraiture for the popular press and highlights creative possibilities for 21st century portrayal.

Images courtesy of the artist, Pond Press, and the ACE Gallery in Los Angeles.

From an era in which employees are tested to make sure they aren't taking drugs, we might see a new approach in which employers test them to make sure they are.

to a broader range of technologies, and because many are delivered within the patient-physician relationship, the government would have to intrude into that relationship in significant new ways. Moreover, the FDA is likely to have approved many enhancement drugs for legitimate medical purposes, with enhancement use taking place on an "off-label" basis. So there would have to be some way for the enhancement police to identify people for whom the drugs had been legally prescribed to treat illness, but who were misusing them for enhancement purposes.

This leads to a far more profound difficulty. The War on Drugs targets only manufacture, distribution, and possession. There is virtually no effort to punish people merely for using an illegal substance. But a successful ban on biomedical enhancement would have to prevent people from obtaining benefits from enhancements that persisted after they no longer possessed the enhancements themselves, such as the muscles built with the aid of steroids or the cognitive improvement that lasts for several weeks after normal people stop taking a certain medicine that treats memory loss in Alzheimer's patients. In short, a ban on enhancements would have to aim at use as well as possession and sale.

To imagine what this would be like, think about the campaign against doping in elite sports, where athletes must notify antidoping officials of their whereabouts at all times and are subject to unannounced, intrusive, and often indecent drug tests at any hour of the day or night. Even in the improbable event that regular citizens were willing to endure such an unprecedented loss of privacy, the economic cost of maintaining such a regime, given how widespread the use of highly effective biomedical enhancements might be, would be prohibitive.

A ban on biomedical enhancements would be not only unworkable but unjustifiable. Consider the objections to enhancement in sports. Why are enhancements against the rules? Is it because they are unsafe? Not all of them are: Antidoping rules in sports go after many substances that pose no significant health risks, such as caffeine and Sudafed. (A Romanian gymnast forfeited her Olympic gold medal after she accidentally took a couple of Sudafed to treat a cold.) Even in the case of vilified products such as steroids, safety concerns stem largely from the fact that athletes are forced to use the drugs covertly, without medical supervision. Do enhancements give athletes an "unfair" advantage? They do so only if the enhancements are hard to obtain, so that only a few competitors obtain the edge. But the opposite seems to be true: Enhancements are everywhere. Besides, athletes are also tested for substances that have no known performance-enhancing effects, such as marijuana. Are the rewards from enhancements "unearned"? Not necessarily. Athletes still need to train hard. Indeed, the benefit from steroids comes chiefly from allowing athletes to train harder without injuring themselves. In any event, success in sports comes from factors that athletes have done nothing to deserve, such as natural talent and the good luck to have been born to encouraging parents or to avoid getting hurt. Would the use of enhancements confound recordkeeping? This doesn't seem to have stopped the adoption of new equipment that improves performance, such as carbon-fiber vaulting poles, metal skis, and oversized tennis racquets. If one athlete used enhancements, would every athlete have to, so that the benefit would be nullified? No, there would still be the benefit of improved performance across the board—bigger lifts, faster times, higher jumps. In any case, the same thing happens whenever an advance takes place that improves performance.

The final objection to athletic enhancement, in the words of the international Olympic movement, is that it is against the "spirit of sport." It is hard to know what this means. It certainly can't mean that enhancements destroy an earlier idyll in which sports were enhancement-free; as we saw before, this never was the case. Nor can it stand for the proposition that a physical competition played with the aid of enhancements necessarily is not a "sport." There are many sporting events in which the organizers do not bother to test participants, from certain types of "strong-man" and power-lifting meets to your neighborhood pickup basketball game. There are several interesting historical explanations for why athletic enhancement has gained such a bad rap, but ulti-

mately, the objection about "the spirit of sport" boils down to the fact that some people simply don't like the idea of athletes using enhancements. Well, not exactly. You see, many biomedical enhancements are perfectly permissible, including dietary supplements, sports psychology, carbohydrate loading, electrolyte-containing beverages, and sleeping at altitude (or in artificial environments that simulate it). Despite the labor of innumerable philosophers of sport, no one has ever come up with a rational explanation for why these things are legal and others aren't. In the end, they are just arbitrary distinctions.

But that's perfectly okay. Lots of rules in sports are arbitrary, like how many players are on a team or how far the boundary lines stretch. If you don't like being all alone in the outfield, don't play baseball. If you are bothered by midnight drug tests, don't become an Olympian.

The problem comes when the opponents of enhancement use in sports try to impose their arbitrary dislikes on the wider world. We already have observed how intrusive and expensive this would be. Beyond that, there are strong constitutional objections to using the power of the law to enforce arbitrary rules. But most important, a ban on the use of enhancements outside of sports would sacrifice an enormous amount of societal benefit. Wouldn't we want automobile drivers to use alertness drugs if doing so could prevent accidents? Shouldn't surgeons be allowed to use beta blockers to steady their hands? Why not let medical researchers take cognitive enhancers if it would lead to faster cures, or let workers take them to be more productive? Why stop soldiers from achieving greater combat effectiveness, rescue workers from lifting heavier objects, and men and women from leading better sex lives? Competent adults who want to use enhancements should be permitted to. In some instances, such as in combat or when performing dangerous jobs, they should even be required to.

MARTIN SCHOELLER, *Christine Roth*, Photographic C-print, 89 x 72 inches, 2004.

Protecting the vulnerable

Rejecting the idea of banning enhancements doesn't mean that their use should be unregulated. The government has

MARTIN SCHOELLER, *Kristy Hawkins*, Photographic C-print, 89 x 72 inches, 2008.

several crucial roles to play in helping to ensure that the benefits from enhancement use outweigh the costs.

In the first place, the government needs to protect people who are incapable of making rational decisions about whether to use enhancements. In the language of biomedical ethics, these are populations that are "vulnerable," and a number of them are well recognized. One such group, of course, is people with severe mental disabilities. The law requires surrogates to make decisions for these individuals based on what is in their best interests.

Another vulnerable population is children. There can be little disagreement that kids should not be allowed to decide on their own to consume powerful, potentially dangerous enhancement substances. Not only do they lack decisionmaking capacity, but they may be much more susceptible than adults to harm. This is clearly the case with steroids, which can interfere with bone growth in children and adolescents.

The more difficult question is whether parents should be free to give enhancements to their children. Parents face powerful social pressures to help their children excel. Some parents may be willing to improve their children's academic or athletic performance even at a substantial risk of injury to the child. There are many stories of parents who allow their adolescent daughters to have cosmetic surgery, including breast augmentation. In general, the law gives parents considerable discretion in determining how to raise their children. The basic legal constraint on parental discretion is the prohibition in state law against abuse or neglect, and this generally is interpreted to defer to parental decisionmaking so long as the child does not suffer serious net harm. There are no reported instances in which parents have been sanctioned for giving their children biomedical enhancements, and the authorities might conclude that the benefits conferred by the use of an enhancement outweighed even a fairly significant risk of injury.

Beyond the actions of parents, there remains the question of whether some biomedical enhancements are so benign that children should be allowed to purchase them themselves. At present, for instance, there is no law in the United States against children purchasing coffee, caffeinated soft drinks, and even high-caffeine–containing energy drinks. (Laws prohibiting children from buying energy drinks have been enacted in some other countries.)

At the same time, it may be a mistake to lump youngsters together with older adolescents into one category of children. Older adolescents, although still under the legal age of majority, have greater cognitive and judgmental capacities than younger children. The law recognizes this by allowing certain adolescents, deemed "mature" or "emancipated"

minors, to make legally binding decisions, such as decisions to receive medical treatment. Older adolescents similarly may deserve some degree of latitude in making decisions about using biomedical enhancements.

Children may be vulnerable to pressure to use enhancements not only from their parents, but from their educators. Under programs such as No Child Left Behind, public school teachers and administrators are rewarded and punished based on student performance on standardized tests. Private schools compete with one another in terms of where their graduates are accepted for further education. There is also intense competition in school athletics, especially at the collegiate level. Students in these environments may be bulldozed into using enhancements to increase their academic and athletic abilities. Numerous anecdotes, for example, tell of parents who are informed by teachers that their children need medication to "help them focus"; the medication class in question typically is the cognition-enhancing amphetamines, and many of these children do not have diagnoses that would warrant the use of these drugs.

Beyond students, athletes in general are vulnerable to pressure from coaches, sponsors, family, and teammates to use hazardous enhancements. For example, at the 2005 congressional hearings on steroid use in baseball, a father testified that his son committed suicide after using steroids, when in fact he killed himself after his family caught him using steroids, which the boy had turned to in an effort to meet his family's athletic aspirations.

Another group that could be vulnerable to coercion is workers. Employers might condition employment or promotion on the use of enhancements that increased productivity. For example, an employer might require its nighttime work force to take the alertness drug modafinil, which is now approved for use by sleep-deprived swing-shift workers. Current labor law does not clearly forbid this so long as the drug is relatively safe. From an era in which employees are tested to make sure they aren't taking drugs, we might see a new approach in which employers test them to make sure they are.

Members of the military may also be forced to use enhancements. The military now conducts the largest known biomedical enhancement research project. Under battlefield conditions, superiors may order the use of enhancements, leaving soldiers no lawful option to refuse. A notorious example is the use of amphetamines by combat pilots. Technically, the pilots are required to give their consent to the use of the pep pills, but if they refuse, they are barred from flying the missions.

The ability of government regulation to protect vulner-

MARTIN SCHOELLER, *Carmella Cureton*, Photographic C-print, 89 x 72 inches, 2007.

MARTIN SCHOELLER, *Kim Harris*, Photographic C-print, 89 x 72 inches, 2003.

able groups varies depending on the group. It is important that educators not be allowed to give students dangerous enhancements without parental permission and that parents not be pressured into making unreasonable decisions by fearful, overzealous, or inadequate educators. The law can mandate the former, but not easily prevent the latter. Coaches and trainers who cause injury to athletes by giving them dangerous enhancements or by unduly encouraging their use should be subject to criminal and civil liability. The same goes for employers. But the realities of military life make it extremely difficult to protect soldiers from the orders of their superiors.

Moreover, individuals may feel pressure to use enhancements not only from outside sources, but from within. Students may be driven to do well in order to satisfy parents, gain admittance to more prestigious schools, or establish better careers. Athletes take all sorts of risks to increase their chances of winning. Workers may be desperate to save their jobs or bring in a bigger paycheck, especially in economically uncertain times. Soldiers better able to complete their missions are likely to live longer.

Surprisingly, while acknowledging the need to protect people from outside pressures, bioethicists generally maintain that we do not need to protect them from harmful decisions motivated by internal pressures. This position stems, it seems, from the recognition that, with the exception of decisions that are purely random, everything we decide to do is dictated at least in part by internal pressures, and in many cases, these pressures can be so strong that the decisions may no longer appear to be voluntary. Take, for example, seriously ill cancer patients contemplating whether or not to undergo harsh chemotherapy regimens. Bioethicists worry that, if we focused on the pressures and lack of options created by the patients' dire condition, we might not let the patients receive the treatment, or, in the guise of protecting the patients from harm, might create procedural hurdles that would rob them of their decisionmaking autonomy. Similarly, these bioethicists might object to restricting the ability of workers, say, to use biomedical enhancements merely because their choices are highly constrained by their fear of losing their jobs. But even if we accept this argument, that doesn't mean that we must be indifferent to the dangers posed by overwhelming internal pressure. As we will see, the government still must take steps to minimize the harm that could result.

Individuals may be vulnerable to harm not only from using enhancements, but from participating in experiments to see if an enhancement is safe and effective. Research subjects are protected by a fairly elaborate set of rules, collec-

tively known as the "Common Rule," that are designed to ensure that the risks of the research are outweighed by the potential benefits and that the subjects have given their informed consent to their participation. But there are many weaknesses in this regulatory scheme. For one thing, these rules apply only to experiments conducted by government-funded institutions or that are submitted to the FDA in support of licensing applications, and therefore they do not cover a great deal of research performed by private industry. Moreover, the rules were written with medically oriented research in mind, and it is not clear how they should be interpreted and applied to enhancement research. For example, the rules permit children to be enrolled as experimental subjects in trials that present "more than minimal risk" if, among other things, the research offers the possibility of "direct benefit" to the subject, but the rules do not say whether an enhancement benefit can count as a direct benefit. Specific research protections extend to other vulnerable populations besides children, such as prisoners and pregnant women, but do not explicitly cover students, workers, or athletes. In reports of a project several colleagues and I recently completed for the NIH, we suggest a number of changes to current regulations that would provide better protection for these populations.

Ensuring safety and effectiveness

Beginning with the enactment of the Pure Food and Drug Act in 1906, we have turned to the government to protect us from unsafe, ineffective, and fraudulent biomedical products and services. Regardless of how much freedom individuals should have to decide whether or not to use biomedical enhancements, they cannot make good decisions without accurate information about how well enhancements work. In regard to enhancements in the form of drugs and medical devices, the FDA has the legal responsibility to make sure that this information exists.

The FDA's ability to discharge this responsibility, however, is limited. In the first place, the FDA has tended to rely on information from highly stylized clinical trials that do not reflect the conditions under which enhancements would be used by the general public. Moreover, the deficiencies of clinical trials are becoming more apparent as we learn about pharmacogenetics—the degree to which individual responses to medical interventions vary depending on the individual's genes. The FDA is beginning to revise its rules to require manufacturers to take pharmacogenetics into consideration in studying safety and efficacy, but it will be many years, if ever, before robust pharmacogenetic information is publicly available. The solution is to rely more on data from actual use. Recently the agency has become more adamant about monitoring real-world experience after products reach the market, but this information comes from self-reports by physicians and manufacturers who have little incentive to cooperate. The agency needs to be able to conduct its own surveillance of actual use, with the costs borne by the manufacturers.

Many biomedical enhancements fall outside the scope of FDA authority. They include dietary supplements, many of which are used for enhancement purposes rather than to promote health. You only have to turn on late-night TV to be bombarded with claims for substances to make you stronger or more virile. Occasionally the Federal Trade Commission cracks down on hucksters, but it needs far greater resources to do an effective job. The FDA needs to exert greater authority to regulate dietary supplements, including those used for enhancement.

The FDA also lacks jurisdiction over the "practice of medicine." Consequently, it has no oversight over cosmetic surgery, except when the surgeon employs a new medical device. This limitation also complicates the agency's efforts to exert authority over reproductive and genetic practices. This would include the genetic modification of embryos to improve their traits, which promises to be one of the most effective enhancement techniques. Because organized medicine fiercely protects this limit on the FDA, consumers will have to continue to rely on physicians and other health care professionals to provide them with the information they need to make decisions about these types of enhancements. Medical experts need to stay on top of advances in enhancement technology.

Even with regard to drugs and devices that are clearly within the FDA's jurisdiction, its regulatory oversight only goes so far. Once the agency approves a product for a particular use, physicians are free to use it for any other purpose, subject only to liability for malpractice and, in the case of controlled substances, a requirement that the use must comprise legitimate medical practice. Only a handful of products, such as Botox, have received FDA approval for enhancement use; as noted earlier, enhancements predominantly are unapproved, off-label uses of products approved for health-related purposes. Modafinil, for example, one of the most popular drugs for enhancing cognitive performance, is approved only for the treatment of narcolepsy and sleepiness associated with obstructive sleep apnea/hypopnea syndrome and shift-work sleep disorder. Erythropoietin, which athletes use to improve performance, is approved to treat anemias. The FDA needs to be able to require manufacturers of products such as these to pay for the agency to collect and disseminate data on off-label experience. The agency also

has to continue to limit the ability of manufacturers to promote drugs for off-label uses, in order to give them an incentive to obtain FDA approval for enhancement labeling.

An enhancement technology that will increase in use is testing to identify genes that are associated with nondisease characteristics. People can use this information to make lifestyle choices, such as playing sports at which they have the genes to excel, or in reproduction, such as deciding which of a number of embryos fertilized in vitro will be implanted in the uterus. An area of special concern is genetic tests that consumers can use at home without the involvement of physicians or genetic counselors to help them interpret the results. Regulatory authority over genetic testing is widely believed to be inadequate, in part because it is split among the FDA and several other federal agencies, and there are growing calls for revamping this regulatory scheme that need to be heeded.

Any attempt to regulate biomedical enhancement will be undercut by people who obtain enhancements abroad. The best hope for protecting these "enhancement tourists" against unsafe or ineffective products and services lies in international cooperation, but this is costly and subject to varying degrees of compliance.

To make intelligent decisions about enhancement use, consumers need information not only about safety and effectiveness, but about whether they are worth the money. Should they pay for Botox injections, for example, or try to get rid of facial wrinkles with cheaper creams and lotions? When the FDA approved Botox for cosmetic use, it ignored this question of cost-effectiveness because it has no statutory authority to consider it. In the case of medical care, consumers may get some help in making efficient spending decisions from their health insurers, who have an incentive to avoid paying for unnecessarily costly products or services. But insurance does not cover enhancements. The new administration is proposing to create a federal commission to conduct health care cost-effectiveness analyses, among other things, and it is important that such a body pay attention to enhancements as well as other biomedical interventions.

Subsidizing enhancement

In these times of economic distress, when we already question whether the nation can afford to increase spending on health care, infrastructure, and other basic necessities, it may seem foolish to consider whether the government has an obligation to make biomedical enhancements available to all. Yet if enhancements enable people to enjoy a significantly better life, this may not be so outlandish, and if universal access avoids a degree of inequality so great that it undermines our democratic way of life, it may be inescapable.

There is no need for everyone to have access to all available enhancements. Some may add little to an individual's abilities. Others may be so hazardous that they offer little net benefit to the user. But imagine that a pill is discovered that substantially improves a person's cognitive facility, not just their memory but abilities such as executive function—the highest form of problem-solving capacity—or creativity. Now imagine if this pill were available only to those who already were well-off and could afford to purchase it with personal funds. If such a pill were sufficiently effective, so that those who took it had a lock on the best schools, careers, and mates, wealth-based access could drive an insurmountable wedge between the haves and have-nots, a gap so wide and deep that we could no longer pretend that there is equality of opportunity in our society. At that point, it is doubtful that a liberal democratic state could survive.

So it may be necessary for the government to regard such a success-determining enhancement as a basic necessity, and, after driving the cost down to the lowest amount possible, subsidize access for those unable to purchase it themselves. Even if this merely maintained preexisting differences in cognitive ability, it would be justified in order to prevent further erosion of equality of opportunity.

The need for effective regulation of biomedical enhancement is only going to increase as we enter an era of increasingly sophisticated technologies. Existing schemes, such as the rules governing human subjects research, must be reviewed to determine whether additions or changes are needed to accommodate this class of interventions. Government agencies and private organizations need to be aware of both the promise and the peril of enhancements and devote an appropriate amount of resources in order to regulate, rather than stop, their use.

Maxwell J. Mehlman is the Arthur E. Petersilge Professor of Law, director of the Law-Medicine Center, and professor of Bioethics at Case Western Reserve University. He is the author of The Price of Perfection: The Individual and Society in the Era of Biomedical Enhancement *(Johns Hopkins University Press, forthcoming, spring 2009).*