2 Human Growth Hormones for Children of Idiopathic Short Stature: Medical Treatment or Enhancing Therapy?

2.1 Introduction

Before turning our attention to new bioethical dilemmas, let us examine in some detail the recent decision by the FDA to approve the use of human growth hormone (hGH) for the treatment of children of idiopathic short stature (ISS). The case of the hGH is representative of the many challenges regulators are likely to face in the not-too-distant future. Like many reproductive treatments, synthetic hGH originally was developed to treat a narrowly defined medical condition, chronic growth hormone deficiency in children. As for many other drugs, the use of hGH has expanded over time to include indications initially not envisaged by the company that developed it.

In this chapter, we examine the role the FDA played in sanctioning the shift from purely therapeutic uses to what many have described as the cosmetic use of hGH. "Cosmetic use" is the term the FDA uses to identify treatments or drugs that are not designed to cure a medical condition, or that are intended to treat a condition that affects only the physical appearance of an individual. In the following discussion, we prefer to use the term "enhancing." "Cosmetic" and "enhancing" are not always or necessarily synonymous terms. In the present case, however, "enhancing treatment" better captures the nature of the underlying ethical dilemma. The FDA decision to approve what may be described as an enhancing treatment then provides considerable insight into how existing regulatory agencies are likely to resolve controversies surrounding the use of medical technologies that are neither clearly therapeutic nor uniquely enhancing.

Until the mid-1980s, children with severe growth hormone deficiency could only be treated with growth hormone obtained from cadavers. The amount of hGH so obtained was minuscule compared to the number of children in need of treatment; the cure was extremely expensive and not entirely safe, and some children treated with natural hGH contracted Creutzfeldt-Jakob Disease.[1] Recombinant DNA technology changed all this, making it possible for biotech companies to produce a once-scarce biological resource in large quantities of very high and consistent quality. Human growth hormone was one of the very first drugs to be produced through recombinant DNA technology, the use of which use was approved by the FDA in 1985 for the treatment of severe growth deficiency.

In subsequent years, the availability of synthetic hGH quickly increased, though the treatment has remained very expensive. Since its introduction in 1985, human growth hormone has been prescribed for a variety of approved and unapproved indications, including inadequate

[1] American Academy of Pediatrics and Committee on Drugs and Committee on Bioethics, "Considerations Related to the Use of Recombinant Human Growth Hormone in Children," *Pediatrics* 99, no. 1 (1997).

endogenous growth hormone secretion, chronic renal insufficiency, and Turner Syndrome, among others.[2] With the fall 2003 approval of the use of synthetic hGH for the treatment of idiopathic short stature, the FDA sanctioned a medical treatment that is neither obviously therapeutic nor clearly enhancing.

Its obscure name notwithstanding, this condition can easily be explained: ISS children are considerably below the mean stature for their sex and age group, yet their short stature cannot be attributed to any physiological deficiency; their growth hormone levels are well within the norm, and their parents' stature is not generally below average. By all accounts, these are short but otherwise healthy, normal children. In this and similar cases, the medical profession simply assumes that the phenomenon under consideration is a condition whose origins are unknown; hence the term "idiopathic."

It should be pointed out that the FDA decision certainly cannot be described as an egregious case of regulatory failure. The FDA did not endorse the prescription of hGHs for every case of idiopathic shortness. The FDA approved this treatment only for extremely short children – that is, for children two standard deviations below the mean for sex and age group. In addition, the regulators were well aware of some of the broader societal implications of their decision. If this was indeed a case of a regulatory agency sanctioning an enhancing therapy, it was neither a spectacular nor an obviously outrageous decision. Paradoxically, it is precisely the ordinary nature of the hGH case that makes it relevant to our discussion. Enhancing medical treatments, as a rule, are unlikely to achieve dramatic improvements. Their effectiveness is often modest or even controversial. In addition, they may raise considerable safety concerns. In sum, enhancing treatments are likely to deliver only incremental benefits – benefits that regulators may not consider important enough to warrant limiting their accessibility on the basis of considerations other than safety and efficacy.

In each of these cases, patient groups and pharmaceutical and biotechnology companies, with the more-or-less active support of the medical profession, are likely to portray a so-called cosmetic treatment as an instance of the therapeutic use of a medical technology. Opponents, for their part, will undermine the enhancing aspects of the treatment in question, or even dispute that the proposed treatment constitutes a medical therapy. This is precisely why the case of the hGH is so insightful: It is a very realistic test of the ability of existing regulatory agencies to recognize the ambivalent nature of new, so-called medical treatments, and to address the ethical dilemmas raised by medical treatments and technologies that are neither purely therapeutic not entirely enhancing.

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[2] These are all approved indications. For a more detailed discussion of the approval history of hGH indications, see Minnesota Department of Health Health Technology Advisory Committee, *The Use of Growth Hormone for Children with Idiopathic Short Stature* (Minnesota Department of Health, 2000 [cited April 24, 2006]); available from http://www.health.state.mn.us/htac/hgh.htm.

2.2 Is There a Need for Legal Guidance?

The FDA approved the cosmetic use of synthetic hGH based on a favorable recommendation by the Endocrinologic and Metabolic Drugs Advisory Committee, one of its many scientific advisory boards. The committee made the recommendation at its June 10, 2003, meeting, the transcripts of which shed considerable light on the committee's rationale for approving the drug's cosmetic use. The transcripts also provide a detailed insight into the workings of scientific advisory boards more generally.

At issue at this committee meeting was the application by Eli Lilly and Company to approve Humatrope, a popular hGH, for the treatment of ISS children. The Eli Lilly application was certainly not the first of its kind. The FDA often has been called upon to approve cosmetic treatments. Therapies to treat baldness, to eliminate wrinkles, to reduce weight, and to treat many other conditions can all be described as cosmetic treatments, or as treatments that can be prescribed for other-than-therapeutic indications. In all these cases, the FDA position has been quite clear: The agency, in evaluating applications, focuses exclusively on its twin statutory mandates of safety and efficacy – whether the drug (or medical device or biologic) in question was designed for therapeutic or cosmetic uses or both. It tends to exclude other considerations, such as whether a specific drug use may or may not be appropriate, acceptable, or desirable.

In the case of hGH, the FDA had no intention to take a different stance. From its point of view, the question of whether treating ISS children with hGH constitutes a cosmetic use was not part of the committee charges. At the same time, the FDA was well aware that the committee might have been tempted to deviate from the prescribed course. As noted by David Orloff, director of the Division of Metabolic and Endocrine Drug Products at the Center for Drug Evaluation and Research (CDER):

> […] I just want to raise one other issue that has not actually been raised here explicitly, but may be in the back of some people's minds, and in the minds of those perhaps listening from the audience. And that is, to some extent, it's kind of the flip side of the clinical significance question that's been asked and will be asked again, and that is whether the use of growth hormone in non-growth hormone deficient short stature represents "cosmetic" use of growth hormone, and […] might be construed somehow as setting a broad precedent for cosmetic use of drugs.
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> The first point I'd like to say is that any decision that's made with regard to growth hormone in this instance will be based upon a judgment of a favorable balance of risk versus benefit for the proposed indication, and that would not, in our minds, be setting a broad policy with regard, generally, to the use of drugs for cosmetic purposes.
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> I'd also propose that it is not the purpose of this meeting to debate the merits of approvals of other drugs for what some – usually those unaffected by the target condition – might construe as cosmetic purposes. And I think it's safe to say that we should concede that once demonstrated to be safe and effective, the choice of whether to attempt therapy for, for example, baldness, or mild acne, or even overweight is up to doctors, patients, and their families, as they weigh the potential benefits of the therapy against the potential risks.
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> And, I guess I said it before, but I'll just point it out one more time: that we don't see a regulatory stance favoring approval for the use of growth hormone putting this division or the agency on a

> slippery slope toward blanket uses of – cosmetic uses of – growth hormone, as well as for other drugs.[3]

As this quote demonstrates, the FDA tried very hard to avoid getting involved in what it probably regarded as a sterile controversy over its role in sanctioning the cosmetic use of hGH. In this, it largely succeeded. The Endocrinologic and Metabolic Drugs Advisory Committee, despite some hesitations, ultimately focused its attention on safety, efficacy, and what medical practitioners label "clinical significance." This is an interesting concept that refines and expands the meaning of effectiveness. A drug or a medical treatment may be effective, in the sense that it may produce the intended medical outcomes, yet it may not be "clinically significant" in the sense that it may be unable to cure the core concerns associated with a condition. In the present case, addressing clinical significance meant that the committee was called upon to determine (1) whether idiopathic shortness should be considered a condition, (2) in what sense this medical condition affects the health and well-being of ISS children, and (3) whether the treatment in question not only raises the final height of affected children but also contributes significantly to mitigating the associated psychological impairment and provides other benefits beyond merely height.

In their presentation to the committee, Eli Lilly and its advisers identified several possible benefits of treating short children with Humatrope, ranging from reaching the minimal height required by some jobs to being able to buy normal clothes and being able to sit at least 10 inches away from a steering wheel, as air bag safety regulations require. A senior Eli Lilly adviser offered considerable evidence about the negative psychological impact of short stature. His presentation was complemented by the testimony of short children describing in considerable detail patterns of bullying and teasing by their peers.

Despite Eli Lilly's considerable efforts to demonstrate not only efficacy but also clinical significance, a large fraction of the committee members was not convinced. Of nine commissioners, five expressed serious doubts about the benefits of hGH treatment, three were unconcerned, and one was agnostic. It is worth quoting some of the dissenting voices at some length:

> […] Just to summarize what was just said, I think that we've been shown that treatment with growth hormone can improve height, but that the effect is, I think, fairly small; on the average, about one-and-a-half inches; and that *there's been no demonstration of the impact of this on quality of life*.[4]

> I think the testimony we've heard, and probably from everybody's own experience, we know the *enormous hurt and pain of the stigma of extreme shortness*. And I think the kind of *changes we've seen here don't address that*. So I'm leaning on the side of thinking that we've heard that, clinically, this much change in height is not enough.[5]

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

[4] Commissioner Grady, Ibid., p.257 emphasis added.

[5] Commissioner Worcester, Ibid., p.267 emphasis added.

> […] I really think there should be *additional data on some type of benefit besides simply the height*. Now, I agree that if the height was dramatic – six inches – you probably wouldn't have to show anything else. But *because the height benefit is much smaller than that*, I am concerned that here is a very expensive treatment, in which the *benefits are not clearly shown*. [6]

Not every committee member subscribed to these views. The committee chair remarked:

> […] In regards to the clinical importance, I think this is the crux of the problem that many of us are having with this. Dr. Grady nicely brought out that there's no really good evidence that one-and-a-half inches or so is going to improve quality of life. I'm also concerned about the resource allocation issues, about who's going to pay for this, and the potential worsening of the drag on health care dollars over time. Nevertheless, I don't think that's really the charge of the committee. The charge of the committee is really to determine whether this is safe and efficacious, and clinically important. [7]

The committee chair went on to explain that in his view, clinical relevance is really a question that must be decided by parents and children in cooperation with their doctors. In other words, clinical relevance, in his view, is really a matter of informed consent. His take on this matter was predicated on the assumption that hGH treatment was indeed effective. This assumption was by no means shared by all committee members.

Several committee members noted that from a statistical standpoint, the treatment seemed moderately effective (with, on average, a gain in final height of one to one-and-a-half inches), but questioned whether such a modest gain would actually have any significant positive impact on the life and well-being of the children. This question was raised several times, but no convincing answer was provided. In addition, it was noted that, based on the data presented by Eli Lilly, individual participants in the clinical trials had responded very differently to the treatment, with some participants not responding at all and others responding very well. In other words, the treatment did not seem to have a sufficiently predictable impact on the final height of the participating children. The only critic invited to give a presentation at the meeting, an internationally renowned endocrinologist, pointed out that in the study presented by Eli Lilly, the final height reached by children in the control group (that is, in the group that had received a placebo) and the final height reached by the children who had received the treatment were in fact quite similar. (This problem is not confined to this particular type of hGH; other hGHs suffer from the same limitation.)[8]

In sum, the committee members seemed to disagree not only on what might constitute efficacy in a narrow technical sense (Is a one-and-a-half inch gain in final height sufficient to demonstrate efficacy?), but also on what the benefits of the treatment might be. These reservations notwithstanding, the committee recommended by an eight-to-two vote and with minimal qualifications that the FDA approve Humatrope for the treatment of ISS children as

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[6] Commissioner Schade, Ibid., p.263 emphasis added.

[7] Commissioner Brunstein, Ibid., p.258.

[8] Harvey J. Guyda, "Four Decades of Growth Hormone Therapy for Short Children: What Have We Achieved?," *The Journal of Clinical Endocrinology & Metabolism* 84, no. 12 (1999).

proposed by Eli Lilly – a rather surprising outcome given the discomfort demonstrated by many committee members, and one that warrants closer scrutiny.

2.3 Discussion

To what extent can the FDA's Endocrinologic and Metabolic Drugs Advisory Committee be regarded as a viable model for untangling future ethical dilemmas? In its present form, this committee is clearly in no position to tackle broader ethical dilemmas, as illustrated by the distinction between therapeutic and enhancing uses of hGHs. The FDA is characterized by an organizational culture centered mostly on safety and efficacy. Tackling broader ethical dilemmas would be not only on dubious statutory ground and outside of FDA's core competencies; it would also not be part of the committee's charge as established in its charter.[9] Thus, it would be unfair to criticize existing regulatory structures for failing to address ethical questions that they were not intended to answer in this first place. The committee recommendation and the FDA decision to approve the cosmetic use of hGH must be evaluated on their own terms.

At first, it is tempting to conclude that the FDA's decision was sound. The FDA has made the hGH treatment available to very short children – children at least 2.25 standard deviations below the average height for their sex and age. Eli Lilly estimates that in the United States there are approximately 400,000 of such children. The agency came to its conclusion after what appears to be a thorough examination of the safety, efficacy, and clinical significance of the proposed treatment. It also emphasized that its decision was not to be interpreted as a general expression of support for cosmetic treatments. In this sense, the FDA decision-making process does not seem to raise any major concerns.

A closer examination of the transcripts suggests a different conclusion. Concerns about clinical significance notwithstanding, the committee members failed to adequately examine perhaps the most important aspect of clinical significance – the empirical evidence concerning the negative impact of short stature on the well-being of ISS children (and short children in general). Remember that the rationale behind Eli Lilly's application was based precisely on the assumption that short stature has an empirically demonstrable and systematic negative impact on children. As mentioned earlier, one of Eli Lilly's consultants spent considerable time making this case, and the committee members seemed generally to accept the presentation's main conclusion. In the eyes of most committee members, and indeed most people confronted with this issue, preventing suffering and long-term psychological harm to short children would be a very strong rationale for supporting the proposed treatment. But the evidence presented by Eli Lilly was vigorously disputed by an internationally renowned endocrinologist invited to the meeting by the

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[9] The committee charter establishes that it is the committee's responsibility to "[…] review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders, and make appropriate recommendations to the Commissioner of Food and Drugs." The complete Charter text is available at http://www.fda.gov/cder/audiences/acspage/Endocrinologiccharter1.htm.

FDA. The expert in question pointed to numerous recent studies showing that short stature in children may be a source of distress but has minimal or no lasting negative effect on their well-being. Yet the subsequent discussion as documented in the transcripts suggests that the expert's opinion did not affect the commissioners' thinking in the least. Nor did any commissioner actually challenge Eli Lilly's core assumption that shortness causes significant psychological harm.

Our own review of the literature also casts considerable doubt on the view that shortness causes lasting psychological harm.[10] As with many scientific and medical controversies, the conclusion that short stature does not cause psychological harm is hardly unassailable. However, it is difficult to ignore two simple facts. First, studies showing psychological harm are generally very old. More recent empirical data and more sophisticated research designs do not support the early conclusions. Second, the majority of the studies reviewed do not show harm. Against this background, the committee's failure to explore more thoroughly the alleged negative psychological impact of short statute on children deserves further scrutiny.

There are two main reasons for this myopic behavior. Both of them suggest important lessons. For one thing, numerous psychological studies have demonstrated that for a dissenting view to be heard, it must have roughly equal weight as other views. In the case of the committee meeting on Humatrope, this requirement clearly was not met. As the frustrated dissenter observed, he was the only critical voice amidst an army of industry representatives, their advisers, and supporting families. Under these circumstances, a dissenting voice will simply be ignored, while the dominant view will be reinforced. This phenomenon is known as group polarization, and it is well documented.[11]

Committee composition is the second factor affecting the likelihood that dissenting views will be heard. The Endocrinologic and Metabolic Drugs Advisory Committee consists of ten members and an executive secretary. Of the ten committee members at the time of the debate on Humatrope, eight represented one branch of endocrinology or another. All of them were university professors, and some of them department chairs. One was a biostatistician, one an epidemiologist, and one – the "consumer representative" (a term meant to identify with a broader lay audience) – was a specialist in women's health. Certainly this was a very distinguished and knowledgeable panel, but their respective medical backgrounds hardly prepared them to question psychological or sociological stereotypes. The presence of a single consumer representative on the committee – the only dissenting voice – had no discernible impact on the committee at large, as predicted by the literature on committee behavior. This is an excellent example of group polarization: The homogeneous nature of the Endocrinologic and Metabolic Drugs Advisory

[10] See Appendix B for details.

[11] See chapter 9.12.1 for an in-depth discussion.

Committee tended, predictably, to reinforce widely held beliefs and marginalize dissenting views.[12]

Group polarization is a common phenomenon in small deliberative bodies, and it is probably responsible for many ill-informed administrative decisions. Its pernicious influence is not limited to small groups, however, as we show throughout this report. Legislators, trade and professional groups, and scientific societies, among others, are not immune to this phenomenon. Fortunately, it appears that in many cases it is relatively easy to reverse group polarization. To this end, small group decision-making bodies must be chartered so as to ensure that all relevant views are represented in roughly equal proportions – a straightforward but often neglected consideration.

The preceding discussion suggests that the current system of scientific advisories, as exemplified by the Endocrinologic and Metabolic Drugs Advisory Committee, is unable to cope with broader ethical dilemmas (a task it was never intended to perform.) It also shows serious limitations in discharging its public mandate. Advocates of the status quo may point out that to ensure balance, the federal government only needs to make sure that the provisions of the Federal Advisory Committee Act of 1972 (FACA) are properly implemented. FACA governs the establishment and operation of all federal advisory committees, including FDA scientific advisory committees.[13] FACA is an example of a good governance law; it was passed mainly to mitigate the excessive influence of organized interest groups. Among other things, FACA requires the convening agency to appoint members to an advisory committee so as to ensure that the committee be "balanced" – in other words, that a broad range of views is represented on the committee.[14]

Can the Endocrinologic and Metabolic Drugs Advisory Committee be considered balanced? The committee charter calls for appointing members with proven expertise in endocrinology, epidemiology, or statistics, and for including a consumer advocate with recognized technical expertise. Given the committee's charge, this composition seems indeed quite reasonable. Nor is there any *prima facie* reason to assume that this committee violates any key FACA provisions. On the other hand, it is difficult to believe that a committee balanced in any strong sense of the term is prone to group polarization. On closer examination, the committee charter and FACA provisions for balanced composition may turn out to be in conflict, but the courts have generally refrained from providing specific guidance on how to ensure balance.[15] As a result, administrative agencies traditionally have had considerable latitude in the interpretation of this provision, latitude that administrations of both parties have routinely exploited for their own narrow political goals.

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[12] Ironically, and perhaps surprisingly, deliberation among committee members in this case did not produce depolarization, but rather the opposite.

[13] See http://www.fda.gov/cder/audiences/acspage/Endocrinologiccharter1.htm.

[14] See Public Law 92-463, Sec. 5(b)(2).

[15] Steven P. Croley and William F. Funk, "The Federal Advisory Committee Act and Good Governance," *Yale Journal on Regulation* 14 (1997).

2.4 Broadening the Ethical Debate

As it stands, the Endocrinologic and Metabolic Drugs Advisory Committee could be described as a decision-making body that is likely to routinely recast ethical dilemmas in narrow medical terms. It is also likely to reduce eminently public choices to private decisions. The heavy reliance on science advisory boards, the skewed composition of these boards, the limited pool of ethical arguments presented to these panels, and their inadequate statutory authority all contribute to this outcome.

Some commentators may argue that that the Public Health Service Act and the Food, Drug, and Cosmetics Act afford the FDA much more regulatory discretion than suggested by current FDA regulatory practices. In particular, under some legal theories, the FDA would be able to include considerations other than safety and efficacy in its approval process. We are in no position to evaluate the merits of this claim, but even if it could be demonstrated that the FDA would have to statutory authority to inject ethical considerations into its decision-making process, the agency is very unlikely to do so. The FDA does not consider regulatory demands other than those pertaining to safety and efficacy as part if its core mission. In the agency's view, these demands represent a regulatory distraction, a misallocation of scarce administrative resources that drag the agency into legal battles with uncertain outcomes. Importantly, the agency's organizational culture and its professional expertise, both of which have developed around safety and efficacy, make the FDA ill-suited to address broad ethical dilemmas.

But what are the ethical dilemmas neglected by the Endocrinologic and Metabolic Advisory Committee? In the remainder of this chapter, we touch upon some of the arguments that in our view have not received sufficient attention. Some have argued that severe hGH deficiency is a physiological impairment that deserves close medical attention, whereas idiopathic short stature is not at all a medical condition.[16] Children can be unhappy about many things; they may not like their noses, for example, but should we be in the business of prescribing nose jobs? In this view, children suffering from severe hGH deficiency and ISS children do not really represent commensurable cases. By prescribing hGH treatment for idiopathic shortness, are we not simply indulging profoundly human but nevertheless unjustifiable parental desires? Should health insurance plans (that is to say, the public) be required to cover the costs of hGH treatment for an adolescent who is desperate to follow in his father's footsteps and embrace a basketball career? At the other extreme, if there is no solid evidence of ubiquitous and systematic harm to short children, why should the state encourage the misallocation of scarce financial resources?

These arguments have been made often and do not require further discussion. By contrast, one question that should have received considerable attention but has barely been acknowledged is what may be called the medicalization of societal problems. Dr. Nancy Worcester, the consumer representative on the Endocrinologic and Metabolic Advisory Committee, was the only commissioner who touched upon this concern, although only marginally so. Not

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[16] Peter H. Schwartz, "Genetic Breakthroughs and the Limits of Medicine: Short Stature, Growth Hormone, and the Idea of Dysfunction," *St. Thomas Law Review* 13 (2001).

coincidentally, she was also one of only two commissioners who voted against the Eli Lilly application.[17] In our view, this concern lies at the heart of many contemporary controversies over new reproductive technologies and biomedical research, and it is worth exploring in some depth.

In its most general form, the argument goes like this: New scientific and medical developments have a differential impact on society. Some technologies tend to reinforce pre-existing, widespread beliefs and cultural orientations; they resonate with the public and as a result they are quickly embraced. Others may actually be incompatible with widely shared cultural values. This means that the latter may be at a disadvantage compared to other technologies more in tune with domestic traditions, values, and orientations. New technologies, in other words, do not fall on a culturally neutral ground; powerful, pre-existing habits of the heart and mind tend to nurture some and reject others.[18]

Applied to the case of human growth hormone, this argument suggests that the tendency to describe idiopathic shortness as a condition deserving medical attention is informed in large measure by at least three deeply entrenched American values: (10 the unshakable belief in the power of technology to solve even the most intractable problems, including political and social ones; (2) a strong sense of individual responsibility and self-reliance; and (3) a deep-seated distrust of government.[19] The obsession with restoring physical height through medication rather than by focusing on the political means to fight intolerance for physical differences is but one example of a pervasive tendency in the contemporary United States to redefine social problems as technological challenges, and to rely on private initiative rather than on political action. It is not too difficult, then, to predict the impact that hGH availability would have on parents with ISS children; it would reinforce a view of short stature as a medical condition rather than as a manifestation (albeit a mild one) of intolerance, to be cured by medical means rather than addressed by PTAs, school districts, and local governments.

The use of synthetic hGH to treat shortness is only the latest example of the medicalization of societal problems. Supposedly miraculous cures peddled as means to solve social and political problems have a long history. In the 1930s, for example, an entrepreneur made a fortune for himself by selling an ointment to African-Americans that promised – correctly as it turned out, at least for a limited period of time – to "whiten" their skin.[20] One could easily imagine a cosmetic product that, unlike its predecessor, has a permanent whitening effect; should this treatment receive FDA blessing only because it is both safe and effective? Wouldn't many of us, and not only African-Americans, reject the notion that racial discrimination should be fought by medication rather than by political means?

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[17] Center for Drug Evaluation and Research, "Endocrinologic and Metabolic Drugs Advisory Committee Meeting," p.322.

[18] Langdon Winner, "Technology Today: Utopia or Dystopia?," *Social Research* 64, no. 3 (1997).

[19] Seymour Martin Lipset, *American Exceptionalism: A Double-Edged Sword* (New York: W.W. Norton & Company, 1996).

[20] Carl Elliott, *Better Than Well: American Medicine Meets the American Dream* (New York: W.W. Norton & Company, 2003), p.191-93.

Whether the broad availability of synthetic hGH will erode our tolerance for physical differences and perhaps, over time, also undermine now widely shared notions of tolerance remains to be seen, but this would certainly be a price too high to pay. The incessant drive toward physical perfection, as illustrated by the staggering sums of money spent every year on cosmetics and plastic surgery, is a reminder that in contemporary America, certain forms of intolerance have already achieved the status of national obsession. The popularity of anti-depressants, on the other end, seems to suggest not merely that many Americans are unable to cope with the difficulties of modern life, but that the pressure to live up to certain supposedly widespread notions of success and "the good life" has become consuming.[21]

The case of the synthetic hGH strongly suggests that existing regulatory institutions are simply inadequate to address the challenges raised by new reproductive treatments and biomedical research. In Homer's *Odyssey,* Achilles resisted the suave but deadly chants of the Sirens by ordering his crew to bind him to the mast of his boat. Like modern argonauts, we may soon be exposed to the chants of medical and scientific Sirens we may be too weak to resist. Achilles' response to the Sirens' threatening chants is an acknowledgment both of human frailty and ingenuity. Modern societies have developed elaborate ways to resist temptation. Mindful of our weakness, we often delegate to regulatory agencies the task of protecting us against our self-destructive inclinations.[22] New reproductive treatments and medical technologies are only the latest illustration of a technological and scientific development that perhaps we are too weak to control. It is certainly not too late to take measures that will protect us against ourselves, but to do so, contemporary debates about new reproductive and medical technologies must be moved decidedly into the public realm. This report is a contribution to this debate.

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[21] Peter D. Kramer, *Listening to Prozac: The Landmark Book About Antidepressants and the Remaking of the Self* (New York: Penguin Books, 1997).

[22] Modern commentators speak of second-order preferences, i.e., preferences about preferences. For example, a drinking habit may be described as a first-order preference, and regulations against drinking as an example of a second-order preference. For a discussion, see Cass Sunstein and Edna Ullmann-Margalit, "Second-Order Decisions," *Ethics* 110 (1999).

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