

Introduction

Biotechnology now makes it possible to enhance human traits as well as treat illnesses and disorders. What it has neglected to establish, however, is a clear line between these two functions, a distinction between what counts as treatment or therapy and what counts as enhancement. The bulk of the literature on enhancements focuses on the ethics of enhancements, not on the criteria that qualify a procedure as an enhancement (President's Council on Bioethics 2003). While the ethical questions regarding the desirability of enhancements are certainly worthy of consideration, so is the issue of what constitutes an enhancement versus a form of treatment or therapy. Scholars have debated the issue of whether a distinction between therapy and enhancement exists, but the placement of that distinction has not yet been sufficiently addressed (Sandel 2004, 5; Kamm 2005, 5; Schwartz 2005, 17). Much like the field of bioethics itself, my study of this issue is a work in progress, so this paper will ask and explore questions relevant to this topic without providing answers to all of them. Nonetheless, they are important questions to ask with important implications for the future of bioethics.

This paper will describe the line between enhancement and therapy, map the terrain and define the terms. It will also investigate where the line is at present, and where and how it has been set by legislation and private companies. It will then illustrate the issues, using two examples, to demonstrate the difficulties and complexities involved. Finally, it will explore the implications of the line for society's financial as well as physical interests, and for healthcare access in the United States. It will conclude by considering the open question of how a company, a government, and a just society should go about setting the line. I hope that asking the questions and exploring their complexities will help draw attention to and prompt serious consideration of the placement of the line between therapy and enhancement.

Defining the Issue: The Existence and Importance of the Line

Some scholars maintain that there is no valid difference between enhancement and therapy (Kamm 2005, 5). Other scholars and I disagree (Sandel 2004; Schwartz 2005). This seemingly abstract concept has concrete and immediate consequences. Scientists may not recognize this line, but insurance companies do. They pay for some procedures. They do not pay for others. Governments discriminate as well: they use Medicare and Medicaid dollars to pay for some procedures and not others. These entities are making a distinction, drawing a line. Its placement may be arbitrary, but that does not mean that no one is making it. Thus, while some scholars may find the line between therapy and enhancement elusive or even illusory, the practice of medical care in the United States has created a *de facto* line that is very real. One might wonder why this question is worth debating, why it matters where the line is set. In answer to that, one commentator writes,

[t]he line that it draws is the boundary of medical obligation. . . . This interpretation has important implications for social policymaking about health care coverage to the extent that society relies on medicine's sense of the medically necessary to define the limits of its obligations to underwrite care. (Jeungst 1998, 44.)

Thus, the line defines society's perception of the scope of legitimate medicine.

Another aspect of the line's importance is its role in determining what society views as "normal" and consequently what it expects of a health care system. The distinction has effects beyond individuals to society in general, in economic costs as well as in public health and public perceptions of medicalization. With this much influence over payment and access to health care, the perceived scope of the medical profession, and issues of distributive justice, the placement of the line between treatment and enhancement is well worth considering, debating, and deliberately determining.

Mapping the Terrain

A meaningful examination of this topic must include a clarification of the terms involved. I shall use the terms "treatment" and "therapy" interchangeably to mean any substance, procedure, or other intervention required to correct a disorder or restore a patient to health. This raises the questions of what qualifies as a disorder or disease, and what constitutes health. It would be overinclusive to call anything that inhibits one's functioning a disorder, but underinclusive to count only ailments that have been recognized as such for centuries. For the purpose of this paper, I will define a "disorder" as a condition in which the patient's ability to function is well below that of a typical person.

The concept of what restores a patient to health necessarily entails a definition of "health". The Compact Oxford English Dictionary defines "health" as "1) the state of being free from illness or injury; or 2) a person's mental or physical condition" (compact OED website). The World Health Organization offers a considerably more thorough definition of "health": "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (World Health Organization website). I will use the term "health" to mean the absence of injury, dysfunction, disease, or disorder (Schwartz 2005, 17).

Defining "disorder" and "health" requires one to set the parameters of what the concept of "normal" includes. Determining these boundaries is difficult and uncertain. Standards of "normality" often refer to averages, but technologies to alter the average have become more advanced and more widely available. Still, for purposes of delineating the difference between therapy and enhancement, I think setting a range around the average is the best proxy available.

I combine elements of these definitions to define "enhancement" as a procedure or intervention that aims to improve a person's physical or mental health, beyond the level of functioning that is typical or normal,

in the absence of injury, dysfunction, disease, or disorder, that is, in a healthy person. Though I realize these definitions are not incontestable, they shall be the meanings of the terms in this paper.

Locating the Line Between Enhancement and Therapy

Based on the definitions outlined above, or similar versions of them, the line between therapy and enhancement is the line where medical necessity stops and optional or elective procedures begin. But who decides what is medically necessary and how do they define it? I will now explore several definitions.

Medically Necessary. In the United States, medical necessity is a matter of state law, so governmental definitions of medical necessity will vary. The Commonwealth of Massachusetts, in which I live, quite helpfully provides not one but two definitions. According to Massachusetts legislation,

- A service is medically necessary if it satisfies two conditions: 1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or aggravate a handicap, or result in illness or infirmity; and 2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to [MassHealth] (*130 Code of Massachusetts Regulations § 450.204(A)*).
- Medical Necessity or Medically Necessary means health care services that are consistent with generally accepted principles of professional medical practice as determined by whether the service:
 - (1) is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
 - (2) is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or
 - (3) for services and interventions not in widespread use, is based on scientific evidence. (*105 Code of Massachusetts Regulations § 128.020.*)

Several large private health insurance companies also assess claims based on medical necessity, and some offer definitions of medical necessity and of their coverage with varying degrees of specificity. The following is a partial list.

- Aetna’s glossary of health care terms defines medically necessary procedures as

[s]ervices or supplies that are appropriate and consistent with the diagnosis in accordance with accepted medical standards as described in the Covered Benefits section of the plan documents. “Medical Necessity,” when used in relation to services, shall have the same meaning as “Medically Necessary Services.” This definition applies only to the determination by the Plan of whether health care services are covered benefits under the plan (Aetna website a).
- Kaiser Permanente’s website provides more concrete examples. “As a general rule, members are covered for medically necessary care including routine medical office visits, health assessments, immunizations, Pap tests, mammograms, and well-child checkups. Coverage also includes necessary laboratory and radiology testing, hospitalization, and surgery.” (Kaiser Permanente website a)
- BlueCross/BlueShield (at least in Massachusetts) begins with the expansive statement that, “Our plans are just as unique as your health care needs. We offer a variety of plan designs that offer access to a wide network of doctors and hospitals dedicated to providing high-quality, affordable

health care.”(BlueCross/BlueShield of Massachusetts website) It then follows that by providing more specific details based on whether one has an HMO, PPO, or a POS.

- Cigna’s description declares, “[c]overage Positions are only one of the tools used when a decision is needed regarding whether a particular medical service is covered for a particular member. (Cigna website)

Enhancement. One could also locate the line by examining what these governments and insurance companies say about enhancement. As far as I could find, neither federal law nor Massachusetts law defines “enhancement” in this sense. Only one insurance company uses the term “enhancement.” One of its policies, for example, is that “Aetna considers androgens and anabolic steroids for performance enhancement *not* medically necessary” (Aetna website b). Interestingly, while the insurance companies are straining to restrict procedures to what is medically necessary, the pharmaceutical company Pfizer seems to be promoting enhancement wholeheartedly. It announces, “We dedicate ourselves to humanity’s quest for longer, healthier, happier lives through innovation in pharmaceutical, consumer and animal health products” (Pfizer, Inc. website).

Disability. Another way to find the line, to approach the question of what constitutes disease or dysfunction and who truly requires medical attention, is to turn to the topic of disability. The current, operational legal definition of “disability” in the Americans With Disabilities Act of 1990 (ADA) focuses on impairment that limits major life activities (42 U.S.C. 12102(2) (1994)). The Massachusetts General Laws include a clause about dependency on others for daily needs (5 Mass. Gen. Laws Annotated 19C §1).

All of these policies, governmental and corporate, help determine where the line is placed by articulating a range of views of what is medically necessary and limiting them based on what similar entities say of enhancements and disability. This still does not pinpoint the location of the line, for there are many lines, but they are clustered in the same general area. Thus, we are left with a definite, but somewhat fuzzy, collection of lines, located beyond disability, right at the line of medical necessity, but not further.

If setting the line is left to governments, there will likely be much debate about where it should be, as governments have responsibilities to their citizens but also limited resources. If the question is left to private companies, it will largely depend on whether it is insurance companies or pharmaceutical companies drawing the line, as each has economic incentives to push the line one way or the other. Regardless of what happens in the future, the present situation links the line to the contested concept of medical necessity, beyond disability but before enhancement.

Examples

I next offer two examples of medical issues that demonstrate the difficulty of setting the line between treatment and therapy and why this is an issue with such enormous impact. The two will include one for physical health: chronic pain; and one for mental health: depression. They make good test-cases for several reasons. Both conditions exist along a spectrum of severity and a scale that is subjective for each patient. Both also depend on the patient’s self-description. Finally, examining the characterization of these two disorders is important and representative because both are quite prevalent in American society.

Chronic pain. I begin with chronic pain. At what point on the spectrum of a person’s pain does it become a disease or disorder? Presumably somewhere between the occasional headache and daily migraines. A recent series on NBC Nightly News on “The Mystery of Pain” reported that “many medical experts call it the country’s No. 1 public health problem: chronic, debilitating pain” (Bazell 2005). Pain, the fifth vital sign, “is not just a symptom, but a disease” in itself (Koman 2005, 48, 50). Chronic pain occurs when the “pain message system goes awry ...” (Id. at 46) and “[p]ain signals keep firing in the nervous system for

weeks, months, even years”(National Institute of Neurological Disorders and Stroke website). The result can have dire consequences. “Untreated pain has significant impact on the pain sufferer and [his or her] family”(American Academy of Pain website). The insurance company Kaiser Permanente recognizes that,

[c]hronic pain – the kind that is almost always with you or that happens frequently – can take its toll on your health, sense of well-being, relationships with family and friends, and ability to work. (Kaiser Permanente website b.)

Unfortunately, many patients recount tales of insurance companies’ refusal to cover expensive pain treatments (Koman 2005, 50).

This case provides interesting insight into the subjectivity, individual and cultural, of interpreting whether a specific disorder requires treatment or therapy, or whether treating it would simply be enhancement. On an individual level, chronic pain is inherently subjective as “the unique characteristics of each individual impact [his or her] experience of pain” (American Academy of Pain Management website). This makes it extremely difficult to determine where the line should be for chronic pain; what might be a necessary treatment for one person might be an enhancement for another.

On a much broader level,

people in much of the nonindustrialized world believe that pain is an inherent component of living and endure it in silence. . . . In the United States, however, people tend to equate personal freedom and the pursuit of happiness with a guaranteed freedom from pain. (Koman 2005, 51.)

Even within the U.S., people have very different expectations of how much pain one should have to suffer.

The *Pain in America: A Research Report* done in 2000 found that four out of five Americans believe that pain is a part of getting older, and approximately sixty-four percent would see a doctor only if their pain became unbearable. Sixty percent of the respondents said that pain was just something that you have to live with. (American Academy of Pain Management website.)

Given this subjectivity, self-reporting, and variation in the level of expectation of pain, it would be especially difficult to find a single point on the treatment-enhancement spectrum where chronic pain belongs.

Depression. The second example, depression, is equally hard, for it too has a spectrum of its own. A particularly difficult question in this case is baseline: what level of mood is considered “normal” such that its negative elements do not require treatment? And what level of mood is bad enough that remedying it with even the most powerful treatments and medicines could not be considered enhancement? “Clinical depression is more than just the ‘blues,’ being ‘down in the dumps,’ or experiencing temporary feelings of sadness we all have from time to time” (National Institutes of Health website a). “It takes more than just tearfulness or a feeling of sadness on the part of the client to indicate the presence of depression” (National Institutes of Health website b). It makes it easier for insurance companies to require a diagnosis from a mental health professional in order to recognize the patient’s illness as a disorder. Despite the ease of this procedure, however, the theoretical questions remain for the mental health professionals: “[h]ow happy were we, in fact, designed to be?” (Wolpe 2002, 390). How depressed does one’s mood have to be and how much loss of interest does the patient have to have in order for it to count as depression?

Remedies bring questions of their own. One commentator asks,

If Prozac can lift everyone’s mood, what then becomes “normal” or “typical” affect, and will grouchiness or sadness or inner struggle then be pathologized? And if we can all be happy and

well-adjusted through Prozac, should insurance pay for everyone to reach that state of bliss?
(Wolpe 2002, 388.)

Thus, both chronic pain and depression provide examples of how difficult it is to find where therapy ends and enhancement begins.

V. Implications for Health Care Access and Societal Costs

In addition to the perception of legitimacy and scope of medicine issues, the main implication that answering the therapy-enhancement question has is financial. Determining on which side of the therapy-enhancement line a service, procedure, or medicine falls determines who, if anyone, will pay for it. Imagine I go to my doctor, who gives me a prescription for a medicine. If I am lucky enough to have insurance and the insurance company agrees that the medicine is therapeutic, then the insurance will pay for it. If, however, I am one of the 45.8 million people without insurance in America, I will have to come up with the money myself or forego the treatment (U.S. Census Bureau 2005). The situation becomes even more complicated if, though I think the medicine is a treatment, the insurance company decides that it is an enhancement and therefore will not pay for it. Then, having insurance will not help me. If I am lucky enough to be able to afford the medicine on my own, then I get it, but I have to pay for it out-of-pocket. And if I am not lucky enough to be able to afford it, whether I am insured or not, I simply do not get my medicine.

Therefore, the outcome of therapy-enhancement decisions determines who pays, and thus who has access to certain medicines and services. This impact is especially powerful given, for instance, the prevalence of the two examples discussed earlier. An “estimated 50 million Americans live with chronic pain caused by disease, disorder, or accident” (American Academy of Pain Management website). In addition to the physical cost, the financial cost to society is significant:

The loss of productivity and daily activity due to pain is substantial. In a study done in 2000 it was reported that 36 million Americans missed work in the previous year due to pain and that 83 million indicated that pain affected their participation in various activities. (Id.)

When the issue is depression, the effect is even more substantial. Depression affects 19 million Americans each year (National Institutes of Health website a) and it is the “leading cause of disability in the United States”(National Institutes of Health website c). Put simply, “[u]ntreated depression is costly” (National Institute of Mental Health website). “Depression exacts an economic cost of over \$30 billion each year. . . .” (National Institutes of Health website a). It “counts for close to \$12 billion in lost work days each year,” and more than \$11 billion in other costs from decreased productivity (National Institutes of Mental Health website). Thus, the number of patients and the costs they incur multiply; and, in a society that does not acknowledge health care as a right and that has a large gap between people who can afford to pay anyway and people who cannot, those costs make the difference between access to health care and none. Especially for those with no medical insurance, but also for those with insurance who cannot afford to pay out-of-pocket, the access that is granted or denied based on whether a procedure is deemed a treatment or an enhancement is crucial. What began as an abstract thought exercise about how to divide some services from others becomes a million-, perhaps billion-, dollar financial question, and potentially a matter of life and death.

Conclusion

In conclusion, I would like to pose some open questions and offer a few ideas about how a society, government, or company should go about setting the line between treatment and enhancement. “What standards of ‘medical care’ do we use when we desire to distribute medical care fairly and equitably in

society?” (Wolpe 2002). “What’s need? What’s want? What are people’s rights? What can we afford to pay?” (Finley 2000, 847). One final issue is how to address the subjectivity issue. Where on the spectrum the line between treatment and enhancement falls might vary from person to person, and health care as a whole will have to figure out a way to assign each person the right spot.

But even if we had answers to some of these complex questions, other problems would remain. On the topic of access to medical care, society, government, and private industry must perform a balancing act. That is not to say balancing between quantity and quality, but quantity and quantity. The fewer people, the more services the government or company can provide; but the fewer services they provide, the more people they can serve. As long as there is nearly infinite need and limited resources, society will need to establish and preserve this balance somehow.

The treatment-enhancement model has flaws, including how to categorize preventive care, the ease of inventing new maladies, and a vulnerability to overmedicalization. With regard to all of these challenges, though, I still maintain that the therapy-versus-enhancement model is the best approximation for distinguishing what is included in society’s definition of health care and what should be included in financial health care coverage, public and private. Erik Parens writes,

Like many distinctions, the treatment/enhancement distinction is permeable, unstable, and can be used for pernicious purposes. If used carefully, however, it can be one tool to start important conversations about the sorts of health care services that a just system of health care should provide. (Parens 1998, S13.)

This issue is incredibly important and I hope this paper will function as just such a tool.

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