## RISK AND DISEASE

PETER H. SCHWARTZ

**ABSTRACT** The way that diseases such as high blood pressure (hypertension), high cholesterol, and diabetes are defined is closely tied to ideas about modifiable risk. In particular, the threshold for diagnosing each of these conditions is set at the level where future risk of disease can be reduced by lowering the relevant parameter (of blood pressure, low-density lipoprotein, or blood glucose, respectively). In this article, I make the case that these criteria, and those for diagnosing and treating other "risk-based diseases," reflect an unfortunate trend towards reclassifying risk as disease. I closely examine stage 1 hypertension and high cholesterol and argue that many patients diagnosed with these "diseases" do not actually have a pathological condition. In addition, though, I argue that the fact that they are risk factors, rather than diseases, does not diminish the importance of treating them, since there is good evidence that such treatment can reduce morbidity and mortality. For both philosophical and ethical reasons, however, the conditions should not be labeled as pathological. The tendency to reclassify risk factors as diseases is an important trend to examine and critique.

Some of the most common "diseases" of modern medicine—including hypertension, high cholesterol, and diabetes—are defined based on risk. Take hypertension, for example. A blood pressure is defined as "elevated" if there is evidence that lowering it will reduce cardiovascular risk. The existence of modifiable risk is similarly central to the definition of high cholesterol and diabetes, in those cases for the parameters of low-density lipoprotein (LDL) and blood glucose, respectively. Symptoms are secondary: many patients who have hypertension, high

Indiana University Center for Bioethics, Indiana University School of Medicine, 410 W. 10th Street, Suite 3100, Indianapolis, IN 46202.

E-mail: phschwar@iupui.edu.

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cholesterol, or mild diabetes are asymptomatic. The presence of risk that can be lowered is the key reason many patients are defined as having these diseases.

This focus on risk developed during the second half of the 20th century due to multiple factors, ranging from advances in epidemiological science to the economic interests and marketing practices of pharmaceutical companies (Greene 2007). But defining modifiable risk as pathology also raises important conceptual and ethical issues. The central question is whether these "risk-based diseases" (as I shall call them) are really pathological. In this paper, I claim that they are not. Focusing on stage 1 hypertension and high cholesterol, I argue that most patients diagnosed with these disorders have only a risk factor for future disease, not a current pathological condition.

First, I describe the guidelines for diagnosing and treating high blood pressure and high cholesterol and review the evolution of these criteria. I then describe definitions of the concept of "disease" and argue that neither stage 1 hypertension nor high cholesterol fits the best ones. I claim that this conclusion does not weaken the importance of diagnosing and treating such conditions, relying on Norman Daniels's (1985, 2000) model of health-care justice. I conclude by exploring how labeling stage 1 hypertension and high cholesterol as pathological creates ethical problems by veiling the complex risk/benefit judgments that are part of a fully informed decision to treat them.

# TWO RISK-BASED DISEASES: HYPERTENSION AND HIGH CHOLESTEROL

For both stage 1 hypertension and high cholesterol, the levels that count as deserving medical attention are those for which there is evidence that treatment can reduce the risk of future cardiovascular disease. To focus the discussion, I shall discuss use an imaginary patient named MH, a 60-year-old woman who is otherwise healthy and taking no medications, but who has a blood pressure of 150/80 mm Hg and an LDL level of 140 mg/dL.

## Hypertension

Because of her systolic blood pressure of 150 mm Hg, MH has hypertension, specifically stage 1 hypertension, diagnosed for patients with a systolic blood pressure of 140–159 mm Hg or a diastolic blood pressure 90–99 mm Hg (JNC 2003, referred to hereafter as JNC 7). If modifications in diet and exercise cannot reduce the blood pressure, then pharmacological treatment is indicated. Symptoms are not the issue, since most patients with stage 1 hypertension are asymptomatic. In addition, these patients usually have no identifiable pathological changes in the systems that regulate blood pressure. What matters is that for

<sup>&</sup>lt;sup>1</sup>In keeping with the practice of other writers in this area, I shall treat the terms *disease* and *pathological condition* as roughly equivalent.

patients with blood pressure in this range, there is good evidence that using available medications to lower the blood pressure also reduces cardiovascular risk. As the guidelines state: "The ultimate public health goal of antihypertensive therapy is to reduce cardiovascular and renal morbidity and mortality" (p. 25).

Admittedly, patients with more severe hypertension, such as those with stage 2 hypertension (blood pressure  $\geq 160/100$  mm Hg), may have significant symptoms, such as headache and visual changes. At particularly elevated blood pressures, urgent hypertension occurs, where there is evidence of damage to the eyes or kidneys. For these levels of hypertension, treatment may be justified partly based on symptoms and demonstrable pathology, but this does not apply in general for stage 1 hypertension, or even for many patients with stage 2 hypertension.

The current guidelines reflect a transformation in ideas about hypertension that occurred during the second half of the 20th century, as the condition evolved from one defined in terms of symptoms and clear pathological signs to one defined in terms of risk. For example, as Jeremy Greene (2007) points out, when Franklin Delano Roosevelt had blood pressures of 260/150 mm Hg in the early 1940s, no treatment was indicated or initiated, partly due to the absence of any specific symptoms (p. 7). This changed in the 1950s and 1960s, as hypertension was redefined as a condition that could be asymptomatic—the "silent killer"—and diagnostic guidelines were formulated based on specific bloodpressure levels. Multiple factors played a role in this transformation, including the advent of epidemiological research that identified risk factors for cardiovascular disease (most importantly the Framingham study), the use of actuarial tables by life insurance companies, and the economic interests of pharmaceutical companies. This last factor played a particularly large role, especially through marketing practices that have had wide-ranging effects on medical research and practice (Greene 2007).

Over this period, the definition of hypertension has continually expanded. For instance, guidelines released in 1984 reduced the diastolic cutoff from 95 mm Hg to 90 mm Hg (JNC 1984). At this point, systolic blood pressures of 140–159 mm Hg were still considered "borderline" in patients with normal diastolic pressure and no other risk factors, and physicians could choose not to treat. Less than 10 years later, new guidelines recommended treatment for all such patients, thus resulting in the criteria that determine that the patient MH counts as having a condition that should be treated.

Since the guidelines are determined by evidence about modifiable risk, there is no limit to how many people in society can be counted as having this disease. Although MH has hypertension, her blood pressure is also near the median for women her age (JNC 7). In fact, due to the typical slow increase of blood pressure with aging, more than 90% of Americans living to 85 years old will develop hypertension, according to current guidelines (JNC 7). Again, what matters is not the specific level of an individual's blood pressure and/or cardiovascular risk, but that the risk can be reduced with available and safe medical treatment.

## Hypercholesterolemia

MH also qualifies as having high cholesterol by current criteria (NCEP 2002, referred to hereafter as ATP III). According to these guidelines, the cutoff for specific patients depends on the number of other risk factors they have for coronary heart disease (CHD), such as age, smoking, or hypertension). In patients with zero or one risk factors, the cutoff for diagnosis and treatment is an LDL level of 160 mg/dL; for patients with more than two risk factors, it's 130 mg/dL (ATP III). For patients with CHD, or with a particularly high risk of developing it (such as patients who have diabetes), the cutoff drops to 100 mg/dL (ATP III). Patient MH has two risk factors—age ≥ 55 years and hypertension—so her cutoff is 130 mg/dL. Her LDL level of 140 mg/dL counts as high.

The guidelines for the diagnosis and treatment of high cholesterol have been explicitly formulated in relation to patients' probability of developing cardiovascular disease, as can be seen by the link between the presence of risk factors and the level of LDL that counts as abnormal. Treating MH is justified by evidence that her overall morbidity and mortality from cardiovascular disease would be lower if she were placed on a statin medication (an HMG-coA reductase inhibitor such as Zocor or Lipitor). As for stage 1 hypertension, symptoms are not the issue, since the vast majority of patients with high cholesterol will be asymptomatic (Dale and Federman 2007). The only exception is the very small number of patients who have extremely high levels of cholesterol due to the genetic condition of familial hypercholesterolemia and who often exhibit signs such as xanthomas (Dale and Federman, 2007).

Many people will count as having high cholesterol even though their level is near average or even below. MH's LDL is actually below the mean for women her age (143 mg/dL; ATP III, Appendix III-A). As for the definition of hypertension, the idea of *elevated* risk here refers to the existence of risk that can be lowered, rather than any comparison with the mean for the population.

All these features of the diagnosis of high cholesterol can be seen in the long delay between the recognition of cholesterol as a risk factor in the 1950s and 1960s and the institution of widespread treatment in the 1990s. The problem was that before the advent of the statin medications, treatments or diets that could lower cholesterol had no significant effect on morbidity or mortality (Greene 2007). In the 1990s, a series of large, randomized, placebo-controlled studies showed that using statin medications to lower cholesterol in certain patient populations could reduce cardiovascular disease and mortality. The earliest studies were done with patients who had already had a heart attack or stroke and had elevated levels of cholesterol, and later studies then moved on to show benefits in patients without documented CHD and with lower and lower levels of cholesterol (Greene 2007).

Many of these studies were funded by pharmaceutical companies and were designed to justify expanding the definition of high cholesterol (Greene 2007).

Nevertheless, the research showed convincingly that cardiovascular morbidity and mortality could be reduced in these populations by lowering cholesterol. The question is not whether reducing cholesterol reduces risk of CHD, since it clearly does for many patients, but whether classifying the condition of "high cholesterol" as a disease is appropriate. I argue that it is not.

### Other Risk-Based Diseases

This paper focuses on hypertension and high cholesterol, but there are other conditions similarly defined on the basis of the presence of modifiable risk. For example, in the late 1990s the cutoff for diagnosing diabetes was reduced to a fasting blood glucose of 126 mg/dL, from the previous 140 mg/dL, greatly expanding the number of patients who count as having this disorder (Report of the Expert Committee 1997; Schwartz and Woloshin 1999). The reason for this shift is that even though such patients will often have no symptoms, research suggests that starting treatment at the lower levels can reduce risk of microvascular damage (e.g., retinopathy).

Obesity and osteoporosis are other conditions where the presence of modifiable risk has become definitive of disease. There are differences among these risk-based diseases, including their prevalence, associated symptoms and risks, and the availability of pharmaceutical or other medical options for treating them, and I shall not discuss all these conditions here. I only wish to note that the trend towards defining disease on the basis of modifiable risk is not limited to the conditions of hypertension and high cholesterol.

# HYPERTENSION AND HIGH CHOLESTEROL AND THE DEFINITION OF DISEASE

The current definitions of hypertension and high cholesterol seriously strain traditional concepts of disease. Although by current guidelines patient MH has stage 1 hypertension and high cholesterol, I will argue that she does not have a disease. In particular, her conditions do not meet the criteria laid out by some of the most important accounts of the concept of disease—in particular, the "dysfunction-requiring" theories (Boorse 1977, 1987, 1997; Wakefield 1992a, 1992b, 1999a, 1999b)—and thus she should be considered healthy. It is true that some approaches to defining disease—such as the "malady" account of Culver and Gert (1982)—would classify stage 1 hypertension and high cholesterol as pathology. But, I shall argue, this reflects the well-known flaw with such approaches, that they tend to classify healthy conditions as diseases.

A quick note here about terminology: when writing about the idea of normal functioning and pathology, theorists use various terms for the notion they are trying to capture, ranging from *disease* to *disorder* to *malady*. In all these cases, though, the writers specify that they are referring to the general notion of "path-

ology," which is meant to include diseases, syndromes, injuries, and so forth (Boorse 1997; Culver and Gert 1982; Wakefield 1999a). I shall use the term *disease* here, but again with the stipulation that I am interested in the more general notion of pathology. The question is whether the bulk of patients diagnosed with risk-based diseases truly have pathology or only a risk factor for developing pathology.

## Dysfunction-Requiring Accounts of Disease

Analyses of the concept of disease can be separated into those that are "dysfunction-requiring" (DR)—those that include a criterion referring to the presence of dysfunction—and those that avoid any such criterion, and thus are "non-dysfunction-requiring" (non-DR) (Schwartz 2007a). In addition to proposing and defending a seminal version of the DR approach, Christopher Boorse (1977, 1987, 1997) also makes a point of rejecting any criterion that refers to the "disvalue" of a condition. This is the most notorious part of his definition, and much discussion of it focuses on this commitment to "naturalism" (Reznek 1987). But there is no reason why an account cannot include a DR criterion as well as a criterion referring to the disvalue of the condition. Jerome Wakefield (1992a, 1992b, 1999a, 1999b) proposes just such an account, arguing that for a condition to be a disease it has to be a "harmful dysfunction"—in other words, it must reflect biological dysfunction and must be judged as "harmful."

Here I shall assume a DR approach. It doesn't matter for my purposes whether there is an additional requirement requiring that the condition is harmful, since hypertension and high cholesterol and the other risk-based diseases would certainly satisfy such a criterion. But they do not satisfy the dysfunction requirement: most patients currently classified as having stage 1 hypertension or high cholesterol do not have any dysfunction. By the DR approach, therefore, these patients do not have a disease.

Boorse's theory provides the clearest account of judgments regarding dysfunction and their role in judgments about disease-status. Here are the three key parts of his definition:

- 1. The *reference class* is a natural class of organisms of uniform functional design; specifically, an age group of a sex of a species.
- 2. A *normal function* of a part or process within members of the reference class is a statistically typical contribution by it to their individual survival and reproduction.
- 3. A *disease* is a type of internal state that is either [a] an impairment of normal functional ability, i.e. a reduction of one or more functional abilities below typical efficiency, or [b] a limitation on functional ability caused by environmental agents (Boorse 1997, pp. 7–8; *a* and *b* added under 3 for clarity).

Most diseases count as such because of criterion 3a rather than 3b. Consider congestive heart failure (CHF) in a 50-year-old man. The human heart has the function of pumping blood; this is what it does that typically contributes to survival and reproduction. If the heart in a typical 50-year-old man has an ejection fraction of 50%, and the heart of the individual with CHF has an ejection fraction of just 15%, the latter's heart is beating significantly "below typical efficiency," and it thus counts as pathological according to premise 3a.

A number of factors will play a role in determining exactly how low a heart's ejection fraction must be before it counts as dysfunctional rather than just on the low side of normal (Schwartz 2007b), and there will always be some arbitrariness in drawing this line (Boorse 1977, 1987). In most cases, however, it is clear when a level of functioning is abnormal, since it falls below that of a vast majority of the members of the reference class and brings serious symptoms and functional deficits (Boorse 1977, 1987). In such classic conditions as renal failure, emphysema, or hip fracture, the kidney, lungs, or femur, respectively, are unable to carry out their function at anything like typical efficiency.

### Hypertension

Now consider these issues for the diagnosis of hypertension in patient MH. Using Boorse's terminology (premise 3a), I would argue that because there is no internal part or process that is functioning below "typical efficiency," there is no disease.

The relevant biology is complex but relatively well understood. Myriad physiological factors affect a person's blood pressure, including arterial resistance and elasticity, the strength and rate of cardiac contractions, kidney function, and numerous hormones that affect all these. Complex feedback loops usually keep blood pressure in a relatively narrow range. I'll call this interrelated web the "blood-pressure system" for brevity.

The first clear function of the blood-pressure system is making sure that blood pressure does not drop too low, which can interfere with blood flow to the brain and other vital organs. Fainting, for instance, occurs when the blood pressure drops too low to adequately perfuse the brain. But MH's blood pressure of 150/80 mm Hg is certainly high enough to adequately perfuse vital organs. Her blood-pressure system is functioning normally in this regard.

Another function of the blood-pressure system is to keep blood pressure from getting dangerously high. At a blood pressure of 210/130 mm Hg, for instance, patients frequently will have a headache and visual changes, and at times there will be demonstrable dysfunction of the kidneys, eyes, or brain. At this blood pressure level, called "urgent hypertension," arteries and arterioles constrict, which protects target organs from the excessive pressures but drastically diminishes blood flow. For this reason, a DR account has no trouble classifying urgent hypertension as a disease. A patient like MH, with stage 1 hypertension, however,

does not exhibit these problems, since her "elevated" blood pressure causes no symptoms or dysfunction in other organs.

Stage 2 hypertension falls somewhere in the middle: patients may be like MH—with no symptoms and no dysfunction—or they may have such problems. Thus, some patients will probably count as having a disease by a DR account and others won't. For simplicity, I shall focus on stage 1 hypertension here, where such signs or symptoms are rare.

It is reasonable to ask whether I have overlooked a possible function of the blood-pressure system that could justify classifying patients like MH as harboring dysfunction. Perhaps the system should be counted as having the function of keeping blood pressure low enough to minimize the risk of future cardiovascular disease. If the system has that function, then, one might think, there could be dysfunction present in patients with stage 1 hypertension.

But there are two steps to this suggestion, and each has important problems. First, the idea of assigning the blood-pressure system the function of minimizing future cardiovascular risk is at least strained. Function is assigned (as in premise 2, above) by looking at the contributions the system makes to survival and reproduction at the current time or under specific possible circumstances. So claiming that a system has the function of reducing future risk is odd at least.

Second, even if we assign the blood-pressure system the function of minimizing future cardiovascular risk, in a patient like MH it appears that it is functioning at "typical efficiency" for doing this. Remember that there is a wide range of blood pressures in women of her age, and 150/80 mm Hg does not fall far from the mean. Although she may have slightly higher risk of a future heart attack than someone with a lower blood pressure, this looks more like a part of normal variation than like dysfunction. What matters for the guidelines concerning diagnosing and treating hypertension is just that her risk is higher than it could be with available medications. It is untenable to label the blood-pressure system as dysfunctioning for this reason alone.

## Considering Hunter-Gatherer Societies

Not all societies, admittedly, have such a high prevalence of blood pressures in the range of stage 1 hypertension. In traditional hunter-gatherer societies, for instance, 60-year-olds have an average blood pressure of just 110/70 (Law and Wald 2002). In comparison to individuals in such a group, MH's blood pressure places her at an uncommonly high risk of cardiovascular disease. From this perspective, MH's blood-pressure system might be considered to be failing to function at "typical efficiency" for controlling the risk of cardiovascular disease (again, assuming that is accepted as a function of the system).

This conjecture, however, has little to do with judging whether her blood pressure counts as dysfunctional by premise 3a. According to that premise, the functional efficacy must be compared to other members of the reference class (of

individuals of her age and gender in the current population), and, I have argued, by this test her blood-pressure system will appear functional.

Premise 3b appears more relevant to the proposal that her blood-pressure and cardiovascular risk should be compared to those found in individuals living in traditional societies. According this premise, an internal state counts as dysfunctional if it represents "a limitation on functional ability caused by environmental agents." The higher average blood pressure of contemporary society is almost certainly due to environmental factors, such as increased intake of salt, fat, and calories, coupled with decreased exercise and increased body mass index. At first glance, it looks like this perspective could justify counting stage 1 hypertension as dysfunction.

On closer examination, however, this approach runs into serious problems. In particular, using premise 3b in this way would result in the conclusion that basically everybody living in contemporary society harbors dysfunction. Even people with normal blood pressures by current guidelines have a much increased risk of cardiovascular disease compared to people living in a hunter-gatherer society. From this perspective, the current cutoffs for diagnosing stage 1 hypertension would make little sense.

In addition, for basically all members of contemporary society, the risk of cancer is also most likely orders of magnitude higher than in traditional settings, due to the presence of pollutants and other toxins and aspects of modern life. These environmental agents impact myriad mechanisms at the genetic, cellular, and tissue level, resulting in increased rates of cancer (Dale and Federman 2007).

Premise 3b faces other significant problems as well, so much so that Boorse (2002) has recently discussed removing it from his account. He originally added the premise to handle some hypothetical cases where a single agent, such as a toxin or a virus, causes widespread dysfunction. Using it in cases where the overall environment has changed in so many ways simply introduces too many complications to rely on this to justify counting stage 1 hypertension as dysfunction.

Finally, given how the guidelines for diagnosing hypertension have evolved, it would be surprising if facts about risks in traditional hunter-gatherer societies were crucial. As summarized above, the guidelines regarding this condition are based on evidence that treating the levels above the cutoffs can reduce overall cardiovascular morbidity and mortality. Whether or not lower levels were common at previous times in human history seems irrelevant.

## High Cholesterol

As described above, MH also has an LDL of 140 mg/dL and thus counts as having high cholesterol. But again, there is no reason to see her as harboring dysfunction. Cholesterol has various functions in the body, including use in cellular membranes, and there are numerous systems that determine the levels of the various molecules that participate in cholesterol metabolism (Dale and Federman 2007). An LDL of 140 mg/dL causes no demonstrable problems, and there

is no reason to think that this level is too high or too low for the body's needs. Therefore there is also no clear reason to see the systems that metabolize, transport, and store cholesterol as dysfunctioning in any way.

In contrast, patients with familial hypercholesterolemia develop dangerously high levels due to mutations in the proteins involved in cholesterol metabolism, and thus clearly do harbor dysfunction (Dale and Federman 2007). No such dysfunctions have been identified in the great majority of people like MH with high cholesterol. As mentioned above, her LDL level is actually below the median for women her age in the United States (ATP III, Appendix III-A).

In short, it is not the lack of symptoms that stops hypertension or high cholesterol from counting as diseases, but the absence of any dysfunction. There are numerous asymptomatic diseases, such as small tumors or early cirrhosis or kidney failure, for instance, but in those cases there is demonstrable dysfunction. In the case of cancer, certain mechanisms are failing to perform their usual function of controlling cell division (Dale and Federman 2007). In the case of stage 1 hypertension and high cholesterol, in contrast, there is no dysfunction, as well as usually no symptoms, and thus no disease.

The only approach that would classify MH's cholesterol level as disease would be, first, to assign the system of cholesterol metabolism and storage as having the function of minimizing future cardiovascular risk, and second, to compare modern individuals to people living in hunter-gatherer societies. Such an approach faces the same problems it did when discussing hypertension, perhaps most importantly the consequence that all modern individuals would most likely be counted as harboring dysfunction. If the notion of dysfunction applied to a case like this, it would be a poor criterion for the presence of disease.

## Non-Dysfunction-Requiring Definitions of Disease

Many definitions of "disease" do not include a requirement that biological dysfunction is present, and such non-DR theories may classify stage 1 hypertension and high cholesterol as diseases. For example, consider Culver and Gert's (1982) "malady" account: "A person has a malady if and only if he has a condition, other than his rational beliefs and desires, such that he is suffering, or at increased risk of suffering, an evil (death, pain, disability, loss of freedom or opportunity, or loss of pleasure) in the absence of a distinct sustaining cause" (Culver and Gert 1982, p. 81). Stage 1 hypertension and high cholesterol will count as maladies since they carry an "increased risk of suffering . . . an evil—in other words, a cardiovascular event that would cause death, pain, or disability.

This classification, however, should not lead us to conclude that stage 1 hypertension or high cholesterol are in fact diseases, due to the serious defects in non-DR accounts. In particular, Culver and Gert's analysis counts as maladies many conditions that are clearly not pathological. For example, in a bigoted society, having a certain skin color will bring risk of "loss of freedom or opportunity," and thus would be a malady. Similarly, being female in a sexist society or being

a pacifist in a warlike society could be maladies. Even pregnancy, a prototypically healthy state, will count as a malady due to the risks it brings. (In a later article, Culver and Gert have accepted the counterintuitive classification of pregnancy as malady; Gert, Culver, and Danner Clouser 1997). Finally, the vague concept of "increased risk" could justify counting all contemporary Westerners as having a "malady," due to the fact that they have higher risks of heart disease and cancer than those living in traditional, hunter-gatherer societies.

In short, non-DR definitions are overly inclusive, and this feature leads them to classify stage 1 hypertension and high cholesterol as diseases. Like others, I believe that this over-inclusiveness and other problems make the non-DR approach unattractive as an account of the concept of disease in biology or medicine. Advocates of the non-DR approach might point to its inclusion of the risk-based diseases as a virtue and might claim that the existence of such diseases favors the non-DR approach over DR accounts, but I would reject this: classifying stage 1 hypertension and high cholesterol as pathological highlights the weakness of the non-DR approach, not its strength.

## STAGE 1 HYPERTENSION, HIGH CHOLESTEROL, AND HEALTH-CARE JUSTICE

Concluding that stage 1 hypertension and high cholesterol are not diseases might seem to significantly weaken the basis for treating them. The motivation for labeling modifiable risk as pathological, after all, came from the emphasis that medicine puts on disease. Health insurance generally covers treatment for illness, not for healthy conditions. Treatment of heart failure is covered, for instance, but cosmetic surgery is not. Interventions on healthy states often are classified as "enhancements" rather than treatment (Daniels 2000) and are viewed skeptically by many.

If stage 1 hypertension and high cholesterol are not diseases, as I have argued, then medical interventions for them will not be treatment but instead will be prevention. And given the disease-centered model of current medical care and health insurance, there is some ambiguity about the status of preventive services. On the one hand, it is treatment offered to healthy people, like cosmetic surgery or other "enhancements," but on the other hand, it is a way to combat disease. What can we say about the status of preventive services in medicine, now that it appears that care for stage 1 hypertension and high cholesterol will usually fall in this category?

To address this question, I shall draw on a prominent account of health-care justice presented by Norman Daniels (1985, 2000). According to his account, which is situated within John Rawls's political philosophy, the "primary rationale of medical obligations" is treating disease. In short, the basic health-care package—the standard health insurance policy, in many systems—will be focused on treating diseases defined by a DR account. This is not to say that being a treat-

ment for a disease is a strictly necessary or sufficient condition for being included in the package: some treatments for disease may be excluded due to their expense or burden (Daniels 2000). And some interventions on healthy states—conditions where there is no disease present—may be covered for specific ethical reasons. For example, Daniels (2000) argues that abortion may be a necessary service to provide to pregnant women, even though no disease is present, due to the need to protect equality for women. Still, the primary rationale for medical care includes mostly treatment for disease. It appears from this perspective that there is a chance that treatment for stage 1 hypertension and high cholesterol, like other preventive services, will fall outside the primary rationale of health care.

A closer examination of Daniels's account, however, shows that such care will be included under the primary rationale. In short, preventive care—reducing the risk of future diseases—will be just as central to health care as treating diseases once they arise.

To understand this, it is necessary to review the reason that providing standard treatments for disease is considered as falling in the primary rationale of medicine according to Daniels's theory. The key issue is the need to protect fair equality of opportunity, a central concern of liberal political philosophy. In a Rawlsian system, people must have fair equality of opportunity to compete for positions that carry rewards such as higher wages or other goods. Fair equality of opportunity does not require that all members of society have an equal chance of obtaining desirable positions. A person with less than average intelligence, for instance, will not have as good a chance of becoming a physician as smarter individuals. But some reasons for differential opportunity are not acceptable—for instance, if there is discrimination on the basis of gender or race.

Rawls's principle of fair equality of opportunity goes much further than this, though. He writes that, overall, "those with similar abilities and skills should have similar life chances. More specifically . . . those who are at the same level of talent and ability, and have the same willingness to use them, should have the same prospects of success regardless of their initial place in the social system" (Rawls 1971, p. 73). Thus, the need to assure fair equality of opportunity as much as possible is what justifies publicly funded education, for instance. Without such a system, children who are born to poorer families will not be able to compete with children of equal ability and willingness to work who are born to richer families. There is little prospect of eliminating all such differences, of course, but they should be minimized to a reasonable degree.<sup>2</sup>

According to Daniels's account, the basic health-care package is supported by similar reasoning. If a person has a disease, he or she will be at a disadvantage competing for desirable positions with healthy people who have the same abili-

<sup>&</sup>lt;sup>2</sup>Decisions about whether to implement or modify possible mechanisms for protecting fair equality of opportunity may involve difficult tradeoffs between freedom and equality. In the Rawlsian system, such decisions may need to be made by participants in the original position (Daniels 2000).

ties and willingness to apply them. Thus, providing a health-care package focused on treating diseases will serve fair equality of opportunity. Medical enhancements that would improve a healthy person's ability to compete—such as a pill that improves intelligence or diminishes the need to sleep, for instance—would generally not be covered by the standard package, since they don't further fair equality of opportunity.

With Daniels's account explicated in this way, it becomes clear that whether or not stage 1 hypertension and high cholesterol count as diseases, their diagnosis and treatment will fall under the primary rationale of medical care. By treating these conditions and preventing future cardiovascular events in some people, fair equality of opportunity is furthered. If the goal is to further equality of opportunity, it is even better to prevent a heart attack than to treat it after it has occurred.

#### CONCLUSION

Thus, although stage 1 hypertension and high cholesterol should not be classified as diseases, their treatment should be seen as just as central to health care as treatments for disease. A natural question, then, is whether it matters if these conditions are described as diseases or not. I believe that it does, for two reasons. First, there is the simple point that we should call these conditions what they are. The growing attention paid to identifying and reducing risk should not be allowed to warp the notion of disease. It would be regrettable if the desire to improve preventive care resulted in an unnecessary blurring of the distinction between health and disease.

Second, labeling stage 1 hypertension and high cholesterol as diseases has the potential of undermining patient understanding. A doctor who recommends treatment for these conditions is really proposing an intervention to reduce risk, not treat disease. The treatment carries the upfront cost of the medication, the burden of taking a pill every day and visiting the doctor regularly, and the risk of side effects. The payoff is a reduction in the risk of future cardiovascular disease. But when hypertension or high cholesterol is described as pathological, patients may hear only that they have a disease and need treatment.

It is important to remember that the benefit of treating conditions like stage 1 hypertension and high cholesterol is a reduction in risk of only a certain magnitude, not a guarantee of protection. For example, a patient like MH may have a baseline risk (without treatment) of a 1 in 20 chance of having a heart attack in the next 10 years. Getting treated for her hypertension and high cholesterol

<sup>&</sup>lt;sup>3</sup>There are important challenges to his theory, for example, questioning whether it adequately justifies treating diseases of old age, which occur after the competition for offices is over. Discussion of these issues is ongoing, but the theory is certainly one of most important and well-defended accounts in this area.

may reduce her risk to 1 in 40. Another way to put this is that even without treatment, she has just a small chance of having a heart attack in the next decade, and she can reduce this risk even further by starting treatment. These specific quantities of risk and risk reduction are rarely disclosed to patients or understood by them, and thus the informed-consent process for such decisions is often inadequate (Braddock et al. 1997, 1999; Epstein et al. 2004; Paling 2003).

Admittedly, simply insisting that risk-based "diseases" be described as risk factors will not solve the extensive problems in modern medicine regarding doctor-patient communication and patient understanding. Many more changes will be needed to significantly improve the situation. But describing hypertension or cholesterol as risk factors, rather than as diseases, would be an important first step.

Although I have focused my discussion here on stage 1 hypertension and high cholesterol, these are representative of a larger group of conditions where modifiable risk is classified as disease (including diabetes, osteoporosis, and obesity). And all these conditions reflect the growing focus of medicine on identifying and modifying risk, with the next frontier most likely centered on genetic risk factors. Improved prevention in all these areas can have significant benefits for individuals and public health, but it also carries real risks, not least of all the medicalization of normal life. Since questions about this trend can only be clearly discussed if we pay attention to the distinction between treatment and prevention, it is important to be careful about any blurring of the line between these crucial, but separate, goals of health care. Analyzing the representation and framing of risk in medicine is an important task for the philosophy of medicine and ethics.

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